Texas Forensic Science Commission

Justice Through Science

FINAL REPORT ON COMPLAINT BY LISA GEFRIDES AGAINST THE HOUSTON FORENSIC SCIENCE CENTER

July 20, 2018

REPORT OF THE
TEXAS FORENSIC SCIENCE COMMISSION

Complaint by Lisa Gefrides re:
Houston Forensic Science Center (HFSC)
Forensic Biology

[Approved at Quarterly Meeting]
July 20, 2018
Austin, Texas

Table of Exhibits

This report contains observations and recommendations regarding the complaint filed by Lisa Gefrides on January 20, 2017 (*See* Gefrides Complaint and Exhibits at **Exhibit A**).

I. SUMMARY OF THE COMMISSION'S STATUTORY AUTHORITY

A. Legislative Background and Membership

The Texas Legislature created the Texas Forensic Science Commission ("Commission") during the 79th Legislative Session by passing House Bill 1068 (the "Act"). The Act amended the Texas Code of Criminal Procedure to add Article 38.01, which describes the composition and authority of the Commission.[1] During subsequent legislative sessions, the Texas Legislature further amended the Code of Criminal Procedure to clarify and expand the Commission's jurisdictional responsibilities and authority.[2]

The Commission has nine members appointed by the Governor of Texas.[3] Seven of the nine commissioners are scientists or medical doctors and two are attorneys (one prosecutor nominated by the Texas District and County Attorney's Association, and one criminal defense attorney nominated by the Texas Criminal Defense Lawyer's Association).[4] The Commission's Presiding Officer is Jeffrey Barnard, MD. Dr. Barnard is the director of the Southwestern Institute of Forensic Science and the Chief Medical Examiner of Dallas County, Texas.

B. Accreditation Jurisdiction

The Texas Code of Criminal Procedure prohibits forensic analysis from being admitted in criminal cases if the entity conducting the analysis is not accredited by the Commission:[5]

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[1] *See* Act of May 30, 2005, 79th Leg., R.S., ch. 1224, § 1, 2005.
[2] *See e.g.*, Acts 2013, 83rd Leg., ch. 782 (S.B.1238), §§ 1 to 4, eff. June 14, 2013; Acts 2015, 84th Leg., ch. 1276 (S.B.1287), §§ 1 to 7, eff. September 1, 2015, (except TEX. CODE CRIM. PROC. art. 38.01 § 4-a(b) which takes effect January 1, 2019).
[3] TEX. CODE CRIM. PROC. art. 38.01 § 3.
[4] *Id.*
[5] Until the 84th Legislative Session, the accreditation program was under the authority of the Department of Public Safety ("DPS").

> "…a forensic analysis of physical evidence under this article and expert testimony relating to the evidence are not admissible in a criminal action if, at the time of the analysis, the crime laboratory conducting the analysis was not accredited by the commission under Article 38.01."[6]

The term "forensic analysis" is defined as follows:

> "Forensic analysis" means a medical, chemical, toxicologic, ballistic, or other expert examination or test performed on physical evidence, including DNA evidence, for the purpose of determining the connection of the evidence to a criminal action, except that the term does not include the portion of an autopsy conducted by a medical examiner or other forensic pathologist who is a licensed physician.[7]

The term "crime laboratory" is broadly defined, as follows:

> "Crime laboratory" includes a public or private laboratory or other entity that conducts a forensic analysis subject to this article.[8]

The forensic discipline discussed in this report is DNA analysis, which must be accredited by the Commission in order for the analysis and related testimony to be admissible in a criminal action.[9] The laboratory that is the subject of this report, Houston Forensic Science Center ("HFSC") is accredited by the Commission and the ANSI-ASQ National Accreditation Board ("ANAB") under the International Organization for Standardization ("ISO") accreditation standard 17025.[10]

C. Investigative Jurisdiction

Texas law requires the Commission to "investigate, in a timely manner, any allegation of professional negligence or professional misconduct that would substantially affect the integrity of the results of a forensic analysis conducted by an accredited laboratory, facility or entity."[11] The Act also requires the Commission to: (1) implement a reporting system through which accredited

[6] TEX. CODE CRIM. PROC. art. 38.35 § (a)(4).
[7] *Id.* at § (a)(4).
[8] *Id.* at § (d)(1).
[9] *Id at* §(a)(4).
[10] *See* http://www.txcourts.gov/fsc/accreditation/ for a list of accredited laboratories.
[11] TEX. CODE CRIM. PROC. art. 38.01 § 4(a)(3).

laboratories, facilities or entities may report professional negligence or professional misconduct; *and* (2) require all laboratories, facilities or entities that conduct forensic analyses to report professional negligence or misconduct to the Commission.[12]

As part of its accreditation authority, the Commission may also:

- Establish minimum standards that relate to the timely production of a forensic analysis to the agency requesting the analysis;
- Validate or approve specific forensic methods or methodologies; and
- Establish procedures, policies and practices to improve the quality of forensic analyses conducted in this State.[13]

The Commission may, at any reasonable time, enter and inspect the premises or audit the records, reports, procedures, or other quality assurance matters of a crime laboratory that is accredited or seeking accreditation.[14]

D. Important Limitations on the Commission's Authority

The Commission's authority contains important statutory limitations. For example, no finding by the Commission constitutes a comment upon the guilt or innocence of any individual.[15] The Commission's written reports are not admissible in civil or criminal actions.[16] The Commission has no authority to subpoena documents or testimony. The information the Commission receives during the course of any investigation is dependent upon the willingness of stakeholders to submit relevant documents and respond to questions posed. The information gathered in this report has ***not*** been subjected to the standards for admission of evidence in a courtroom. For example, no individual testified under oath, was limited by either the Texas or

[12] *Id.* at § 4(a)(1)-(2).
[13] *Id.* at § 4-d(b-1).
[14] *Id.* at § 4-d(b-2).
[15] *Id.* at § 4(g).
[16] *Id*. at § 11.

Federal Rules of Evidence (*e.g.*, against the admission of hearsay) or was subjected to cross-examination under a judge's supervision.

II. SUMMARY OF THE COMPLAINT

The complaint alleges recurring non-conformities in the HFSC DNA laboratory including issues with contamination, proficiency testing and inadequate root cause analysis. The complainant also alleges the laboratory recognized the non-conformities had occurred yet did not take sufficient action to successfully remediate the non-conformities.

Requirements for corrective action in response to non-conforming work product are addressed by the ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Standards under which crime laboratories are accredited. After a non-conformity is identified, these standards require root cause analysis, implementation and selection of corrective actions, and monitoring the results to ensure that the corrective actions implemented have been effective.

The Federal Bureau of Investigation Quality Assurance Standards ("FBI QAS") also require DNA laboratories to identify the root cause of non-conformities and implement corrective and preventative actions, as necessary.

III. INVESTIGATIVE PROCESS

The Commission assembled a review panel including Commissioners Dr. Bruce Budowle and Dr. Sheree Hughes-Stamm and Jody Koehler, the Commission's Senior Scientific Advisor (*See* Budowle CV at **Exhibit B**; *See* Hughes-Stamm CV at **Exhibit C;** and Koehler CV at **Exhibit D**.)

A. Documents Reviewed

The Commission's staff reviewed approximately 100 quality incidents (e.g. corrective actions) ranging from 2012 through 2017. Other documents reviewed included: FBI QAS audits (internal and external) from 2014 to 2017, management system reviews from 2015-2017, the forensic biology decontamination experimental study plan, the PrepFiler Hamilton Validation, and the AB robotics validation. The laboratory was very responsive in providing documents during this process. The laboratory also has an external website that provides final quality system documentation for non-conformities, standard operating procedures for all disciplines, and the laboratory's quality manual. The website is accessible at the following link: https://records.hfscdiscovery.org.

B. Staff Interviews

During staff interviews, Dr. Budowle and Ms. Koehler interviewed 12 analysts (from a total of 33 FTE's in the DNA section). The primary concern voiced by the group was a need for improvement in the internal training program. Comments included the perception that the section lacks a defined training program, there is no designated training coordinator, and training/competency sets do not mimic actual casework. The need for improvement in the training program was also identified in the 2017 internal DNA audit. Some analysts also expressed a perception that "quantity" of casework was more important than "quality" of casework, others expressed their belief that the quality of the work environment needs to be improved. One analyst described internal training on DNA mixtures as lacking sufficient structure and direction. Some analysts noted high turnover in the section, with 17 people having left the DNA section since 2016. Other analysts expressed a perception that upper management does not fully appreciate the analysts' concerns with respect to these issues.

IV. OBSERVATIONS

A. Assessment of Professional Negligence/Misconduct

Article 38.01 of the Texas Code of Criminal Procedures requires the Commission to describe whether professional negligence or misconduct occurred for complaints filed involving accredited laboratories and accredited forensic disciplines. Neither "professional negligence" nor "professional misconduct" is defined in the statute. The Commission has defined both terms in its policies and procedures and published rules.[17] The term "professional negligence" is defined as follows:

> "Professional Negligence" means the actor, through a material act or omission, negligently failed to follow the standard of practice generally accepted at the time of the forensic analysis that an ordinary forensic professional or entity would have exercised, and the negligent act or omission would substantially affect the integrity of the results of a forensic analysis. An act or omission was negligent if the actor should have been but was not aware of an accepted standard of practice required for a forensic analysis.

The term "professional misconduct" is defined as follows:

> "Professional Misconduct" means the actor, through a material act or omission, deliberately failed to follow the standard of practice generally accepted at the time of the forensic analysis that an ordinary forensic professional or entity would have exercised, and the deliberate act or omission would substantially affect the integrity of the results of a forensic analysis. An act or omission was deliberate if the actor was aware of and consciously disregarded an accepted standard of practice required for a forensic analysis.

The complainant did not allege any intentional wrongdoing, and the Commission found no evidence of misconduct. The Commission also did not find sufficient support to issue a finding of professional negligence against the laboratory, because staff made multiple good faith efforts to address the nonconformities described by the complainant. However, the Commission agrees with the complainant's observations that those efforts still resulted in inadequate root cause analysis,

[17] The Commission's policies and procedures have been developed into administrative rules and will ultimately be published in 37 TEX. ADMIN. CODE §15.

inadequate corrective action, and inadequate evaluation of corrective actions. While it is not uncommon for forensic laboratories to struggle with effective root cause analysis, shortcomings in this area may have serious implications for the effectiveness of the overall quality system of the laboratory as described in further detail below.

B. Complaint Substance vs Review Panel Observations

1. Inadequate Root Cause Analysis

The laboratory did an excellent job summarizing quality events in the DNA section but did not conduct a sufficient inquiry to determine the true root cause of the events. The review panel observed several quality incidents where root cause analysis was attempted but fell short of identifying the baseline cause. While there was an effort to reduce contamination by improved use of personal protective equipment (PPE) and cleaning of instruments and workspace, there did not appear to be a further effort to assess to what extent internal processes, (e.g., analyst training), may have been responsible for weaknesses in the system.

One example was a series of events in which the DNA section detected contamination in blanks (reagent blanks and/or controls) processed with the samples. Analysts detected the contamination, however, neither the DNA section nor the quality assurance staff attempted to identify whether sample to sample contamination may have occurred. Examples of action by the laboratory are included in the internal contamination memo dated November 4, 2016 that attempted to address increases in contamination events in 2016. (*See* Internal Contamination Memo 2016 at **Exhibit E**). Another increase in contamination occurred in 2017 indicating that the true root cause may not have been adequately addressed (*See* CAR 2017-075 at **Exhibit F**). Interviews with staff led Dr. Budowle and Ms. Koehler to the conclusion that inadequacy of the

training program was the true root cause for the contamination that occurred with relative frequency and was not addressed effectively in CAR 2017-075.

Many of the contamination incidents were attributable to newer analysts, and the staff interviewed understood overall training weaknesses to be the root cause. However, this observation was not reflected in the documents generated by the quality system. Specific weaknesses in the training program included: (1) training assignments did not mimic actual casework; (2) the training process was "rushed"; (3) there was a lack of consistency due to the fact that different senior analysts provided training to new analysts depending on scheduling availability; and (4) some training was substantively inadequate. These shortcomings, which can lead to weaknesses in essential skills among analysts, could easily lead to contamination incidents regardless of how many times the laboratory emphasized the importance of using PPE and cleaning instruments and workspaces.

2. Inadequate corrective action

While the laboratory has been proactive in taking corrective action to address non-conformities in the DNA section, because the true root cause was not identified, the corrective actions that followed were inadequate to prevent recurrence. An example is proficiency tests (CTS 14-574 and CTS 14-575) where the laboratory detected semen yet according the proficiency test provider, the test was comprised of female-only bodily fluids. An outside laboratory (Bode Cellmark Forensics) examined the slides HFSC had examined and concluded initially that no spermatozoa were detected. Once HFSC contacted Bode and told them HFSC had observed spermatozoa, Bode examined the slides again and stated they also observed spermatozoa on two of the three slides. The presence of spermatozoa on a test that ostensibly contained female-only

body fluids should have raised a red flag regarding the possibility of contamination not only in the proficiency test sample but also in other samples that may not have been as easily detected.

In response to the proficiency test discrepancy, the DNA section held a section-wide meeting to discuss transfer of contact DNA in the laboratory. The laboratory then moved to a DNA-based male screening technique which eliminated the need for analysts to identify spermatozoa. However, this change in analytical approach does not address whether similar potential contamination issues may have occurred in casework that was processed before moving to the DNA-based male screening technique. Finally, the internal contamination memo from November 4, 2016 and CAR 2017-075 show many similarities in the corrective actions taken. If the corrective actions taken in 2016 had been adequate there may have been significant improvement in 2017, instead of repetition of similar issues.

3. Inadequate evaluation of implemented corrective actions

When corrective actions are implemented, it is imperative to evaluate their effectiveness to ensure quality issues do not recur. More effective follow-up by the HFSC DNA and quality sections after the rise in contamination events from 2016 should have reduced the contamination events in 2017. The effect of corrective action should have been monitored with follow up especially given that some of the corrective actions were substantively the same as in 2016. Other examples unrelated to contamination events include proficiency tests being submitted to the test provider with clerical errors (e.g., incorrect or omitted results) and samples from different cases being given the same unique identifiers. The proficiency test issues occurred four separate times from 2014-2016. The duplication of sample identifiers occurred five separate times in 2015. While the laboratory attempted some follow-up to evaluate the effectiveness of the corrective actions, because they did not identify the true root case, the events recurred.

V. CORRECTIVE ACTIONS AND RECOMMENDATIONS

The Commission commends Robin Guidry, DNA Technical Leader, and Peter Stout, Chief Executive Officer of HFSC, for providing their full support and commitment to the review process since the original complaint was filed. The DNA analysts interviewed were also forthcoming, cooperative and eager to participate in positive training initiatives and discussions with the review panel. The following areas of improvement were identified by the review panel:

1. Improve DNA training program, update the training manual and ensure consistent implementation, including the following:

    a. Hire a dedicated training coordinator who has subject matter expertise and can be readily informed regarding new technologies utilized by the laboratory;

    b. Identify and utilize personnel who are good instructors;

    c. Perform evaluation of trainers by trainees and management; and

    d. Ensure practice/competency sets are consistent with the magnitude and complexity of samples encountered during casework.

2. Assess the quality assurance (QA) program to ensure QA personnel are effective and have the authority to perform their job proactively;

3. Evaluate the extent to which shortcomings in root cause analysis may exist in other forensic disciplines outside of DNA;[18]

4. Ensure performance of adequate root cause analysis for quality events;

5. Ensure adequate evaluation of the effectiveness of implemented corrective actions;

6. Due to observations regarding the possibility of carryover contamination, in collaboration with Dr. Budowle and Ms. Koehler, develop a plan to review of a body of cases for which carryover risk may be present.

7. Due to observatonis regarding inadequacies in the training program particularly with respect to interpretation of DNA mixtures, review a representative sample of DNA mixture casework for newly qualified analysts to ensure protocols are being applied appropriately.

[18] *See e.g.*, Report of Texas Forensic Science Commission dated January 23, 2014 noting inadequacies in the quality system with respect to a blood alcohol analysis nonconformity.

HFSC has implemented important and significant changes in the last few months, including the following:

1. Retained ANAB expert to provide Root Cause Analysis Training for all division managers and supervisors on May 29, 2018;

2. Hired FBIO Training Coordinator who starts July 23, 2018;

3. Hired Assistant CODIS Administrator who started June 18, 2018;

4. Posted CODIS Liaison position, laboratory is currently evaluating resumes;

5. Purchased Small Pond for contamination detection with a target implementation date of summer 2018;

6. Conducted round tables with all Forensic Biology staff to enhance training programs for screening, analytical procedures, and DNA data analysis; and

7. Completed procurement process to outsource DNA analysis to Bode Cellmark Forensics for at least 10 months, which will enable the laboratory to focus on intensive training and improve internal training processes.

HFSC should continue the action items outlined above and address any Commission recommendations that have not yet been addressed. Finally, the Commission requests that HFSC provide Commission staff with quarterly updates regarding the progress made on the items outlined above until such time as all items on the list have been addressed.

1198.17.01

TEXAS FORENSIC SCIENCE COMMISSION • COMPLAINT FORM *(Cont.)*

1. PERSON COMPLETING THIS FORM

Name: Lisa Gefrides, MS
Address: 16806 Glenshannon Dr
City: Houston
State: Texas Zip Code: 77059
Home Phone: 7137035472
Work Phone: 7137035472
Email Address *(if any)*: LISA.GEFRIDES@GMAIL.COM

2. SUBJECT OF COMPLAINT

List the full name, address of the laboratory, facility or individual that is the subject of this disclosure:

Individual/Laboratory: Houston Forensic Science Center
Address: 1301 Fannin St, Ste. 170
City: Houston
State: Texas Zip Code: 77002
Date of Examination, Analysis, or Report:
Type of forensic analysis: Forensic Biology
Laboratory Case Number *(if known)*:

Is the forensic analysis associated with any law enforcement investigation, prosecution or criminal litigation?
Yes ☐ No ☐

* If you answered "Yes" above, provide the following information *(if possible)*:

* Name of Defendant:

* Case Number/Cause Number:
(if unknown, leave blank)

* Nature of Case:
(e.g burglary, murder, etc.)

* The county where case was investigated, prosecuted or filed:

* The Court:

* The Outcome of Case:

* Names of attorneys in case on both sides *(if known)*:

Your relationship with the defendant:

Self	☐	Family Member	☐
Parent	☐	Friend Attorney	☐
None	☐	Other *(please specify)*:	

If you are not the defendant, please provide us with the following information regarding the defendant:
Name:
Address *(if known)*:
Home Phone:
Work Phone:

3. WITNESSES

Provide the following about any person with factual knowledge or expertise regarding the facts of the disclosure. Attach separate sheet(s), if necessary.

First Witness *(if any)*:
Name:
Address:
Daytime Phone:
Evening Phone:
Fax:
Email Address:

Second Witness *(if any)*:
Name:
Address:
Daytime Phone:
Evening Phone:
Fax:
Email Address:

Third Witness *(if any)*:
Name:
Address:
Daytime Phone:
Evening Phone:
Fax:
Email Address:

4. DESCRIPTION OF COMPLAINT

Please write a brief statement of the event(s), acts or omissions that are the subject of the disclosure.

The Houston Forensic Science Center's Biology Laboratory's quality assurance program is not adequately identifying and controlling errors associated with the testing of biological evidence.

Naturally, when humans are involved in a process, mistakes will occur. Laboratory personnel are no exception. A good laboratory will have safeguards in place to detect errors and ensure they are contained. When a laboratory error occurs, the laboratory must determine the source of the error (root cause), determine whether other cases/samples are affected (quantify the scope of the error and whether steps to contain it are needed), correct the error (corrective action), and take steps to prevent the error from repeating (preventive action).

The Houston Forensic Science Center's Biology Laboratory is not taking adequate steps to diagnose the source of lab errors, to determine whether other cases/samples may be affected, and to prevent recurrence. Because of this, it is likely that cases have been reported with incorrect results.

Issue 1: Proficiency test results

On three proficiency tests used to evaluate the effectiveness of personnel and procedures to perform casework, the HFSC detected semen on samples that were female blood (only). This incorrect positive result likely is attributed to cross-contamination during slide making or misidentification of cellular material as sperm cells. There is no documentation that the laboratory reviewed actual case files to determine whether similar mistakes were made in casework.

Issue 2: Contamination

Between 2012-2014, the HFSC laboratory reported nine contamination events over a three-year period. Since 2015, the laboratory has reported six additional contamination events with another twenty still under investigation (at least twenty-six in less than two years).

In every instance, the laboratory failed to review additional cases to determine whether non-blank samples processed concurrently or similarly were affected. Not only has the laboratory failed to make process improvements to reduce occurrence, it has not processed additional control samples to better identify and quantify sample errors.

Most contamination and sample switch events were only identified because the events involved a blank (no DNA control) sample. As blank samples comprise a small portion of the samples tested (~10%) and because sample to sample contamination – particularly between samples from the same case – is difficult to detect, it is likely that the laboratory is failing to detect many contamination events.

These instances of contamination cannot be isolated events. Instead, they indicate a pervasive systemic issue. A thorough review of the laboratory's quality system and case work should be undertaken to guarantee the validity of its findings. Furthermore, the laboratory should amend their sample processing strategy to separate known and questioned samples during DNA testing, separate DNA processing of suspect samples from victim and crime scene samples, and process additional blank control samples to better monitor samples errors and show that any process improvements the laboratory undertakes are effective.

Issue 3: Repeated quality issues

The Houston Forensic Science Center's Biology Laboratory is not taking adequate steps to control the source of lab errors, as the repetitive nature of its quality incidents suggests:

•Four corrective action reports involve proficiency tests where the laboratory submitted incorrect (or omitted) results due to clerical errors. (2014-014, 2015-003, 2016-004, 2016-083)
•Five separate times in 2015, samples from different cases were given the same unique identifiers (sample names). (2015-006, 2015-007, 2015-010, 2015-018, 2015-022)
•At least 26 contamination events have occurred since 2015.

Issue 4: 2016 Internal Audit

The Houston Forensic Science Center's Biology Laboratory is not taking adequate steps to diagnose the source of lab errors. The laboratory's mindset is likely the basis for this failure as evidence by the laboratory's response to their own internal audit findings:

For each of the 9 audit findings on their 2016 Internal Audit (2016-IA-10 through 2016-IA-18), the laboratory concluded the following:

"This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology…) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's [sic] issued through internal audits."

The root cause of all quality issues should be addressed to better understand system failures.

In conclusion, these issues indicate a quality system that is not functioning in a manner to prevent compromised results. A thorough review of the Biology Division's quality system and case work should be undertaken to guarantee the validity of its findings. Based on the outcome of the review, a laboratory-wide quality review may be necessary.

5. EXHIBITS AND ATTACHMENT(S)

Whenever possible, disclosures should be accompanied by readable copies **(NO ORIGINALS)** of any laboratory reports, relevant witness testimony, affidavits of experts about the forensic analysis, or other documents related to your disclosure. Please list and attach any documents that might assist the Commission in evaluating the complaint. Documents provided will **NOT** be returned. List of attachments:

The following Corrective and Incident Reports can be located online at http://www.hfscdiscovery.org/:

Issue 1: Proficiency Test (2015-001)

Issue 2: Contamination (2014-010, 2014-013, 2014-027, 2015-024, 2016-005, 2016-032, 2016-049, 2016-050)

Issue 3: Proficiency tests (2014-014, 2015-003, 2016-004, 2016-083), Mislabeling (2015-006, 2015-007, 2015-010, 2015-018, 2015-022), Contamination (2014-010, 2014-013, 2014-027, 2015-024, 2016-005, 2016-032, 2016-049, 2016-050)

Issue 4: 2016-IA-10 through 2016-IA-18

The following Corrective and Incident Reports are attached (3):

1. 2012-005 to 017 contains information for Issues 2 and 3: Contamination (2012-007, 2012-008, 2012-014, 2012-017)

2. 2013-011 to 2014-015 contains information for Issues 2 and 3: Contamination (2013-018, 2014-004, 2014-009)

3. Email regarding 20 contamination events that are not yet closed.

4. My CV

6. YOUR SIGNATURE AND VERIFICATION

By signing below, I certify that the statements made by me in this disclosure are true. I also certify that any documents or exhibits attached are true and correct copies, to the best of my knowledge.

Signature:

Date Signed: January 20, 2017 - 1:04am

LISA A. GEFRIDES, MS
Forensic Serology/DNA Consultant

PROFESSIONAL EXPERIENCE

2013-current	Consultant Forensic Biology & DNA
2009-2013	Co-founder & Member Forensic Test Preparation, LLC/ABCTestprep.com
2005- 2011	DNA Technical Assessor (Auditor) Consultant National Forensic Science Technology Center (NFSTC)
2004- 2011	DNA Analyst I – Compliance/R&D Manager Harris County Institute of Forensic Sciences Forensic Genetics Laboratory Joseph A. Jachimcyzk Forensic Center, Houston, TX DNA Compliance/R&D Manager; supervised a staff of 5-8 DNA Analysts; responsible for training of new laboratory analysts; section QA/QC Liaison; responsible for validation and implementation of new technologies; serology casework, STR-DNA casework (ABI-3130XL), expert testimony (Harris & Montgomery Counties)
2000- 2004	DNA Analyst II Harris County Medical Examiner's Office DNA Laboratory Joseph A. Jachimcyzk Forensic Center, Houston, TX MtDNA casework (ABI 377), serology casework, STR-DNA casework (ABI 310, ABI 3100-Avant), CODIS, Trace evidence collection from homicide victims, expert testimony (Harris & Montgomery Counties)
1999- 2000	Research Assistant II Bluebird Developmental Neurogenetics Laboratory Department of Neurology Baylor College of Medicine, Houston, TX Predoctoral Fellow, EPA Training Grant USA-EPA, NHEERL, Research Triangle Park, NC Curriculum of Toxicology, UNC-Chapel Hill
1995- 1998	Research Assistant Birth Defects Research Laboratory Texas A&M University, College Station, TX

OTHER EXPERIENCE

1995- 1998	Teaching Assistant Department of Biochemistry and Biophysics Texas A&M University, College Station, TX *Advanced Human Genetics* (1 semester) *Introduction to Genetics Laboratory* (5 semesters)

EDUCATION

January 2015	Certificate of Biblical and Theological Studies (CBTS) Dallas Theological Seminary
December 1998	M.S. Genetics Department of Veterinary Anatomy and Public Health Texas A&M University GPA 4.0
December 1994	B.A. Anthropology/ Genetics minor Texas A&M University *Cum Laude* (GPA 3.6)

CONTINUING EDUCATION & MEETINGS

January 2001	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX) Topics included mtDNA extraction from difficult samples
February 2001	Training at the FBI DNAUII (Washington, DC) on mtDNA analysis
July 23-Aug. 3, 2001	Two-week training course at the FBI Academy on Forensic Mitochondrial DNA Sequencing and Analysis (Quantico, VA)
September 9, 2002	CODISmt 5.2W Usability Review at SAIC—8 hour training/evaluation on new CODIS software for mtDNA focusing on Missing Person Database (SAIC facility)
January 9-10, 2003	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX) Topics included Crime Scene Investigation, Animal DNA Forensics, Ethics, and Identification of non-standard bodily fluids
March 18-19, 2003	DNA-VIEW software and statistics training—6 hour training by software developer
May 5-6, 2003	DNA Auditor Training, Austin, TX --- 16 hour course presented by the FBI
July 31-Aug. 1, 2003	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX)
November 17-21, 2003	Grant Writing Class (40 hours)--- Northeast Counterdrug Training Center, Fort Indiantown Gap, PA
January 15-16, 2004	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX)
November 15-17, 2004	10th Annual National CODIS Conference (Crystal City, VA)
January 20-21, 2005	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX)
September 12-13, 2005	"Forensic DNA Statistics" presented by Dr. George Carmody (16 hours).

March 20-21, 2006	"Bloodstain Pattern Recognition and Examination of Bloodstained Clothing Workshop" (16 hours) presented by Michael J. VanStratton and Kevin R. Winer
October 23-24, 2006	12th Annual National CODIS Conference (Crystal City, VA)
June 7-8, 2007	Grant Progress Assessment (GPA) Program: FBI DNA Audit Refresher Training & Annual Training for GPA Assessors (Washington, DC)
July 10, 2007	Future Trends in Forensic DNA Technology (ABI) (Austin, TX)
July 23-25, 2007	DNA Grantees Meeting (NIJ) (Arlington, VA)
October 2-4, 2007	18th International Symposium on Human Identification (Hollywood, CA)
August 7-8, 2008	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX)
December 9, 2008	Mixture Interpretation Workshop (8 hours) presented by Gary Shutler, PhD and Phil Hodge, MS from the Washington State Highway Patrol.
January 13, 2009	Ethics Seminar "Is there a science to right and wrong? Responsibilities of forensic scientists in today's crime laboratories" (2 hour)
January 27, 2009	Forensic DNA Training Workshop (8 hours) by John Butler, PhD from NIST
February 18-21, 2009	American Academy of Forensic Science 61st Annual Meeting (Denver, CO)
March 13, 2009	Introduction to Uncertainty in Forensic Chemistry (On-demand portion), NIJ/RTI International on-line course worth 1 contact hour
November 3-4, 2009	DNA Auditor Training, Houston, TX --- 16 hour course presented by the FBI
January 28-29, 2010	Association of Forensic DNA Analysts and Administrators (AFDAA) meeting (Austin, TX)
Jan/Feb 2010	Ethics in Forensic Science, West Virginia University Extended Learning (online)

MANAGEMENT TRAINING

January 25, 2005	"Supervising and Motivating Difficult People" (4 hours)
May 30, 2007	Understanding and Implementing the Fair Labor Standards Act, the Americans with Disabilities Act and the Family and Medical Leave Act. Eileen C. Begle (3.5 hours)
December 5, 2007	Building Organizational Excellence. Walter Natemeyer. (4 hours)
December 11, 2007	Preventive Counseling. Jay Aldis (3 hours)
March 20, 2008	Hiring, Lawful Documentation, and Evaluations and Counseling. (3.5 hours)
November 19, 2008	Coaching for Continuous Improvement (4 hours)
January 15, 2009	Performance Management Part 2: Conducting Successful Conversations. Deedee Ostfeld. (4 hours)

December 14, 2009 Achieving Communication Effectiveness (1.5 hours). Vital Learning on-line.

May 24, 2010 Communicating Up (1.5 hours). Vital Learning on-line course.

PUBLICATIONS

Lisa A. Gefrides and Katherine E. Welch. 2011. Forensic Biology: Serology and DNA. In The Forensic Laboratory Handbook Procedures and Practice, 2nd edition. A. Mozayani and C. Noziglia eds. Humana Press (Springer Science+Business Media). pp. 15-50.

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ABSTRACTS

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Jennifer Stipanovic, B.S., F-ABC, Kimberly Kerlec, B.S., Cindy Klein, M.S., Wendi Phelps, M.S., Sapana Prajapati, B.S., MB(ASCP), Dennis Yip, M.S., F-ABC, Mark Powell, M.S., F-ABC, Lisa Gefrides, M.S., F-ABC, Roger Kahn, Ph.D., F-ABC. "Validation of the Tecan Evo 150 for use in forensic casework." *Genetic Identity Conference Proceedings*, 21st International Symposium on Human Identification (2010): http://www.promega.com/geneticidproc/ussymp21proc/abstracts/poster_2.pdf [accessed 3/11/11).

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Speaker. Sexual Assault Kit Processing. Presented to the SANE/ Forensic Nursing Course at the HCHD Administration Building on May 20, 2009.

Speaker. Sexual Assault Kit Processing. Presented to the Sexual Assault Response Regional Group at the Houston Area Women's Center, 1010 Waugh, Houston, Texas 77019 on April 30, 2009.

Speaker. A Y-STR Mixture Calculator for Forensic Casework. Presented at AAFS on February 20, 2009.

Speaker. Y-STR Mixture Database. Presented at AFDAA August 7, 2008.

Poster Presentation. The Effective Detection and Treatment of Consumable Contamination. 18th International Symposium on Human Identification. October 2, 2007.

Speaker. Understanding New Toxicology and DNA Testing. Harris County District Attorney's Office, October 6, 2005.

Speaker. Forensic Biology: Serology & DNA. Leadership Houston Justice Day 2005. April 14, 2005.

Speaker. ABI 3100-Avant Validation for Forensic Casework. Presented at AFDAA January 20, 2005. Austin, TX.

Speaker. DNA & Serology (Collection and Preservation of DNA evidence). For Harris County Sheriff's Office Intermediate Crime Scene Class. Dec. 8, 2004.

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Speaker. DNA and Serology. For Sexual Assault Family Violence Investigators Course (SAFVIC), April 3, 2003. Tomball, TX.

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Poster. LA Gefrides, K Kohl, DA Wideman, B Moore, J Mathew, and A Mozayani. Validation of the QIAamp DNA Mini Kit for Use in Mitochondrial DNA Casework. SWAFS November 2001, San Antonio, TX.

PROFESSIONAL ORGANIZATIONS & APPOINTMENTS

2001-2011	Association of Forensic DNA Analysts and Administrators (AFDAA)
2003-2011	Clinical Instructor Voluntary Faculty Department of Pathology Baylor College of Medicine, Houston, TX
2005- 2011	NDIS Audit Review Panel Member
2007- 2012	Fellow, American Board of Criminalistics
2010- 2011	American Society of Crime Laboratory Directors

From the Desk of
Robin D. Guidry
Criminalist Specialist
Crime Laboratory
Tuesday, February 14, 2012

Subject: Failure to Complete the DNA Monthly Clean-Up Tasks

It was discovered well into January, 2012, that the monthly clean-up check-list for the DNA section had not been completed for December, 2011. Jennifer Clay and Kirbie Watson were the assigned analysts for the month.

The applicable maintenance tasks had been completed (e.g., 7500 monthly maintenance, 3130 spectral), but the weekly tasks of replenishing reagents and pipette tips, replacing expired reagents, and cleaning up work areas was not performed and thusly not documented.

Efforts to minimize this type of oversight, such as administrative email alerts at the beginning of one's clean-up month, will be explored. This issue was also addressed at the DNA sectional meeting that occurred on January 25, 2012.

cc: Irma Rios, Laboratory Director JWilson 2/15/2012
cc: Lori Wilson, Quality Assurance Manager

Robin -
we need a response from Jennifer Clay & Kirbie Watson as to why they did NOT complete assigned tasks. What will be done if this recurs? What will be done to prevent this?
Irma Rios 2-15-12

2012-005

From the Desk of
Robin D. Guidry
Criminalist Specialist
Crime Laboratory
Monday, February 20, 2012

Subject: Follow-Up to Re-analysis of Samples with PBS Buffer

To ensure the accuracy of analysis conducted at this laboratory, semen-detection cases processed from December 1, 2011 through December 21, 2011 were re-evaluated to ensure that potential staining problems did not interfere with the accuracy of reported results. Casework observations suggested that the use of SERATEC® PSA-SEMIQUANT Cassette Tests kit buffer in lieu of PBS buffer interfered with the ability of sperm to either fix to slides for microscopic reading or to properly absorb the dyes included in Seri's XMAS TREE STAIN for microscopic analysis.

