



**Quality Division Use Only**

Quality Tracking #:	<input type="text" value="2018-078"/>	Classification:	<input type="text" value="Corrective Action"/>
Non-Conformance Level:	<input type="text" value="Class II"/>	Section:	<input type="text" value="Biology/DNA"/>
Date of Discovery:	<input type="text" value="08/10/18"/>	Date of Incident:	<input type="text" value="05/23/18"/>

<b>Forensic Case Number(s), if applicable:</b>	<b>Agency Case Number(s), if applicable:</b>
2018-058: 2018-06676 and 2018-06863 2018-068: 2018-09065 and 2018-08931 2018-069: 2018-09440 and 2018-09439	2018-058: 053353118 and 055337118 2018-068: 077530318 and 077001618 2018-069: 080206018 and 080585018

**Description of Non-conformance:**  
Reagent blanks were contaminated in three of the differential extractions performed by one Forensic Biology staff member between May 23 and July 13, 2018. Each contamination event is being treated as an incident (as is the laboratory's practice) but, because there were three events within the course of two months that all involved the same staff member, a corrective action was initiated. Please see 2018-058/ID #28622, 2018-068/ID #30384 and 2018-069/ID #30403 for further information regarding each incident.

**Actions Taken:**  
While these contamination events were being investigated, the staff member was removed from performing differential extractions on casework. The staff member was observed performing differential extractions by an experienced analyst on August 15, 2018, and again on September 6, 2018. The experienced analyst did not observe any areas of concern or opportunities for improvement. All controls were acceptable and free from contamination. While people's behaviors may be affected when being observed (i.e. the Hawthorne effect), in light of the fact there was also no evidence of contamination in the resulting data, the staff member was allowed to resume casework differential extractions. The staff member was authorized to perform the differential extraction procedure in casework on February 23, 2017. These contamination events occurred over a year after his release into casework and, coupled with the fact that the source of the contamination was not a sample in the batch nor the staff member himself, there is no evidence to support that this staff member's training was insufficient. Within the given time frame, a total of 72 differential extraction protocols were performed by five staff members and 21 of them were performed by this staff member. Therefore, although he was the staff member responsible for performing the three extractions that had unresolvable DNA activity, his other 18 differential extraction procedures were determined to be acceptable and free from contamination. The staff member was interviewed regarding his practices and potential process improvements.



**Summary of Root Cause Analysis:**

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

The Biology section has had a significant decrease in the number of contamination events. Between October 2017 and September 2018, the Biology section had five contamination incidents which involved unresolved DNA activity; one involving a non-casework/QC extraction (please refer to 2018-027/ID# 24215); one that was determined to have occurred during the examination process (please refer to 2018-070/ID# 30462); and the other three which occurred over the course of two months which are the subject of this corrective action. Given the low-level nature of all three contamination events, sourcing the contaminant and determining process improvements is challenging. All attempts to source the contaminants assume that each profile is from a single contributor which may not be accurate. However, all three of the contamination profiles differed from each other and were eliminated as being from staff and/or visitors or from the samples in the same extraction set. Therefore, the laboratory believes the plastic consumables may be the source of the contamination. The laboratory purchases either sterile plastic consumables or autoclaves non-sterile plastic consumables in order to render them sterile prior to use in casework. The staff member identified the reagent blank tubes as being a potential source of contamination. While the laboratory's practice is to autoclave the reagent blank tubes when they are received, the tubes are then placed "in circulation" at the bench for potentially several months after. The tubes are kept in the autoclave bags that are folded over when not in use, but the bags cannot be sealed. The laboratory does not have a measure in place to monitor the number of tube bags that are open at one time or to monitor the amount of time that has lapsed since the tubes were autoclaved. In practice, several bags of tubes can be "in circulation" at one time, thus prolonging each bag's exposure to potential contaminants. The laboratory has now instilled a practice of autoclaving the tubes in plastic screw-top containers which will allow the tubes to be sealed between uses. Additionally, the laboratory communicated to staff that only one container of reagent blank tubes may be "in circulation" at one time. These process improvements were communicated to all technicians. While the temperature in the laboratory has not been determined to be the root cause of these contamination events, it is still of note that these three events occurred over the summer because the laboratory experienced a "spike" in contamination in the summer of 2016 and 2017. While the laboratory does not record the ambient temperature in the extraction room (which prevents the viewing of historical data), thermometers were installed on July 31, 2018, for staff to initiate a work stoppage if the ambient temperature exceeds 78 degrees Fahrenheit.

**Additional Information/Follow-Up:**

Detailed information regarding each of the three incidents: Quality Report 2018-058: instrument: QIAcube A and EZ1 A date: Wednesday, May 23, 2018 quantification values of RB1\_QC18-0193 SF: small target: 0.0006, large target: 0.0009 and male target: 0.001 quantification values of RB1\_QC18-0193 EF: small target: 0.0003, large target: 0.0004 and male target: 0.0006 Quality Report 2018-068: instrument: QIAcube E and EZ1 E date: Thursday, July 5, 2018 quantification values of QC18-0257 SF: small target: Undetermined, large target: 0.0001 and male target: 0.0004 Quality Report 2018-069: instrument: QIAcube B and EZ1 D date: Friday, July 13, 2018 quantification values of QC18-0266 EF: small target: 0.0005, large target: 0.0005 and male target: undetermined

Section Manager: Courtney Head

Date: 11/07/18

Division Director: Amy Castillo

Date: 11/08/18



**Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.**

**Technical Leader:** Robin Guidry

**Date:** 11/02/2018

**CODIS Administrator:** Jennifer Clay

**Date:** 11/06/2018

**Quality Director:** Lori Wilson

**Date Closed:** 11/09/18