- Fifty-seven cases that were processed between December 1, 2011 and December 21, 2011 were re-evaluated.
- Of the 57 cases, 36 (63.2 %) warranted the issuance of a supplemental report, as the initial reports had already been issued by the analyst. The supplemental reports note the retesting and whether the initial results were confirmed or not.
- Of the 57 cases, retention and not retesting was the chosen course of action due to extremely limited sample sizes for two cases (Inc #s 032304806 and 067443506).
- Of the 57 cases, retesting with PBS buffer resulted in 4 cases (7.0%) having different results. For the following cases, the initial screening results were negative for semen. However, the following changes were observed:
    - Inc #156376311: Item 1.1 was microscopically positive when PBS buffer was used, but had previously been microscopically negative when the SERATEC® kit buffer was used
    - Inc # 152898311: Items 1.2 and 1.3 were microscopically positive when PBS buffer was used, but had previously been microscopically negative when the SERATEC® kit buffer was used
    - Inc #082140711: Item 1.8 was microscopically positive when PBS buffer was used, but had previously been microscopically negative when the SERATEC® kit buffer was used
    - Inc #074288109: Item 1.8 was positive for p30 when PBS buffer was used, but had previously been p30 negative when the SERATEC® kit buffer was used

While the reported results of the vast majority of the cases were unchanged when retested using PBS buffer, a few cases yielded different results, making this effort well worth the extra time and expense. For the 4 cases with different results, DNA analysis is now warranted, where it previously would not have been. Had retesting not taken place, potentially probative evidence may have never been uncovered.

Robin D. Guidry
Criminalist Specialist (Acting Technical Leader)

2-27-12

CORRECTIVE & PREVENTIVE ACTION REPORT

Tracking Number	2012 - 007
Incident Number	033876811, 119632711, 103113611, 070988107, ~~095913311~~ 095913311, 109146111 & 031247711
Reported On	April 9,2012
Reported By	Jennifer Clay (PR#123898)
Description of Issue	Peaks observed below threshold in reagent blank 274KG12 (RBK031912KG).
Description of Root Cause	Unable to determine root cause. After a re-amplification all samples yielded expected results and reagent blank 274KG12 (RBK031912KG) was clean.
Description of Action Taken to Prevent Recurrence	All clean work environment techniques as outlined in our SOP will continue to be used.

Attach evidence that corrective action has been completed successfully (if applicable).

Action Completed By Jen Clay on 4/30/12.

Reviewed by Lab Manager [signature] on 4-30-12.

Reviewed by Quality Manager [signature] on 5/1/2012.

Additional Action Taken (if applicable)

On April 9, 2012, I noticed possible peaks below our interpretation threshold in reagent blank 274KG12 (RBK031912KG). The reagent blank as well as all related samples were re-amplified on the same day. Acting Technical Leader Robin Guidry was notified as well. All samples were then run on project SS041012. No more peaks were observed in the reagent blank and all samples yielded expected results. At the request of Robin Guidry, the originally amplified reagent blank was reset up and run on project SS041112. One peak was observed above our interpretation threshold and several more observed below threshold. The contamination appears to have been introduced at amplification. The original amplification plate was set up using the Tecan robot. The re-amplification of the samples was set up manually by analyst Shauna Schoonover.

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KG

CORRECTIVE & PREVENTIVE ACTION REPORT

:king Number	2012-008
dent Number	058851589
orted On	May 7, 2012
orted By	Clay Davis

scription of Issue	Allele being called below threshold for reagent blank 283KG12 (RBK032612KG1). This reagent blank is a combination of two reagent blanks 240KG12 (RBK031312KG) and 283KG12 (RBK032612KG1). The first injection of this reagent blank produced a peak at D19S433 between 50-100RFU, a re-set up and second injection still produced the peak visually but the peak was now below 50RFU. There is only one peak but it happens to be at a smaller locus, so it is difficult to determine if this is true DNA activity or spurious activity. Either way, it is below the analytical threshold of 100 RFUs.
scription of Root Cause	The root cause of this possible allele below threshold is difficult to determine. It could be the result of a myriad of causes, such as, but not limited to, carry over from the original sample, gloves not changed throughout the extraction and loading process, or tubes not properly sealed during extraction and loading of samples. Because the sample (131KG12RE2) did not produce a viable profile, the sample and reagent blank will not be used for interpretation. This reagent blank will not be re-amplified to determine whether this activity is reproducible. Without the re-amplification, we cannot be certain the reagent blank extract is producing the peak or if this is from carry over from the amplification set up or loading process.
scription of Action Taken to vent Recurrence	The analyst Karen Gincoo will continue to practice sterile laboratory procedures and limit talking and traffic within areas where samples are being processed. The analyst(s) should change gloves often during the extraction, amplification, and loading processes. She will continue to ensure that tubes are closed during handling and continue to promote a DNA-free environment with continuous cleaning, before, during, and after sample-handling.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By Clay Davis on 5.7.12.

iewed by Lab Manager [signature] on 5-7-12.

iewed by Quality Manager [signature] on 5/7/2012.

ditional Action Taken applicable) [signature] 5/7/12

Tracking Only - No further action taken at this time 5/7/2012

CORRECTIVE & PREVENTIVE ACTION REPORT

:king Number	2012-009
dent Number	176495910
orted On	May 15, 2012
orted By	Robin Guidry

cription of Issue	While preparing samples for an overnight digestion, DNA Technician Karen Gincoo discovered that she did not have enough of Proteinase K lot # 139313083 to add to reagent blank sample #295KG12, when she already added it to her evidentiary samples (#'s 293KG12 & 294KG12). She proceeded to add a different lot of Proteinase K (lot #136266121) to her reagent blank to ensure that all reagents added to the above samples were also added to her reagent blank. That same day, she inquired about this solution with Acting Technical Leader R. Guidry, who indicated this was not acceptable because the same lot # needed to be used on both the samples and the reagent blank. It was discovered that a sufficient volume of the initial lot # of Proteinase K (lot #139313083) was available for use on reagent blank sample #295KG12. As a result, the evidentiary reagent blank from 3/29/12 had two separate lots of Proteinase K added (lot #139313083 and #136266121). While this was not ideal, it would satisfy the need to demonstrate that all reagents applied to a sample were proven to be free of contaminating DNA prior to use. However, in trying to understand how she ran out of reagent mid-extraction, R. Guidry realized Karen not only processed the case reference sample just prior to handling the associated evidence sample (for which she had sufficient Proteinase K), but had also set the samples up beside one another on the same heat block for overnight incubation. The samples were essentially being processed side-by-side. This was a huge concern, given the anticipated high level DNA concentration of the known and what was expected to be low level DNA concentration of the evidence samples. The extraction was permitted to proceed to determine what the DNA results were. If the evidence and the reference DNA profiles were different, contamination was not a likely occurrence. However, if the samples yielded the same DNA profile, it would be impossible to rule out contamination as the cause. If the evidence samples yielded the same DNA profile, out of an abundance of caution, they would be re-extracted and the original DNA results would not be reported because these results could not be relied upon.
cription of Root Cause	It was immediately made clear to K. Gincoo by R. Guidry why her actions were unacceptable and she understood. Karen believes that her haste resulted in this oversight.
cription of Action Taken to vent Recurrence	The DNA profile from the initial evidentiary extraction did in fact match that of the reference sample with which it was extracted. For this reason, the evidence samples were re-extracted at a later time, to help ensure that the profile obtained originated from the samples themselves, and not possible contamination from the higher level reference sample. The results of the re-extraction were concordant with the initial extraction results, suggesting that contamination was not the cause of the matching DNA profiles. On the morning after the initial discovery, a meeting was held with DNA analysts C. Davis and P. Hill, along with Karen, to explain the situation and prepare them for the potential re-extraction. There was a concern that the evidentiary samples were in limited supply and re-extraction may warrant written consumption permission; the DNA analysts were instructed, should they be the one to review the case file, to closely review the quantification data for guidance in deciding how much sample could be consumed in the potential re-extraction.

Furthermore, the DNA SOPs were updated to specify the need to extract evidentiary samples in a separate time and/or location from reference samples. Previously it was common practice, but now the policy dictates this separation.

Attach evidence that corrective action has been completed successfully (if applicable).

on Completed By LVC on 5-15-12.

ewed by Lab Manager See above R. Guidry, TL on .

ewed by Quality Manager [signature] on 5/17/2012.

litional Action Taken
pplicable) [signature] 5-15-12

Discussions w/ Technical Leads on May 14. Technician re-trained on policy/procedure. No further action taken at this time - JBW

2012-010

From the Desk of
Robin D. Guidry RDG
Police Administrator
Crime Laboratory

Sunday, June 10, 2012

Subject: **October 2011 Monthly Maintenance Not Performed on the 7500 Real Time PCR System**

On Friday, June 8, 2012, it was discovered that the monthly maintenance had not been performed on the 7500 Real Time PCR System in October, 2011, even though the 7500 was used on casework, starting in October, 2011. For each month since October, 2011, the appropriate maintenance has been performed on this instrument.

The DNA Monthly Clean-Up schedule was updated in February, 2012, to include the 7500, in addition to the 7000 Sequence Detection System, for documentation of the appropriate maintenance.

cc: Lori Wilson, Quality Assurance Manager, Crime Laboratory Lwilson 6/11/2012
Irma Rios, Laboratory Director, Crime Laboratory
Irma Rios 6-11-12

CORRECTIVE & PREVENTIVE ACTION REPORT

cking Number	2012-012
ident Number	077165311 and 071177311
ported On	May 21, 2012
ported By	Diana Crossan (PR# 136431), Criminalist

scription of Issue

On 05/21/12 the following samples were extracted by differential extraction:

Sample 369DC12 - Item 1.2.1 – Portion of vaginal swabs – SF from INC# 077165311
Sample 370DC12 - Item 1.2.1 – Portion of vaginal swabs – SF from INC# 071177311
Sample 371DC12 - Item 9.1.1 – Portion of stain from panties - SF from INC# 071177311
Sample 372DC12 - RBS052112DC

Sample 373DC12 – Item 1.2.1 – Portion of vaginal swabs – EF from INC# 077165311
Sample 374DC12 – Item 1.2.1 – Portion of vaginal swabs – EF from INC# 071177311
Sample 375DC12 – Item 9.1.1 – Portion of stain from panties – EF from INC# 071177311
Sample 376DC12 – RBE052112DC

The differential extraction procedure is documented in the DNA SOP under section 7.6 pages 13-15. After the initial digestion, analyst Diana Crossan realized that the TNE used for the digestion had expired, which is a deviation from the SOP. The lot number of this TNE was 062411DC with an expiration date of 05/20/12.

escription of Root Cause

The samples had already been put on the block for digestion and so analyst Diana Crossan informed Technical Leader, Robin Guidry, PR# 136530, of the incident once she became available from attending a meeting. Robin Guidry stated that a CAPA needed to be generated and that the DNA Analyst who would be writing the case should be informed of the event. She also said that the samples would have to be re-extracted. All of the above samples were re-extracted by D. Crossan with a new reagent blank each for the sperm and epithelial fractions labeled as 391DC12 and 392DC12 respectively. All of the samples yielded expected results, including the reagent blanks. The report will reflect results obtained from the re-extraction.

escription of Action Taken to revent Recurrence

In order to prevent this kind of mistake from happening again in the future, it is recommended that not only should the analyst be paying close attention in noting lot numbers, expiration dates and QC dates, but they should record all of the reagent information on the extraction sheet and then have the information verified by another analyst to catch a mistake before the extraction is even started. As of right now, analysts will record reagent information and have it verified at a later time on the extraction sheet after the extraction has started. In order to prevent this from reoccurring, it may be recommended that the verification be done prior to starting the extraction Robin Guidry did discuss the idea of having the reagent's information recorded and verified before an extraction at the next DNA meeting held on 05/25/12. It was discussed and decided tha the reagent's information should be recorded prior to starting the extraction, but that the verification could be done anytime during the extraction.

Attach evidence that corrective action has been completed successfully (if applicable).

ction Completed By	Diana Crossan	on 7/2/12
eviewed by Lab Manager		on 7-9-12
eviewed by Quality Manager		on 7/13/2012

Additional Action Taken

CORRECTIVE & PREVENTIVE ACTION REPORT

king Number	2012-013
dent Number	097200511, 045131011, and 122026111
orted On	Jun 11, 2012
orted By	Diana (Crossan) Donley (PR# 136431), Criminalist

cription of Issue

Sample Switch
Criminalist Diana (Crossan) Donley (PR# 136431) extracted evidentiary samples in Inc#s 097200511, 045131011, and 122026111. The following are the corresponding sample numbers, incident numbers, and items extracted in the batch:

Sample #, Incident # and Item Descriptions:

377DC12 097200511 – 4.2.1 – Portion of "SW #2 right ankle" swabs - SF
378DC12 045131011 – 1.2.1 – Portion of vaginal swabs - SF
379DC12 045131011 – 1.3.1 – Portion of vaginal swabs - SF
380DC12 122026111 – 2.3.1 – Portion of "labia minora" swabs - SF
381DC12 122026111 – 2.5.1 – Portion of anal swabs - SF
382DC12 122026111 – 2.7.2.1 – Portion of stain from panties – SF
383DC12 RBS052212DC

384DC12 097200511 – 4.2.1 – Portion of "SW #2 right ankle" swabs – EF
385DC12 045131011 – 1.2.1 – Portion of vaginal swabs – EF
386DC12 045131011 – 1.3.1 – Portion of vaginal swabs – EF
387DC12 122026111 – 2.3.1 – Portion of "labia minora" swabs – EF
388DC12 122026111 – 2.5.1 – Portion of anal swabs – EF
389DC12 122026111 – 2.7.2.1 – Portion of stain from panties – EF
390DC12 RBE052212DC

Timeline of Events

May 22, 2012: Samples extracted by Criminalist Donley
May 29, 2012: Samples quantified by Criminalist M. Bryan Davis (PR #141059)
Results:
389DC12: Undet.
390DC12: 149.97 ng/uL
June 4, 2012: Dilution of 390DC12 re-quanted by Criminalist Davis, given it exceeded 50.0 ng/uL
Results:
390DC12 (1:20): 7.40 ng/uL
June 6, 2012: Samples amplified and prepped for CE load by Criminalist Davis
June11, 2012: Criminalist Davis notified Criminalist Donley of the potential for a sample switch, given the high quant value of a sample for which DNA was not expected; Criminalist Donley immediately notified the Technical Leader, Robin Guidry (PR #136530); TL Guidry asked Criminalist Donley to examine the data to try to determine where the profile in the RB may have come from; TL Guidry also indicated that the samples would need to be re-extracted.

scription of Root Cause

Criminalist Donley analyzed the run data from the original extraction on June 11, 2012 and noted that the same DNA profile was observed in samples 387DC12, 388DC12, and 390DC12, while sample 389DC12 had no interpretable result. This suggests that samples 389DC12 and 390DC12 were switched during extraction of the samples, since the reagent blank should not have yielded a DNA profile. Criminalist Davis made the dilution for re-quatitation from the neat tube labeled 390DC12 and again obtained a detectable amount of DNA consistent with the initial quantification data, suggesting the switch occurred prior to the initial quantitation.

	Criminalist Donley acknowledges that she could have caused this sample switch by mislabeling the final tubes for samples 389DC12 and 390DC12 or by switching the sample tubes after removal from the centrifuge just prior to the final tube transfer of the samples. All of the associated samples were re-extracted by Criminalist Donley. The reagent blanks of the re-extraction yielded no DNA, thus permitted the use of this new data. Data from the initial extraction will not be used for interpretation and the associated DNA reports will reflect results obtained from the re-extraction.
scription of Action Taken to vent Recurrence	For future extractions, Criminalist Donley will work at a slower pace and will pay more careful attention when transferring samples between tubes and when removing sample tubes from the centrifuge to ensure they are in the proper order, so as to minimize the potential for this incident to occur again.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By Diana Donley on 7/12/12.

iewed by Lab Manager [signature] on 7-16-12.

iewed by Quality Manager [signature] on 7/17/2012.

ditional Action Taken pplicable)

CORRECTIVE & PREVENTIVE ACTION REPORT

king Number	2012-014
dent Number	184934607
orted On	Jul 30, 2012
orted By	Clay Davis (PR# 125253)

cription of Issue	The first injection of sample 190BC12 on project MBDBC061412 produced a mixture with alleles below threshold. A request dated 7-19-12 was made to DNA Technician Ben Cambridge (141062) (BC) to re-inject for 20 seconds to bring up alleles below threshold. The re-injection on project BC071912 produced no data for sample 190BC12. A complete re-set up of the 3130 plate was requested on 7-20-12 for this sample. The re-set up and injection of sample 190BC12 on project BC072312 produced a full male profile that was different than the original sample data on project MBDBC061412. The profile developed in the re-set up injection is consistent with the profiles developed from samples 180BC12, 182BC12 & 183BC12.
cription of Root Cause	The incident was discussed with fellow analyst Diana Donley (136431) (DD) and Tech Lead Robin Guidry (136530) and it was decided to re-amplify both evidence samples (190BC12 & 191BC12) associated with this case and compare those results with the original injection on project MBDBC061412. Diana Donley and I sat down and confirmed that the re-injection worksheets had the correct well number for sample 190BC12 and that the sample names were correct. All names and well numbers were correct. The re-amplified samples were requested on 7-24-12 and ran on project BC072412. Both newly amplified samples (190BC12RA & 191BC12RA) are consistent with the original samples injected and will be used in the interpretation and results for this case. A meeting was called on 7-24-12 with Ben Cambridge, Robin Guidry, Michael Bryan Davis (141059) and Clay Davis to discuss how the samples could have been switched. Ben suggested a simple mis-read of the sample name 190BC12 versus 180BC12. Another possible explanation is that the error occurred when viewing the second re-injection worksheet, where the two samples listed were 190BC12(well 1F - amp plate 053012BC) and 185DC12 (well 1A - amp plate 061112BC). An association of sample 190BC12 with well 1A instead of 1F would have produced the unknown male that was seen in the second re-injection request; sample1A on this plate is sample 180BC12. So either a misread of the sample ID or the wrong association with sample name and well number could have produced the male DNA profile observed in the second injection.
scription of Action Taken to vent Recurrence	During the meeting held on 7-24-12 with Robin Guidry, Ben Cambridge, Clay Davis and Michael Bryan Davis suggestions were made to help prevent this from happening in the future. The group discussed getting ideas and procedures from other DNA technicians about how they process samples and how they keep the large volume of samples that we process in order. A suggestion was made to Ben C. to make a copy of paperwork (either grid or TECAN printout) before going into the amp room and circling or highlighting the samples needed for that re-injection, based upon the analysts' re-work request worksheets (e.g., re-amp or re-inject). Ben C. committed to being more diligent about double checking sample names, well locations and plate names in the future.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By Clay Davis on 7-30-12.

iewed by Lab Manager [signature] on 7-30-12.

iewed by ~~Quality Manager~~ Director, Testing [signature] on 8-6-12.

ditional Action Taken pplicable) BC 7-30-12 DD 7/30/12 8/6/2012

MBD 7/30/12

CWD CLD

CORRECTIVE & PREVENTIVE ACTION REPORT

acking Number	2012-015
cident Number	#075069710 and #178324410
eported On	OCT 2, 2012
eported By	Karen Gincoo and M. Bryan Davis

escription of Issue

Incident #075069710 was included in Batch 35 for DNA analysis. While Bryan Davis (PR#141059) and I (Karen Gincoo PR#129764) were labeling sample tubes for this incident number, we discovered a discrepancy. While the outer packaging indicated that the samples were from incident #075069710, the tubes contained within were actually labeled as being from incident #178324410 (see photos). The incident number on the tubes labeled by the screener was #178324410. The outer packaging, however, was correct, #075069710 (see photos). The item numbers on the tubes (3.1.1, 3.2.1, and 9.1) were consistent with the evidence retained in incident #075069710.

escription of Root Cause

Next, I retrieved the evidence retained for incident #178324410 from the walk-in-freezer. I observed that the date on the evidence tape matched the date on the evidence tape on incident #075069710, indicating that both sets of portions were packaged and placed into the walk-in-freezer on the same day. The evidence contained in the 6"x 9" envelope for incident #178324410 was consistent with the items retained, per the screening report.

escription of Action Taken to revent Recurrence

The most likely explanation is this was a transcriptional error made by the screening analyst, Kirbie Watson, when she was labeling her tubes for portioning. The screening analyst is no longer with the Crime Lab, and therefore we are unable to have her address what is likely improper labeling. In both cases, the item numbers on the tubes corresponded with the items retained in each report. Furthermore, there is no replication of item numbers: incident #075069710 includes item #s 3.1.1, 3.2.1, and 9.1 and incident #178324410 includes item #s 1.1.1, 4.4.1.1, 4.5.1.1, and 4.6.1.

Attach evidence that corrective action has been completed successfully (if applicable).

ction Completed By	Karen Gincoo M Bryan Davis	10/11/12 on 10/11/12
eviewed by Lab Manager	[signature]	on 10-11-12
eviewed by Quality Manager	[signature]	on 10/12/2012

dditional Action Taken f applicable)

The portions in the incorrectly labeled tubes were tested, but to ensure that the correct samples have been tested and that reported results are completely accurate, the remaining samples (3.1, 3.2, and 9) will be recalled from the Property Room for re-portioning and subsequent DNA analysis.

Analyst will follow-up once analysis of reportioned samples is complete. [signature]

CORRECTIVE & PREVENTIVE ACTION REPORT

racking Number	2012 - 017
ıcident Number	089098612, 031022991, 078344011, 061428511, ~~1676976~~ 16769761 CWD 16769761O, 149195410
eported On	Dec 20, 2012
eported By	C. Davis (PR# 125253)

)escription of Issue

On 12-20-12 while analyzing reagent blank 906MBD12 processed on run data SS121912, a partial profile was seen above 50 RFU's in this reagent blank. Technical Leader R. Guidry (PR# 136530) was notified and a re-amplification was requested for this sample on the same day. Re-amplification of 906MBD12 revealed a complete profile; this profile was compared to the DNA profiles of the employees as well as the DNA profiles from the extraction batch. The unknown DNA profile was discovered to be that of analyst M.B. Davis (PR# 141059). Analyst M.B. Davis (PR# 141059) and Technical Leader R. Guidry were notified of the issue and all three of us had a discussion regarding this issue. Analyst C.Davis (PR# 125253) notified fellow analyst A.Castillo (PR# 139273) of the issue with the reagent blank and how it affects batch 45 due to C.Davis and A. Castillo both writing and reviewing cases in this batch.

)escription of Root Cause

The root cause of the contamination is difficult to determine. It could be a result of a myriad of causes, such as, but not limited to, gloves not changed during the extraction process, talking during the extraction batch, touching or handling items not decontaminated during the analysis of the evidence items. All samples associated with this reagent blank will be re-extracted; if consumption of any of the samples is needed then a request will be made to the officer or District Attorney.
Note: The DNA profile from Analyst M.B. Davis is used for the NIST traceable and has been used for training purposes in serology and DNA.

)escription of Action Taken to Prevent Recurrence

A discussion between R. Guidry (Tech leader), C. Davis (analyst) and M.B. Davis (analyst) listed possible explanations of how this issue could have occurred. M.B. Davis believes that his DNA was introduced into the tube through possible contaminated gloves or talking when the reagent blank tube was introduced into the extraction batch. Analyst M.B. Davis will continue to follow sterile techniques which include minimize talking in extraction, pre-amp and post-amp rooms. Gloves will be changed often and a no talking policy will be practiced by this analyst.

Attach evidence that corrective action has been completed successfully (if applicable).

Action Completed By C. Davis on 12.28.12.

Reviewed by Lab Manager [signature] on 12-28-12.

Reviewed by Quality Manager MBD M. Boyd Davis MBD 1/4/2013 on 1/4/2013.

Additional Action Taken (if applicable)

M. Boyd Davis 12/28/12

[signature] 10/28/12

CORRECTIVE & PREVENTIVE ACTION REPORT

Tracking Number	2013-011
Incident Number	133691198
Reported On	Jul 2, 2013
Reported By	Shamika Kelley
Description of Issue	A sample was processed and the data appeared to be a mixture with low RFU and possible dropout. Therefore, the sample was re-amplified. After re-amplification, the data appeared to be a single source sample. The sample was then re-amplified for a second time to confirm the data. The data was confirmed to be a single source sample.
Description of Root Cause	A plausible explanation would be that as the sample plate was being loaded during amplification, one sample was loaded twice into a well that already contained sample. This is what possibly caused the data to appear as a mixture.
Description of Action Taken to Prevent Recurrence	Since the incident, the analyst has developed a system during the loading process to double check that the correct sample goes into the correct well and that the samples are only loaded once.

Attach evidence that corrective action has been completed successfully (if applicable).

Action Completed By Shamika Kelley on 7/02/13.

Reviewed by Lab Manager — on 7/2/13.

Reviewed by Quality Manager [signature] on 7/8/2013.

Additional Action Taken (If applicable) Briefly describe the system developed by the analyst to prevent samples from being loaded inaccurately.

Upon taking the samples from the cooler & placing them into a rack, I make e to use an empty rack as well. As the samples are loaded onto the sample te. they are moved from the full rack to the empty rack to indicate they've en loaded onto the sample plate. Simultaneously, the tips for the pipettes being used in the same order that the samples are loaded onto the sample ate. For example, the tip located at the top left of the tip box will be used the sample located at A1 on the sample plate. The next tip down will be used B1 and so on until all the samples are properly loaded. This method serves a second check that the samples were loaded in the correct sample wells.

7/11/2013

CORRECTIVE & PREVENTIVE ACTION REPORT

king Number	2013-012
dent Number	121706893
orted On	Jul 11, 2013
orted By	Jisel Ballon
cription of Issue	On July 10, 2013 Jisel Ballon (PR #150997) noticed that the chain of custody in LIMS for incident #121706893 did not have correct documentation for the location of item 2.1. Item 2.1 was noted as being packaged with parent in LIMS; however, while Elizabeth Richey (PR# 151453) was doing an inventory of item 1 on June 26, 2013, she noted that item 2.1 was packaged with item 1. On July 10, 2013, Elizabeth Richey re-opened item 1 to confirm its inventory, and it was discovered that item 2.1.1 (not item 2.1) was packaged with item 1. Elizabeth Richey corrected the documentation that in fact item 2.1.1 was packaged with item 1; therefore, LIMS did not have correct documentation for the location of item 2.1.1. The evidence tape on the item indicates the date of repackaging as April 23, 2013 by Rebecca Gonzales (PR #139392).
scription of Root Cause	Item 2.1.1 was not documented correctly regarding its location. Per Quality Manual, the chain of custody must include documentation of evidence transferred to and from individuals/storage locations.
scription of Action Taken to vent Recurrence	The analyst will continue to be diligent when documenting the transfer of items of evidence. The location of this item will be changed in LIMS to indicate that it was placed in item 1 on April 23, 2013 by a LIMS administrator.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By	J. Ballon	on 7/12/13.
iewed by Lab Manager	[signature]	on 7/16/13.
iewed by Quality Manager	[signature]	on 7/19/2013.
ditional Action Taken applicable)	[signature]	7/12/13
	[signature]	7/15/13 7/24/13

ify via LIMS that the chain has been corrected. [signature]
should item 2 1.1 be packaged w/ parent item #1 or with parent item #2?

23·13, Item 2.1.1 was taken out of Item 1 & placed back into Item 2 by Rebecca
mates. -RG
BW 7/29/2013

CORRECTIVE & PREVENTIVE ACTION REPORT

acking Number	2013-014
cident Number	100655107
eported On	June 13,2013
eported By	J. Clay (PR# 123898)

escription of issue

During the technical review of Inc#100655107 it was brought to the attention of analyst Jennifer Clay (PR# 123898) by analyst Clay Davis (PR# 125253) that items C9WV\C9WW.2.1 and C9WV \C9WW.3.1 had not been portioned according to the description in LIMS or the descriptions on the extraction worksheet. Analyst J. Clay contacted the technician Elizabeth Richey (PR# 151453) in order to determine what had happened. Elizabeth stated she received these two items already portioned. According to LIMS as well as the paperwork within the file, items C9WV\C9WW.2.1 and C9WV\C9WW.3.1 were not portioned at screening by analyst Amy Castillo (PR #139273). We are unable to determine if the evidence was actually consumed because the original packaging was discarded. Since we were unable to locate any remaining sample at this time, there is a possibility the item was consumed without notifying appropriate personnel. Please see DNA SOP Section 4.4 Evidence Handling:

"Consumption of Evidence
The evidence quality and quantity will be preserved as much as possible without sacrificing the quality of the analyses. Whenever possible, at least half of the evidence sample will be preserved for possible re-analysis. When this is not possible, appropriate personnel (submitting officer, prosecuting attorney, and/or defense attorney) will be notified prior to the consumption of evidence and permission to consume will be requested. Samples will not be consumed without first having documented permission, preferably in writing. Furthermore, wherever possible, efforts should be made to limit the consumption of DNA extracts."

The DNA results of items C9WV\C9WW.2.1 and C9WV\C9WW.3.1 are consistent with the complainant's reference profile. There are no indications of a second contributor. Statements from all individuals who handled the case are provided below.

escription of Root Cause

Analysts Elizabeth Richey (PR#151453), Amy Castillo (PR#139273), Ben Cambridge (PR#141062), and Kerry Todd (PR#141057) have provided written accounts of there involvement with this case. Please see statements below:

Statement provided by Elizabeth Richey:
"Items C9WV\C9WW.2.1 and C9WV\C9WW.3.1 (swabs from the FNSC from the right and left hands, respectively) for incident 100655107 were assigned to Elizabeth Richey (PR# 151453) for extraction. Prior to receiving the evidence, she looked at the serologist notes to determine the amounts sent to DNA. The notes stated that for both items, two swabs were retained for DNA analysis. Therefore Elizabeth foresaw that she either had to portion the items, if not previously done so, or she had to process them as large volume extractions. The items were enclosed in an envelope which contained these two items, plus a known blood stain card for Anthony Moore (item C9WV\C9WW.1). Elizabeth opened this envelope on 05-14-13, and she noticed that the swabs were already in microcentrifuge tubes and they looked to contain only ~one swab each, rather than two. Even though there were no portions made for these items in LIMS, she assumed that these were portions since the items were in tubes that are used for portioning and the swabs looked to be about half the amount that the serologist stated to have retained for DNA analysis. The outer envelope and the inner envelopes for items C9WV\C9WW.2.1 and C9WV\C9WW.3.1 were discarded, and the blood stain card was given to Benjamin Cambridge for portioning. She extracted the entirety of each of the swabs contained in the tubes on 05-14-13, and noted on her extraction sheet that she received one swab for each item and took all for analysis. When the possibility of there being missing swabs came to our attention, Elizabeth requested the original morgue kit (item C9WV\C9WW) from the property room on 06-13-13 and opened it to see if there

were any swabs of the FNSC contained in the parent. No swabs were found, but the fingernail clippings, sticks, and clippers still remained for each of the two items in question."

Statement provided by Amy Castillo:
"Per the worksheet filled out on 12/9/10 I inventoried the morgue kit for this case. I also swabbed the fingernail scrapings and clippings with two swabs. The swabs taken were retained (un-portioned), along with the un-portioned blood stain card. Per the official chain of custody I packaged these three items together (items C9WV\C9WW.1, C9WV\C9WW.1.2.1, C9WV \C9WW.1.3.1). Per my notes two swabs were taken and were not portioned, I do not remember the details of what I did in this case except by my notes therefore I would have expected there to be two un-portioned swabs for both the left (C9WV\C9WW.1.3.1) and right (C9WV\C9WW.1.2.1) hand and an un-portioned bloodstain card (C9WV\C9WW.1) in the sealed envelope stored in room temperature storage from 1/6/11 until recently."

Statement provided by Ben Cambridge:
"On 05/14/2013 I received item C9WV\C9WW.1 (bloodstain card - Anthony Moore ML# 07-2273) in a sealed bloodstain card envelope. The item was transferred directly to me from E. Richey as detailed in the chain of custody in LIMS. I made two portions of the bloodstain card (items C9WV \C9WW.1.1 and C9WV\C9WW.1.2) and then sealed it in the bloodstain card envelope with evidence tape. Having noticed that the original outer envelope containing the item had been discarded in a biohazard waste container, I sealed the bloodstain card in a new yellow envelope and returned it to room temperature storage shelf B-RT-07D on 05/14/2013 as accurately reflected in the chain of custody."

Statement provided by Kerry Todd:
"I (Kerry Todd, Criminalist, PR#141057) received items BXFX\BXFY, BXG1\BXG2 and BXG3\BXG4 from case L07-3045/100655107 on April 2, 2013. After the analysis was complete on these items, I portioned item BXG1\BXG2.1 (swab from Band-Aid), item BXG1\BXG2.2 (stain from Band-Aid) and item BXG3\BXG4.2 ("From kitchen knife" swabs). The portions from the items were retained by taking approximately half of the total swab amount from each item and placing it in a serology tube. Once the portion is placed inside the serology tube, the tube is labeled with the incident number, my initials and item number. Typically, I repackage the portions in the tubes by placing them into individual small zip lock bags. I seal the top of the small zip lock bag containing the portion with evidence tape. I place the date and my initials on the evidence tape. After this occurs with each portion, I place all the evidence portions in a larger manila envelope with the appropriate barcodes on the front along with my initials. The manila envelope was sealed with evidence tape with the date and my initials on it. Lastly, the manila envelope containing the portions was placed in Freezer 13 on April 19, 2013."

escription of Action Taken to event Recurrence

This seems to be an isolated incident. In the future, should an analyst or technician notice a discrepancy between the description of the item (portion vs. non-portioned items) and the item actually received, a supervisor or other qualified individual should be notified. In our section meeting on June 27, 2013, the issue was discussed with all analysts to help prevent any future issues. Internal temporary packaging can be discarded only if all pre-portioned items contained within the packaging are consumed. In our current method of processing cases portions are usually made at screening. Sgt. M. Miller has been notified of the incident. Please see page C16 for email communication.

Attach evidence that corrective action has been completed successfully (if applicable).

tion Completed By _____ on 7/26/13.

viewed by Lab Manager _____ on 7/26/13.

viewed by Quality Manager _____ on 7/29/2013.

ldditional Action Taken applicable)

BC ER DC

Inc# 100655107 page#C18

QA-CAPA- 2010.1

effective 01-04-2011

Inc#100655107

Pmar#r.197

ncident Number Update Request

Houston Police Forensic Services
1200 Travis
Houston, Texas
Harris County
77002
Phone: 713-308-2600

Current Date 7/19/13

yee Number:	139392
yee Name:	Rebecca Gonzales
:	rebecca.gonzales@houstonpolice.org
:	713-308-2612

Info

nt:	121706893

/erified via OLO

es

D

Describe The Problem in Detail:

Item 2.1.1 is stated in LIMS to be packaged with parent. This item was found to be packaged with item 1 on 6/26/13. The evidence tape on the item has the date of repackaging as 04/23/13. This is the date the item was actually repackaged under item 1. Could you go in LIMS and transfer item 2.1.1 into the custody of item 1 on 04/23/13?

Internal Use Only Action Taken:

Sample Parent Relationship has been changed to item # 1
a note has been added to the custody comments for this item.

al Signature Rebecca Gonzales

al Signature Supervisor Robin D. Guidry

il : hector.sustaita@cityofhouston.net

Internal Use Only

LIMS Administrator Hector Arjona-Sustaita

Date

2/18/2010

CORRECTIVE & PREVENTIVE ACTION REPORT

2013-017

Tracking Number	2013-017
Incident Number	PAR-B 2013
Reported On	Sept.19, 2013
Reported By	Clay Davis (PR# 125253)
Description of Issue	During the analysis of project MBD080113 by C. Davis (PR# 12553), the injection of sample 308PL13, well B2 of amplification plate MBD080113, was found to have excessive artifacts. A request for re-injection of sample 308PL13 was sent to P. Lentz (PR# 151448) on 8-5-13 along with 8 other samples from two different plates, PL080113 and MBD080113. The re-injection of sample 308PL13 on project PL080613 produced a profile that was not consistent with the initial injection from project MBD080113. After analyzing and reviewing the DNA profile produced in this re-injection, it was determined that the re-injection sample was from plate PL080113 and not from the amplification plate MBD080113. A re-injection request was sent to P. Lentz on 8-6-13 and the sample was re-injected on project BC080613 with the results being consistent with the original injection from project MBD080113.
Description of Root Cause	Statement provided by Peter Lentz: "The incident was discussed between C. Davis (PR#125253) and myself (P. Lentz) and it was determined that I had re-injected well B2 from plate PL080113 instead of well B2 from plate MBD080113."
Description of Action Taken to Prevent Recurrence	Peter Lentz will double check sample names, wells, and plates on all runs in the future and will take more care in handling multiple plates.

Attach evidence that corrective action has been completed successfully (if applicable).

Action Completed By Clay Davis on 10.4.13.

Reviewed by Lab Manager [signature] on 10-4-13.

Reviewed by Quality Manager [signature] on 10/4/2013.

Additional Action Taken (If applicable)

[signature] 10-4-13

CORRECTIVE & PREVENTIVE ACTION REPORT

king Number	2013-018
dent Number	080008113, 082259013, 112386312, 102925900, 045323313, 071332513, 072450813, 181795510, 073558113, 160892912, 069421813 + 052636013
orted On	Sep 19, 2013
orted By	Clay Davis (Pr# 125253)

cription of Issue	During the analysis of Project BC082913, the negative control labeled as NEG082813BC appeared to have one peak above our analytical threshold of 50RFU at vWA and three locations below 50RFU's but consistent with true DNA activity. This negative control is associated with the evidentiary samples for Batch 26. A request was made the same day for a re-set up of the plate with just the positive, negative and ladder being processed. An analysis of the re-set up plate labeled as BC082913C revealed the peaks to be reproducible upon re-injection with the same configuration as mentioned in the original injection (1 peak > 50RFU's, 3 locations <50 RFU's). An immediate request for a re-amplification of the entire plate of evidence samples was requested. On 9-3-13 the re-amplification plate was processed and the negative controls as well as all the reagent blanks in the set were clean and free of DNA.
cription of Root Cause	The root cause of this contamination cannot be conclusively determined. The contaminated negative control was compared to the positive control and to the analyst, Ben Cambridge (PR# 141062), who set up the amplification on 08-29-13. Analyst Jennifer Clay (PR # 123898) and I also compared all DNA profiles from the evidence samples associated with this negative control as well as all lab staff DNA profiles to the low level DNA profile found in the negative control and none were consistent with this DNA profile. The TECAN EVO 150 was used to set up the amplification reaction of the evidentiary samples first and then used to setup a plate of known reference samples with controls labeled as POS082913PL and NEG082913PL. This second setup was done without prior knowledge of the problem with the evidentiary amplification negative. The positive control for the reference plate produced the expected results with the negative control being clean. All DNA profiles from the known references were also compared to the low level DNA profile of the contaminated amplification negative control and, none were consistent.
scription of Action Taken to vent Recurrence	Analyst Ben Cambridge will continue to follow all sterile techniques as outlined in the DNA SOP for extraction, quantification, amplification and plate set-up. The TECAN is wiped down daily and a routine flush is performed between each reaction setup. Even though the subsequent negative controls were clean the TECAN negative was replaced by analyst Ben Cambridge upon learning of the incident.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By Clay Davis on 9.19.13.

viewed by Lab Manager [signature] on 9-20-13.

viewed by Quality Manager [signature] on 10/4/2013.

ditional Action Taken applicable)

2013-018

Jen. C. Clay 9/19/13

Benjamin Cambridge 9/19/13

CORRECTIVE & PREVENTIVE ACTION REPORT

Tracking Number	~~2013-018~~ 2013-019
Incident Number	092787509
Reported On	Aug 6, 2013
Reported By	Karen Gincoo

2013-019

Description of Issue

Criminalist Clay Davis received a call on August 5, 2013 from ADA Rachel Palmer about the complainant's reference sample in case Inc#088322509/L09-12679 (cross-referenced case). The DNA profile from Inc# 092787509 was used for comparison to evidence in Inc#088322509/ L09-12679. The ADA was confused because the morgue evidence was described as being from Eligah Williams who is still alive. It should have been identified as being from Undra Williams, the deceased complainant and daughter of Eligah Williams. The complainant's name was initially listed as Eligah Williams in OLO for both Inc#088322509/L09-12679 and Inc# 092787509, but has since been changed to Undra Williams in Inc #092787509. (see Correspondence Record dated 8/5/13 by Clay Davis for ADA Palmer's explanation)

It was discovered through that conversation that Inc# 092787509 had the morgue evidence containing the reference sample for the complainant. As ADA Palmer stated to Clay Davis, there had been a mix up in the complainant's name: Undra Williams is the actual complainant and Eligah Williams is the complainant's father.

When this evidence was initially processed in July 2011 by Criminalist Karen Gincoo, the complainant name used was verified using the ML # on the morgue evidence and the information in OLO about the complainant. The complainant's name had been later changed from Eligah Williams to Undra Williams in OLO by the investigating officer, but after the information was already printed out of OLO by lab personnel. LIMS was also inaccurate in the reported complainant name.

Property Room #003 was requested from the property room.
Criminalist Juli Rehfuss re-inventoried the morgue evidence on August 6, 2013. The morgue evidence did not have the complainant's name; instead, it was labeled with "Unknown, Unknown" and " ML #09-2098".

Description of Root Cause

Incorrect information in OLO and in LIMS, coupled with no associated name on the morgue evidence, resulted in the improper identification of morgue evidence. Also, the cross-referenced case Inc#088322509/L09-12679 also showed Eligah Williams as the complainant instead of Undra Williams. Furthermore, the bloodstain card from the morgue evidence failed to yield a DNA profile given extreme degradation. As a result, the gender of the complainant's known was not available for verification.

Description of Action Taken to Prevent Recurrence

This issue has been discussed via email and in sectional meetings with the entire Biology Section. In the event of an "unknown" name or name discrepancy on the morgue evidence, the analyst will contact the investigator to confirm the complainant's name in writing instead of verifying this information through the method described above. If written verification cannot be obtained, the morgue evidence will be described using the ML # and as being from "unknown" in the examination documentation and laboratory reports. These points will be included in the next SOP revision.

Reports associated with this case will be amended to reflect the correct complainant name.

Attach evidence that corrective action has been completed successfully (if applicable).

Action Completed By Karen Gincoo on 10/1/13.

eviewed by Lab Manager _____ on 10-1-13.

eviewed by Quality Manager _____ on 10/4/2013.

dditional Action Taken
f applicable)

10.1.13

KJ

CORRECTIVE & PREVENTIVE ACTION REPORT

king Number	2013-021
dent Number	035987805, 056226712, 014276213, 063985513, 018527713, 054559312.
orted On	10/18/2013
orted By	Maria A. Rumble

cription of Issue	Analyst upon removing amp plate from the 9700 discovered that in the last well, only master mix was present due to a smaller volume than what was in the other wells. It was discovered that analyst accidentally did not remove the negative from the sample setup file that was imported into the TECAN. The TECAN was told that there was one more sample than there actually was. Due to the upload of the csv file with the negative not omitted, the TECAN was told there was a negative where a sample was supposed to be. Samples located after the negative were shifted up one. This also caused an incorrect volume to be amplified for any samples behind the negative. The samples located after the negative were manually re-amplified using the correct template volumes.
cription of Root Cause	Analyst error and oversight is the root cause. Analyst should have double checked to make sure the negative was removed and that all wells had the same volume after using the TECAN to prepare the amp plate.
cription of Action Taken to vent Recurrence	Analysts will visually inspect that all wells of the quant or amp plate have the same amount of volume and that the correct file is uploaded into the TECAN. Per communication with the technical leader, the SOP will also be updated requiring a witness to verify the order and identity of the tubes coincide on the racks and in the software.

Attach evidence that corrective action has been completed successfully (if applicable).

ion Completed By MARumble on 11/15/13.

iewed by Lab Manager [signature] on 11-22-13.

iewed by Quality Manager [signature] on 12/2/2013.

ditional Action Taken applicable) see attached

2013-021

CORRECTIVE & PREVENTIVE ACTION REPORT

2014-002

king Number	2014-002
dent Number	n/a
orted On	Jan 14, 2014
orted By	Robin D. Guidry

cription of Issue	On 1/2/2014, Criminalist Vanessa Alvarez notified Criminalists Belinda Salinas and Diana Donley via email that her review of the records for the dry baths and thermomixers indicated that some of the units checked on October 21 and 22, 2013 were checked using expired NIST thermometers (NIST #3 and #4). Those units include dry baths #1 and #6 in the y-screening area and thermomixer #1 and dry bath #9 in the not-yet-on-line QiaCube laboratory. All blocks used for the extraction of DNA samples were calibrated using current NIST thermometers. During the investigation of this issue, it was also discovered that NIST thermometer #7 had not been subjected to a performance check in October, 2013. Additionally, NIST thermometers #3 and #4 were used to calibrate the DNA extraction heat blocks, despite being expired, on October 17, 2012.
cription of Root Cause	The cause is believed to be rooted in the lack of marking on the actual thermometers regarding their expiration and/or need for performance check. There is ample paper documentation of when the NIST thermometers expire and/or need a performance check, but this historically has not been transferred to the actual units. At the time of these checks in October, 2013, the NIST thermometers were stored in a single location, regardless of whether they are out of calibration and no longer in service.
cription of Action Taken to vent Recurrence	Corrective Actions: 1. NIST #7 underwent a performance check on January 8, 2014. 2. Dry baths #1 and #6 in the y-screening area and the thermomixer #1 and dry bath #9 in the QIACube laboratory have been recalibrated using current NIST thermometers on January 8, 2014 and January 13, 2014, respectively. Preventative Actions: 1. Each current NIST thermometer has been transferred to a bag that is labeled with the expiration date. 2. Expired NIST thermometers have been stored separately from the current thermometers. 3. A single individual, Christine Konecny, has been tasked with maintaining the section's NIST thermometers. 4. The heat block calibration form has been updated to require the analyst to include not only the NIST thermometer used, but also its expiration date. 5. The DNA monthly checklist has been updated to require the monthly review of whether NIST thermometers are expired and/or in need of a performance check.

Attach evidence that corrective action has been completed successfully (if applicable).

on Completed By Diana Donley, Belinda U. Salinas on 1-14-14

iewed by Lab Manager on 1-14-14 1-14-14

iewed by Quality Manager on 1/15/2014

ditional Action Taken
pplicable) verified w/ C Konecny that expired thermometers are labeled as such & stored separately. Must not be used for heat procedure

CORRECTIVE & PREVENTIVE ACTION REPORT

...cking Number	2014- 004
...dent Number	Batch 34 (see list of incident numbers below)
...ported On	Dec 30, 2013
...ported By	Lloyd Halsell III
...scription of Issue	On November 18, 2013, while analyzing run BC111513 for Batch 34, I noticed two peaks below threshold in the amplification negative control, NEG111513BC. A request was made to re-set up the load plate and re-inject this negative control. This data was analyzed on November 18, 2013 from run BC111813. The peaks persisted and a decision was made to have all samples associated with this amplification negative control re-amped. Upon re-amplification on November 19, 2013; run BC111913, the negative control displayed no peaks.
...scription of Root Cause	The root cause is difficult to determine since the potential contamination was so minimal. It is clear that it did occur during or after amplification setup.
...scription of Action Taken to ...event Recurrence	On December 4, 2013, following the detection of other peaks below threshold in separate amplification negative controls, multiple amplifications of the TE currently in use was undertaken to determine if it might be the source of the peaks. Duplicate amplifications were made from the conical tube in Quant set up room, the tube aliquot for the Tecan, the TE trough used on the Tecan, and the stock TE. No concerning activity was detected in any of the samples. As a precaution all aliquots of TE in the Quant set up room were discarded and replaced, including the trough on the Tecan. The Tecan was wiped down with DNAway and ethanol. Additionally the Tecan in post-amp was wiped down as well.

Attach evidence that corrective action has been completed successfully (if applicable).

...tion Completed By ____________ on 12-30-13.

...viewed by Lab Manager ____________ on ~~1-15-13~~ 1-15-14.

...viewed by Quality Manager ____________ on 1/22/2014.

...dditional Action Taken (...applicable)

Incident numbers:
002920113, 110399812, 127475513, 054054813, 092787509, 109165313, 113684710, 066994213, 178104010, 077734613, 057331113

[illegible] <35 rfu, analytical threshold for our laboratory is 50 rfu. This was reported for tracking purposes only. [illegible] above showed the buffer was not affected.
[illegible] 1/23/2014

CORRECTIVE & PREVENTIVE ACTION REPORT

cking Number	2014-004
ident Number	121060012
ported On	Dec 30, 2013
ported By	Lloyd Halsell III

scription of Issue	On December 4, 2013, while analyzing run BC120313, one peak below threshold was detected in the amplification negative control, NEG120313BC. A request was made to re-set up the load plate and re-inject this negative control. This data was analyzed on December 4, 2013 from run BC120413. The peak persisted and a decision was made to have all samples associated with this amplification negative control re-amped. Upon re-amplification on December 4, 2013; run BC120513, the negative control displayed no peaks.
scription of Root Cause	The root cause is difficult to determine since the potential contamination was so minimal. It is clear that it did occur during or after amplification setup.
scription of Action Taken to event Recurrence	On December 4, 2013, following the detection of other peaks below threshold in separate amplification negative controls, multiple amplifications of the TE currently in use was undertaken to determine if it might be the source of the peaks. Duplicate amplifications were made from the conical tube in Quant set up room, the tube aliquot for the Tecan, the TE trough used on the Tecan, and the stock TE. No concerning activity was detected in any of the samples. As a precaution all aliquots of TE in the Quant set up room were discarded and replaced, including the trough on the Tecan. The Tecan was wiped down with DNAway and ethanol. Additionally the Tecan in post-amp was wiped down as well.

Attach evidence that corrective action has been completed successfully (if applicable).

tion Completed By	[signature]	on 12-30-13
viewed by Lab Manager	[signature]	on 1-15-14
viewed by Quality Manager	[signature]	on 1/22/2014

ditional Action Taken applicable)

CORRECTIVE & PREVENTIVE ACTION REPORT

racking Number	2014-005
ncident Number	073173313
eported On	Oct 8, 2013
eported By	Peter Lentz
escription of Issue	During the process of combining previously extracted DNA with the remaining extracted DNA of the same sample, the extract of a consumed sample was mistakenly combined with the extract of another sample during the concentration step.
escription of Root Cause	I had two samples that were to be combined and concentrated to attempt a better DNA profile. Samples 548PL13 (Item 2.2, Inc #073173313) and 550PL13 (Item 6.1, Inc #037002913) were extracted and set up under the hood for combination before being concentrated. As I arranged the tube rack with the old extracts, I noticed there was not a 1000ul pipet in the hood that I was using so I moved all my samples and racks to another hood that I had just cleaned. After this move, I vortexed and spun down the old extracts and switched their places on the rack. I mistakenly added the new extract from sample 548PL13 (Item 2.2, Inc # 073173313) to the old extract for 478BC13 (Item 6.1.1 INC# 037002913). Because these samples were consumed and no sample remains for testing, these items will be reported as inconclusive due to a failure to satisfy this laboratory's quality assurance standards.
escription of Action Taken to revent Recurrence	In the future, if there is more than one Microcon needed, I will do them individually before proceeding. More care will be taken when combining samples and I will not change my plans in the middle of setting up for analysis. Furthermore, per Technical Leader R. Guidry, the DNA extraction SOP will be updated to require a witness when DNA extracts are to be combined.

Attach evidence that corrective action has been completed successfully (if applicable).

ction Completed By _____ on 1-14-14.

eviewed by Lab Manager _____ on 1-14-14.

eviewed by Quality Manager _____ on 1/22/2014.

dditional Action Taken f applicable)

HOUSTON POLICE DEPARTMENT
CRIME LABORATORY

CORRECTIVE AND PREVENTIVE ACTION REPORT

☒ CHECK IF ADDITIONAL PAGES ARE USED

SECTION 1

Date: Apr 14, 2014

CAPA #: 2014-008

DESCRIPTION OF ISSUE/NON-CONFORMANCE: On 2/21/14, the Quality Assurance Manager and I were informed that Peter Lentz allegedly did not follow proper protocol when investigating possible contamination for a sample extracted 2/5-6/14 in Inc #155416912. It was alleged that he did not amplify the actual reagent blank sample when he was attempting to determine if activity was reproducible upon re-amplification. The "examination documentation" produced by Peter for this re-amplification indicates that he did use the reagent blank sample for the re-amplification, which contradicts the allegation. I measured the sample in question on 2/25/14 and the measurement I obtained is consistent with Peter not having actually re-amplified the reagent blank sample. Peter was removed from casework on 2/25/14 pending a review. A review with the Internal Affairs Division began on 2/27/14.

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description: Class I ☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: The motivation to not follow protocol, as alleged, is unclear at this time and may be apparent at the conclusion of the review.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

The samples associated with the reagent blank in question were already re-extracted on 2/17-18/14 due to low-level activity in the re-amplification of the reagent blank in question. However, given the allegation, the Harris County District Attorney's Office was notified of the alleged failure to follow protocol (along with the Texas Forensic Science Commission and the laboratory's accrediting bodies, ASCLD/LAB and DPS) and provided with a list of all cases with which Peter was involved. Retesting has been requested and has

SECTION MANAGER: [signature]

Date: Apr 14, 2014

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: Review ongoing at this time. [illegible]

QUALITY MANAGER: [signature]

Date: 4/17/2014

LABORATORY DIRECTOR: [signature]

Date: 4-17-14

2014-008
cont'd

commenced on many cases by ADAs, while the lab has initiated retesting on cases for which Peter handled samples but reports had not yet been issued. Examples of unethical behavior and the potentially far-reaching consequences in a forensic laboratory were discussed at the most recent laboratory-wide meeting on 4/10/14. DNA protocol will be enhanced to require that steps taken to verify possible contamination will be performed by a third party within the lab.

4/14/14

HOUSTON POLICE DEPARTMENT
CRIME LABORATORY

CORRECTIVE AND PREVENTIVE ACTION REPORT

☒ CHECK IF ADDITIONAL PAGES ARE USED

SECTION 1

Date: Mar 4, 2014

CAPA #: 2014-009

DESCRIPTION OF ISSUE/NON-CONFORMANCE: On 03/03/14 it was noted by Criminalist Diana Donley during data analysis, that item 1.1 (portion of known blood from the victim), sample 76MR14Y, contained possible allelic activity. This sample should have had no result, as YSTRs was being performed and this sample was a reference from a known female. Criminalist Diana Donley requested that sample 76MR14Y be re-injected to confirm activity. On 03/04/14 76MR14Y was re-injected and allelic activity was confirmed. Criminalist Diana Donley then requested a re-amplification of sample 76MR14Y and informed Technical Leader R. Guidry of possible contamination in the sample.

This is in regards to Proficiency CTS-14-571-U2566C. DD

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description CLASS I ☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: On 03/05/14 contamination was confirmed, as a partial profile was produced from the re-amplification of sample 76MR14Y. The alleles in the partial profile of 76MR14Y were consistent with alleles found in sample 77MR14Y, item 2.1 (portion of known blood from the suspect), which had been extracted next to 76MR14Y. It is suspected that the contamination of 76MR14Y came from the neighboring sample 77MR14Y during the extraction process. Sample 76MR14Y was then re-extracted on 03/06/14 by DNA technician Maria Rumble. Upon re-extraction, 76MR14REY, produced no results.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

DNA technician Maria Rumble, in an effort to prevent any future occurrences of contamination will continue to exercise caution while handling samples. Great care will also be taken when handling sample tubes, i.e. changing gloves, using DNA away or a Kimwip when transferring samples from tube to tube.

SECTION MANAGER: [signature] Date: Mar 14, 2014

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: n/a

QUALITY MANAGER: [signature] Date: 3/17/2014

LABORATORY DIRECTOR: [signature] Date: 3-17-14

HOUSTON FORENSIC SCIENCE CENTER

CORRECTIVE AND PREVENTIVE ACTION REPORT

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SECTION 1

Date: 06/03/2014 CAPA #: 2014-015

DESCRIPTION OF ISSUE/NON-CONFORMANCE: On Monday May 12, 2014, while I, Kristina Blackmon, was reviewing the quant data for Batch 20-2014 samples, I noticed that extract #440KB14 (Inc#144712412 Item 2.2 – Portion of known buccal swabs from Leaundrea Fields) displayed a male quant value. Then I noticed the next extract #441KB14 (Inc#144712412 Item 3.2 – Portion of known buccal swabs from Marcellus Sampson) displayed a female quant value. I had extracted these samples on May 8, 2014. Both of these samples were being re-extracted due to the involvement of Peter Lentz in the initial testing; they had been tested in June, 2013 and reported in July, 2013. I verified that the extract tubes for these extract numbers corresponded with the labeling on the extraction sheet, meaning that if a switch was to have occurred, it occurred during the extraction and was not a tube misplacement at quant set-up. I notified DNA analyst Diana Donley of the

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description II ☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: Analyst error and oversight are believed to be the cause of this sample switch. I should have verified that the sample tube containing the portion corresponded to the extraction worksheet as well as the Fitzco tube loaded onto the EZ1 instrument.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

Both samples were re-extracted and only the results of my second extraction were reported.
To prevent this situation from reoccurring, I will remain more conscientious of the samples I am extracting and constantly visually inspect that the correct samples are being extracted in the correct order.

SECTION MANAGER: [signature] Date: 6-3-14

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: No impact to laboratory reports. Switch noted during re-extraction (See 2014-008).
No further action taken at this time – [illegible] 7/25/2014

QUALITY MANAGER: [signature] Date: 6/23/2014

LABORATORY DIRECTOR: [signature] Date: 7-3-14

Kristina Blackmon 6/3/14

Description of Issue:

On Monday May 12, 2014, while I, Kristina Blackmon, was reviewing the quant data for Batch 20-2014 samples, I noticed that extract #440KB14 (Inc#144712412 Item 2.2 – Portion of known buccal swabs from Leaundrea Fields) displayed a male quant value. Then I noticed the next extract #441KB14 (Inc#144712412 Item 3.2 – Portion of known buccal swabs from Marcellus Sampson) displayed a female quant value. I had extracted these samples on May 8, 2014. Both of these samples were being re-extracted due to the involvement of Peter Lentz in the initial testing; they had been tested in June, 2013 and reported in July, 2013. I verified that the extract tubes for these extract numbers corresponded with the labeling on the extraction sheet, meaning that if a switch was to have occurred, it occurred during the extraction and was not a tube misplacement at quant set-up. I notified DNA analyst Diana Donley of the situation and she advised me to continue with amplification and capillary electrophoresis of my original extracts but to also take another portion of each sample and re-extract them. I took another portion of each sample and re-extracted them on May 12, 2014. Extract # 440KB14RE and 441KB14RE were quantified, amplified and loaded onto the 3130 for data analysis. On May 16, 2014, review of DNA electropherograms for samples 440KB14 and 441KB14 confirmed that a sample switch had occurred in my initial extraction. Extract 440KB14, which should have yielded a female DNA profile, was observed to be a male DNA profile. Extract 441KB14, which should have yielded a male DNA profile, was observed to be a female DNA profile. On May 23, 2014, all other samples that were extracted with 440KB14 and 441KB14 were checked as possibly having been switched. It was concluded that only 440KB14 and 441KB14 were switched because: 1) an extraction confirmation had been performed; or 2) the reference was not excluded from evidence associated with its case. In addition, a comparison of the results issued in July, 2013 with my initial extraction data showed that a switch had occurred. The results of my re-extraction are concordant with the results initially reported in July, 2013; these results are also consistent with Leaundrea Fields being female and Marcellus Sampson being male.

Root Cause Analysis:

Analyst error and oversight are believed to be the cause of this sample switch. I should have verified that the sample tube containing the portion corresponded to the extraction worksheet as well as the Fitzco tube loaded onto the EZ1 instrument.

Proposed Corrective Action:

Both samples were re-extracted and only the results of my second extraction were reported.

To prevent this situation from reoccurring, I will remain more conscientious of the samples I am extracting and constantly visually inspect that the correct samples are being extracted in the correct order.

To: Aimee Grimaldi, M.S.; Callan M. Hundl; Robin Guidry, MS ABC-F; Jennifer O'Callaghan
Cc: Peter Stout, Ph.D.; Ron Sandberg; Lloyd Halsell III, MS F-ABC; Elizabeth Richey, MS, F-ABC; Quality; Ashley Henry, MA
Subject: Re: 39.14 Request for Documents (Miranda, Abel)

PRIVILEGED AND CONFIDENTIAL ATTORNEY COMMUNICATION

Colleagues:

Aimee and I just spoke by phone. You explained that HFSC received the evidence on April 12, 2015, and completed the analysis (with written report) on March 11, 2016. Therefore, the window for records responsive to Category No. 12 is from October 12, 2014, to September 11, 2016. (I'm confident you guys already have made this calculation, but I'm stating it here for the sake of the team as a whole.)

I agree that HFSC should not provide IRs or CARs until the reports are closed. In light of the almost-two-year window, we're likely to be updating our response until Christmas or later. Fortunately, we can direct Olvera to our e-discovery website for these reports as they become available. We'll need to lay this out in our initial response to the request, and, again, I will plan on helping you with that language.

Let me know if you disagree with any of the above. Also, please keep Ashley Henry in the loop for the matter, since CS/CM will be responsible for HFSC's response. Onward.

Tom

From: Aimee Grimaldi, M.S.
Sent: Monday, June 20, 2016 10:01 AM
To: Tom P. Allen; Callan M. Hundl; Robin Guidry, MS ABC-F; Jennifer O'Callaghan
Cc: Peter Stout, Ph.D.; Ron Sandberg; Lloyd Halsell III, MS F-ABC; Elizabeth Richey, MS, F-ABC; Quality
Subject: Re: 39.14 Request for Documents (Miranda, Abel)

Hi Tom,

Quality has approximately 20 Biology Incidents or CARs regarding contamination events that are not yet closed. We have draft reports for these but Paula and I are still working on the root cause analysis. Since these are in draft stage we are not going to include these in this request. Please let us know your thoughts on this.

06/20/2016 2015-06112 PAGE* C50

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION CORRECTIVE ACTION REPORT

Quality Division use only

Quality CAR # 2015-001 Date Submitted: 4/29/2015

Level/Type of Discrepancy/ Non-Conformance: II Date Closed: 5/6/2015 JBW

Date of this Report: 4/28/2015 Division: FAD FCN: (If applicable)

Date of Incident: 2/6/2015 Section: Forensic Biology

Description of Discrepancy/Non-conformance:

Three samples among CTS proficiency tests 14-574 and 14-575 were reported as positive for semen, via spermatozoa visualization, but CTS consensus results and the CTS explanation on sample preparation identified these items as negative for semen. See the attached memos dated 2/6/15 for additional information.

Root Cause of Discrepancy/ Non-conformance:
(If possible to determine)

In two of three slides, the identification of spermatozoa was corroborated by a private laboratory. It is unclear at this time if the sperm identification is the result of sample preparation by CTS or from slide preparation here in the lab.

* It should be noted that Bode initially reported slides negative as per Report dated 3-6-15. CR 5-6-15

If not discovered at this point, where else in the process would this incident have been discovered:

This issue was identified by the laboratory during the testing and CTS was contacted to make them aware of discrepant results from test participants within this lab. When issued to this lab, CTS reports indicated the discrepant results.

Actions Taken:

1. Instead of testing each proficiency sample for each available screening test, moving forward, samples will be treated more like casework. Samples will not necessarily proceed to microscopy if acid phosphatase results are negative. This approach was taken with CTS tests 15-571 and 15-572 this year.
2. Starting on CTS test 15-571, fewer screening analysts will maintain proficiency on microscopy, given qPCR has replaced conventional serological methods, such as microscopy, as the primary method for screening sexual assault kits for semen.
3. The Biology SOP for semen identification has been updated to address instances when only one spermatozoa is observed:
    a. the slide must be verified by a second qualified analyst who must initial and date the examination documentation
    b. a second slide must be created and stained using the same supernatant, when possible.
    c. if a spermatozoon is again observed, the slide must be verified by a second qualified analyst who must initial and date the examination documentation; this sample may be reported as positive for the

Recd 5-6-15 CR

presence of spermatozoa. If the second slide is negative for the presence of spermatozoa, the sample shall be reported as inconclusive for the presence of spermatozoa.

4. On Friday, March 13, 2015, all members of the Forensic Biology section attended a section-wide meeting, with the following exceptions: Brittany Beyer (absent), Clay Davis (absent), Shamika Kelley (maternity leave), and Katherine Morgan (absent). One of the journal club articles presented related to possible contamination within the lab. Below is an excerpt from my meeting notes that I discussed after this particular article's presentation by Zoraya Reyes:

- Transfer of contact DNA in the lab:
  - Secondary and tertiary transfers are very possible; we cannot avoid what happens prior to receipt in lab but we can prevent further transfer when in our possession; we would never know if we contaminated within the lab, as we have no expectation of what DNA is on what item; but, by employing extremely careful and deliberate lab techniques, we can minimize the possibility of transfer and more confidently respond as to why we do not think transfer occurred in the lab (e.g., on the stand)
  - Assume everything is dirty (swab sticks are NOT clean, evidence packaging is NOT clean)
  - How to pull gloves from box and put on; do not handle fingers or palms with your bare hands
  - Clean hand, dirty hand method
  - Change gloves anytime evidence is handled; do NOT touch reagents or supplies without new gloves!!!
  - Gloves must be clean when accessing reagents or tubes
  - Reagents should not be in close proximity to evidence
  - Folders and exam documents should not be in close proximity to evidence, or treated as clean
  - Do not go "into" bags of tubes; pour out # of tubes needed, discard extras (do not return extra to bag)
  - Do not handle evidence and packaging without changing gloves in between; packaging has been handled by countless folks before arriving in lab and we know gloves, much less clean gloves, were not used in each of those events
  - Be aware of what you touch before touching evidence or reagents (e.g., mask, ear buds, chair, freezer door handle, etc.)
  - Do not treat paper or labels you grabbed from your desk area as clean

5. The three slides in question were submitted to Bode Technologies, a private and independent accredited laboratory, for a 2nd read on 1/6/2015. Initially, all slides were reported by Bode as negative for spermatozoa (report dated March 6, 2015). In an email dated March 16, 2015, after having reviewed the case file/examination documents, I inquired with Bode on the likelihood of whether examination documents would reflect if "sperm-like" objects were observed. I noted in that email that we did observe spermatozoa on each of the 3 slides. On March 19, 2015, Bode notified this lab that upon additional review, they did observe sperm on 2 of the 3 slides. See attached email.

X

6. The Biology SOP will be edited further to require that only one sample is loaded onto a slide for microscopic examination. The microscopic slides used in the lab are designed to enable the loading of 3 individual stains per slide. To rule out the theoretical possibility of a transfer of spermatozoa from one stain area to another, only one sample will be loaded on a slide (e.g., if a bubble in the liquid sample pops, could it possibly cause a spermatozoa to be propelled from one area on the slide to another?).

Technical Personnel: _____ **Date:** _____

* It should be noted that the Technical Leads did NOT Notify Bode that the proficiency provider did NOT identify sperm. CR 5-6-15

4pb

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION CORRECTIVE ACTION REPORT

Immediate Supervisor: _____ Date: _____

Section Manager: [signature] Clerra West Date: 4/29/15

CODIS Administrator: _____ Date: 4/29/15
(If applicable)

Additional Information/ Follow Up (If applicable):

Quality Director: [signature] Date: 5/6/2015

Division Director: _____ Date: _____

~~Identity~~ Level II determined because sperm was also identified by consultant laboratory. SBW 5/6/2015

fpb

Houston Forensic Science Center

INTEROFFICE MEMO

To: Irma Rios, Director of Forensic Analysis Division

From: Robin Guidry, Manager – Forensic Biology RG

Cc: Lori Wilson, Quality Director LW 5/6/2015
Courtney Head, Supervisor – Forensic Biology CH

Date: February 6, 2015

Re: CTS Proficiency Test Number 14-575: Positive (Non-Consensus) Semen Results: EPDAJR(U2588D)

Item #4 was reported to CTS as "positive" for the presence of semen. Please see the table below for screening results. This is inconsistent with the majority of results submitted to CTS, according to the CTS Summary Report, as well as the CTS manufacturer's statement on how the samples were prepared.

When all screening results were complete and the cases were being batched for DNA processing, I noticed the discrepant results and reached out to CTS to notify them of the inconsistencies amongst the cases processed in this lab. Of eight cases, six yielded a negative semen result for item #4, one yielded an inconclusive result (due to presumptively positive results for PSA), and one yielded positive results (due to the observation of one spermatozoon). Please see the attached email. CTS was not aware of any issues regarding this particular test at the time of my email communication.

The spermatozoon was verified by a second qualified analyst. The analyst who screened EPDAJR/U2588D and obtained a positive result for item #4 also screened TMFHRE/U2588B and obtained a negative result for item #4.

A review of the CTS Summary Report for Test Number 14-575 dated January 7, 2015 showed that only this lab reported item #4 as positive for semen. Something to consider is that many of the labs included in the summary only tested for semen on item #4 using an alternate light source and acid phosphatase (they did not test for spermatozoa). Had this laboratory discontinued testing after negative alternate light source and acid phosphatase reactions, there would be no non-consensus spermatozoa results to be reported. It has been this lab's practice to employ all tests for which an analyst is competent, so that proficiency can be demonstrated for each test. Moving forward, however, proficiency samples will be treated more like casework in that testing will be discontinued on non-intimate samples that are negative for alternate light source and acid phosphatase, as is done in casework. Furthermore, only those analysts who use microscopy regularly and on casework will continue to perform

Recd 5-6-15

microscopy on proficiency tests. Given the laboratory has moved to using qPCR in the vast majority of sexual assault cases, microscopy is no longer a primary screening tool for case work samples.

The analyst's interpretation and reporting as "positive" are compliant with the results and therefore laboratory protocol. However, in an effort to better understand the issue, the laboratory has submitted the slide produced for microscopy in this proficiency test to an accredited private laboratory for review. A follow-up memo will be issued with those results, which are anticipated by the end of February, 2015.

In addition to an external review of the slide in question, the following protocol changes have been made to Biology SOP #7 (Semen Detection):

1. When only one spermatozoon is observed:
    a. the slide must be verified by a second qualified analyst who must initial and date the examination documentation
    b. a second slide must be created and stained using the same supernatant, when possible.
    c. if a spermatozoon is again observed, the slide must be verified by a second qualified analyst who must initial and date the examination documentation; this sample may be reported as positive for the presence of spermatozoa. If the second slide is negative for the presence of spermatozoa, the sample shall be reported as inconclusive for the presence of spermatozoa.

Semen Detection Screening Results

Case # and Sample #	ALS Screening Results	Acid Phosphatase Screening Results	Microscopic Screening Results	PSA Screening Results
EPDAJR/U2588D, item #4	Negative	Negative	1 sperm observed*	Negative

*Verified by a second qualified analyst

Given the positive semen detection results, this item was subjected to a differential DNA extraction. No DNA results were obtained in the sperm cell fraction of this item, which is consistent with the screening results obtained for this item.

RNC

HOUSTON POLICE DEPARTMENT
CRIME LABORATORY

CORRECTIVE AND PREVENTIVE ACTION REPORT

☐ CHECK IF ADDITIONAL PAGES ARE USED

SECTION 1

Date: Apr 8, 2014

CAPA #: 2014-010

DESCRIPTION OF ISSUE/NON-CONFORMANCE: Contamination was detected in a reagent blank (11MS14 – RBS012714MS) for HPD Case #116874113. The observed peaks appear to be from the samples (sperm fractions) positioned before the reagent blank.

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description: II

☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: Mary Symonds performed the differential extraction. Benjamin Cambridge performed the quantification, genetic analysis, re-amplification and genetic analysis of the re-amp. Amplification and re-injection were performed by Peter Lentz. The reagent blank was re-injected and then re-amplified to confirm the presence of the alleles. Fewer alleles were present after re-amp; however they remained consistent with the DNA profile from the preceding samples. The reproducibility of the contamination indicates that it could have occurred from sample-to-sample during extraction or during the set up for quant or amp. Either way, the associated samples cannot be used for interpretation.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

All associated samples were re-extracted and all associated reagent blanks yielded acceptable data. DNA Analyst Mary Symonds poured new aliquots of reagents before re-extracting the affected samples. DNA Analyst Mary Symonds and DNA Technician Benjamin Cambridge will continue to exercise extreme caution while handling samples in the laboratory.

SECTION MANAGER: [signature]

Date: 4/14/14

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: See Tech Leader email dated 4/23/2014 (a total of 3 contamination events reported since Jan. 2013) No further action taken at this time.

5/6/2014

QUALITY MANAGER: [signature]

Date: 4/28/2014

LABORATORY DIRECTOR: [signature]

Date: 5-6-14

Wilson, Lori

From: Guidry, RobinD
Sent: Friday, May 09, 2014 6:06 PM
To: Wilson, Lori
Cc: Rios, Irma
Subject: Extraction contamination

Lori,
As you know, the Biology/DNA Unit of the Houston Forensic Science Center documents issues, such as DNA contamination, via the Corrective And Preventative Action (CAPA) form. This allows the detection of possible trends and presents any preventative measures that the lab may elect to employ.

In 2011, there were 18 CAPA-worthy events, 6 of which involved extraction contamination (33.3%). In 2012, there were 11 CAPA-worthy events, 3 of which involved extraction contamination (27.3%). In 2013, there were 18 CAPA-worthy events, 1 of which was associated with contamination at amplification in a negative PCR control (5.6%). In 2014 to-date, there have been 8 CAPA-worthy events, 3 of which involved contamination (38%). Of those 3, 1 (12.5%) was associated with amplification contamination, while the other 2 (25%) were associated with extraction (1 reagent blank and 1 sample, both with low-level contamination). Please note that many of the CAPAs generated in 2013 and 2014 are associated with the massive outsourcing project of almost 10,000 cases and involve chain of custody documentation.

For perspective, the DNA lab has experienced a significant increase in production and therefore extractions. As the number of extractions increases, so does the potential for a contamiantion event.

- 472 DNA reports were issued in 2011
- 887 DNA reports were issued in 2012
- 1078 DNA reports were issued in 2013
- 330 DNA reports have been issued in 2014 (YTD)

The reduction in extraction contamination from 2011 to 2013 appears significant, and I suspect there is less due to an increased use of automation and a decreased use of manual extractions. 2014 has observed a percentage-wise increase of issues related to contamination, but year-to-date, is as high as 2012 and one half of 2011. One of the 2 extraction contaminations in 2014 was detected in a differential extraction, which is still a fully manual process; we are transitioning to an automated differential extraction at this time. The contamination events do not appear to be analyst-specific.

This lab continues to strive to completely avoid contamination through the use of good laboratory practices but also relies on mechanisms such as the extraction reagent blank to detect it when it is present. We will continue to employ good lab practices and will continue to document events and their corrective and preventative measures taken via the CAPA form. We will also continue to monitor contamination events for any trends and take action when necessary.

Thank you,
Robin

Robin D. Guidry, M.S., F-ABC
Police Administrator
Houston Forensic Science Center
Phone: 713-308-2620
Fax: 713-308-2645
Email: robind.guidry@houstonpolice.org

2014-13

HOUSTON FORENSIC SCIENCE CENTER
1200 Travis St., 20th Floor
Houston, TX 77002
(713) 929-6760

Houston Forensic Science Center

Inter-Office Correspondence

June 13, 2014

MEMORANDUM FOR: [redacted]

SUBJECT: Root Cause Analysis of an Erroneous Identification made by [redacted]

BACKGROUND SUMMARY:

1. The training procedure implemented by the Houston Forensic Science Center's Latent Print Unit requires all newly hired latent print examiners to be thoroughly competency tested prior to entering into any dependent supervised casework. Based on the documentation of qualifications and background experience the five (5) newly hired Certified Latent Print Examiners provided, a modified training program was implemented to test their knowledge and abilities in the area of Latent Prints. The competency testing program developed for the examiners was a two part test. A written competency test was developed consisting of 50 questions that would test the examiner's knowledge of the biology, history, processing techniques, various chemical development mediums, and the methodology if the science of friction skin identification. The second phase of the final competency testing consisted of a comparison examination developed from a three year old proficiency test from the testing agency CTS. The test was CTS Latent Print Test #11-517. The original test was scanned into Adobe Photoshop CS4 with the unknown latent images scanned at 2400 ppi resolution and the record finger and palm print cards scanned at 1000 ppi resolution. All information indicating which CTS version of the test was removed or redacted from the image. The scanned images were then printed using an Epson Stylus Pro 4900 high resolution ink jet printer. Four copies of the comparison competency test were made. The answer sheet was scanned as an Adobe PDF document with all extraneous information associated with the original CTS test cropped out.

2. On the cover of the final comparison competency test, the directions were as follows:

   "Instructions: This is an assessment of your ability to identify or exclude latent prints when compared against known records. The test consists of twelve (12) latent images and four (4) records consisting of ten print and palm prints. You will have 8 hours to complete this assessment. No copies or scratch paper are allowed to leave the testing area. Please use a blue or black ink pen and write legibly on the answer sheet provided. You ARE allowed the use of your PC, scanner, and Photoshop software or your fingerprint loupe while in the process of completing this assessment. All work must be conducted independently."

3. The comparison test was administered to [redacted] on June 3, 2014. All examiners taking the test have been certified by the International Association for Identification. All of the above examiners successfully passed the examination.

4. On June 5,2014, [redacted] was given the test with the above directions. Upon grading the test using the CTS answer key, it was discovered that he had erroneously identified Latent Image 5H. Todd was informed of this in the afternoon and advised that a resolution would be provided soon.

5. Per the Code of Ethics for Certified International Association for Identification Latent Print Examiners and the IAI Certification Manual Section X; subsection B under Technical Errors, the Secretary of the Certification Board, [redacted], was notified on June 6, 2014 of the erroneous identification. Upon presentation of the facts, [redacted] determined that since no report involving actual casework was issued and the erroneous identification was discovered in competency testing, it was unnecessary for [redacted] to lose his status as a CLPE and in-house remedial assessments would be appropriate.

CAUSE ANALYSIS:

1. [redacted] was instructed on June 6, 2014 to scan the latent identified and also the erroneous finger into Adobe Photoshop and chart what he saw during his analysis and comparison of the latent to known to better understand the thought process and determine possible causes. He was also instructed to provide a summary of possible factors as to why he erroneously identified the latent print. [redacted] provided me with a summary of what he found and possible causes for the misidentification. (See Attached Summary from [redacted]).

2. Upon analyzing the documentation and speaking with Todd, the following possible factors were likely contributors to the erroneous identification decision:

   A. [redacted] was in a supervisory capacity prior to accepting the position with HFSC and did not routinely compare latent prints as a supervisor.
   B. Although the directions stated a computer, scanner, and Photoshop software could be used, [redacted] used a comparison loupe. He advised he was not aware he could have asked for access and his previous experience with comparing latent prints were conducted on the computer.
   C. The location [redacted] was taking his test was in the common area with many people walking and communicating around him.
   D. [redacted] started with the HFSC Latent Print unit on June 2, 2014 and was started with his competency testing within a few days. A summary of his explanations indicated that he also has external stressors that may have contributed to the erroneous identification.

CORRECTIVE ACTION PLAN

1. All further competency testing will be conducted in an environment that is free from extraneous noise and distractions.

2. Notifications will be posted that testing is in progress and to not disturb the person(s) taking the tests.

3. [redacted] will be administered a series of new competency tests to determine his skills and abilities further. This will consist of no less than four (4) additional comparison competency tests. These tests will be conducted using Photoshop software and he will be required to chart his conclusions so there will be a documented visual representation of the process. Once competency has been established and no errors have been noted, a new final comparison test will be issued. Upon successful completion of the re-testing phase, [redacted] will proceed into the dependent supervised casework portion of the HFSC Latent Print Training Program.

4. If further erroneous identifications are made during the re-evaluation phase, a re-evaluation of [redacted] will need to be conducted to determine if he can remain in a Latent Print Examiner position with the Houston Forensic Science Center.

Timothy Schmahl, CLPE
Latent Print Unit Manager

To: Aimee Grimaldi, M.S.; Callan M. Hundl; Robin Guidry, MS ABC-F; Jennifer O'Callaghan
Cc: Peter Stout, Ph.D.; Ron Sandberg; Lloyd Halsell III, MS F-ABC; Elizabeth Richey, MS, F-ABC; Quality; Ashley Henry, MA
Subject: Re: 39.14 Request for Documents (Miranda, Abel)

PRIVILEGED AND CONFIDENTIAL ATTORNEY COMMUNICATION

Colleagues:

Aimee and I just spoke by phone. You explained that HFSC received the evidence on April 12, 2015, and completed the analysis (with written report) on March 11, 2016. Therefore, the window for records responsive to Category No. 12 is from October 12, 2014, to September 11, 2016. (I'm confident you guys already have made this calculation, but I'm stating it here for the sake of the team as a whole.)

I agree that HFSC should not provide IRs or CARs until the reports are closed. In light of the almost-two-year window, we're likely to be updating our response until Christmas or later. Fortunately, we can direct Olvera to our e-discovery website for these reports as they become available. We'll need to lay this out in our initial response to the request, and, again, I will plan on helping you with that language.

Let me know if you disagree with any of the above. Also, please keep Ashley Henry in the loop for the matter, since CS/CM will be responsible for HFSC's response. Onward.

Tom

From: Aimee Grimaldi, M.S.
Sent: Monday, June 20, 2016 10:01 AM
To: Tom P. Allen; Callan M. Hundl; Robin Guidry, MS ABC-F; Jennifer O'Callaghan
Cc: Peter Stout, Ph.D.; Ron Sandberg; Lloyd Halsell III, MS F-ABC; Elizabeth Richey, MS, F-ABC; Quality
Subject: Re: 39.14 Request for Documents (Miranda, Abel)

Hi Tom,

Quality has approximately 20 Biology Incidents or CARs regarding contamination events that are not yet closed. We have draft reports for these but Paula and I are still working on the root cause analysis. Since these are in draft stage we are not going to include these in this request. Please let us know your thoughts on this.

06/20/2016 2015-06112 PAGE* CSO

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☐ Preventive ☐ Tracking/Documentation Only Inc. Report #: 2014-027

Date: Oct 31, 2014

DESCRIPTION OF DISCREPANCY/ NON/CONFORMANCE:

On 9/11/14, DNA Analyst Clay Davis observed allelic activity in a reagent blank during his review of the data. Reagent blank sample 682MR14 was re-injected the same day and the activity was replicated. On 9/12/14, the reagent blank was re-amplified by a second technician and the activity was again reproduced. This activity was consistent with the known DNA profile of DNA Technician Maria Rumble who extracted, quantified, amplified and loaded this reagent blank and its associated samples. The Technical Leader was notified as soon as the contamination was confirmed.

Date: Sep 11, 2014

CAUSE OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine)

When notified of the contamination, the analyst evaluated her actions and was unable to pinpoint a cause for the contamination. All extractions by this technician since this event have been acceptable; she believes she is using the same preventative measures that she routinely incorporates into her laboratory procedures. Even though the analyst recalls following good laboratory practices, at some point prior to amplification, it appears her own DNA was introduced to the reagent blank tube.

When unusual circumstances occur during an extraction (e.g., a tube is dropped onto the bench top during handling), analysts are asked to make a note on examination documentation for easier troubleshooting or explanation should data and/or controls exhibit unusual activity later. The analyst did not make any such notes and does not recall the need to do so. Because contamination is generally not detected immediately in the process, but rather only once samples have been quantified, amplified, and subjected to fragment separation, it can be very difficult to identify the exact cause of the contamination event, especially given the sensitivity of the DNA testing process.

LEVEL/TYPE OF DISCREPANCY/NON-CONFORMANCE (see Quality Manual for description): CLASS II

EFFECT OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine)

Because a reagent blank was found to be unacceptable, the data of the associated samples may not be used for interpretation. Samples will need to be re-extracted. Additional time and resources will be used to complete the re-extraction of the associated samples. Consumption orders have been requested from case officers for each case due to limited sample remaining for each item. Three cases are associated with this reagent blank: INC#024911686/L86-3529/2014-13476, INC# 141044213, and INC# 074776514/ 2014-14668. Consumption has been granted for all but INC#024911686/L86-3529/2014-13476; the case investigator is seeking input from the prosecuting attorney.

This is the 682nd sample extracted by Maria this year and this is the first contaminated reagent blank. At the section-wide Forensic Biology meeting held September 26, 2014, this issue was discussed and analysts were reminded to exercise extreme caution and awareness when handling samples during extraction by not touching things such as chairs, face, face masks, etc. with gloved hands and to change gloves as frequently as needed.

If not discovered at this point, where else in the process would this incident have been discovered?

Because the review of all examination documentation and controls, including reagent blanks, is a required step in data analysis and the technical review of data, this issue, if not caught when it was during the analyst's initial review of the data, would have been caught in the technical review of this case. The DNA review checklist requires the reporting analyst and the technical reviewer to acknowledge that controls are acceptable.

Corrective Actions/Preventive Measures Taken (if applicable):

Per laboratory protocol, given the unacceptable reagent blank control, re-testing has commenced for INC# 141044213 and INC# 074776514/2014-14668. Re-extraction is pending consumption permission for INC#024911686/L86-3529/2014-13476.

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☒ ~~Preventive~~ (now) ☐ Tracking/Documentation Only

Inc. Report #: 2014-027

ANALYST: MARIA A. RUMBLE Date: 10/31/14

SECTION MANAGER: ROBIN D. GUIDRY Date: 10/31/14

CODIS ADMINISTRATOR (if applicable): Cleva West Cleva West Date: 10/31/14

ADDITIONAL INFORMATION/ FOLLOW UP (if applicable): provide follow up once all cases have been reworked and reported.

QUALITY DIRECTOR: Date: 11/5/2014

LABORATORY DIRECTOR: Date: 11-7-14

Date Closed: ~~11/7~~ 12/2/2014 (now) see email dated 12/11/14

Clay Davis 10.31.14

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-024

Date Submitted: 2/18/2016 ~~1/12/2016~~ JBW

Date Closed: 3/18/2016 JBW

Date of this Report: 12/11/2015

Division: FAD

FCN: 2013-20123 / 073206213 (If applicable)

Date of Incident: 2/27/2015

Section: DNA

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

A request for YSTR analysis was made on 2-16-15 for case 073206213 (2013-20123) for the items associated with tissue/fluid from a fetus (Items 1.5, 1.6, 1.7 & 1.8). The four items were amplified with YSTRs on 2-20-15 by M. Bryan Davis. Analysis of the amplified items was performed and a mixture was observed in Item 1.5. Since this sample type was DNA from tissue/fluid from a fetus, a mixture of YSTR's in this item was not anticipated.

A comparison of the staff YSTR database revealed that the analyst that amplified the evidence with YSTRs was consistent with the "extra" alleles present in Item 1.5.

A re-amplification was requested on 5-28-15 for Item 1.5; the second YSTR DNA profile produced a partial single-source profile with no indications of a second contributor.

The extra alleles observed in the original YSTR amplification were most likely introduced at the YSTR amplification setup and not in the original extraction of the item. This theory is supported by the fact that the autosomal profile consisted of a major component consistent with the biological mother and 2 minor alleles that are consistent with the DNA profile developed on other portions of the fetal tissue/fluid. These 2 minor alleles are not consistent with M. Bryan Davis. Therefore, the re-amplification results for Item 1.5 are deemed acceptable and will be used for reporting purposes.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

The Quality Division requested associated electropherograms.

Signed Incident Form received 2/18/16 by J Wilson. Incident will not be closed until timeline related to delayed reporting to CHHD is received.

See timeline dated by JWilson on 3/16/2016.

Please note that timeline was compiled by TL Halsell.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel: Clay Davis Boyen Davis no longer employed by HFSC Date: 2.4.16

Section Manager: [signature] Date: 2/8/16

Division Director: [signature] LSA 1-26-16 Date: 2-16-16

Quality Director: [signature] Date: 3/18/2016

Technical Leader: [signature] HALSELL 1-25-16

[signature] LSA 1-26-16

CODIS Admin.: Clara West 2/16/16

2-16-16 Resolving Quality Incident 2015-024 was a bit lengthy. Review was initiated for this incident & FAD managers were reminded of process in FAD managers' meeting held 2-15-16. Process map was provided.
Clara Rios 2-16-16

Clara Rios Received 2-9-16 Submitted 2/18/16

Time line to address delayed reporting of CAR 2015-024 regarding Incident number 073206213 to the Quality Division

- 2-20-15: Item 1.5 (3225MR14) is amplified with YSTR
- 2-27-15: Item 1.5 (3225MR14) is run on CE
- 5-28-15: Item 1.5 (3225MR14) is requested for re-amplification and re-amplified
- 5-29-15: Item 1.5 (3225MR14) re-amplification is run for CE
- 12-14-15: DNA report is issued with results for Item 1.5

During the time that this case was identified and processed for YSTR analysis there was not a set schedule for the routine processing of YSTR requests. In February of 2015 two large YSTR amplifications were performed that consisted of most of the open requests. One reason for such a large run was that only two technicians were competent in processing YSTR samples. These samples were not part of an active batch and the cases were to be written by the few analysts that could issue YSTR reports. The analyst would work on these cases between their ongoing batches when they had time.

The data was initially reviewed in February 2015, but that analysis was not case specific. The first analysis was meant to check the controls and overall profiles as compared to amplified target and therefore the contamination was not detected at this time. The case was reviewed by the reporting analyst in May 2015. During the review conducted by the reporting analyst the contamination was detected.

After the re-amplification results were obtained it is possible that the complexity of the case and the case type extended the completion date. This case request was a paternity testing case in which statistical analysis for paternity calculations was necessary. Due to the complexity of the case, many discussions and consultations occurred as to how it should be reported.

CWS 3.24.16 LSA 3-23-16

JW 3/28/16 JDW 3/18/16

Timeline prepared by Cloyd Hartsell 3/28/16 CW 03/29/16

CWS 3-30-16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-005	**Date Submitted:**	3/1/2016
Non-Conformance Level	CLASS I	**Date Closed:**	6/14/2016

Date of this Report:	5/23/2016	**Division:**	FAD	**FCN:**	2014-19609/120012514 & 2014-22128/136106214 (If applicable)
Date of Incident:	3/11/2015	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

The epithelial fraction reagent blank, RBE031115IH-1 (266IH15), was extracted on 3-11-15 on Batch 21. The extraction batch contained two cases, 2014-19609 (Incident # 120012514) and 2014-22128 (Incident # 136106214). The reagent blank was quantified on 3-12-15 and had a value of 0.0006 ng/µl. Amplification occurred on 4-3-15, with CE following on 4-6-15. The reagent blank contained a single peak above threshold with additional peaks that were distinguishable from background below analytical threshold.

The data was initially reviewed on 4-13-15, however this was not a case specific review. The reporting analyst did not review the CE run until 7-20-15 and the technical reviewer until 10-2-15.

Actions Taken:

Re-injection was requested on 7-27-15 and occurred on 8-5-15. The peaks persisted so the reagent blank was requested for re-amplification on 8-6-15 and occurred on 8-12-15, with CE following on 8-12-15.The peaks persisted after re-amplification.

The extraction batch and employee profile list were examined for possible sources, none were identified.

All samples from case 2014-22128 had been initially amplified. All samples with case 2014-19609 were either male negative or inconclusive, so no samples were amplified. To troubleshoot the source of the contamination, the sample immediately adjacent to the reagent blank, 265IH15, was requested for amplification on 9-3-15 and set up on 9-10-15. This profile was not consistent with the reagent blank.

All other samples from case 2014-19609 were requested for amplification on 9-15-15 and set up on 9-16-15. Several did not generate a DNA profile and those that did generate results were all consistent with the same female profile and not consistent with the contaminant.

Since no ADA was assigned to these cases to issue permission to consume, re-extraction did not occur. The acceptable sperm fractions were reported out and the associated epithelial fractions were reported as not meeting quality assurance standards.

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

If not discovered at this point, where else in the process would this incident have been discovered?

The DNA review checklist requires the reporting analyst and the technical reviewer to acknowledge that controls are acceptable. This incident would have been discovered during review.

Technical Personnel:		**Date:** 06-10-16
Immediate Supervisor:		**Date:** 6/13/16
Section Manager:		**Date:** 6/3/16
CODIS Administrator (if applicable):		**Date:** 6/3/16
Division Director:		**Date:** 6/3/16

Tech Lead: S-2476

Summary of Root Cause Analysis:

In this particular case the contamination was reproduced after re-amplification which suggests that the contaminant was most likely introduced to the extract at either the extraction or quantification steps. A likely root cause of this particular contamination event could be attributed to poor sample handling at either of these processes. Because the source of this contaminant is not a sample processed on Batch 21 nor an employee, extraneous DNA could have been deposited into the laboratory and introduced to this reagent blank during processing.

Additional Information/Follow-Up:

The Forensic Biology Section will be performing lab decontamination on a routine basis. Additional PPE requirements have also been implemented to prevent contamination issues. Lab coat, gloves, hair coverings and face masks are now required during screening, extraction, quantification, and amplification. In the post-amplification laboratory, gloves and a lab coat are required. This PPE is not optional and anyone entering the areas where these procedures are performed must abide by these requirements.

Quality Director: Jon Wilson **Date:** 6/14/2016

released for signatures 5/24/16 HKG

This time line addresses the delayed reporting of CAR 2016-005 regarding Incident numbers 2014-22128 (136106214) and 2014-19609 (120012514) to the Quality Division.

RBE031115IH-1 (266IH15) was extracted as part of SAK batch 2015-21.

- 3-11-15 – Extraction
- 3-12-15 – Quantification
- 4-3-15 – Amplification
- 4-6-15 – CE
- 4-13-15 – Initial review for poor injections
- 7-20-15 – Review by report writer
- 7-27-15 – Requested for reinjection
- 8-5-15 – CE of reinjection
- 8-6-15 – Requested for reamplification
- 8-12-15 – Reamplification
- 8-12-15 – CE of reamplificaiton
- 9-1-15 – Email to Tech Lead asking how to report since there was no ADA assigned. Tech lead responds to report acceptable fractions and others as inconclusive and an incident report will be necessary. TL asks about other samples being amplified. Clearly a conversation was had in person based on the tone of the emails.
- 9-3-15 – Sample 265IH15 requested for amplification as part of troubleshooting
- 9-10-15 – Amplification of 265IH15
- 9-10-15 – CE of 265IH15
- 9-15-15 – Additional samples requested for amplification for trouble shooting
- 9-16-15 – Amplification of additional samples
- 9-16-15 – CE of additional samples
- 11-30-2015- 2014-22128 reported
- 12-21-15 – 2014-19609 reported

The cause of the delayed reporting of this corrective action to the Quality Division it not known. However, in October 2015 a re-organization of Biology section management occurred in which an Alternate Technical Leader was designated. This restructure could have contributed to reporting delay. The TL designated at the time of this event was involved in the troubleshooting of this contamination event and investigated the event thoroughly.
The ATL notified the Quality Division that a corrective action was necessary in February 2016. Since February 2016, the Quality Division and the ATL have worked together to close this corrective action report.

Time line provided by Lloyd Halsell III, Acting Technical Leader

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-032

Date Submitted: 3/29/2016

Date Closed: 5/10/16

Date of this Report:	3/29/2016	**Division:**	FAD	**FCN:** (If applicable)	2016-02382/1541611115 2015-12890/~~13~~ 12134231 2015-07396/018032415
Date of Incident:	3/14/2016	**Section:**	Biology		

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

Reagent blank 1343LS16 for Extraction Batch 28-2016 was originally quanted on 03/14/16 and yielded a quant value of 0.01274ng/µL. This reagent blank was amplified on 03/15/16 and then it was loaded on 03/15/16 (project ZR031516). The reagent blank produced a clean profile with no DNA activity. Since this DNA result was not concordant with the sample's quant value, this reagent blank was then re-quanted along with an adjacent sample, 1342LS16, to verify quantitation results. After the re-quantification, the reagent blank and adjacent sample's quant results were N/A, suggesting that no DNA was present. The re-quantification result corresponded with the reagent blank's DNA result of no DNA activity present. Therefore, this reagent blank and the associated data are deemed acceptable.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

It is unclear how extraneous DNA was deposited in the original quantification of the reagent blank yielding a result of 0.01274 ng/µl. A thorough laboratory clean was performed on 3/28/2016 to decontaminate the work areas of any extraneous DNA that may have been deposited. In addition, the section plans to perform this lab clean on a routine basis. As of 4/8/2016 additional PPE requirements have also been implemented as a preventive measure to prevent contamination. The required PPE in the pre-amplification areas include a lab coat, gloves, face masks, and head coverings.

Technical Personnel:	[signature]	Date:	5-6-16
Section Manager:	[signature]	Date:	5/6/16
Division Director:	[signature]	Date:	5/9/16
Quality Director:	[signature]	Date:	5/10/2016
Tech lead:	[signature] HARSTELL		5-6-16

CODIS Admin.: [signature] 5/10/16

released for signatures 4/20/16 AKA

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-049 **Date Submitted:** 4/21/2016

Date Closed: 4/26/2016

Date of this Report: 4/4/2016 **Division:** FAD **FCN:** 2014-15820

Date of Incident: 3/22/2016 **Section:** Forensic Biology **Incident #: (If applicable)** 08722561 4

5-4-16 PHE

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On 3/22/16, when the substrate from the portion tube containing item 10.8.1 was being transferred into a spin basket during the extraction procedure the DNA technician noticed that there was a strand of apparent hair on the swab in the tube. The technician continued to transfer the swab into the spin basket making sure the apparent hair remained with the swab. The technician retained the spin basket with the apparent hair and placed it into Freezer 1. The technician recorded this information on a laboratory information worksheet that was included as part of the case record.

On 3/24/16 a DNA analyst analyzed the data obtained from Item 10.8.1. The analyst had knowledge that an apparent hair was observed on the swab from the laboratory information worksheet and keep that in mind when analyzing the data. The data obtained was a major/minor mixture where the major component was consistent with the complainant in the case and the minor component was insufficient for comparison. The other samples in the case were also analyzed and the results from the majority of those samples were consistent with the data obtained from Item 10.8.1. It does not appear that the apparent hair noted on the swab had any impact on the results for Item 10.8.1. It is unclear where the apparent hair came from as the screening analyst did not note any observations of a hair in the screening notes for Item 10.8.1. Item 10.8.1 is a portion of "S#8 L. wrist" swabs. The data obtained from Item 10.8.1 will be reported.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

Three technicians were interviewed to determine the procedure for portioning an evidence swab with an apparent hair attached. All three screeners stated that if a hair was observed during the portioning process that it would be noted in their case notes. In addition, standard procedure is to portion one half of an evidence swab for extraction. During the portioning procedure, the technician would portion the area of the swab that did not contain the apparent hair. It is unclear if the apparent hair was present during the screening procedure and overlooked or if it was introduced during processing. Hair coverings have since been implemented as a required PPE in the screening, extraction, and pre-amplification areas of the laboratory.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel:	[signature]	**Date:**	04-25-16
Section Manager:	[signature]	**Date:**	4/26/16
Division Director:	[signature]	**Date:**	4-26-16
Quality Director:	[signature]	**Date:**	4/26/2016
Tech Lead:	[signature] HALSTEAD		4-25-16
	[signature]		4/26/16
CODIS Admin:	[signature]		4/26/16

The swab was in the process of analysis when the hair was first ...ted. Since analysis had already begun, the sample, including the ...ssible hair, proceeded through the analytical process. Based upon ...e DNA results obtained, the hair did not impact the results and ...erefore, the results were deemed acceptable.

Rev 4/26/16
[initials]

released for signatures 4/25/16

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

2016-05328 HPD Incident # 039908716 SPW
2015-01631 013341215 5/31/2016
2015-10459 065238415

Quality Division use only

Quality Tracking # 2016-050 **Date Submitted:** 4/22/2016

Date Closed: 5/31/2016

Date of this Report: 4/22/2016 **Division:** FAD **FCN:** 2016-05328, 2015-01631, 2015-10459 (If applicable)

Date of Incident: 4/13/2016 **Section:** Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

Reagent blank for the epithelial fraction of extraction batch 39, RBE041316LS-1 (1825LS16), produced a possible allele below analytical threshold. This reagent blank yielded a quant value of 0.0ng/µl and showed no other signs of contamination. Re-injection of this reagent blank was requested since the possible allele was in a locus bin and had good morphology. Upon re-injection the allele was reproduced and now above analytical threshold at 58 RFUs. The reagent blank was then re-amplified to determine if this possible allele was reproducible at the amplification process. Upon re-amplification the possible allele was not present and therefore this reagent blank and the associated data were deemed acceptable.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

In response to contamination events, the Forensic Biology Section will be performing lab decontamination on a routine basis. Additional PPE requirements have also been implemented to prevent contamination issues. Lab coat, gloves, hair coverings and face masks are now required during screening, extraction, quantification, and amplification. In the post-amplification laboratory, gloves and a lab coat are required. This PPE is not optional and anyone entering the areas where these procedures are performed must abide by these requirements.

Technical Personnel: [signature] Date: 05-24-2016

Section Manager: [signature] Date: 5/25/16

Division Director: [signature] Date: 5/25/16

Quality Director: [signature] Date: 5/31/2016

Tech Lead: [signature] 5-5-16

Incident Tracking Report Issued by: Quality Director — COIS Admin.: Clem West 5/27/16

released for signatures 4/26/16 AKA

HOUSTON FORENSIC SCIENCE CENTER

CORRECTIVE AND PREVENTIVE ACTION REPORT

☒ CHECK IF ADDITIONAL PAGES ARE USED

SECTION 1

Date: Jul 16, 2014

CAPA #: 2014-014

DESCRIPTION OF ISSUE/NON-CONFORMANCE: The Quality Manager submitted incomplete data sheets for CTS tests 14-572-U2588A, B and G. The sheets submitted contained only screening results rather than screening and DNA results. This is a violation of QAS 13.1 because the DNA results were not submitted to the proficiency test provider in order to be included in the provider's published external summary report.

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description CLASS III ☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: Handwritten data sheets were completed by screeners and typed data sheets were completed by DNA analysts upon completion of all analysis. Because the Quality Manager did not review the sheets as closely as warranted, the forms with only screening results were submitted.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

Screeners will no longer complete data sheets. Only one set of typed and complete forms will remain in each proficiency case record. DNA results will be reported as internal results only. The PRC (through the ASCLD/LAB Proficiency Program Manager) will be preemptively notified since the DNA results were not submitted to the test provider as required by QAS standards. see attached

SECTION MANAGER: [signature]

Date: 7-24-14

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: anticipated revision to SOP; additional info will be provided after revision SPW 8/4/2014

QUALITY MANAGER: Lori Wilson Digitally signed by Lori Wilson DN: cn=Lori Wilson, o=HPD, ou=Crime Lab, email=lori.wilson@houstonpolice.org, c=US Date: 2014.07.16 07:24:40 -05'00'

Date: Jul 24, 2014

LABORATORY DIRECTOR: [signature]

Date: 7-28-14

CAPA 2014-014 continued

Proposed Corrective Actions/Recommendations to Address the Deficiency and Prevent Recurrence: continued

Note: the DNA results that were not submitted were reviewed by the DNA Technical Leader and found to be concordant with CTS published data. The involved technicians and DNA analysts performed the tests properly.

May 28, 2014

Patti Williams, Proficiency Program Manager
139 J Technology Drive
Garner, NC 27529

Re: CTS Test Number 14-571, 9RBUJE
Houston Police Department Crime Laboratory/Houston Forensic Science Center
ASCLD/LAB Certificate #317

HOUSTON FORENSIC SCIENCE CENTER
1200 Travis St., 20th Floor
Houston, TX 77002
(713) 929-6760

Dear Ms. Williams:

I am writing to notify you of a potential non-consensus for CTS test #14-571 (9RBUJE). The results reported for this case include data that this above our analytical threshold (50 RFUs) but below our stochastic threshold (200 RFUs) for the Identifiler Plus PCR Amplification Kit. The analyst followed laboratory protocol by reporting the data in sample #2 and sample #4 with the appropriate indications of data being below our stochastic threshold.

In sample # 2, a reference sample, the loci with activity below the stochastic threshold (D5S818, Amelogenin, and FGA) all exist as heterozygous loci, meaning DNA data is not missing, assuming it is a single-source sample. This assumption is clearly stated in the "results and interpretations" section of the associated DNA report. Further, given this is a reference sample, statistics will not ever be performed on this item and therefore whether allelic activity exceeds the stochastic threshold is not as significant.

In sample #4, an evidence sample, there is data at D19S433 that is above the analytical threshold but below the stochastic threshold. Like item #2, this sample is assumed to be single-source, as is indicated in the "results and interpretations" section of the associated DNA report and in the legend of the allele chart of the associated DNA report. Unlike item #2, statistics may be applied, if warranted because this is an evidentiary item. Per laboratory protocol, which is influenced by the 2010 *SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories,* "a presumed single-source locus with two alleles may be used for comparison and statistical analysis, should one or both of the alleles not exceed the stochastic threshold."

It is also laboratory protocol to include defined symbols where appropriate. "Proficiency work is to follow as closely as possible that of normal casework. In doing so, DNA results reported to CTS (or other approved external proficiency test provider) should not vary from DNA results included within the case file, as established by the DNA SOPs. For example, notations to distinguish major and minor components in a mixture should be included in results submitted to the test provider, if applicable. If symbols are used in the reporting of data to the proficiency testing agency, they must be defined in the results submission form."

The analyst's interpretation and reporting is compliant with laboratory protocol and will therefore impact casework as well as proficiency tests. There are no planned corrective actions for this potential non-consensus, as the results reported by this analyst are concordant with the CTS consensus data.

Please do not hesitate to contact me, should you require any additional information.

Sincerely,

Robin D. Guidry, Technical Leader
Houston Forensic Science Center

rdg:rdg

cc: Irma Rios, Assistant Director, Houston Forensic Science Center

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☐ Preventive ☐ Tracking/Documentation Only Inc. Report #: 2015-003

Date: Feb 3, 2015

DESCRIPTION OF DISCREPANCY/ NON/CONFORMANCE: See attached memo dated 2/3/15 pertaining to a proficiency test data entry transcription error for PAR-C 2014.

Date: Jan 26, 2015

CAUSE OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine) Human error and possible computer glitch with the CAP system.

LEVEL/TYPE OF DISCREPANCY/NON-CONFORMANCE (see Quality Manual for description): CLASS III

EFFECT OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine) The information reported by examiners was correct. This was verified by the Quality Director through a comparison of paper data sheets and expected results. However, the CAP system shows that one allele was reported incorrectly.

If not discovered at this point, where else in the process would this incident have been discovered?

n/a

Corrective Actions/Preventive Measures Taken (if applicable):

No action can be taken at this point. The test was completed successfully by the examiners. The error occurred during on-line data entry. The HFSC did not order any CAP tests for calendar year 2015. If online entry becomes required for other providers (i.e. CTS), the Quality Division will encourage analysts to complete online data entry, the reviewer will review the data entry, and the Quality Division will review the data a final time. This should prevent a recurrence.

ANALYST: Paula Evans Date: Feb 10, 2015

SECTION MANAGER: Robin Guidry Date: Feb 11, 2015

CODIS ADMINISTRATOR (if applicable): Date: Feb. 11, 2015

ADDITIONAL INFORMATION/ FOLLOW UP (if applicable): Although this is reported by the Quality Division as a Level III transcription error, no action can be taken to correct the data entry. The proficiency test was deemed successful based upon examination documentation. The Quality Division made this error and also investigated this error. The Quality Director consulted with the Biology Section Manager during the review of this incident.

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☐ Preventive ☐ Tracking/Documentation Only

Inc. Report #: 2015-003

QUALITY DIRECTOR: Lori Wilson Digitally signed by Lori Wilson DN: cn=Lori Wilson, o=Houston Forensic Science Center, ou=Quality Division, email=LWilson@HoustonForensicScience.org, c=US Date: 2015.02.11 06:52:16 -06'00'

Date: Feb 11, 2015

LABORATORY DIRECTOR: Shawn Rios

Date: 2-11-15

Date Closed: Feb 11, 2015

It is my recommendation that if data is going to be entered on-line by the QA Division that a 2nd person verify the data while it is being entered into the CAPA website.

2-12-15 Shawn Rios 2-11-15

Houston Forensic Science Center

INTEROFFICE MEMO

To: Case Record for Proficiency Test PAR-C 2014

Cc: Robin Guidry & Irma Rios

From: Quality Division

Date: February 13, 2015

Re: UPDATE: Proficiency Test Transcription Error on PAR-C 2014

The Quality Division inquired with the College of American Pathologists (CAP) to see if any other customers had problems while submitting online proficiency tests. The following issues with the CAP website were discussed:

1. Difficultly logging onto the CAP website. The Quality Division had to login multiple times over an extended time period to gain access to the site. It seemed that the site was down many times that we tried to login.
2. During data entry, the same page was frequently reloaded when the "Next Page" button was selected.

The CAP representative, Tammy, informed the Quality Division that the glitch may have been an issue with an outdated internet browser. She explained that an outdated browser may not communicate with Adobe correctly and that could be why technical issues were experienced during data entry. On November 10, 2014, the day when the data entry, administrative review, and submission occurred, the Quality Division was using the outdated internet explorer browser version 9, the default version on all computers using the HPD network. The Quality Division will ensure that browsers are up to date and compatible with all CAP website features before entering and submitting proficiency test data in the future. The CAP phone conversation with Tammy was recorded and reference number 1677596 was assigned for future inquires.

Lori Wilson

Houston Forensic Science Center

INTEROFFICE MEMO

To: Case Record for Proficiency Test PAR-C 2014

From: Quality Division Lori Wilson

Digitally signed by Lori Wilson
DN: cn=Lori Wilson, o=Houston Forensic Science Center, ou=Quality Division, email=LWilson@HoustonForensicScience.org, c=US
Date: 2015.02.04 13:29:27 -06'00'

Date: February 3, 2015

Re: Proficiency Test Transcription Error on PAR-C 2014

On November 10, 2014 the Quality Division entered and submitted proficiency test results for the College of American Pathologists (CAP) Parentage and Relationship Testing Survey (PAR-C) via the CAP website. During online data entry there was a transcription error made on page 11 where a single allele was recorded at an untested marker, F13B. The online data entry information was administratively reviewed before submission; however, the transcription error was not caught at that time.

The transcription error was discovered upon the review of the expected results provided by CAP. The Quality Division is aware of the error and will be more meticulous when entering and reviewing online data entry for proficiency tests in the future. Although this error did impact the reported results, the examination documentation created during analysis shows that the correct results were obtained.

2/6/15

Alma Wist 2/10/15

Alma Rios 2-11-15

My recommendation is to have someone in QA verify results while entering on the CAP website. dlr 2-11-15 dlr 2-12-15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-004 **Date Submitted:** 2/8/2016

Date Closed: 2/15/2016

Date of this Report: 2/8/2016 **Division:** FAD **FCN:** CTS 15-575 U2588D (If applicable)

Date of Incident: 2/3/2016 **Section:** Biology

No HPD incident # applicable to the external proficiency test.

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

A class III transcriptional error, per the HFSC Quality Manual, was made when the DNA analyst mistakenly switched the result for the sperm and epithelial fractions at locus TH01 on the proficiency test results form for CTS 15-575 U2588D for item 4. The CTS form requires the input of the epithelial fraction above the sperm fraction while HFSC DNA report has the sperm fraction above the epithelial fraction. This could also be the reason the transcriptional error was not identified during TR/AR. The analyst correctly listed the result obtained on the DNA report. The results obtained by this analyst for TH01 are concordant with CTS published data for item 4, resulting in consensus interpretations of the samples tested.

The DNA analyst's interpretation and reporting are compliant with laboratory protocol. There are no planned corrective actions for this potential non-consensus, as the results reported by the analysts are concordant with the CTS consensus data. 2-15-16 It should be Noted that non-consensus is on one loci and is on the proficiency manufacturers' form. [illegible]

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

AR analyst - Christine Vierdraley no longer employed at HFSI

Technical Personnel: [signature] HASELL | DD (TR analyst) **Date:** 2-16-16 12-17-16

Section Manager: [signature] **Date:** 2/15/16

Division Director: [signature] **Date:** 2/15/16

Quality Director: [signature] **Date:** 2/18/2016

Incident Tracking Report Issued by: Quality Director

Tech Lead: [signature] 2-15-16 HASELL

CODIS Admin.: Clara West 2/16/16

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-083 **Date Submitted:** 7/5/2016

Date Closed: 8/25/2016

Date of this Report: 8/4/2016 **Division:** FAD **FCN:** PARF-A 2016 (If applicable)

Date of Incident: 4/5/2016 **Section:** Forensic Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

A class III transcriptional error, per the HFSC Quality Manual, was made when the DNA analyst mistakenly wrote allele "11.1" instead of "11.0"at TPOX for item 3.1 (PARF-03) on the CAP Parentage/Relationship Testing Survey Result Form for test PARF A that was submitted to CAP electronically on April 5, 2016.

The "intended" allele call per CAP, 11.0, was correctly obtained through testing and reported in the HFSC DNA report for FCN PARF-A 2016. The non-consensus was limited to one allele at one locus for one sample on the proficiency manufacturer's results form. The interpretations for all items tested were fully concordant with CAP's published results. The DNA analyst's interpretation and reporting were fully concordant with laboratory protocol. Currently, laboratory protocol requires that technical and administrative reviewers also include the manufacturer's results forms in the review process for proficiency tests. However, this transcriptional error was not discovered at the technical or administrative review. A possible reason that it was not discovered during technical and administrative review could be due to the large number of data transfers onto the data testing survey as well as the electronic portal. To minimize the amount of data transfers it is recommended that data first be entered into the portal and then printed for technical and administrative review.

The electronic submission was verified by a member of the Quality Division. Electronically submitted results were identical to the results hand-written on the results form. It was recommended by the DNA analyst that when submitting results electronically, the DNA allele chart might serve as a second check for the data entry and verification step.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Per the Biology SOP, both the technical and administrative reviews include a review of data in case file & data sheets. The SOP should prevent transcription errors such as this one. This does appear to be an isolated incident. No additional action will be taken at this time. SJV 8/25/2016

Technical Personnel:	Jessica Jemley	**Date:**	8/12/16
Section Manager:		**Date:**	08/17/16
Division Director:		**Date:**	8-22-16
Quality Director:		**Date:**	8/24/2016
DNA Tech. Lead/ Tech. Reviewer:		Date:	August 12, 2016
Admin. Reviewer:	CWD	Date:	8.15.16
CODIS Admin.:	Alexa Wolf	Date:	8/22/16

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-006 **Date Submitted:** 6/30/2015

Date Closed: 8/10/2015

Date of this Report: 4/23/2015 **Division:** FAD **FCN:** 2014-24018, 2014-22949 (If applicable)

Date of Incident: 3/23/2015 **Section:** Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On February 06, 2015, the following unique identifiers were duplicated on QIAcube Batch 10: 37ZR15, 38ZR15, 39ZR15, 40ZR15, 41ZR15 and 42ZR15. These identifiers were originally used in a Chelex Extraction dated January 21, 2015 (FCN 2014-17905 and 2014-17481).

The duplication was noticed when samples were pulled for amplification by a technician. The technician found two sets of tubes having the same unique identifiers in two different racks in cooler 1. Samples were pulled aside to look for the respective Forensic Case Numbers and item descriptions.

It was discovered by referencing a previous extraction worksheet that these samples were in fact duplicated on Q-Batch 10. The first set of samples were from the Chelex extraction; those unique identifiers remain the same. The second set of samples were identified as being associated with FCN 2014-24018 and 2014-22949, and the details of each sample are listed below.

The unique identifier for the second set of samples was modified by adding an "A" at the end as indicated below. This change was made on each tube and notated in each case file.

37ZR15A (2014-24018 Item 5.1.1 Portion of vaginal swabs)
38ZR15A (2014-24018 Item 5.2.1 Portion of rectal swabs)
39ZR15A (2014-24018 Item 5.3.1.1 Portion of swab from fingernail scrapings)
40ZR15A (2014-24018 Item 5.4.1.1 Portion of stain from dress)
41ZR15A (2014-22949 Item 3.1.1 Portion of penile swabs)
42ZR15A (2014-22949 Item 3.2.1 Portion of rectal swabs)

Recd 7-24-15 cR

CW 08/04/15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division Use Only Additional Information/ Follow Up (If applicable):
On 7/10/15 the Quality Division sent the incident report back to the section for edits. The Quality Division also requested extraction worksheets related to this incident.

Technical Personnel: Zorayda Reyes Date: 07-23-2015

Section Manager: [signature] Date: 7/23/2015

Division Director: [signature] Date: 8-4-15

Quality Director: [signature] Date: 8/10/2015

There is a significant delay between date of incident & report date to QA.

7-24-15 Incident 2015-006 relates to a duplication of unique identifiers. It is not clear how this issue will be prevented in the future & whether an evaluation of the procedure was conducted by either QA or the Biology staff. This should be reviewed by the reviewing TL Robin Gordy. [signature] 7-24-15

7-24-15 CODIS Administrator must sign off on INCR [signature] 7-24-15
[signature] 7-24-15

8/4/15: Until more complete LIMS integration is realized, sample identifiers are generated by individual analysts. Once LIMS integration extends to processing of SAKS, LIMS will auto-populate worksheets with a unique identifier for each sample consisting of FCN, item #, & INC/agency # FY14 grant funding through will be requested to expand LIMS implementation beyond DNA casework - RDL 8/4/15

CW 08/04/15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-007

Date Submitted: 3/23/2015

Date Closed: 5/6/2015

Date of this Report: 3/23/2015

Division: FAD

FCN: (If applicable)

Date of Incident: 3/18/2015

Section: DNA

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On 3-16-15 a plate that was processed on genetic analyzer Beta contained excessive artifacts in multiple samples (including the positive control). A request was made by the DNA analyst to re-inject this plate on the other machine (Gamma), in hopes this would clean up the excessive artifacts. On 3-18-15, the plate was processed on Gamma; during the analysis of the plate it was noticed that the positive control (POS031615MR) was blank. This was brought to the attention of the technician who believed this was the result of the machine running out of polymer during the run. Another request was made for this plate to be processed. On 3-19-15, the results of this run on Gamma were analyzed by the DNA analyst. The positive control was again blank. A 3rd request was made for the plate to be set up and to include an additional positive control to ensure an acceptable positive was present on the plate. Before setting up the plate a 4th time, the technician discovered the cause of the "blank" positive. The samples were loaded correctly onto the plate, however during the entering of the sample names into the software of the genetic analyzer, one sample name was entered twice into two consecutive wells, causing the remaining names to be one off from their actual sample wells. Therefore, the samples were injected off by one well from their true locations on the plate. The plate was set up and processed correctly on 3-20-15; all samples and positive produced acceptable data. With the advanced integration of LIMS into DNA assignments in the coming days, LIMS will create files that will be used by the 3130 to identify which sample is located in which plate well. Moving forward, we anticipate this new feature of LIMS to preclude any potential manual mislabeling of samples on the 3130 data collection software.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

DNA Workflow implementation into LIMS is complete. See verification documentation for further details related to the implementation project. SBW 5/6/15

Recd 3-30-15 dl2

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel: _____ Date: 3/24/15

Section Manager: _____ Date: 3/27/15

Division Director: _____ Date: 4-6-15

Quality Director: _____ Date: 4/7/2015

3/29/15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-010 **Date Submitted:** 6/29/2015

Date Closed: 7/8/2015

Date of this Report: 6/30/2015 **Division:** FAD **FCN:** 2012-23650 (If applicable)

Date of Incident: 5/20/2015 **Section:** Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On 5/20/15 a DNA Extraction worksheet was prepared with the following sample numbers: 65KG15 through 76KG15. Upon filing a copy of this worksheet into the extraction binder where the technician keeps track of their sample numbers, it was discovered that a DNA Extraction worksheet dated 4/27/15 also contained samples 65KG15 and 66KG15.

The 4/27/15 worksheet was not filed into the binder at the time of creating the 5/20/15 worksheet and therefore duplicate sample numbers were generated. The technician immediately emailed the Acting Technical Leader about the issue and was instructed to prepare an incident report, make corrections on the sample tubes/extraction worksheets, and all other related documentation pertaining to the 4/27/15 DNA Extraction as follows : add an "A" after the sample numbers (i.e., 65KG15A and 66KG15A).

The retention of a copy of the extraction worksheets has proven in the past to be effective up until this point. The analyst inadvertently did not file the 4/27/15 copy immediately into the binder, thereby causing the oversight.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

On 7/10/15 the Quality Division sent the incident report back to the section for edits. The Quality Division also requested extraction worksheets related to this incident.

Rec'd 7/15

Technical Personnel: Karen Gincoo *no longer employed w/ HFSC **Date:**

Section Manager: [signature] **Date:** 7/23/2015

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Division Director: [signature] Date: 7-24-15

Quality Director: [signature] Date: 8/10/2015

7-24-15 CODIS Administrator needs to sign off on this ~~CAPA~~ INCR as per FBI Guidelines. MR 7-24-15 [signature] 7-24-15

8/4/15: Further LIMS integration is planned. This will extend some features of LIMS integration beyond the processing of DNA casework into other areas including SAKs. LIMS will auto populate sample identifiers to include FCN, item #, & INC/agency #. This will remove the need for analysts to manually assign case identifiers and prevent this issue from recurring – RDL 8/4/15 MR Reviewed 8-4-15

CW 08/04/15 CODIS Administrator Agree 8/10/2015 see comment 7/24/15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-918

Date Submitted: 10/2/2015

Date Closed: 10/13/2015

Date of this Report: 10/6/2015

Division: FAD

FCN: 2014-13585, 2014-16474, 2014-18769, 2014-19557, 2015-01152 (If applicable)

Date of Incident: 3/6/2015

Section: Forensic Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On March 6, 2015, the following unique identifiers were duplicated on QIAcube Batch 9: 195HN15, 196HN15, 197HN15, and 198HN15 (2014-13585, 2014-16474). These identifiers were originally used in an EZ1 extraction dated February 27, 2015 (FCN 2014-18769, 2014-19557, 2015-01152).

The duplication was noticed when examination documentation was reviewed during the root cause analysis for Incident Report #2015-013 (a sample switch).

The unique identifier for the first set of samples was modified by adding an "A" at the end as indicated below. This change was made on each tube and notated in each case file.

195HN15A (2014-18769 Item 1.10.1 Portion of KSS
196HN15A (2014-19557 Item 1.2.1 Portion of KSS
197HN15A (2015-01152 Item 1.5.1 Portion of KSS
198HN15A (RBK022715HN)

Until a more complete LIMS integration is realized for SAK casework, sample identifiers will continue to be generated by individual analysts. Once LIMS integration extends to the processing of SAKs (LIMS updates are being tested at this time), LIMS will autopopulate examination worksheets with a unique identifier for each sample, consisting of the FCN and the item #, thereby removing the need for analysts to maintain and track unique identifiers.

The analyst believes that in this instance, her method of tracking sample numbers, which included maintaining copies of extraction records, was flawed when a DNA analyst requested her copy of the extraction on 2/27/15 but did not return it or make a copy before taking it. The analyst believes that moving forward, and until the LIMS integration is complete, she will scan her records to the share drive so that her records are accessible to all.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

The significant delay between the incident and this report is not well understood; the incident was not discovered until June, 2015 during the review of the involved analyst's casework in response to a separate incident. It was realized on October 2, 2015 during discussions around the quality incidents associated with this analyst that this report was never actually created.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

Click here to enter text.

Technical Personnel:	[signature]	Date:	10/07/15
Section Manager:	[signature]	Date:	10/7/15
Division Director:	Elma Rios	Date:	10-7-15
Quality Director:	[signature]	Date:	10/13/2015
CODIS Admin:	Chris West	Date:	10/9/15

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-022

Date Submitted: ~~12/4/2015~~ 2/18/2016 JBW

Date Closed: 2/18/2016

Date of this Report:	12/4/2015	**Division:**	FAD	**FCN:**	2015-08774, 2014-25334, and 115623199 (If applicable)
Date of Incident:	11/23/2015	**Section:**	Forensic Biology		

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On November 23, 2015 the following unique identifiers were duplicated on an extraction from QIAcube Batch 88; 2710IH15 through 2733IH15. These identifiers were originally used on an extraction from QIAcube Batch 87 dated November 17, 2015.

The duplication was noted when copies of re-amplification paperwork were being made on December 3, 2015. There were two requests which both contained the same unique identifier. After examining the batch extraction paperwork it was discovered that all of the unique identifiers from Batch 87 extraction sheet had been duplicated in Batch 88.

The duplicated unique identifiers for the samples in the Batch 88 were modified to contain an "A" at the end. This change was made on each tube and notated in each case record.

2/2/16 - The future implementation of the SAK assignment in LIMS will prevent this issue from occurring. LIMS will automatically generate unique identifiers for each extract processed. -Ja

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

The Quality Division requested extraction worksheets related to this incident.

See attached email to Amy Castillo for updates. 2/18/2016 JBW Incident closed but may be reopened pending LIMS implementation project.
Final Incident Form received by JBW on 2/18/16. Draft Incident Form done on 12/4/15.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel:	[signature]	**Date:**	01-26-16
Section Manager:	[signature]	**Date:**	1/27/16
Division Director:	[signature]	**Date:**	2-10-16
Quality Director:	[signature]	**Date:**	2/18/2016

Technical Leader: [signature] HALSELL 1-25-16

On 2-12-16 I spoke to Amy Castillo to see if she could assist with SAK Assignment in LIMS. She indicated she could. Clara Rios 2-15-16

CODIS Admin: Clara West 02/16/16

Received 2-10-16 Clara Rios

[signature] received 2/18/16

Lori Wilson, BS ASQ CQA

From: Lori Wilson, BS ASQ CQA
Sent: Thursday, February 18, 2016 7:09 AM
To: Jennifer Clay; acastillo@houstonforensicscience.org; irios@houstonforensicscience.org; Lloyd Halsell III, MS F-ABC
Cc: Aimee Grimaldi, M.S.
Subject: SAK Assignment in LIMS as Referenced in Quality Incident 2015-022

Amy-
This incident tracking form indicates that your group will assist Biology with implementation of SAK assignments into LIMS. This is needed because there have been incidents in which the same unique identifiers were reused on casework. Please provide ongoing updates concerning this project to the Quality Division. These updates will be used as documentation of action taken to correct this issue.

Thanks. Please let Aimee or me know if you have any questions.

HOUSTON POLICE DEPARTMENT
CRIME LABORATORY

CORRECTIVE AND PREVENTIVE ACTION REPORT

☐ CHECK IF ADDITIONAL PAGES ARE USED

SECTION 1

Date: Apr 8, 2014

CAPA #: 2014-010

DESCRIPTION OF ISSUE/NON-CONFORMANCE: Contamination was detected in a reagent blank (11MS14 – RBS012714MS) for HPD Case #116874113. The observed peaks appear to be from the samples (sperm fractions) positioned before the reagent blank.

CLASSIFICATION OF NONCONFORMANCE: see Quality Manual for description: TT

☐ PREVENTIVE ACTION ONLY

ROOT CAUSE ANALYSIS: Mary Symonds performed the differential extraction. Benjamin Cambridge performed the quantification, genetic analysis, re-amplification and genetic analysis of the re-amp. Amplification and re-injection were performed by Peter Lentz. The reagent blank was re-injected and then re-amplified to confirm the presence of the alleles. Fewer alleles were present after re-amp; however they remained consistent with the DNA profile from the preceding samples. The reproducibility of the contamination indicates that it could have occurred from sample-to-sample during extraction or during the set up for quant or amp. Either way, the associated samples cannot be used for interpretation.

PROPOSED CORRECTIVE ACTIONS/RECOMMENDATIONS TO ADDRESS THE DEFICIENCY AND PREVENT RECURRENCE:

All associated samples were re-extracted and all associated reagent blanks yielded acceptable data. DNA Analyst Mary Symonds poured new aliquots of reagents before re-extracting the affected samples. DNA Analyst Mary Symonds and DNA Technician Benjamin Cambridge will continue to exercise extreme caution while handling samples in the laboratory.

SECTION MANAGER: [signature]

Date: 4/14/14

SECTION 2 (MANAGEMENT REVIEW AND RESOLUTION)

FINAL RESOLUTION: See Tech Leader email dated 4/23/2014 (a total of 3 contamination events reported since Jan. 2013) No further action taken at this time.

5/6/2014

QUALITY MANAGER: [signature]

Date: 4/28/2014

LABORATORY DIRECTOR: [signature]

Date: 5-6-14

Wilson, Lori

From: Guidry, RobinD
Sent: Friday, May 09, 2014 6:06 PM
To: Wilson, Lori
Cc: Rios, Irma
Subject: Extraction contamination

Lori,
As you know, the Biology/DNA Unit of the Houston Forensic Science Center documents issues, such as DNA contamination, via the Corrective And Preventative Action (CAPA) form. This allows the detection of possible trends and presents any preventative measures that the lab may elect to employ.

In 2011, there were 18 CAPA-worthy events, 6 of which involved extraction contamination (33.3%). In 2012, there were 11 CAPA-worthy events, 3 of which involved extraction contamination (27.3%). In 2013, there were 18 CAPA-worthy events, 1 of which was associated with contamination at amplification in a negative PCR control (5.6%). In 2014 to-date, there have been 8 CAPA-worthy events, 3 of which involved contamination (38%). Of those 3, 1 (12.5%) was associated with amplification contamination, while the other 2 (25%) were associated with extraction (1 reagent blank and 1 sample, both with low-level contamination). Please note that many of the CAPAs generated in 2013 and 2014 are associated with the massive outsourcing project of almost 10,000 cases and involve chain of custody documentation.

For perspective, the DNA lab has experienced a significant increase in production and therefore extractions. As the number of extractions increases, so does the potential for a contamiantion event.

- 472 DNA reports were issued in 2011
- 887 DNA reports were issued in 2012
- 1078 DNA reports were issued in 2013
- 330 DNA reports have been issued in 2014 (YTD)

The reduction in extraction contamination from 2011 to 2013 appears significant, and I suspect there is less due to an increased use of automation and a decreased use of manual extractions. 2014 has observed a percentage-wise increase of issues related to contamination, but year-to-date, is as high as 2012 and one half of 2011. One of the 2 extraction contaminations in 2014 was detected in a differential extraction, which is still a fully manual process; we are transitioning to an automated differential extraction at this time. The contamination events do not appear to be analyst-specific.

This lab continues to strive to completely avoid contamination through the use of good laboratory practices but also relies on mechanisms such as the extraction reagent blank to detect it when it is present. We will continue to employ good lab practices and will continue to document events and their corrective and preventative measures taken via the CAPA form. We will also continue to monitor contamination events for any trends and take action when necessary.

Thank you,
Robin

Robin D. Guidry, M.S., F-ABC
Police Administrator
Houston Forensic Science Center
Phone: 713-308-2620
Fax: 713-308-2645
Email: robind.guidry@houstonpolice.org

2014-13

HOUSTON FORENSIC SCIENCE CENTER
1200 Travis St., 20th Floor
Houston, TX 77002
(713) 929-6760

Houston Forensic Science Center

Inter-Office Correspondence

June 13, 2014

MEMORANDUM FOR: [redacted]

SUBJECT: Root Cause Analysis of an Erroneous Identification made by [redacted]

BACKGROUND SUMMARY:

1. The training procedure implemented by the Houston Forensic Science Center's Latent Print Unit requires all newly hired latent print examiners to be thoroughly competency tested prior to entering into any dependent supervised casework. Based on the documentation of qualifications and background experience the five (5) newly hired Certified Latent Print Examiners provided, a modified training program was implemented to test their knowledge and abilities in the area of Latent Prints. The competency testing program developed for the examiners was a two part test. A written competency test was developed consisting of 50 questions that would test the examiner's knowledge of the biology, history, processing techniques, various chemical development mediums, and the methodology if the science of friction skin identification. The second phase of the final competency testing consisted of a comparison examination developed from a three year old proficiency test from the testing agency CTS. The test was CTS Latent Print Test #11-517. The original test was scanned into Adobe Photoshop CS4 with the unknown latent images scanned at 2400 ppi resolution and the record finger and palm print cards scanned at 1000 ppi resolution. All information indicating which CTS version of the test was removed or redacted from the image. The scanned images were then printed using an Epson Stylus Pro 4900 high resolution ink jet printer. Four copies of the comparison competency test were made. The answer sheet was scanned as an Adobe PDF document with all extraneous information associated with the original CTS test cropped out.

2. On the cover of the final comparison competency test, the directions were as follows:

   "Instructions: This is an assessment of your ability to identify or exclude latent prints when compared against known records. The test consists of twelve (12) latent images and four (4) records consisting of ten print and palm prints. You will have 8 hours to complete this assessment. No copies or scratch paper are allowed to leave the testing area. Please use a blue or black ink pen and write legibly on the answer sheet provided. You ARE allowed the use of your PC, scanner, and Photoshop software or your fingerprint loupe while in the process of completing this assessment. All work must be conducted independently."

3. The comparison test was administered to [redacted] on June 3, 2014. All examiners taking the test have been certified by the International Association for Identification. All of the above examiners successfully passed the examination.

4. On June 5,2014, [redacted] was given the test with the above directions. Upon grading the test using the CTS answer key, it was discovered that he had erroneously identified Latent Image 5H. Todd was informed of this in the afternoon and advised that a resolution would be provided soon.

5. Per the Code of Ethics for Certified International Association for Identification Latent Print Examiners and the IAI Certification Manual Section X; subsection B under Technical Errors, the Secretary of the Certification Board, [redacted], was notified on June 6, 2014 of the erroneous identification. Upon presentation of the facts, [redacted] determined that since no report involving actual casework was issued and the erroneous identification was discovered in competency testing, it was unnecessary for [redacted] to lose his status as a CLPE and in-house remedial assessments would be appropriate.

CAUSE ANALYSIS:

1. [redacted] was instructed on June 6, 2014 to scan the latent identified and also the erroneous finger into Adobe Photoshop and chart what he saw during his analysis and comparison of the latent to known to better understand the thought process and determine possible causes. He was also instructed to provide a summary of possible factors as to why he erroneously identified the latent print. [redacted] provided me with a summary of what he found and possible causes for the misidentification. (See Attached Summary from [redacted]).

2. Upon analyzing the documentation and speaking with Todd, the following possible factors were likely contributors to the erroneous identification decision:

   A. [redacted] was in a supervisory capacity prior to accepting the position with HFSC and did not routinely compare latent prints as a supervisor.
   B. Although the directions stated a computer, scanner, and Photoshop software could be used, [redacted] used a comparison loupe. He advised he was not aware he could have asked for access and his previous experience with comparing latent prints were conducted on the computer.
   C. The location [redacted] was taking his test was in the common area with many people walking and communicating around him.
   D. [redacted] started with the HFSC Latent Print unit on June 2, 2014 and was started with his competency testing within a few days. A summary of his explanations indicated that he also has external stressors that may have contributed to the erroneous identification.

CORRECTIVE ACTION PLAN

1. All further competency testing will be conducted in an environment that is free from extraneous noise and distractions.

2. Notifications will be posted that testing is in progress and to not disturb the person(s) taking the tests.

3. [redacted] will be administered a series of new competency tests to determine his skills and abilities further. This will consist of no less than four (4) additional comparison competency tests. These tests will be conducted using Photoshop software and he will be required to chart his conclusions so there will be a documented visual representation of the process. Once competency has been established and no errors have been noted, a new final comparison test will be issued. Upon successful completion of the re-testing phase, [redacted] will proceed into the dependent supervised casework portion of the HFSC Latent Print Training Program.

4. If further erroneous identifications are made during the re-evaluation phase, a re-evaluation of [redacted] will need to be conducted to determine if he can remain in a Latent Print Examiner position with the Houston Forensic Science Center.

Timothy Schmahl, CLPE
Latent Print Unit Manager

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☐ Preventive ☐ Tracking/Documentation Only Inc. Report #: 2014-027

Date: Oct 31, 2014

DESCRIPTION OF DISCREPANCY/ NON/CONFORMANCE:

On 9/11/14, DNA Analyst Clay Davis observed allelic activity in a reagent blank during his review of the data. Reagent blank sample 682MR14 was re-injected the same day and the activity was replicated. On 9/12/14, the reagent blank was re-amplified by a second technician and the activity was again reproduced. This activity was consistent with the known DNA profile of DNA Technician Maria Rumble who extracted, quantified, amplified and loaded this reagent blank and its associated samples. The Technical Leader was notified as soon as the contamination was confirmed.

Date: Sep 11, 2014

CAUSE OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine)

When notified of the contamination, the analyst evaluated her actions and was unable to pinpoint a cause for the contamination. All extractions by this technician since this event have been acceptable; she believes she is using the same preventative measures that she routinely incorporates into her laboratory procedures. Even though the analyst recalls following good laboratory practices, at some point prior to amplification, it appears her own DNA was introduced to the reagent blank tube.

When unusual circumstances occur during an extraction (e.g., a tube is dropped onto the bench top during handling), analysts are asked to make a note on examination documentation for easier troubleshooting or explanation should data and/or controls exhibit unusual activity later. The analyst did not make any such notes and does not recall the need to do so. Because contamination is generally not detected immediately in the process, but rather only once samples have been quantified, amplified, and subjected to fragment separation, it can be very difficult to identify the exact cause of the contamination event, especially given the sensitivity of the DNA testing process.

LEVEL/TYPE OF DISCREPANCY/NON-CONFORMANCE (see Quality Manual for description): CLASS II

EFFECT OF DISCREPANCY/ NON-CONFORMANCE: (if possible to determine)

Because a reagent blank was found to be unacceptable, the data of the associated samples may not be used for interpretation. Samples will need to be re-extracted. Additional time and resources will be used to complete the re-extraction of the associated samples. Consumption orders have been requested from case officers for each case due to limited sample remaining for each item. Three cases are associated with this reagent blank: INC#024911686/L86-3529/2014-13476, INC# 141044213, and INC# 074776514/ 2014-14668. Consumption has been granted for all but INC#024911686/L86-3529/2014-13476; the case investigator is seeking input from the prosecuting attorney.

This is the 682nd sample extracted by Maria this year and this is the first contaminated reagent blank. At the section-wide Forensic Biology meeting held September 26, 2014, this issue was discussed and analysts were reminded to exercise extreme caution and awareness when handling samples during extraction by not touching things such as chairs, face, face masks, etc. with gloved hands and to change gloves as frequently as needed.

If not discovered at this point, where else in the process would this incident have been discovered?

Because the review of all examination documentation and controls, including reagent blanks, is a required step in data analysis and the technical review of data, this issue, if not caught when it was during the analyst's initial review of the data, would have been caught in the technical review of this case. The DNA review checklist requires the reporting analyst and the technical reviewer to acknowledge that controls are acceptable.

Corrective Actions/Preventive Measures Taken (if applicable):

Per laboratory protocol, given the unacceptable reagent blank control, re-testing has commenced for INC# 141044213 and INC# 074776514/2014-14668. Re-extraction is pending consumption permission for INC#024911686/L86-3529/2014-13476.

HOUSTON FORENSIC SCIENCE CENTER

Print Form

INCIDENT REPORT

☒ Corrective ☒ ~~Preventive~~ from ☐ Tracking/Documentation Only

Inc. Report #: 2014-027

ANALYST: MARIA A. RUMBLE Date: 10/31/14

SECTION MANAGER: ROBIN D. GUIDRY Date: 10/31/14

CODIS ADMINISTRATOR (if applicable): Cleva West Date: 10/31/14

ADDITIONAL INFORMATION/ FOLLOW UP (if applicable): provide follow up once all cases have been reworked and reported.

QUALITY DIRECTOR: Date: 11/5/2014

LABORATORY DIRECTOR: Date: 11-7-14

Date Closed: ~~11/7~~ from 12/22/2014 see email dated 12/11/14

Clay Davis 10.31.14

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2015-024

Date Submitted: 2/18/2016 ~~1/12/2016~~ JBW

Date Closed: 3/18/2016 JBW

Date of this Report: 12/11/2015 **Division:** FAD **FCN:** 2013-20123 / 073206213 (If applicable)

Date of Incident: 2/27/2015 **Section:** DNA

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

A request for YSTR analysis was made on 2-16-15 for case 073206213 (2013-20123) for the items associated with tissue/fluid from a fetus (Items 1.5, 1.6, 1.7 & 1.8). The four items were amplified with YSTRs on 2-20-15 by M. Bryan Davis. Analysis of the amplified items was performed and a mixture was observed in Item 1.5. Since this sample type was DNA from tissue/fluid from a fetus, a mixture of YSTR's in this item was not anticipated.

A comparison of the staff YSTR database revealed that the analyst that amplified the evidence with YSTRs was consistent with the "extra" alleles present in Item 1.5.

A re-amplification was requested on 5-28-15 for Item 1.5; the second YSTR DNA profile produced a partial single-source profile with no indications of a second contributor.

The extra alleles observed in the original YSTR amplification were most likely introduced at the YSTR amplification setup and not in the original extraction of the item. This theory is supported by the fact that the autosomal profile consisted of a major component consistent with the biological mother and 2 minor alleles that are consistent with the DNA profile developed on other portions of the fetal tissue/fluid. These 2 minor alleles are not consistent with M. Bryan Davis. Therefore, the re-amplification results for Item 1.5 are deemed acceptable and will be used for reporting purposes.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

The Quality Division requested associated electropherograms.

Signed Incident Form received 2/18/16 by J Wilson. Incident will not be closed until timeline related to delayed reporting to QDiv is received.

See timeline dated by JWilson on 3/15/2016.

Please note that timeline was compiled by TL Halsell.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel: Clay Davis Boyen Davis no longer employed by HFSC Date: 2.4.16

Section Manager: [signature] Date: 2/8/16

Division Director: [signature] LSA 1-26-16 Date: 2-16-16

Quality Director: [signature] Date: 3/18/2016

Technical Leader: [signature] MALSELL 1-25-16

[signature] LSA 1-26-16 CODIS Admin.: Clara Wiest 2/16/16

2-16-16 Resolving Quality Incident 2015-024 was a bit lengthy. Review was initiated for this incident & FAD managers were reminded of process in FAD managers' meeting held 2-15-16. Process map was provided.
Clara Ríos 2-16-16

Clara Ríos Received 2-9-16 [signature] Submitted 2/18/16

Time line to address delayed reporting of CAR 2015-024 regarding Incident number 073206213 to the Quality Division

- 2-20-15: Item 1.5 (3225MR14) is amplified with YSTR
- 2-27-15: Item 1.5 (3225MR14) is run on CE
- 5-28-15: Item 1.5 (3225MR14) is requested for re-amplification and re-amplified
- 5-29-15: Item 1.5 (3225MR14) re-amplification is run for CE
- 12-14-15: DNA report is issued with results for Item 1.5

During the time that this case was identified and processed for YSTR analysis there was not a set schedule for the routine processing of YSTR requests. In February of 2015 two large YSTR amplifications were performed that consisted of most of the open requests. One reason for such a large run was that only two technicians were competent in processing YSTR samples. These samples were not part of an active batch and the cases were to be written by the few analysts that could issue YSTR reports. The analyst would work on these cases between their ongoing batches when they had time.

The data was initially reviewed in February 2015, but that analysis was not case specific. The first analysis was meant to check the controls and overall profiles as compared to amplified target and therefore the contamination was not detected at this time. The case was reviewed by the reporting analyst in May 2015. During the review conducted by the reporting analyst the contamination was detected.

After the re-amplification results were obtained it is possible that the complexity of the case and the case type extended the completion date. This case request was a paternity testing case in which statistical analysis for paternity calculations was necessary. Due to the complexity of the case, many discussions and consultations occurred as to how it should be reported.

CMS 3.24.16 LSA 3-23-16

JM 3/28/16 JPW 3/18/16

Timeline prepared by Lloyd Hartsell Jr. CLH 03/29/16

CLH 3-30-16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-005	**Date Submitted:**	3/1/2016
Non-Conformance Level	CLASS I	**Date Closed:**	6/14/2016

Date of this Report:	5/23/2016	**Division:**	FAD	**FCN:**	2014-19609/120012514 & 2014-22128/136106214 (If applicable)
Date of Incident:	3/11/2015	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

The epithelial fraction reagent blank, RBE031115IH-1 (266IH15), was extracted on 3-11-15 on Batch 21. The extraction batch contained two cases, 2014-19609 (Incident # 120012514) and 2014-22128 (Incident # 136106214). The reagent blank was quantified on 3-12-15 and had a value of 0.0006 ng/µl. Amplification occurred on 4-3-15, with CE following on 4-6-15. The reagent blank contained a single peak above threshold with additional peaks that were distinguishable from background below analytical threshold.

The data was initially reviewed on 4-13-15, however this was not a case specific review. The reporting analyst did not review the CE run until 7-20-15 and the technical reviewer until 10-2-15.

Actions Taken:

Re-injection was requested on 7-27-15 and occurred on 8-5-15. The peaks persisted so the reagent blank was requested for re-amplification on 8-6-15 and occurred on 8-12-15, with CE following on 8-12-15.The peaks persisted after re-amplification.

The extraction batch and employee profile list were examined for possible sources, none were identified.

All samples from case 2014-22128 had been initially amplified. All samples with case 2014-19609 were either male negative or inconclusive, so no samples were amplified. To troubleshoot the source of the contamination, the sample immediately adjacent to the reagent blank, 265IH15, was requested for amplification on 9-3-15 and set up on 9-10-15. This profile was not consistent with the reagent blank.

All other samples from case 2014-19609 were requested for amplification on 9-15-15 and set up on 9-16-15. Several did not generate a DNA profile and those that did generate results were all consistent with the same female profile and not consistent with the contaminant.

Since no ADA was assigned to these cases to issue permission to consume, re-extraction did not occur. The acceptable sperm fractions were reported out and the associated epithelial fractions were reported as not meeting quality assurance standards.

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

If not discovered at this point, where else in the process would this incident have been discovered?

The DNA review checklist requires the reporting analyst and the technical reviewer to acknowledge that controls are acceptable. This incident would have been discovered during review.

Technical Personnel:		**Date:** 06-10-16
Immediate Supervisor:		**Date:** 6/13/16
Section Manager:		**Date:** 6/3/16
CODIS Administrator (if applicable):		**Date:** 6/3/16
Division Director:		**Date:** 6/3/16

Tech Lead: S-2476

Summary of Root Cause Analysis:

In this particular case the contamination was reproduced after re-amplification which suggests that the contaminant was most likely introduced to the extract at either the extraction or quantification steps. A likely root cause of this particular contamination event could be attributed to poor sample handling at either of these processes. Because the source of this contaminant is not a sample processed on Batch 21 nor an employee, extraneous DNA could have been deposited into the laboratory and introduced to this reagent blank during processing.

Additional Information/Follow-Up:

The Forensic Biology Section will be performing lab decontamination on a routine basis. Additional PPE requirements have also been implemented to prevent contamination issues. Lab coat, gloves, hair coverings and face masks are now required during screening, extraction, quantification, and amplification. In the post-amplification laboratory, gloves and a lab coat are required. This PPE is not optional and anyone entering the areas where these procedures are performed must abide by these requirements.

Quality Director: Jon Wilson **Date:** 6/14/2016

released for signatures 5/24/16 HKG

This time line addresses the delayed reporting of CAR 2016-005 regarding Incident numbers 2014-22128 (136106214) and 2014-19609 (120012514) to the Quality Division.

RBE031115IH-1 (266IH15) was extracted as part of SAK batch 2015-21.

- 3-11-15 – Extraction
- 3-12-15 – Quantification
- 4-3-15 – Amplification
- 4-6-15 – CE
- 4-13-15 – Initial review for poor injections
- 7-20-15 – Review by report writer
- 7-27-15 – Requested for reinjection
- 8-5-15 – CE of reinjection
- 8-6-15 – Requested for reamplification
- 8-12-15 – Reamplification
- 8-12-15 – CE of reamplificaiton
- 9-1-15 – Email to Tech Lead asking how to report since there was no ADA assigned. Tech lead responds to report acceptable fractions and others as inconclusive and an incident report will be necessary. TL asks about other samples being amplified. Clearly a conversation was had in person based on the tone of the emails.
- 9-3-15 – Sample 265IH15 requested for amplification as part of troubleshooting
- 9-10-15 – Amplification of 265IH15
- 9-10-15 – CE of 265IH15
- 9-15-15 – Additional samples requested for amplification for trouble shooting
- 9-16-15 – Amplification of additional samples
- 9-16-15 – CE of additional samples
- 11-30-2015- 2014-22128 reported
- 12-21-15 – 2014-19609 reported

The cause of the delayed reporting of this corrective action to the Quality Division it not known. However, in October 2015 a re-organization of Biology section management occurred in which an Alternate Technical Leader was designated. This restructure could have contributed to reporting delay. The TL designated at the time of this event was involved in the troubleshooting of this contamination event and investigated the event thoroughly.
The ATL notified the Quality Division that a corrective action was necessary in February 2016. Since February 2016, the Quality Division and the ATL have worked together to close this corrective action report.

Time line provided by Lloyd Halsell III, Acting Technical Leader

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-032 **Date Submitted:** 3/29/2016

Date Closed: 5/10/16

Date of this Report: 3/29/2016 **Division:** FAD **FCN:** 2016-02382/154101715 2015-12890/13 121342315 2015-07396/018032416 (If applicable)

Date of Incident: 3/14/2016 **Section:** Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

Reagent blank 1343LS16 for Extraction Batch 28-2016 was originally quanted on 03/14/16 and yielded a quant value of 0.01274ng/µL. This reagent blank was amplified on 03/15/16 and then it was loaded on 03/15/16 (project ZR031516). The reagent blank produced a clean profile with no DNA activity. Since this DNA result was not concordant with the sample's quant value, this reagent blank was then re-quanted along with an adjacent sample, 1342LS16, to verify quantitation results. After the re-quantification, the reagent blank and adjacent sample's quant results were N/A, suggesting that no DNA was present. The re-quantification result corresponded with the reagent blank's DNA result of no DNA activity present. Therefore, this reagent blank and the associated data are deemed acceptable.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

It is unclear how extraneous DNA was deposited in the original quantification of the reagent blank yielding a result of 0.01274 ng/µl. A thorough laboratory clean was performed on 3/28/2016 to decontaminate the work areas of any extraneous DNA that may have been deposited. In addition, the section plans to perform this lab clean on a routine basis. As of 4/8/2016 additional PPE requirements have also been implemented as a preventive measure to prevent contamination. The required PPE in the pre-amplification areas include a lab coat, gloves, face masks, and head coverings.

Technical Personnel: _____ **Date:** 5-6-16

Section Manager: _____ **Date:** 5/6/16

Division Director: _____ **Date:** 5/9/16

Quality Director: _____ **Date:** 5/10/2016

Tech Lead: _____ HALSTELL 5-6-16

CODIS Admin.: Clara West 5/10/16

released for signatures 4/20/16 AKA

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Quality Division use only

Quality Tracking # 2016-049 **Date Submitted:** 4/21/2016

Date Closed: 4/26/2016

Date of this Report: 4/4/2016 **Division:** FAD **FCN:** 2014-15820

Date of Incident: 3/22/2016 **Section:** Forensic Biology **Incident #: (If applicable)** 087225614

5-4-16 PHE

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

On 3/22/16, when the substrate from the portion tube containing item 10.8.1 was being transferred into a spin basket during the extraction procedure the DNA technician noticed that there was a strand of apparent hair on the swab in the tube. The technician continued to transfer the swab into the spin basket making sure the apparent hair remained with the swab. The technician retained the spin basket with the apparent hair and placed it into Freezer 1. The technician recorded this information on a laboratory information worksheet that was included as part of the case record.

On 3/24/16 a DNA analyst analyzed the data obtained from Item 10.8.1. The analyst had knowledge that an apparent hair was observed on the swab from the laboratory information worksheet and keep that in mind when analyzing the data. The data obtained was a major/minor mixture where the major component was consistent with the complainant in the case and the minor component was insufficient for comparison. The other samples in the case were also analyzed and the results from the majority of those samples were consistent with the data obtained from Item 10.8.1. It does not appear that the apparent hair noted on the swab had any impact on the results for Item 10.8.1. It is unclear where the apparent hair came from as the screening analyst did not note any observations of a hair in the screening notes for Item 10.8.1. Item 10.8.1 is a portion of "S#8 L. wrist" swabs. The data obtained from Item 10.8.1 will be reported.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

Three technicians were interviewed to determine the procedure for portioning an evidence swab with an apparent hair attached. All three screeners stated that if a hair was observed during the portioning process that it would be noted in their case notes. In addition, standard procedure is to portion one half of an evidence swab for extraction. During the portioning procedure, the technician would portion the area of the swab that did not contain the apparent hair. It is unclear if the apparent hair was present during the screening procedure and overlooked or if it was introduced during processing. Hair coverings have since been implemented as a required PPE in the screening, extraction, and pre-amplification areas of the laboratory.

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

Technical Personnel:	Dr Merkel	**Date:**	04-25-16
Section Manager:		**Date:**	4/26/16
Division Director:		**Date:**	4-26-16
Quality Director:		**Date:**	4/26/2016
Tech Lead:	HALSTED		4-25-16
			4/26/16
CODIS Admin:	Clara West		4/26/16

The swab was in the process of analysis when the hair was first ted. Since analysis had already begun, the sample, including the ssible hair, proceeded through the analytical process. Based upon e DNA results obtained, the hair did not impact the results and erefore, the results were deemed acceptable.

RCM 4/26/16

released for signatures 4/25/16 KMM

HOUSTON FORENSIC SCIENCE CENTER
QUALITY DIVISION INCIDENT TRACKING REPORT

2016-05328 HPD Incident # 039808716 SPW
2015-01631 013341215 5/31/2016
2015-10459 065238415

Quality Division use only

Quality Tracking # 2016-050 **Date Submitted:** 4/22/2016

Date Closed: 5/31/2016

Date of this Report: 4/22/2016 **Division:** FAD **FCN:** 2016-05328, 2015-01631, 2015-10459 (If applicable)

Date of Incident: 4/13/2016 **Section:** Biology

In this space, record details of the incident, include dates. Do not include analysts names unless otherwise instructed by the Section Manager or Division Director(s):

Reagent blank for the epithelial fraction of extraction batch 39, RBE041316LS-1 (1825LS16), produced a possible allele below analytical threshold. This reagent blank yielded a quant value of 0.0ng/µl and showed no other signs of contamination. Re-injection of this reagent blank was requested since the possible allele was in a locus bin and had good morphology. Upon re-injection the allele was reproduced and now above analytical threshold at 58 RFUs. The reagent blank was then re-amplified to determine if this possible allele was reproduced at the amplification process. Upon re-amplification the possible allele was not present and therefore this reagent blank and the associated data were deemed acceptable.

Quality Division Use Only
Additional Information/ Follow Up (If applicable):

In response to contamination events, the Forensic Biology Section will be performing lab decontamination on a routine basis. Additional PPE requirements have also been implemented to prevent contamination issues. Lab coat, gloves, hair coverings and face masks are now required during screening, extraction, quantification, and amplification. In the post-amplification laboratory, gloves and a lab coat are required. This PPE is not optional and anyone entering the areas where these procedures are performed must abide by these requirements.

Technical Personnel: [signature] Date: 05-24-2016

Section Manager: [signature] Date: 5/25/16

Division Director: [signature] Date: 5/25/16

Quality Director: [signature] Date: 5/31/2016

Tech Lead: [signature] 5-5-16

Incident Tracking Report Issued by: Quality Director COIS Admin.: Clem West 5/27/16

released for signatures 4/26/16 AKG

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-10	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS III	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	N/A
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #2:
Source: ISO 5.5.6
Requirement: The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.
Finding: Review of the Tecan 150 maintenance logs indicated that not all weekly maintenance listed in the SOP was being completed and/or analysts were not initialing and/or dating the log as required.

Actions Taken:

Forensic Biology Quality Assurance Designee , reviewed the Tecan 150 maintenance records with Analyst on 6/28/16. It does appear that there have been instances of incomplete records, primarily with regard to the weekly shut off of the Tecan 150. Given this is a daily task, the current worksheet is somewhat ambiguous regarding the documentation of the shut off. For example, if it is already off from the previous work day, an analyst might not mark the maintenance record because s/he did not actually shut off the Tecan workstation at the end of the week. Because of this ambiguity and other areas for improvement, the Tecan maintenance worksheet has been updated with input from the technicians using the instrument, while still adhering to the current SOP requirements. Further, FB management will create and complete a checklist for section management to document monthly reviews of quality-related records, including but not limited to, instrument maintenance records. Finally, the FB staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that care should be taken to complete forms as indicated (e.g., insert initials and date if requested, not only one or the other).

If not discovered at this point, where else in the process would this incident have been discovered?

If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance. Implementation of the monthly quality review by FB management should also provide opportunities for possible future non-conformances to be discovered.

Technical Personnel: n/a – SBW **Date:** —

DNA Technical Leader

~~**Immediate Supervisor:**~~ **Date:** 7/31/16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

Section Manager: [signature] **Date:** 073116

CODIS Administrator (if applicable): [signature] **Date:** 08/05/16

Division Director: [signature] **Date:** 8-5-16

Summary of Root Cause Analysis:

This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: [signature] **Date:** 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-11	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS III	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	N/A
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #3:

Source: ISO 4.3.2.2

Requirement: c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?

Finding: The following forms were removed from the "Reagent Prep Binder" because they were either uncontrolled or obsolete. Some of these reagents are no longer made in house.

Serology

- TRIS-HCl – 1M pH 8.0
- TRIS-HCl – 2M pH 8.0
- Luminol Reagent Prep worksheet (not prepared in 2015 or 2016)
- Nuclear Fast Red Solution
- Picroindigocarmine (PIC)
- Pht Stock solution form
- Pht solution Working Form
- PBS Phosphate buffered saline
- PBS 10X form (not made in 2015 nor 2016)

DNA

- Chelex salt, 20% w/v
- Carrier RNA (cRNA) for EZ1 extractions
- DNA reagent Prep worksheet
- QIAamp DNA mini kit buffer AW1 and AW2
- TE Buffer 10/0.1 Mm, pH8.0
- Stain extraction buffer
- Sodium Dodecyl Sulfate (SDS) 20%
- Sodium chloride, 5M
- Sarcosyl solution 20% W/V
- Proteinase K solution
- EDTA Solution, 0.5 M pH 8.0
- Dithiothreitol (DTT, 0.39 M)
- Dithiothreitol (DTT, 1 M)
- Digest Buffer pH 7.5.

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

Actions Taken:
The outdated forms listed above were removed from the laboratory. Additionally, FB management will create and complete a checklist for section management to document monthly reviews of quality-related records, including but not limited to, the removal of obsolete forms and SOPs from the laboratory. Finally, the FB staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that should they encounter an obsolete form or SOP in the laboratory, they should remove it.

If not discovered at this point, where else in the process would this incident have been discovered?
If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance. Implementation of the monthly quality review by FB management should also provide opportunities for possible future non-conformances to be discovered.

Technical Personnel:	n/a - FBW	**Date:**	
~~Immediate Supervisor:~~ DNA Technical Leader		**Date:**	7/20/16
Section Manager:		**Date:**	07/21/16
CODIS Administrator (if applicable):	Clara Watt	**Date:**	7/20/16
Division Director:		**Date:**	8-5-16

Summary of Root Cause Analysis:
This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: _____ **Date:** 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-12	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS III	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	N/A
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #4:
Source: ISO 4.3.2.3
Requirement: Are management system documents generated by the lab uniquely identified? Does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?
Findings:

- The form used to check the SERI Christmas Tree Stain reagent was not controlled with the required worksheet identifiers nor was it controlled in QMS. In addition, this reagent did not have a quality form as described in the SOP ("also contain the test date, signature of the analyst performing the quality control, a second reader signature, if applicable, and date and any supporting documentation")
- LIMS worksheets do not contain footers or headers that contain document control information (issue date, issuing authority) and are not listed on the master document list.

Actions Taken:

A controlled form has been created for the quality check of the Christmas Tree Stain, uniquely identified as FAD-BIO-WS-QC-CTS.1.

The DNA Technical Leader has submitted a request for IT to incorporate the date of issue and/or revision identification, and issuing authority(ies) on the following LIMS-generated worksheets that are currently in use:

- Portion Worksheet
- EZ1 Extraction Worksheet
- Duo Quantitation Worksheet
- Tecan Pre-Quant Deck Map
- Tecan Duo Quantitation Worksheet
- ID+ Amplification Plate Worksheet
- Tecan ID+ Amplification Setup
- Tecan ID+ Amplification Worksheet
- Tecan ID+ Amplification Worksheet – Amp Calc
- Pre-Amp Submission
- 3130 Plate Submission

The DNA Technical Leader has also updated the master document list to include each of the worksheets listed above.

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

If not discovered at this point, where else in the process would this incident have been discovered?
If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance.

Technical Personnel: n/a — Not Date: —

DNA Technical Leader
~~Immediate Supervisor:~~ Date: 7/31/16

Section Manager: Date: 07/31/16

CODIS Administrator (if applicable): Date: 08/05/16

Division Director: Date: 8-5-16

Summary of Root Cause Analysis:
This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: Date: 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-14	**Date Submitted:**	7/1/2016
Non-Conformance Level	II	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #6:
Source: QM 5.4.1.
Requirement: Sectional SOPs will contain instructions for the use of equipment.
Finding: A cross-linker was used to UV plastic ware as a secondary measure of decontamination when the piece of equipment was not properly maintained nor had an SOP on how to use it.

Actions Taken:

Staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that instruments or equipment marked as "out of service" or "not for casework use" may not be used for casework applications. FB management will explore supplementing the FB SOPs with instructions for the use, maintenance, and cleaning of the cross-linkers so that they may be used in the future.

If not discovered at this point, where else in the process would this incident have been discovered?

If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance.

Technical Personnel:	n/a	**Date:**	
DNA Technical Leader **~~Immediate Supervisor~~:**		**Date:**	7/20/16
Section Manager:		**Date:**	07/21/16
CODIS Administrator (if applicable):	Clara West	**Date:**	7/20/16
Division Director:		**Date:**	8/5/16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

Summary of Root Cause Analysis:
This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: S Watson **Date:** 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-15	**Date Submitted:**	7/1/2015
Non-Conformance Level	CLASS III	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #7:
Source: ISO 4.13.2
Requirement: Does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?
Finding: The page numbering and forensic case number on the case files is illegible at times and is not corrected on the documentation. This was observed in many case files during case file review.

Actions Taken:

Staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that case file pagination must be reviewed to ensure that the forensic case #s and page #s are clear. If not, information must be manually corrected. FB management will look for opportunities to adjust the footer of HFSC-generated documents that may be impacted. FB management will create and complete a checklist for section management to document monthly reviews of quality-related records, including but not limited to, case file reviews.

If not discovered at this point, where else in the process would this incident have been discovered?

If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance. Implementation of the monthly quality review by FB management should also provide opportunities for possible future non-conformances to be discovered.

Technical Personnel:	n/a FBDM	**Date:**	
DNA Technical Leader Co **~~Immediate Supervisor:~~**		**Date:**	7/20/16
Section Manager:		**Date:**	07/21/16
CODIS Administrator (if applicable):	Clara West	**Date:**	7/20/16
Division Director:		**Date:**	8-5-16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

Summary of Root Cause Analysis:

This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: [signature] **Date:** 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-16	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS II	**Date Closed:**	9/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:**	(If applicable)
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #8:

Source: ISO 4.2.1

Requirement: The laboratory shall establish, implement, and maintain a management system appropriate to the scope of its activities. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

Finding: DNA SOP 2.5.2.1 states that 'DNA technicians and analysts shall attempt to read at least one current scientific article per month'. There is no documentation to show that articles were reviewed between August 2015 and February 2016.

Actions Taken:

The less than consistent article reading may be attributed to the interim nature of the FB management from May, 2015 through June, 2016, as typically, article reading corresponded to meeting attendance. An acting DNA Technical Leader was in place from May, 2015 through July, 2015 due to FMLA leave; an interim Forensic Biology section manager, an interim DNA Technical Leader, and interim supervisors were in place from October, 2015 through June, 2016. The DNA SOP will be updated to require scientific article quarterly. Additionally, once implemented QUALTRAX will enable better record keeping of readings (similar to SOP and QM reviews). Finally, FB management will create and complete a checklist for section management to document monthly reviews of quality-related records, including but not limited to, required article reading.

If not discovered at this point, where else in the process would this incident have been discovered?

If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance. Implementation of the monthly quality review by FB management should also provide opportunities for possible future non-conformances to be discovered.

Technical Personnel:	-n/a-	**Date:**	
DNA Technical Leader **Immediate Supervisor:**		**Date:**	7/20/16
Section Manager:		**Date:**	07/21/16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

CODIS Administrator (if applicable): Clare Wilt Date: 7/20/16

Division Director: Jenna Ruiz Date: 8-5-16

Summary of Root Cause Analysis:
This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: [signature] Date: 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-17	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS III	**Date Closed:**	9/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:**	(If applicable)
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #9:

Source: ISO 5.2.5

Requirement: Does the laboratory maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel?

Finding: There was no documented continuing education, as required for DNA analysts per FBI QAS, in the Q Files of nine analysts.

One staff member is authorized to conduct certain tasks in biology. However, that individual has not provided an SOQ that describes current duties. Records of previous training and transcripts have not been provided to the quality division.

Actions Taken:

Continuing education records have been provided to the Quality Division for each of the nine analysts in question, a result of the internal audit. Continuing education requirements had been met; the records had not yet been provided to the Quality Division.

An SOQ, previous training records, and transcripts have since been provided for the one staff member in question, as a result of the internal audit.

Staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that records of attendance, such as certificates of attendance, must be provided to the Quality Division as soon as is practicable after the continuing education event.

If not discovered at this point, where else in the process would this incident have been discovered?

If not discovered at this point, it seems that a future audit would be the most probable opportunity to discover this non-conformance.

Technical Personnel: n/a — Issued **Date:** —

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

~~Immediate Supervisor:~~ DNA Technical Leader _____ Date: 7/20/16

Section Manager: _____ Date: 07211 6

CODIS Administrator (if applicable): _____ Date: 7/20/16

Division Director: _____ Date: 8-5-16

Summary of Root Cause Analysis:

This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: _____ Date: 8/5/2016

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-IA-18	**Date Submitted:**	7/1/2016
Non-Conformance Level	CLASS II	**Date Closed:**	8/5/2016

Date of this Report:	6/27/2016	**Division:**	FAD	**FCN:** (If applicable)	
Date of Incident:	5/9-13/2016	**Section:**	Forensic Biology/DNA		

Description of Discrepancy/Non-conformance:

2016 Internal Audit Finding #10:
Source: DNA SOP 3.3.3.1.9
Requirement: Signs may be posted to designate appropriate personal protective equipment (PPE) in certain areas. PPE shall be worn in these areas as indicated.
Finding: A DNA technician was observed on three separate occasions not wearing the required hair covering in the extraction room.

Actions Taken:

The DNA technician in question is no longer employed by the Houston Forensic Science Center as of May 31, 2016. However, staff was reminded at the Forensic Biology section-wide meeting on June 30, 2016 that PPE are required in the laboratory areas in which signs are posted.

If not discovered at this point, where else in the process would this incident have been discovered?

At this time, the issue appears to be isolated to a particular staff member. Any future instances of failure to don appropriate PPE appropriately cannot be predicted.

Technical Personnel:	N/A	**Date:**	—
DNA Technical Leader **~~Immediate Supervisor~~:**		**Date:**	7/20/16
Section Manager:		**Date:**	07/21/16
CODIS Administrator (if applicable)**:**		**Date:**	7/20/16
Division Director:		**Date:**	8/5/16

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

Summary of Root Cause Analysis:

This nonconformance was identified through the May-June 2016 internal audit. The focus of this internal audit was to verify that the quality management system and technical sections (Biology, Controlled Substances, Toxicology, Firearms, Latent Prints, Audio/Video and Digital Forensics) were compliant to the HFSC QA manual, ISO/IEC 17025 standard and ANAB requirements. There will be no root cause analysis completed on nonconformance's issued through internal audits.

Additional Information/Follow-Up:

Quality Director: [signature] **Date:** 8/5/2016

NAME: Bruce Budowle

TITLE: Professor, Director, Center for Human Identification
University of North Texas Health Science Center

BUSINESS ADDRESS, PHONE NUMBER, and EMAIL ADDRESS:

Center for Human Identification
University of North Texas Health Science Center
3500 Camp Bowie Boulevard
Ft. Worth, Texas 76107

bruce.budowle@unthsc.edu

BIRTH DATE: October 13, 1953

BIRTH PLACE: San Pedro, California

MARITAL STATUS: Married

EDUCATION:

King College Bristol, Tennessee	B.A. - 1975 (Biology)
Virginia Polytechnic Institute and State University Blacksburg, Virginia	Ph.D. - 1979 (Genetics)

DISSERTATION: Phase Change in Hedera helix L.

RESEARCH AND/OR PROFESSIONAL EXPERIENCE:

1974	Undergraduate Research Scientist, King College, Bristol, Tennessee
1976 - 1979	Graduate Teaching Assistantship in Biology, Virginia Polytechnic Institute and State University, Blacksburg, Virginia
1979 - 1982	Postdoctoral Fellow in Immunogenetics, Awarded by the National Cancer Institute, University of Alabama in Birmingham, Alabama
1982	Consultant to Department of Criminal Justice University of Alabama in Birmingham
1983 - 1985	Consultant to Beckman Instruments, Inc. Palo Alto, California
1983 - 1994	Research Chemist, Forensic Science Research and Training Center, Laboratory Division, FBI Academy, Quantico, Virginia
1994 - 1997	Chief, Forensic Science Research Unit, Laboratory Division, FBI Academy, Quantico, Virginia
1985 - 2008	Adjunct Professor, School of Continuing Education,

	University of Virginia, FBI Academy Campus
1987 - 1988	Council Member, International Electrophoresis Society
1987 - 1988	Vice President, America's Branch of the Electrophoresis Society
1988 - 1990	Vice President, International Electrophoresis Society
1989 - 1991	Council Member, American Electrophoresis Society
1989 - 1998	Associate Editor, Applied and Theoretical Electrophoresis
1990 - present	Editorial Board, BioTechniques
1990 - 1991	Visiting Instructor, Rush Presbyterian - St. Luke's Medical Center.
1990 - present	Editorial/Advisory Board, International Journal of Legal Medicine
1991 - 2005	Chairman of the DNA Commission of the International Society of Forensic Haemogenetics
1994	Defense Science Board, Mitochondrial DNA, AFDIL
1994 - 1998	Editor, Crime Laboratory Digest
1995 - 2000	Chairman of The Scientific Working Group on DNA Analysis Methods
1995 - 2000	DNA Advisory Board, DNA Identification Act, Federal Bureau of Investigation
1995 - 2005	Editorial Board, Genetic Analysis: Biomolecular Engineering
1998 - 2001	The Research and Development Working Group, National Commission on the Future of DNA Evidence, National Institute of Justice
1998 - 2009	Senior Scientist - Biology, Laboratory Division, Federal Bureau of Investigation
1999 - present	Editorial Board, Forensic Science Communications
1999 - present	Editorial Board, Legal Medicine (Japanese Society of Legal Medicine)
1999 - 2003	Research Professor, Institute for Biosciences, Bioinformatics, and Biotechnology, George Mason University, Manassas, Virginia
1999 - 2003	Affiliate Professor, Department of Biology, George Mason University, Fairfax, Virginia
2000	Outside Reviewer for German Proficiency Testing System (GEDNAP)

2001-2002	Celera DNA Advisory Board, Mitochondrial DNA/WTC
2001-2003	Kinship and Data Analysis Panel for WTC Victim Identification
2002	Steering Committee, Colloquium on Microbial Forensics, American Society of Microbiology
2002 - 2004	Chair of Scientific Working Group Microbial Genetics and Forensics
2002	Co-organizer of Microbial Forensics Meeting, The Banbury Center, Cold Spring Harbor Laboratory
2002 - 2008	Adjunct Faculty, Department of Pathology, University of North Texas Health Science Center, Ft. Worth, Texas
2003 - 2008	National Biodefense Analysis and Countermeasures Center Advisory Group
2002 - 2007	National Interagency Genomics Science Coordinating Committee, National Science Foundation
2003	Disease Informatics Senior Coordinating Committee, National Science Foundation
2004	Co-organizer of Second Microbial Forensics Meeting, Identifying Gaps, sponsored by the Department of Homeland Security, The Banbury Center, Cold Spring Harbor Laboratory
2004 - 2007	Editorial Board, Forensic Science International
2004	Participant in Expert Meeting on Microbial Forensics, National Academy of Sciences, Washington, D.C., June 22-25, 2004
2004	Participant in Biosecurity Threats in the 21st Century: Re-examining how we define the "problem" and mitigate the effects, National Academy of Sciences, Minneapolis, MN, July 15, 2004
2004	Invited Lecturer, Post Graduate Course in Forensic Genetics, Finish Graduate School in Population Genetics and department of Forensic Medicine, University of Helsinki, Finland, September 20-21, 2004
2004	Member of Steering Committee on the Animal Forensics Working Group of the International Society of Animal Genetics
2004 - present	Member of Scientific Working Group for the NIAID-funded Bioinformatics Resource Center (BRC) at The Institute for Genomic Research (TIGR)
2005	Co-organizer of Third Microbial Forensics Meeting, sponsored by the Department of Homeland Security, Evidence Collection, Storage, and Extraction, The Banbury Center,

Cold Spring Harbor Laboratory

2006 Participant in Advancing the International Biosecurity Dialogue: Clarifying Definitions, National Academy of Sciences, Washington, D.C., January 27, 2006

2006 Participant in Genomics and Global Pathogens, The American Academy of Microbiology, Washington, D.C., September 27-28, 2006

2006 Lecturer in Science Exposition and Ethics Course, Watson School of Biological Science, Cold Spring Harbor, New York, November 29, 2006

2006 International Fellow, Institute of Environmental Science and Research, New Zealand, December 1-13, 2006

2006 - 2008 Steering Committee Member, Scientific Working Group on Chemical, Biological, Nuclear and Radiological Analyses

2007 Member of National Planning Committee for Workshop on Plant Pathogen Forensics: Filling the Gaps, sponsored by Oklahoma State University, Oklahoma City, Oklahoma, January 11-13, 2007

2007 - present Editorial Board, Forensic Science International Genetics

2007 Co-organizer of Fourth Microbial Forensics Meeting, Enduring Research Pathways, sponsored by the Department of Homeland Security, The Banbury Center, Cold Spring Harbor Laboratory

2008 Invited Outside Reviewer on DNA Technology for National Research Institute of Police Science, National Police Agency, Chiba, Japan, January 15-16, 2008

2008 Visiting Fellow, Faculty of Health Science and Medicine, Bond University, Gold Coast, Australia, June 23-July 5, 2008

2008 - present Visiting Professor, Faculty of Health Science and Medicine, Bond University, Gold Coast, Australia

2008 - present Member, Expert Working Group on Human Factors in Latent Print Analysis, NIST and NIJ

2009 - present Professor, Department of Forensics and Investigative Genetics, University of North Texas Health Science Center, Ft. Worth, Texas

2009 - present Executive Director, Institute of Investigative Genetics, University of North Texas Health Science Center, Ft. Worth, Texas

2009 Invited Speaker, Overview of Microbial Forensics and the Concepts of Validation, Committee on Review of the

	Scientific Approaches used during the FBI's Investigation of the 2001 *Bacillus anthracis* Mailings, First Meeting, National Academy of Sciences, July 30-31, 2009
2009	Invited Speaker, Low Copy Number Typing Issues, Mixture Interpretation Issues, Committee on Science, Technology and Law, National Academy of Sciences, October 19, 2009
2009 - present	Co-Editor-in-Chief, BMC Investigative Genetics
2010	Member of Steering Committee for Forensic Death Investigation Symposium, National Institute of Justice, Scottsdale, AZ, June 7-9, 2010
2010	Consultant to Cyprus Institute of Neurology and Genetics Laboratory of Forensic Genetics UN Missing Persons Identification Program, Cyprus, September 20-24, 2010
2010 - present	Adjunct Faculty, Department of Biological Sciences, University of North Texas, Denton, TX
2010	Co-organizer of Fifth Microbial Forensics Meeting, Microbial Forensics in the Era of Genomics, sponsored by the Department of Homeland Security, The Banbury Center, Cold Spring Harbor Laboratory, November 7-10, 2010
2011	Co-organizer of Lyme Disease Diagnostics in the Proteomics-Genomics Era, The Banbury Center, Cold Spring Harbor Laboratory, April 10-13, 2011
2011	Visiting Professor, Department of Forensic Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, June 2011.
2011	Member of Organizing Committee, Microbial Evolution and Cutting Edge Tools for Outbreak Investigations, Center for Disease Control and Prevention, Atlanta, GA, September 14-16, 2011.
2011 - present	Editorial Board, American Journal of Forensic Medicine and Pathology
2012 - present	Member of Academic Committee, Key Laboratory of Forensic Genetics, Institute of Forensic Science of Ministry of Public Security, Beijing, China
2012	Member of planning committee for the Forum on Microbial Threats Workshop: The science and applications of microbial genomics: predicting, detecting, and tracking novelty in the microbial world, Institute of Medicine, Board on Global Health, National Academy of Sciences, June 12-13 2012.
2012- 2017	Member of the Technical Advisory Group to the Board of the Houston Forensic Science Center, LGC, Inc.
2013-2016	Member of the International Expert Committee for the Biology Division of Health Sciences Authority, Singapore

2013- present	Appointment with Center of Excellence in Genomic Medicine Research (CEGMR), King Abdulaziz University, Jeddah, Saudi Arabia.
2013-2014	Member of Committee for the Science Needs for Microbial Forensics: Developing an Initial International Science Roadmap, Institute of Medicine, Board on Global Health, National Academy of Sciences.
2013-2015	Visiting Professor, Science Without Borders, Universidade Federal Do Rio De Janeiro, Centro De Ciências Da Saúde, Instituto De Biofísica Carlos Chagas Filho
2014-2015	Member of Committee on PCR Standards for the BioWatch Program, Board of Life Sciences, Division on Earth and Life Sciences, Board of Health Sciences Policy, Institute of Medicine, Board on Global Health, National Research Council, National Academy of Sciences.
2014 – present	Associate Editorial Board of Biosafety and Biosecurity of Frontiers in Bioengineering and Biotechnology
2016 – present	Director of the Center for Human Identification, University of North Texas Health Science Center, Ft. Worth, Texas
2016	GAO Meeting on Gaps in Capabilities for Attributing the Source of a Biological Attack, Washington, DC, April 20-21, 2016.
2016	Tackling Low Cost Nucleic Acid Test for the Developing World: Catalyzing Innovation in Sample Preparation, Scientific Advisory Board, Bill & Melinda Gates Foundation, Seattle, WA, May 25, 2016.
2016 - present	Member of the Texas Forensic Science Commission.
2017 - present	Vice-Chair, Department of Microbiology, Immunology and Genetics, University of North Texas Health Science Center, Ft. Worth, Texas.

MEMBERSHIPS IN PROFESSIONAL AND SCHOLARLY ORGANIZATIONS:

International Society for Forensic Genetics
American Society of Microbiology

HONORS AND OTHER SPECIAL COMMENTS:

1) Pi Alpha Sigma (1972)
2) Undergraduate Research Award (1974)
3) Graduate State Tuition Scholarship (1976 - 1979)
4) Phi Kappa Phi (1976)
5) Sigma Xi (1978)
6) American Academy of Forensic Sciences Recognition Award (1981)
7) Attorney General's Award for Exceptional Service (1991)
8) Jefferson Award, University of Virginia (1991)
9) Forensic Scientist of the Year, MAAFS (1996)
10) Honorary Member of the Finnish Society of Forensic Medicine (1998)

11) Director's Award for Excellence in Investigative Support (2000)
12) Paul L. Kirk Award, Criminalistics Section, American Academy of Forensic Sciences (2001)
13) University of Alabama at Birmingham's 2004 Ireland Distinguished Visiting Scholar
14) Honorary Member of the Mediterranean Academy of Forensic Sciences (2004)
15) Health Care Hero Award, Dallas Business Journal (2010)
16) GSA Outstanding Faculty Award 2016, GSBS, UNTHSC

RESEARCH INTERESTS:

Forensic Science
Genetic Marker Systems
Technique Development
Molecular Biology
Population Genetics
Human Genetics
Microbial Forensics
Pharmacogenomics

PUBLICATIONS:

1. Budowle, B., Go, R. C. P. and Acton, R. T.: Isoelectric focusing of hair proteins. In: Electrophoresis '81 (Allen, R. C. and Arnaud, P., eds.) Walter de Gruyter, Berlin, pp. 585-590, 1981.

2. Budowle, B., Go, R. C. P., Barger, B. O. and Acton, R. T.: Properdin factor B polymorphism in black Americans. J. Immunogenetics 8:519-521, 1981.

3. Budowle, B. and Acton, R. T.: A technique for the detection of variable electrophoretic patterns of hair proteins. Electrophoresis 2:333-334, 1981.

4. Budowle, B., Acton, R. T. and Barger, B. O.: A method for the dialysis of micro-samples. Anal. Biochem. 118:399-400, 1981.

5. Budowle, B., Reitnauer, P. J., Barger, B. O., Go, R. C. P., Roseman, J. M. and Acton, R. T.: Properdin factor B in type 1 (insulin-dependent) diabetic patients. Diabetologia 22(6):483-485, 1982.

6. Acton, R. T., Balch, C. M., Budowle, B., Go, R. C. P., Roseman, J. M., Soong, S-J., and Barger, B. O.: Immunogenetics of melanoma. In: Melanoma Antigens and Antibodies (Reisfeld, R. A. and Ferrone, S., eds.) Plenum Publishing Corporation, New York, pp. 1-21, 1982.

7. Reitnauer, P. J., Go, R. C. P., Acton R. T., Murphy, C. C., Budowle, B., Barger, B. O. and Roseman, J. M.: Evidence for genetic admixture as a determinant in the occurrence of IDDM in U.S. Blacks. Diabetes 31:532-537, 1982.

8. Budowle, B., Barger, B. O., Balch, C. M., Go, R. C. P., Roseman, J. M. and Acton, R. T.: Associations of Properdin factor B with melanoma. Cancer Genetics and Cytogenetics 5:247-251, 1982.

9.Budowle, B., Acton, R. T., Barger, B. O., Blackstock, R., Crist, W., Go, R. C. P., Humphrey, G., Ragab, A., Roper, M., Vietti, T. and Dearth, J.: Properdin factor B and acute lymphocytic leukemia (ALL). Cancer 50: 2369-2371, 1982.

10. Acton, R. T., Balch, C. M., Barger, B. O., Budowle, B., Go, R. C. P., Soong, S-J., and Roseman, J. M.: The occurrence of melanoma and its relationship with host, lifestyle and environmental factors. In: Melanoma-1 (Constanzi, J. J., ed.), Martinus Nijhoff Publishers, The Hague, pp. 151-182, 1983.

11. Budowle, B., Go, R. C. P., Roseman, J. M., Barger, B. O. and Acton, R. T.: C4 phenotypes in Caucasians from the southeastern United States. In: Electrophoresis '82 (Stathakos, D., ed.), Walter de Gruyter, Berlin, pp. 715-723, 1982.

12. Budowle, B., Roseman, J. M., Go, R. C. P., Crist, W. and Dearth, J.: Complement phenotypes for prediction of risk and prognosis for acute lymphocytic leukemia (ALL). In: Cancer: Etiology and Prevention (Crispen, R. G., ed.) Elsevier Biomedical, New York, pp. 109-123, 1983.

13. Budowle, B., Roseman, J. M., Go, R. C. P., Louv, W. C., Barger, B. O. and Acton, R. T.: Phenotypes of the fourth complement component (C4) in black Americans from the southeastern United States. J. Immunogenetics 10 (3):199-204, 1983.

14. Budowle, B., Louv, W. C., Barger, B. O., Go, R. C. P., Roseman, J. M. and Acton, R. T.: Age at onset of insulin-dependent diabetes mellitus associated with BfF1. Immunogenetics 17:437-440, 1983.

15. Budowle, B., Dearth, J., Bowman, P., Melvin, S., Crist, W., Go, R., Kim, T., Iyer, R. J., Roseman, J., Barger, B., and Acton, R.: Genetic predisposition to acute lymphocytic leukemia in American Blacks. Cancer 55:2880-2882, 1985.

16. Budowle, B., Roseman, J. M., Go, R. C. P., Barger, B. and, Acton, R. T.: The complement component C4 in black Americans with type 1 (insulin-dependent) diabetes mellitus. Diabetologia 26:166-168, 1984.

17. Budowle, B.: A method to increase the volume of sample applied to isoelectric focusing (IEF) gels. Forens. Sci. Int. 24(4):273-277, 1984.

18. Budowle, B.: A reproducible method for dialysis of multiple small volume samples. BioTechniques 1(4):176-177, 1983.

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20. Budowle, B. and Gambel, A.: An alternative gel system for group III gels. Crime Lab Digest 11 (1):12-13, 1984.

21. Budowle, B.: Increasing the sensitivity of protein detection of a silver stain for agarose gels. Electrophoresis 5(3):174-175, 1984.

22. Budowle, B.: Phosphoglucomutase-1 subtyping of human bloodstains on ultrathin-layer polyacrylamide gels. Electrophoresis 5(3):165-167, 1984.

23. Budowle, B.: An ultrathin-layer polyacrylamide gel isoelectric focusing method for transferrin subtyping. Electrophoresis 6(2):97-99, 1985.

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25. Budowle, B.: Typing esterase D by isoelectric focusing. Electrophoresis 5(5):314-316, 1984.

26. Budowle, B. and Davidson, L.: Electrophoresis: The theory and evolution of electrophoretic methods. Crime Lab Digest 11 (3): 45-50, 1984.

27. Budowle, B. and Chow, G. H.: Discontinuous polyacrylamide gel electrophoresis for typing haptoglobin in bloodstains. J. Forens. Sci. 30(3):893-897, 1985.

28. Budowle, B. and Scott, E.: Transferrin subtyping of human bloodstains. Forens. Sci. Int. 28:269-275, 1985.

29. Budowle, B.: An agarose gel method for typing phosphoglucomutase-1, esterase D or glyoxalase I. J. Forens. Sci. 30(4):1216-1220, 1985.

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33. Budowle, B.: Subtyping group-specific component or esterase D using the same ultrathin-layer polyacrylamide gel format. Electrophoresis 7:141-144, 1986.

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35. Budowle, B.: Principles of isoelectric focusing. In: Proceedings of the International Symposium on the Forensic Application of Electrophoresis, Government Printing Office, Washington, D. C., pp. 121-126, 1984.

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37. Budowle, B. and Eberhardt, P.: Ultrathin-layer polyacrylamide gel isoelectric focusing for the identification of hemoglobin variants. Hemoglobin 10(2):161-172, 1986.

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44. Budowle, B. and Gambel, A.: Negative gold staining for electrophoretic protein profile interpretations. Acta Histochemica et Cytochemica 19(5):647-654, 1986.

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53. Budowle, B., Deadman, H. A., Murch, R. S. and Baechtel, F. S.: An introduction to the methods of DNA analysis under investigation in the FBI Laboratory. Crime Laboratory Digest 15(1):8-21, 1988.

54. Budowle, B., Adams, D.E., Comey, C.C., and Merril, C.R.: Mitochondrial DNA: A possible genetic material suitable for forensic analysis. In: Advances in Forensic Science (Lee, H.C. and Gaensslen, R.E., eds.), Year Book Medical Publishers, Chicago, pp. 76-97, 1990.

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microbial world, Institute of Medicine, Board on Global Health, National Academy of Sciences, Washington, DC, 2012.

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Congress of the International Society of Forensic Genetics, Krakow, Poland, 2015.

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FUNDING

PI; Improved Tools and Interpretation Guidelines for Examining Limited Low Copy Number DNA Obtained from Degraded Single Source Samples: Bones, Teeth, and Hairs; Awarded by the National Institute of Justice; Award Number: 2009-DN-BX-K188; 10/01/2009 – 9/30/2011; Total: $935,992.00.

Co-PI; Development of an Expert System for Automated Forensic mtDNA Data Analysis; Awarded by the National Institute of Justice; Award Number: 2009-DN-BX-K171; 10/01/2009 - 03/31/2011; Total: $353,857.00.

Co-PI; Establishing the quantitative basis for sufficiency: threshold and metrics for friction ridge pattern detail quality and foundation for a standard; Awarded by Virginia Tech subcontract; the National Institute of Justice; Award Number: 2009-DN-BX-K229; 10/01/2009 - 09/30/2011; Total: $854,907.00; Subcontract: $123,120.00.

PI; Addressing Quality and Quantity; the Role of DNA Repair and Whole Genome Amplification in Forensically Relevant Samples; Awarded by the National Institute of Justice; Award Number: 2010-DN-BX-K227; 10/01/2010 – 09/30/2012. Total: $363,613.00

PI; Identity, Lineage, and Phenotypic SNP Identification, Assay Development, and Data Interpretation; Awarded by the 2010 Intelligence Community Postdoctoral Research Fellowship Program; Award Number: 2010*0937130*000; 09/01/2010 – 08/31/2010; Total: $239,076.00.

PI; Indel Study; Awarded by Life Technologies; Project ID RP0060; 10/18/2010 –04/01/2011; Total: $30,000.00.

PI; Research Collaboration; Awarded by Promega Corporation; 10/01/2010 – 09/30/2012; Total: $142,006.28

Co-PI; Comprehensive Training Program in Forensic DNA Interpretation and Statistics; Awarded by National Institute of Justice; Award number: NIJ-2010-93494, 2010-DN-BX-K239; 10/01/10-09/30/12; Total: $999,481.00.

PI; Microbial Forensics Technical and Scientific Process; Awarded by Signature Science; Award number: 2012-030-0002; 02/01/2012-01/31/2013; Total: $131,164.98.

Co-PI; Testing, Evaluation and Demonstration of New Technologies; Awarded by RTI International subcontract; Awarded by the National Institute of Justice; Award number: 2011-DN-BX-K564; 10/01/2011 – 09/30/2012; Total: $375,000.00.

PI; Development of Reference Sample DNA Profiling for Databases Using Next Generation Sequencing Technologies; Awarded by the National Institute of Justice; Award Number: 2012-DN-BX-K033; 10/01/2012 – 6/30/2014; Total: $747,797.00.

PI; NIJ Ph.D. Graduate Research Fellowship Program FY 2012; Awarded by the National Institute of Justice; Award Number: Award 2012-IJ-CX-0016; 10/01/2012 – 09/30/2013; Total: $24,988.00.

PI; Validation of Rapid DNA Typing System; Awarded by Department of Defense; Contract Number: HQ0034-13-P-0002; 1/28/2013 – 01/27/2014; Total: $32,659.80.

PI; Microbial Forensics Technical and Scientific Process; Awarded by Signature Science; Renewal of Award number: 2012-030-0002; 02/01/2013-01/31/2014; Total: $131,164.98.

Co-PI; Testing, Development of Improved Insertion-Deletion Assays for Human and Ancestral Identifications from Degraded Samples; Awarded by the National Institute of Justice; Award number: 2013-DN-BX-K036; 10/01/2013 – 09/30/2015; Total: $336,282.96.

PI; Microbial Forensics Technical and Scientific Process; Awarded by Signature Science; Renewal of Award number: 2012-030-0002; 02/01/2014-01/31/2015; Total: $131,164.98.

PI; Deadwood Project, Historic Preservation Archives Department Deadwood, South Dakota; 09/01/2014-12/31/2014; Total: $3000.00.

PI; Familial Searching; Awarded by RTI International subcontract; 09/05/2014-12/31/2014; Total: $ $71,550.77.

PI; Novel Collection Device for Enhanced DNA Recovery and Release from Biological Stain Samples; Awarded by the National Institute of Justice; Award Number: 2014-DN-llX-K031; 01/01/2015 – 12/31/2016; Total: $487,884.00.

PI; Human Microbiome Species and Genes for Human Identification; Awarded by the National Institute of Justice; Award Number: 2015-NE-BX-K006; 01/01/2016 – 12/31/2017; Total: $589,701.00.

PI; Enhancing Mixture Interpretation with Highly Informative STRs; Awarded by the National Institute of Justice; Award Number: 2015-DN-BX-K067; 01/01/2016 – 12/31/2017; Total: $585,415.00.

Co-PI; Enhanced Sample Preparation and Data Interpretation Strategies for Massively Parallel Sequencing for Human Identification in Missing Persons and DVI Casework; Awarded by the National Institute of Justice; Award Number: 2015-DN-BX-K067; 01/01/2016 – 12/31/2017; $294,805.59.

PI; DNA Capacity Enhancement and Backlog Reduction Program, FY15, Awarded by the National Institute of Justice; Award Number: 2015-DN-BX-0057, 01/01/2016 – 12/32/2017; $507,165.00.

PI; Using DNA Technology to Identify the Missing, FY15, Awarded by the National Institute of Justice; Award Number: 2015-DN-BX-K070; 01/01/2016 to 12/31/2017; $2,238,750.00.

PI; Management and Support of the National and Missing Persons System, FY15, Awarded by the National Institute of Justice; Award Number: 2011-MU-BX-K063; 10/01/2016 to 09/30/2017; $5,866,325.85.

PI; DNA Analysis of Sexual Assault Evidence, Interagency Agreement Texas Department of Public Safety, 09/01/2016 – 12/31/2016; $192,990.00.

PI; Typing Highly Degraded DNA Using Circularized Molecules and Target Enrichment; Awarded by the National Institute of Justice; Award Number: 2016-DN-BX-0154; 01/01/2017 – 12/31/2018; $682,474.00.

PI; Application for Funding to Support the National Missing and Unidentified Persons System (NamUs); Awarded by the National Institute of Justice; Award Number: 2016-MU-BX-K007; 10/01/2016 – 09/30/2017; $4,700,000.00.

PI; FY 2016 DNA Capacity Enhancement and Backlog Reduction Program; Awarded by the National Institute of Justice; Award Number: 2016-DN-BX-0114; 01/01/2017 – 12/31/2018; $473,465.00.

PI; Evaluation and Implementation of High Throughput Second Generation Sequencing for Mitochondrial DNA Testing in Missing Persons and Forensic Casework at the UNT Center for Human Identification; Awarded by the National Institute of Justice; Award Number: 2016-DN-BX-K001; 01/01/2017 – 12/31/2018; $727,072.00.

PI; FY17 Graduate Research Fellowship in Science, Technology, Engineering, and Mathematics; Awarded by the National Institute of Justice; Award Number: Award 2017-IJ-CX-0010; 08/01/2017 – 07/31/2018; Total: $46,155.00.

PI; Reducing Human Trafficking Through Forensics in Central America; Awarded by the U.S. Department of State; Award Number: S-INLEC-17-GR-1013; 09/20/2017 – 09/20/2018; $3,301,122.48.

PI; Development of a Mitochondrial Mixture Database and Interpretation Tool; Awarded by the National Institute of Justice; Award Number: 2017-DN-BX-0134; 01/01/2018 – 12/31/2019; Total: $556,910.00.

PI; Application for Funding to Support the National Missing and Unidentified Persons System (NamUs); Awarded by the National Institute of Justice; Award Number: 2016-MU-BX-K007 (continuation); 10/01/2017 – 09/30/2018; $7,455,832.00.

PI; FY 2017 DNA Capacity Enhancement and Backlog Reduction Program; Awarded by the National Institute of Justice; Award Number: 2016-DN-BX-0114; 01/01/2018 – 12/31/2019; $494,555.00.

GRADUATED STUDENTS

Masters

Shamika Kelley, Masters, Thesis Practicum: Assessment of DNA transfer events involving routine human behavior, May 2010.

David Warshauer, Masters, Thesis Practicum: An evaluation of saliva-based DNA transfer, August 2011.

Alyssa Koehn, Masters Thesis: Identification of unknown PCR products generated during STR analysis of bone samples, May 2013.

Andrea Moore, Masters Thesis: STR typing of reference samples with rapid DNA technology, May 2014.

Lisa Skandalis, Masters Thesis: Population variances in the whole mitochondrial genome impacting capture for human identification, May 2015.

Allison Conway, Masters Thesis: A validation of STRmix for forensic casework, May 2017.

Doctoral

Pamela Marshall, Doctoral Dissertation: Improved tools for the robust analysis of low copy number and challenged DNA samples, May 2014.

David Warshauer, Doctoral Dissertation: Development of a comprehensive massively parallel sequencing panel of single nucleotide polymorphism and short tandem repeat markers for human identification, August 2015.

Xiangpei Zeng, Doctoral Dissertation: Selection of Highly Informative Markers for Apportionment of Ancestry and Population Affiliation, May 2016.

Sarah Schmedes, Doctoral Dissertation: Genetic Profiling of Skin Microbiomes for Forensic Human Identification, September 2017.

POST-DOCTORAL FELLOWS

Meredith Turnbough 2010-2011

Bobby Larue 2010-2012

Seung Bum Seo 2012-2014

Jennifer Churchill 2014-2018

Angela Ambers 2015-2018

Maiko Takahashi 2015-present

Xiangpei Zeng 2016-2017

August Woerner 2016-2017

Magdalena Bus 2018 - present

Sheree Hughes-Stamm, PhD
Assistant Professor of Forensic Science
Director of Graduate Programs
Department of Forensic Science
College of Criminal Justice
Sam Houston State University

Degrees Earned

Ph.D., 2012, Forensic Genetics, Health Science & Medicine, Bond University, Gold Coast, AUSTRALIA. Forensic DNA typing of highly degraded samples

BSc., 1997, (Hons Eq.) Human Anatomy & Physiology, University of Queensland, Brisbane, AUSTRALIA

Professional Licensure and Certifications
N/A

Peer-Review Publications and Artistic Performances/Exhibitions

Articles

Amanda Wheeler, Natalia Czado, David Gangitano, Meredith Turnbough, Sheree Hughes-Stamm. (2016) Comparison of DNA Yield and STR Success Rate from Different Tissues in Embalmed Bodies. International Journal of Legal Medicine (in press, June 2016)

Amy Sorensen, Elizabeth Rahman, Cassandra Canela, David Gangitano, Sheree Hughes-Stamm. (2016) Preservation and Rapid Purification of DNA from Decomposing Human Tissue Samples. Forensic Science International;Genetics (in press, Feb 2016)

Sheree Hughes-Stamm, Frauke Warnke, Angela van Daal. (2015) An alternate method for extracting DNA from environmentally challenged teeth for improved DNA analysis. Legal Medicine, 18, 31 - 36

Rachel Houston, Matthew Birck, Sheree Hughes-Stamm, David Gangitano. (2015) Evaluation of a 13-loci STR multiplex system for Cannabis sativa genetic identification. International Journal of Legal Medicine, 130(3):635-47

Cassandra Schield, Cassandra Campelli, Jennifer Sycalik, Christopher Randle, Sheree Hughes-Stamm, David Gangitano. (2016) Identification and persistence of Pinus pollen DNA on cotton fabrics: A forensic application. Science & Justice, 56(1):29-34

Amy Sorensen, Clare Berry, David Bruce, Michelle Gahan, Sheree Hughes-Stamm, Dennis McNevin. (2015) Direct-to-PCR tissue preservation for DNA profiling. International Journal of Legal Medicine, 130 (3):607 – 13

James White, Sheree Hughes-Stamm, David Gangitano. (2015) Development and validation of a rapid PCR method for the PowerPlex® 16 HS system for forensic DNA identification. International Journal of Legal Medicine, 129(4):715-23

Sarah Bahlmann, Sheree Hughes-Stamm, David Gangitano. (2014) Development and Evaluation of a Rapid PCR Method for the PowerPlex®S5 System for Forensic DNA Profiling. Leg Medicine, 16(4):227-33

P Noseda, M Hernandez, B Gonzalez, S Hughes---Stamm, D Gangitano. (2013) Genetic Study of Three Closely Linked X chromosome STR Markers in an Argentinian Population. J Forensic Investigation. 1(2): 4

Sheree Hughes-Stamm, Mark Barash, Kelly Grisedale, Angela van Daal (2013) Initial evaluation of a 96-plex GoldenGate® Genotyping SNP assay with suboptimal and whole genome amplified samples. Journal of Forensic Investigations. 1 (1); 8-16

S.R. Hughes-Stamm, K.A. Ashton, A. van Daal. (2011) Assessment of DNA Degradation and the Genotyping Success of Highly Degraded Samples. International Journal of Legal Medicine. 125(3):341-8

M.K. Jones, S.R. Hughes-Stamm, T.H. Cribb. (2000) Ultrastructure of the digestive tract of Gyliauchen nahaensis (Platyhelminthes, Digenea), an inhabitant of the hind---gut of herbivorous fishes. Journal of Morphology 246 (3):198-211

S.R. Hughes-Stamm, T.H. Cribb & M.K. Jones. (1999) Structure of the tegument of Gyliauchen nahaensis (Digenea: Gyliauchenidae), with observations on tegument-associated microorganisms. Journal of Parasitology 85:1047-1052

Wen Yang, Malcolm Jones, Jinjiang Fan, Sheree Hughes-Stamm, Donald McManus. (1999) Characterisation of a family of Schistosoma japonicum proteins related to dynein light chains. Biochimica et Biophysica Acta 1432: 13-26

Books
N/A

Chapters
N/A

Proceedings
Amy Sorensen, MS, David Gangitano, PhD, Sheree Hughes---Stamm, PhD. 2014. DNA Preservation and Rapid Purification of Decomposing Human Tissue Samples; A DVI Application. Association of Forensic DNA Analysts and Administrators (AFDAA). 2014 Summer Meeting. Houston, TX

Bodies, Bones and Bombs; Human Identification. 2016. *Esiri Tasker, Charity Beherec, Rachel Houston, Sheree Hughes-Stamm* 2nd Human Identification Solutions (HIDS) Conference. Barcelona, Spain.

Artistic Performances
N/A

Artistic Exhibitions
N/A

Research Monographs and Technical Reports

Final Technical Report - US National Institute of Justice (NIJ) Award #2013---DN---BX---K034

Funded External Grants

US National Institute of Justice (NIJ) Award #2015-DN-BX-K066
(for Jan 2016-Dec 2017) Principal Investigator. Funded for $725,000
Enhanced Sample Preparation and Data Interpretation Strategies for Massively Parallel Sequencing for Human Identification in Missing Persons and DVI Casework
PI: Sheree Hughes-Stamm , Co.PI: Bruce Budowle, Co-Inv: David Gangitano

US National Institute of Justice (NIJ) Award #2013-DN-BX-K034
(for Jan 2014-Dec 2014) Principal Investigator. Funded for $170,000
Preservation of high throughput methods for Human Tissue Samples in Tropical Climates. PI: Sheree Hughes---Stamm , Co.PI: David Gangitano

SHSU Enhancement Research Grant (ERG) $15,000 (2015) Forensic Next Generation DNA tools for decomposed tissues. Co-PIs: Sheree Hughes-Stamm and David Gangitano

SHSU Enhancement Research Grant (ERG) $10,000 (2014)
Biological and environmental factors related to stalking.
PI: Danielle Boisvert
Co.Inv: Todd Armstrong, Matt Nobles, Brian Boutwell, David Gangitano, Sheree Hughes-Stamm

Bond University Faculty of Health Science & Medicine Research Grants (two grants in 2008) $15,000 each

Bond University Research and Consultancy Services (BURCS/BUGSR) Student Support Scheme Grants (2009 and 2011) $3000 each.

Peer-Review Presentations/Posters

Amanda Wheeler, Natalia Czado, David Gangitano, and Sheree Hughes-Stamm. Comparison of DNA Yield & STR Success Rates from Various Tissues in Embalmed Bodies. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Amy Sorensen, Clare Berry, David Bruce, Michelle Gahan, Sheree Hughes-Stamm, and Dennis McNevin. Tissue Preservation with Direct-to-PCR for DNA Profiling: An Alternative DVI Approach. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Carrie Mayes and Sheree Hughes-Stamm. Development and Initial Evaluation of a miRNA System for Forensically Relevant Body Fluids Using Capillary Electrophoresis. Proceedings of the Gordon Research Conference; Forensic Analysis of Human DNA (June 2016).

Esirioghene Tasker, Bobby LaRue, David Gangitano, and Sheree Hughes-Stamm. Analysis of DNA from Post-blast Fragments for Identification and Determination of Ancestry. Proceedings of the Gordon Research Conference; Forensic Analysis of Human DNA (June 2016).

Daniela Anane-Bediakoh, Martin Lopez, Holly Whillock, Sheree Hughes-Stamm, and Amy Castillo. Can DNA Data Be Used to Establish a Cut-Off Time for Juvenile Sexual Assault Exams. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Kyleen Elwick, Sheree Hughes-Stamm, Kimberly Andreaggi, and Michelle Peck. Optimization and Validation of the ForensicGEM Rapid Extraction Method for High-throughput Processing of Cotton Buccal Swabs. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Natalia Czado, Bobby LaRue, Jr., Amanda Wheeler, Rachel Houston, Amy Sorensen, David Gangitano, and Sheree Hughes-Stamm. The Effectiveness of Various Strategies to Improve DNA Analysis of Formaldehyde-Damaged Tissues From Embalmed Cadavers for Human Identification (HID) Purposes. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Rachel Houston, Sheree Hughes-Stamm, and David Gangitano. Evaluation of a 13-Loci Short Tandem Repeat (STR) Multiplex System for *Cannabis sativa* Genetic Identification. Proceedings of the American Academy of Forensic Sciences (Feb 2016).

Rachel Houston, Sheree Hughes-Stamm, David Gangitano. 2015. Evaluation of a 13-loci STR multiplex system for *Cannabis sativa* genetic identification. The 26th International Symposium on Human Identification. Grapevine, TX.

Elizabeth Rahman, David Gangitano, Gabriel Boselli, Sheree Hughes-Stamm . 2015. Evaluation of a One-Step DNA Extraction Method for "touch" Samples. The 26th International Symposium on Human Identification. Grapevine, TX.

A. Sorensen, C. Berry, D. Bruce, M. Gahan, S. Hughes-Stamm and D. McNevin. 2015. Direct-to-PCR Tissue Preservation for DNA Profiling. The 26th International Symposium on Human Identification. Grapevine, TX.

Amy Sorensen, MS, Elizabeth Rahman, BSc, Cassandra Schield, MS, James White, MS, David Gangitano, PhD, Sheree Hughes---Stamm, PhD. 2015. Room Temperature DNA Preservation and Rapid Purification of Decomposing Human Tissue Samples; An Alternative DVI Approach. AAFS 67th Annual Scientific Meeting, Orlando, FL

Amy Sorensen, MS, David Gangitano, PhD, Sheree Hughes---Stamm, PhD. 2014. Room Temperature DNA Preservation and High---Throughput Purification of Decomposing Human Tissue Samples; An Improved DVI Approach. The 22nd International Symposium on the Forensic Sciences. The Australian and New Zealand Forensic Science Society. Adelaide, Australia

Amy Sorensen, MS, David Gangitano, PhD, Sheree Hughes---Stamm, PhD. 2014. Room Temperature DNA Preservation and Rapid Purification of Decomposing Human Tissue Samples; A DVI Application. The 25th International Symposium on Human Identification. Phoenix, AZ.

James White, B.S.*; Sarah Bahlmann, M.S.; Sheree Hughes---Stamm, Ph.D.; David Gangitano, Ph.D. 2014. Development and Evaluation of a Rapid PCR Method for a Commercially Available MiniSTR Kit for Human Identification. AAFS 66th Annual Scientific Meeting, Seattle, WA

Elizabeth Rahman, B.S.*; Sheree Hughes---Stamm, Ph.D. 2014. Preservation of Human Tissue Samples in Tropical Climates. AAFS 66th Annual Scientific Meeting, Seattle, WA

Kourtni Woods, B.S.*, Frank Warnke, DDS, Sheree Hughes---Stamm, Ph.D. 2014. An Improved Method of DNA Extraction From Environmentally Challenged Teeth AAFS 66th Annual Scientific Meeting, Seattle, WA

Sarah Bahlmann, Sheree Hughes---Stamm, David Gangitano. 2013. Development and Evaluation of a Rapid PCR Method for the Powerplex®S5 System for Forensic DNA Profiling. The 23rd International Symposium on Human Identification, Atlanta, USA

S.R. Hughes---Stamm. 2012. The 200 year---old HMS Pandora shipwreck: Combined Forensic Anthropology and Genetic Analysis of the Skeletal Remains Recovered. Australian and New Zealand Forensic Science Society (ANZFSS) Symposium. Hobart, AUSTRALIA

Sheree Hughes---Stamm, Kevin Ashton, Angela van Daal. 2011. STR Genotyping of Environmentally Challenged Skeletal Samples. The 22nd International Symposium on Human Identification, Washington DC, USA

Mark Barash, Wenji Liu, Sheree Hughes---Stamm, Angela van Daal. 2011 Identification of Single Nucleotide Polymorphisms (SNPs) Involved in the Determination of Physical Appearance.
The 22nd International Symposium on Human Identification, Washington DC, USA

Sheree Hughes---Stamm, Kevin Ashton, Angela van Daal . 2010. Assessment of DNA Degradation and the Predictive Genotyping Success of Highly Degraded Samples.
The 21st International Symposium on Human Identification, San Antonio, TX, USA

S.R. Hughes---Stamm, K.A. Ashton, A. van Daal. 2009. Assessment of DNA Degradation and the Genotyping Success of Highly Degraded Samples.
6th International Society of Applied Biological Sciences (ISABS) Conference Human Genome Project Based Applications in Forensic Science, Anthropology and Individualized Medicine. Split, Croatia.

S.R. Hughes---Stamm, K.A. Ashton, A. van Daal. 2008. Measures of DNA Degradation and the Presumptive Genotyping Success of Highly Degraded Samples. Australian and New Zealand Forensic Science Society (ANZFSS) Symposium. Melbourne, AUSTRALIA

M.K. Jones , S.R. Hughes---Stamm, T.H. Cribb. (2000) Morphology of the digestive system of the digenean trematode Gyliauchen nahaensis --- An endocommensal flatworm with a herbivorous diet. New Zealand Society for Parasitology/ Australian Society for Parasitology. Wellington, NZ

Pantaleon M., Hughes---Stamm S.R., Kaye P.L. 1999. Glucose is essential for GLUT3 expression and blastocyst formation in the mouse.
Australian Society for Biochemistry and Molecular Biology Incorporated (ASBMB) Australian and New Zealand Society for Cell & Developmental Biology Incorporated Combined Conference Abstracts. Sym---35---05 (Abstract)

M. Pantaleon, S.R. Hughes---Stamm, P.L.Kaye. 1998. A role for glucose in cleavage stage mouse development. Australian Society for Reproductive Biology. Pg.43

Work or Professional Experiences

Assistant Professor, Forensic Science (2012-current)
Director of Graduate Programs, Department of Forensic Science
Forensic Science Department, Sam Houston State University, Huntsville, TX.

Senior Teaching Fellow (2006-2012)
Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Australia

Teaching Fellow (2002-2006)
School of Physiotherapy and Exercise Science, Griffith University, Gold Coast, Australia Postgraduate Tutor (2000---2001)
Department of Anatomical Sciences, University of QLD, Brisbane, Australia

Research Assistant (1999)
Department of Anatomical Sciences, University of QLD, Brisbane, Australia

Laboratory Technician (1998)
Science Department, University of the Sunshine Coast, Australia

Research Assistant (1997-1998)
Department of Physiology and Pharmacology, University of QLD, Brisbane, Australia Center for Microscopy and Microanalysis, University of QLD, Brisbane, Australia

Anatomy Tutor (1996)
Department of Anatomical Sciences, University of QLD, Brisbane, Australia

Honors and Awards

Australian and New Zealand Forensic Science Society (ANZFSS) National Award, 2012
Bond University Alumni Student Opportunity Award, 2011
Bond University Open Day Graduate Poster Prize, 2009
Australian and New Zealand Forensic Science Society (ANZFSS) Allan Hodda Memorial Award, 2009
Australian Postgraduate Award (APA), 2008
Australian Federation of University Women Fellowship Award, 2001 Australian Society of Reproductive Biology Serono Junior Scientist Award, 1997
Science Faculty Commendation for High Achievement, UQ (GPA>6.0), 1996 & 1997
Golden Key National Honour Society Member For outstanding scholastic achievement (UQ)

Other Competencies

Texas Forensic Science Commissioner, 2014-current
Walker County Voluntary Organizations Active in Disaster (VOAD) (2013- current) American Academy of Forensic Sciences, Trainee Affiliate (2012- current) American Academy of Forensic Sciences, Student Affiliate (2011- 2012)
Australian & New Zealand Forensic Science Society (QLD Branch, Steering Committee) 2008---2012 Bond University Women's Network (Steering Committee) (2009-2012)
Australian Federation of University Women (1997-2000) Advanced Pathology Training Course (1997)

D. JODY KOEHLER

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EDUCATION

Southwest Texas State University
M.S. in Biology **1996**
Minor: Biochemistry
Thesis: "Use of Random Amplified Polymorphic DNA (RAPD) to Identify Largemouth Bass Subspecies and Their Intergrades"

Southwest Texas State University
B.S. in Aquatic Biology **1993**
Minor: Chemistry

AWARDS

Graduate Stipend, Southwest Texas State University	January 1994 – December 1994
Academic Excellence Award, Southwest Texas State University	May 1993, May 1996
Fred and Yetta Richan Aquatic Biology Award, Southwest Texas State University	May 1993
Dean's List, Southwest Texas State University and Texas A&I University	May 1989, May 1992, May 1993
Honor Roll, Texas A&I University	September 1989
Livestock Show and Rodeo Scholarship, Texas A&I University	December, 1988
Alpha Chi-Member	
Houston Golden Key National Honor Society –member	

TEACHING EXPERIENCE

Southwest Texas State University
Laboratory Instructor-Introductory Botany/Aquatic Biology **1994**
Taught laboratory sections of Introductory Botany and Aquatic Biology.

Austin Community College
Adjunct Instructor-Introductory Biology/Microbiology **2002-2005**
Taught lecture and laboratory sections of Introductory Biology and Microbiology. Graded all written work and developed course curriculum.

Concordia University
Adjunct Instructor-Introductory Biology/Forensic Science **2005-2009**
Taught lecture and laboratory sections of Introductory Biology. Taught Forensic Science. Graded all written work and developed course curriculum.

RELATED EXPERIENCE

Texas Forensic Science Commission
Senior Scientific Advisor **November 2017 – Present**
Provide technical expertise to the Texas Forensic Science Commission investigations, assist with t he Commission's laboratory accreditation program and provide vital support to the Licensing Advisory Committee tasked with implementing the forensic analyst licensing program.

ANSI-ASQ National Accreditation Board (ANAB)
Contract Lead Assessor **January 2017-Present**
Lead assessment teams to determine if forensic laboratories are in compliance with international accreditation standards, including standards set by the International Organization for Standardization.

Laboratory Manager, Capitol Area Regional Laboratory **March 2017 – October 2017**
Lead the Capitol Area Regional Laboratory, performing performance reviews, implementing process improvement to ensure the laboratory is meeting the needs of our clients by producing high quality casework in a timely manner, testifying in court, compiling grant progress report data, meeting with employees to ensure their needs are met, working with under-performing employees to ensure they are can perform the job duties that are required of them, serving as the Quality Manger and DNA Technical Leader, and approving expenditures required to operate the laboratory

Texas Department of Public Safety Crime Laboratory

DNA Section Supervisor II/III, Austin Laboratory **November 2006 –March 2017**

Lead a team of 20 DNA analysts, performing performance reviews, implementing process improvement to ensure the section is meeting the needs of our clients by producing high quality casework in a timely manner, testifying in court, compiling grant progress report data, meeting with employees to ensure their needs are met, working with under-performing employees to ensure they are can perform the job duties that are required of them, serving on a subcommittee to standardize the way DNA mixture profiles are interpreted within the crime laboratory, serving as the Technical Leader for our Weslaco Regional laboratory, mentoring new Technical Leaders/supervisors in the Crime Laboratory system, coordinating and overseeing the CODIS review project with private laboratories, and approving expenditures required to operate the DNA Section.

Texas Department of Public Safety

DNA Technical Leader/DNA Section Supervisor **May 2004 – November 2006**

Provided oversight for the technical operations of the DNA section, trained new analysts, provided oversight for proficiency testing of the analysts, troubleshooting instrumentation, evaluated employees' abilities and recommended remedial training if required, conducted administrative review on DNA cases, validated new equipment, performed DNA casework, and investigated crime scenes.

Austin Independent School District

Teacher **August 2002-August 2003**

Taught 7th grade Magnet Science, Medical Technology, and Marine Biology. Supervised the work of 28 students in a biology classroom. Kept accurate records of attendance, students' grades, and documentation of conversations with students and parents. Met the students' and parents' needs on a daily basis in a professional manner. Planned lessons to ensure TEKS guidelines were satisfied.

Texas Department of Public Safety

Criminalist/DNA Technical Leader **November 1996-July 2001**

Trained new employees to perform DNA analysis for the Austin laboratory as well as the regional laboratories. Provided oversight for proficiency testing, quality assurance and quality control, troubleshooting instrumentation, and instrument validation. Testified in court as an expert witness, investigated contamination incidents, and performed DNA analysis on forensic cases. Served as a team member on the system-wide DNA Advisory Board.

Texas Parks and Wildlife Department

Microbiologist **December 1994-November 1996**

Established two DNA laboratories within the Inland Fisheries Division. Performed genetic analysis on fish populations within Texas using protein and DNA analysis methods. Investigated fish health issues.

PUBLICATIONS AND PAPERS

Kathryn Oostdik, Kristy Lenz, Jeffrey Nye, Kristin Schelling, Donald Yet, Scott Bruski, Joshua Strong, Clint Buchanan, Joel Sutton, Jessica Linner, Nicole Frazier, Hays Young, Learden Matthies, Amber Sage, Jeff Hahn, Regina Wells, Natasha Williams, Monica Price, D. Jody Koehler, Melisa Staples, Katie L. Swango, et al. 2014. Developmental validation of the PowerPlex® Fusion System for analysis of casework and reference samples: A 24-locus multiplex for new database standards. FSI: Genetics, Vol. 12: 69-76

Jonelle M. Thompson, Margaret M. Ewing, William E. Frank, Jill J. Pogemiller, Craig A. Nolde, D. Jody Koehler, Alyssandra M. Shaffer, Dawn R. Rabbach, Patricia M. Fulmer, Cynthia J. Sprecher, Douglas R. Storts. 2013. Developmental validation of the PowerPlex® Y23 System: A single multiplex Y-STR analysis system for casework and database samples. FSI: Genetics Vol 7 (2): 240-250.

Johnson, S.K., L.T. Fries, D.J. Williams, and D.G. Huffman. 1995. Presence of the parasitic swim bladder nematode, Anguillicola crassus, in Texas aquaculture. World Aquaculture 26(3):35-36.

Fries, L.T., D.J. Williams, and S.K. Johnson. 1996. Occurrence of Anguillicola crassus, an exotic parasitic swim bladder nematode of eels, in the southeastern United States. Transactions of the American Fisheries Society 125 (5): 794-797.

Williams, D.J., S. Kazianis, and R.B. Walter. 1998. Use of Random Amplified Polymorphic DNA (RAPD) for the Identification of Largemouth Bass Subspecies and Their Intergrades. Transactions of the American Fisheries Society 127 (5): 825-832.

MEMBERSHIPS

American Society of Crime Laboratory Directors
Association of Forensic DNA Analysts and Administrators

AUDITOR QUALILFICATIONS

ANSI-ASQ National Accreditation Board-Lead Assessor (2017)
American Society of Crime Laboratory Directors-Laboratory Accreditation Board-*International* Assessor (2006)
American Society of Crime Laboratory Directors-Laboratory Accreditation Board-Legacy Inspector (2005)
The FBI Quality Assurance Standards for Forensic DNA Testing Laboratories Auditor (STR and Y-STR)-2005, updated training as required

REFERENCES

Available upon request

Houston Forensic Science Center

INTEROFFICE MEMO

To: Quality Case Record for CARs/IRs:
2016-007, 2016-008, 2016-009, 2016-010, 2016-011, 2016-012, 2016-013, 2016-024, 2016-026, 2016-027, 2016-029, 2016-033, 2016-037, 2016-038, 2016-055, 2016-058, 2016-059, 2016-060, 2016-062, 2016-063, 2016-066, 2016-070, 2016-071, 2016-073, 2016-074, 2016-078, 2016-080, 2016-082

Lloyd Halsell III, Acting Technical Leader (October 10, 2015 to July 1, 2016) LSA 11-14-16
Robin Guidry, DNA Technical Leader RG 11/10/16
Jennifer O'Callaghan, Forensic Biology Manager 11/10/2016
Irma Rios, Forensic Analysis Division Director Irma Rios 11-14-16

Cc: Lori Wilson, Quality Director 11/10/2016

Aimee Grimaldi, Quality Specialist Aimee Grimaldi 11/10/2016

From: Paula Evans, Quality Specialist Paula Evans 11/10/16

Date: November 4, 2016

Re: Root Cause Analysis for 2016 First and Second Quarter Contamination Events

Between January and July 2016, multiple instances of contamination were reported to the Quality Division as required by Biology Section SOPs. Contamination is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction. The Biology Section has quality control measures in place to detect possible contamination and ensure the integrity of DNA results obtained from evidence samples. One such quality control measure is the use of a reagent blank during the extraction process. The reagent blank is a control sample that contains no DNA and is used to monitor for contamination from reagents used during the extraction process. In addition, this control is treated as and run in parallel to the casework samples on the batch. For this reason, the reagent blank can also detect contamination introduced during the processing of casework samples.

In accordance with the FBI QAS standard 9.7, the Biology Section has and follows a policy for the detection and control of contamination. Reviewing controls for contamination, including reagent blanks, is part of the DNA analysis process. The detection of contamination is a confirmation that the quality system is robust and is working. When contamination is reported to the Quality Division, each occurrence is investigated by the Biology Section and the Quality Division in an attempt to determine the source of the contamination, analytical step at which the contamination occurred, amount of activity present (number of peaks above and below threshold), and if the contamination can be resolved by reprocessing. In addition to investigating the source of contamination, the Biology Section and the Quality Division ensure that results and statements written in the report are clear, accurate, and transparent. Additional items the Quality Division considers during root cause analysis are: date of occurrence, number of contamination events in a given time frame, amplification kit used, batch number, and automated vs manual processes.

There were instances during the first and second quarters of calendar year 2016 in which possible contamination was reported to the Quality Division and, through the meeting step (the first step of the Quality Incident/Corrective Action Process) or the investigation itself, determined to not be contamination. This memo is intended to address only those situations where contamination was determined to be present.

Potential sources of DNA contamination include but are not limited to contamination between samples during processing, human genomic DNA from the environment, the analyst processing the samples, a vendor maintaining the equipment, or an unknown source. Because DNA testing is sensitive to minute quantities of DNA, it is not always possible to determine the source of exogenous DNA introduced to the reagent blank.

Members of the Biology Section and Quality Division worked together to troubleshoot these instances of contamination. The first step was performing a lab decontamination, which was done on March 28, 2016. On April 8, 2016 the Acting Technical Leader instructed the Forensic Biology Section to perform lab decontamination on a weekly basis. Additional PPE requirements were also implemented for lab staff and visitors to prevent contamination. Lab coat, gloves, hair coverings and face masks are required during screening, extraction, quantification, and amplification. In the post-amplification laboratory, gloves and a lab coat are required. This PPE is not optional and anyone entering the areas where these procedures are performed must abide by these requirements. These preventive measures were put in place in order to minimize the risk of contamination. Since completely eliminating all contamination is unlikely due to the sensitivity of DNA technology, HFSC instituted a DNA Profile Policy on June 23, 2016. This policy requires all HFSC staff members, regardless of position, to submit their DNA for inclusion in the staff DNA database. This allows for a better means to source contamination if it presents itself. Cleaning tube racks and other plasticware with a bleach bath before use was considered but has not been implemented.

When compared to 2015, more contamination events were reported to the Quality Division during the first half of 2016. However, this was partially due to biology SOP changes, increased production, and a change in technical leaders. Seven contamination events that were reported in the first half of 2016 would not have been reported in 2015 because the SOP did not require contamination that was resolved with reamplification to be reported to the Quality Division. For the time period of September 1, 2014 to May 05, 2016, the DNA SOP 2 - Quality Assurance stated the following:

> *Confirmed contamination events will be summarized in a CAPA that will document the details of the contamination event, including the cases involved, the date of detection, the investigative actions taken, the source of the contamination, if known, and any corrective actions taken.*
>
> *Unacceptable activity in a reagent blank or negative control that cannot be readily attributed to an artifact must be investigated to determine if it is reproducible contamination. The first course of action is to re-inject the sample on the genetic analyzer to determine if the activity is in the amplified DNA product or if it was perhaps introduced during post-amplification sample set-up. If not reproduced upon re-injection, the data from samples associated with the reagent blank or amplification negative control may be used for interpretation. If reproduced upon re-injection, the reagent blank is then re-amplified to determine if the activity is in the DNA extract or if it was introduced during the amplification set-up. If reproduced upon re-injection, the samples associated with the amplification negative control must be re-amplified. If not reproduced upon re-amplification, the data from samples associated with the reagent blank may be used for interpretation. If reproduced upon re-amplification, the DNA activity is determined to be in the DNA extract and all samples associated with the contaminated reagent blank must be re-extracted because the data from samples associated with that reagent blank may not be used for interpretation due to unacceptable quality controls.*
>
> *It is recommended that any steps taken to investigate potential contamination are performed by a 2nd technician to establish a transparent exploration.*

Therefore, only confirmed contamination was reported to the Quality Division in calendar year 2015. The Acting Technical Leader informed the Forensic Biology Section on February 16, 2016 that activity, including possible contamination which is resolved, must be reported to the Quality Division so that trends can be evaluated. The DNA SOP was then updated to include the new requirements and issued May 06, 2016. The current SOP states:

> *Unacceptable activity in a reagent blank or negative control that cannot be readily attributed to an artifact must be investigated to determine if it is reproducible contamination. Unacceptable activity includes a pattern of data that can be differentiated from background. A single activity point may not be evidence of contamination. The Technical Leader shall have sole discretion in determining if a single point is acceptable or if it requires further processing.*
>
> *The first course of action is to re-inject the sample on the genetic analyzer to determine if the activity is in the amplified DNA product or if it was perhaps introduced during post-amplification sample set-up. The re-inject plate may be set up again or re-injected from the same plate. If not reproduced upon re-injection, the data from samples associated with the reagent blank or amplification negative control may be used for interpretation.*
>
> *If reproduced upon re-injection, the reagent blank is then re-amplified to determine if the activity is in the DNA extract or if it was introduced during the amplification set-up. If the activity is in the amplification negative control and re-produced upon re-injection the samples associated with the amplification negative control must be re-amplified. If activity in a reagent blank is not reproduced upon re-amplification, the data from samples associated with the reagent blank may be used for interpretation. If reproduced upon re-amplification, the DNA activity is determined to be in the DNA extract and all samples associated with the contaminated reagent blank must be re-extracted because the data from samples associated with that reagent blank may not be used for interpretation due to unacceptable quality controls.*
>
> *Activity that is resolved with re-injections shall be tracked with a contamination log.*
> *Activity that is resolved by re-amplification shall be tracked with an HFSC Incident form.*
> *Activity that is reproduced upon re-amplification shall be tracked with an HFSC Corrective Action Report form. These tracking measures are guidelines only and can be amended by the Technical Leader or HFSC Quality Division.*

In addition to the preventative measures already described, the Quality Division requested that the Forensic Biology Section run a series of tests to gather more data in order to eliminate some possible contributors to contamination. Multiple blanks were run through the entire DNA process to eliminate consumables (e.g. plasticware, trays, tubes) as possible contributors. The data indicated that consumables are not a likely cause of the contamination. However, it should be noted that plasticware contamination could be sporadic and not seen in every tube or plate in a given lot. In addition, the Quality Division spoke with the Biology Section about pursuing options to add quality control measures to the analysis process (e.g., looking at ways to create a database or spreadsheet that had the ability to compare profiles generated by the lab to each other and to crosscheck contamination against multiple batches).

Next, the Forensic Biology Section ran samples in an arrangement (sample, blank, sample, blank) on instrumentation in order to eliminate equipment as a possible contributor to the contamination events. Nine blanks were processed in this fashion. Two of the blanks produced peaks that needed to be evaluated for contamination. After further review, the blanks were deemed acceptable by the Acting Technical Leader. The data gathered from this test indicated that the equipment was not a likely cause of the contamination.

Lastly, the Forensic Biology Section ran contamination-free autosomal samples through the YSTR process to determine the sensitivity of YSTR data. The same nine blanks from above were processed for YSTRs. Three blanks

produced peaks that were distinct from background noise and required examination. The Acting Technical Leader examined the data from this test. Upon examination and secondary processing, two of the peaks were deemed acceptable. However, the third contained a labeled peak that was confirmed contamination. The data suggests that activity may be seen during YSTR analysis that was not originally seen in autosomal analysis. This may be due to the fact that YSTR PCR includes two additional cycles. Two additional cycles make YSTR analysis more sensitive which could increase the potential of developing low-level DNA. Even with the data from this test, most of the possible contamination events were not able to be sourced due to too little information. Too little information means that the partial profile developed could not be sourced to a person, object, consumable, etc.

The amount of samples processed was also considered. During April, May, and June, the Forensic Biology Section performed 8,629 extractions. This was almost a 180% increase when compared to the amount of extractions performed during the first quarter of 2016. Figure 1 below shows the contamination events reported to the Quality Division each month of Quarters 1 & 2. This graph shows a large decrease between March and April. Some of this could be attributed to the additional PPE requirements that were put in place and the additional lab cleaning that was implemented. The initial high volume in February and March may be attributed to a "February push" in which production expectations were increased. However, in May there was a large increase in reporting which is most likely due to the increase in production between the first and second quarters. As the Forensic Biology Section began adjusting to a large increase in production, it appears the contamination began to decrease.

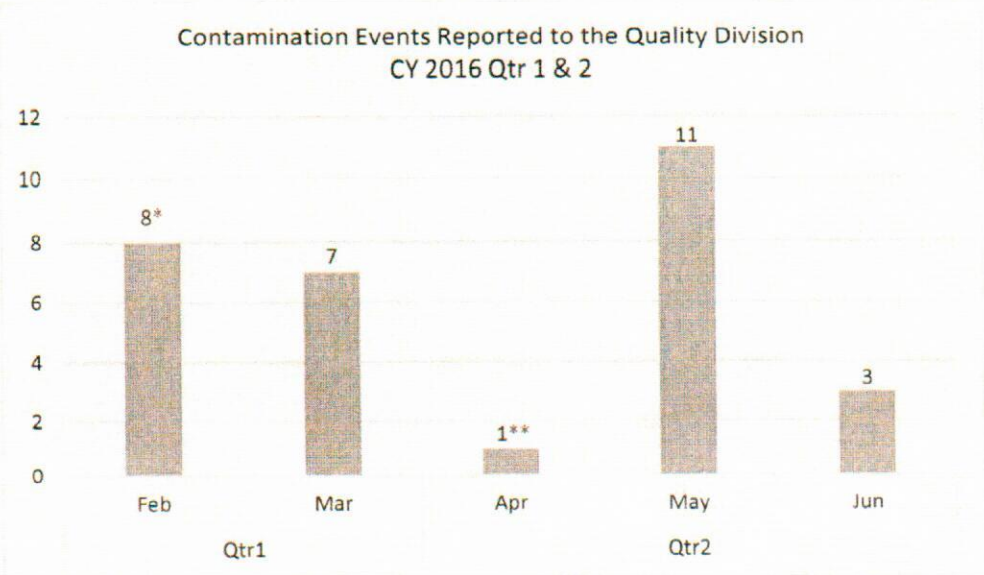

Figure 1. Contamination reported to the Quality Division each month.
**One contamination event reported occurred in 2015 and was closed prior to issuance of this memo.*
***This contamination event was closed prior to issuance of this memo.*

The Quality Division will continue to analyze and monitor corrective action and incident data. The possible causes listed above have all been considered. Unfortunately, the root cause for many of the contamination events is unknown. This is not unusual due to the nature of DNA analysis. Many of the contaminated reagent blanks yielded too little information to conclude the source of the contamination. Recommendations that have been discussed that have not been implemented at the time of this memo are bleach baths for plasticware and the implementation of a system to compare unknown profiles seen in contamination to profiles obtained within a batch or multiple batches. Recently the Quality Division was informed that the weekly decontamination had been discontinued after the SAK project. However, the Biology Section has decided to reinstate the decontamination of

the laboratory on a monthly basis as a preventive measure to reduce the risk of contamination. As of the date of this memo, monthly decontamination had not been implemented.

The incidents/corrective actions that were reported to the Quality Division between January and July 2016 remained open for root cause analysis investigation and trending purposes. This memo documents the measures taken to determine the source(s) of the contamination events and is used to close-out the Quality Division incidents/corrective actions.

THIS FORM IS FOR BIOLOGY/DNA REPORTING ONLY

Quality Division Use Only

Quality Tracking #:	2017-075	**Date Quality Division Notified:**	9/27/2017
Non-Conformance Level:	Class I	**Date Submitted to Management for Review:**	1/29/2018
Date Submitted to Quality for Review:	1/29/2018	**Date Closed:**	1/29/2018

Date of Discovery:	7/1/2017	**Division:**	Biology/DNA Division
Date of Incident:	7/1/2017	**Section:**	Biology/DNA

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
A. 2017-066: 2017-14042, 2017-11029 A. 2017-079: 2017-14996, 2017-14994 A. 2017-081: 2017-15186, 2017-15129, 2017-15141 B. 2017-063: 2017-12708, 2017-12590 B. 2017-082: 2017-15188, 2017-14998, 2017-15145, 2017-15022 C. 2017-056: 2017-11708, 2017-09791, 2017-12202, 2017-10259, 2017-10495 C. 2017-067: 2017-13146, 2017-12577, 2017-12999 C. 2017-073: 2017-10200, 2017-10893, 2016-24547 D. 2017-071: 2017-13512, 2017-14768 E. 2017-062: 2017-13035, 2017-13340 The first column indicates the assigned Quality Division incident number.	A. 2017-066: 091007517, 071212917 A. 2017-079: 097525717, 097528717 A. 2017-081: 098112917, 099946217, 097738817 B. 2017-063: 079049317, 081430717 B. 2017-082: 090406017, 096686517, 099700717, 099388117 C. 2017-056: 075066217, 063002017, 076796717, 066645717, 068070317 C. 2017-067: 085132817, 080809517, 083380517 C. 2017-073: 063767017, 069848317, 162829816 D. 2017-071: 082865217, 096766317 E. 2017-062: 083798517, 084925717 The first column indicates the assigned Quality Division incident number.

Description of Discrepancy/Non-conformance. Do not include analysts' names unless otherwise instructed by the Section Manager or Division Director(s):

There were twenty-two possible contamination events reported within the months of July, August and September, 2017. Of the twenty-two reported events, twelve had DNA activity which was resolved upon re-amplification and the other ten require re-extraction. As is required by the DNA SOP, all twenty-two events were reported to the DNA Technical Leader and/or the Quality Division and subsequently the ten events which require re-extraction were assigned the following incident numbers: 2017-056 (type C), 2017-062 (type E), 2017-063 (type B), 2017-066 (type A), 2017-067 (type C), 2017-071 (type D), 2017-073 (type C), 2017-079 (type A), 2017-081 (type A) and 2017-082 (type B). The other twelve events that were resolved upon re-amplification were not assigned incident numbers but are tracked in Qualtrax for tracking and trending purposes. Results were not reported in any of the affected cases until each contamination event was resolved. If resolution was not possible, the results were not reported.

During this time, the contamination rate was calculated and the observed rate of contamination was above the historical threshold. The rate of contamination is calculated by dividing the number of contamination events in a given month by the number of samples processed (per extraction or amplification process). This rise in the contamination rate triggered the Quality Division to initiate this corrective action and the contamination events were analyzed in an attempt to determine the root cause(s) of this spike.

When analyzed, the contamination events were categorized in six ways:

A. sourced to Client Services/Case Management (CS/CM) Specialist
B. sourced to Forensic Biology staff who did not perform work in the case
C. sourced to another sample in the same batch
D. sourced to Forensic Biology staff member who performed work in the case
E. interpretable but not sourced
F. inconclusive

Actions Taken:

Several actions were taken to educate staff on the importance of preventing contamination, proper use of personal protective equipment (PPE) and good laboratory practices. Contamination prevention was discussed with the entire Forensic Biology staff at the August 23, 2017, technical meeting. At the September 13 section-wide production meeting, management discussed the use of PPE at all times when handling evidence, reagents, and equipment in the laboratory, including computer keyboards. A meeting with the DNA Technical Leader, laboratory staff who perform extraction, quantification, amplification and/or capillary electrophoresis preparation, and a Quality Division Specialist was held on September 19 to solicit and discuss best practices while performing bench-work analysis.

The laboratory implemented several global measures to help prevent contamination. These measures included: regularly scheduled deep cleaning followed by swipe tests to measure effectiveness; revising the monthly clean-up checklist to more clearly define the expectations of a "deep clean"; and reformatting the checklist to effectively convey analyst accountability. Automation instrumentation is now decontaminated prior to and after each use,

rather than only before use. Several physical changes were made inside the Forensic Biology laboratory space to further prevent contamination. PPE gowning stations were created outside of laboratory spaces so that gowning takes place prior to entering extraction rooms or the screening bench area. The laboratory entrance door adjacent to an extraction room was transitioned to an emergency exit-only door to further minimize traffic in the extraction area. Badge access was terminated at that portal. All staff must now enter the laboratory using the main laboratory entrance. The reagent preparation balance was moved out of the area where cleaning/drying racks and autoclaving occurs in order to minimize traffic in that area. Keyboard covers were purchased to ease the decontamination of computer keyboards.

The DNA SOP was enhanced to include more language and discussion surrounding the unintentional introduction of DNA to samples and controls.

Actions taken for each of the six categories of contamination are as follows:

A. As a direct result of the contamination events, the CS/CM Specialist was provided supplemental instruction on proper PPE donning and tube/supply handling. As a result of this instruction, the Specialist continues to don proper PPE while performing all laboratory functions but now has a greater understanding of the potential for unintentional DNA transfer. Specific laboratory space has been designated for the Specialist to perform her job duties (such as autoclaving tubes and cleaning tube racks). Staff were told to not enter this area unless necessary. If staff must enter this area, proper PPE is required. The Specialist continues to minimize her time in any laboratory areas that are undergoing active bench-work which in turn limits her direct contact with casework samples. In addition, because her DNA was detected in reagent blank controls, she is exercising more precaution when stocking consumables and handling tubes for the autoclave process. This greater awareness of the possibility of unintentional DNA transfer is expected to minimize the detection of her DNA on consumables.

B. The laboratory took specific measures to address contamination sourced to Forensic Biology staff who did not perform work on the case. Several of these measures addressed the laboratory's decontamination practices. The autoclaving process was defined with a written procedure and was modified to allow for a longer autoclave time. Tube racks were previously washed only with Liquinox detergent which resulted in them being "clean" but there was no expectation for them to be DNA-free/decontaminated. Now, in addition to Liquinox, tube racks are stored in bleach “baths” after use and until cleaning, and bleach is also used as a decontaminant in the washing process. Tube racks were then set out to dry in an area of the lab where PPE was not required. Staff is now discouraged from unnecessarily entering this area. If staff must enter this area, proper PPE is required. Several other measures addressed best practices for PPE use and sample handling. PPE gowning stations have been created outside of laboratory spaces so that all types of PPE (glove, labcoats, hair nets, masks, etc.) are in one convenient location so that gowning takes place prior to entering extraction rooms or the screening bench area. In addition, staff is now required to wear gloves when using any laboratory keyboard. The laboratory was utilizing an entrance door that was adjacent to an extraction room. This door has now been transitioned to an emergency exit-only door to further minimize traffic in the DNA extraction area. Badge access was terminated at that portal thereby forcing all staff to enter the laboratory via the main laboratory entrance. Finally, daily team huddles were relocated from an office space within the laboratory to an office space that is completely independent of the laboratory (on a separate floor).

C. Measures taken to address contamination sourced to another sample in the same batch included reinforcing good laboratory practices and clean techniques while performing bench-work through discussion, sharing of best practices, and an enhanced training program. The training program has been modified so that it will impart these techniques onto all new staff, not just technicians. The Evidence Handling Laboratory Skills Worksheet was created and is a required training document that will ensure trainees can prepare an appropriate bleach solution, properly clean laboratory equipment, handle and label sample tubes in a manner that minimizes the potential for contamination, and operate a pipette in a manner that minimizes potential contamination.

D. Action taken to address contamination sourced to a Biology staff member who perform work in the case included reinforcing good laboratory practices and clean techniques while performing bench-work through discussion, sharing of best practices, and an enhanced training program.

E. The laboratory took specific measures to address contamination that was interpretable but not sourced (meaning there was enough DNA activity for comparison purposes but the DNA activity does not match any of the samples in our staff database or any of the casework samples that were being processed at or around the same time). These measures included: continuing to search and upload unsourced but comparable profiles to the Local DNA Index System (LDIS) and the GeneMapper ID-X comparison tool; continuing to search International Commission on Missing Persons' (ICMP) Online DNA Elimination Database; providing DNA profiles to vendors for searching in their staff databases; continuing to autoclave sample tubes that can be autoclaved; and a decontamination experiment with HFSC's Research and Development Division. This experimental plan will help to better understand our decontamination practices by examining factors such as different cleaning reagents, time the cleaning reagent is in contact with the surface before wiping, and DNA-free versus sterile swabs.

F. While no actions were taken to specifically address the contamination that was inconclusive, the aforementioned actions are expected to minimize this type of contamination as well. Lastly, the Quality Division conducted interviews, observations and a series of Voice of Customer interviews with limited groups of staff members. These groups were selected according to laboratory job function: screeners, technicians, report writers/analysts and management. Pareto charts were created to summarize the aggregated responses and aid in root cause analysis. The results of the analysis showed the increase of awareness in all interview groups regarding contamination and outlined the steps taken to prevent contamination in the laboratory as mentioned above.

Summary of Root Cause Analysis:

Several causes were identified as contributing to these contamination events: the CS/CM Specialist's laboratory technique, laboratory facilities, training program, and cleaning culture.

The Specialist's responsibilities have evolved over time from transporting evidence to and from the DNA laboratory and the Houston Police Department Property Room to responsibilities that are solely within the laboratory (ie. decontaminating racks and autoclaving tubes). She never entered into the laboratory's formal training program in which she would have been exposed to proper PPE expectations, gained knowledge regarding best laboratory practices and been given a more overall concept of the sensitivity of current day DNA testing. As a result of this recent instruction, she now has a greater awareness regarding the possibility of unintentional DNA transfer.

There are shortcomings in the laboratory's facility. Because of the limitations within the laboratory's physical space, there has historically been a blurred line as to what was considered laboratory space and what was considered office space. While colored tape now outlines the areas of the laboratory in which PPE is required, the laboratory's facilities are still limited in the sense that there is laboratory space and office space abutting one another. HFSC is aware of these facility shortcomings and, although the facility itself cannot be changed, the laboratory has identified environmental risks and, in response to these risks, has heightened awareness regarding workflow, access to PPE and minimizing traffic through designated laboratory space.

The laboratory's training program was identified as needing improvement. Historically the training program lacked clear ownership, lacked instruction for the trainers and did not replicate batch sizes that were comparable to that of casework. All of those concerns have now been addressed. The training program is now facilitated by the Operations and Training Supervisor and emphasis has been placed on good laboratory practices and clean techniques while actively performing bench-work. One staff member was involved in five of the contamination events: one in which her profile was found in a reagent blank of an extraction she did not perform (type B), two in which the contamination was sourced to another sample in the same batch (type C), one in which she was the technician who performed the extraction in the case (type D) and one in which the data was interpretable but not sourced (type E). This staff member was authorized for extraction on April 27, 2017. When this trend was observed, the staff member received supplemental instruction from the Technical Leader and was observed by a more experienced staff member and no concerns were noted.

The laboratory's cleaning culture was not as strong as it needed to be. The laboratory has always participated in weekly cleaning, however lab-wide, monthly deep cleans began in direct response to this spike in contamination events. The Biology laboratory now acknowledges the importance of having a strong cleaning culture especially when there is an increased demand in production. During these monthly deep cleans, production is halted, tasks are evenly distributed among staff and if a staff member completes his assigned task, the expectation for him to then help fellow staff complete their assigned tasks has been clearly communicated by management. Management is also demonstrating the importance of the deep cleans by actively monitoring each clean. Swipe tests have been implemented as a tool to measure the effectiveness of these cleans. Moreover, the cleaning culture of the laboratory has evolved significantly.

Additional Information/Follow-Up:

During evaluation of these contamination events, several potential root causes were considered as contributing factors but ultimately eliminated. These included manual versus robotic procedures, the increased sensitivity of the GlobalFiler amplification kit, the QIACube differential extraction procedure and poor amplification technique.

The amplification procedure allows for both the use of robotics and a manual option. The data does not support the theory that contamination events are more likely to occur in procedures that are performed manually than those done with the aid of robotics. The procedure is only performed manually on a limited basis and the contamination events were not isolated to that subset of amplifications. The laboratory's extraction procedures all rely on robotics, which even further discredits this theory.

The data does not support the theory that the contamination events were directly correlated to the laboratory's implementation of the GlobalFiler amplification kit. This amplification kit has a higher sensitivity than the previous amplification kit and was implemented in casework in January 2017. If the transition to GlobalFiler was a contributing factor, the expectation would have been an increase in contamination events at or around this time frame. However, the spike in contamination events occurred much later in the year, thereby discrediting this theory.

While there was a noted increase in contamination of the reagent blanks that are created as part of the QIAcube differential procedure, this increase has been categorized as correlation and possible causation. The laboratory had an increased amount of differential procedures being performed in the months in which the spike occurred, however there is no evidence that the extraction procedure inherently lends itself to increased contamination. The differential procedure was not modified at or around the time of the spike. Therefore, if the procedure itself inherently caused increased contamination events, a spike would have been expected when the procedure was brought online initially. There were no laboratory contamination events for the months of October, November and December 2017 and the differential procedure is still being performed consistently.

The data does not support the theory that the contamination events that ultimately resolved upon re-amplification were due to poor technique in the original amplification. Upon review of the data, it was not possible to identify a particular staff member whose technique could have been contributing to the contamination events. The activity observed prior to re-amplification was generally low level in nature. Seventy five percent of the events involved less than or equal to one peak above the analytical threshold; ninety percent involved less than or equal to two peaks above the analytical threshold. Lastly, for each of these twelve events, the DNA activity was resolved upon re-amplification and there were no concerns when the amplification procedure was observed.

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