Quality Division Use Only

Quality Tracking #:	2020-097	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	10/29/20	**Date of Incident:**	10/29/20

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2020-05166 2020-05167 2020-04982 2020-05751 2020-11428 2020-07677 2018-14914 2020-12016 2020-12015 2020-11551 2020-12327 2020-11223 2020-11900 2019-07258 2019-19045 2020-11901 2020-12329 2020-12222 2016-13894 2020-08286 2020-12328 2020-12014 2020-05456 2020-12532	048369720 049411820 047803720 054141220 110967720 073751220 121330418 080005020 079897220 112736620 119724720 106070520 114702120 044083719 154008419 114148320 119898120 119156220 091578416 080260320 115129020 079199820 048901520 122107120

Description of Non-conformance:

Allelic activity was observed in five reagent blanks. A vendor issued a letter in August 2020 notifying customers of the presence of sporadic alleles observed in the negative controls of some laboratories.

Additional Information/Follow-Up:

On October 23, 2020, a DNA analyst reviewed data for Batch 129 and peaks were observed to be present in four reagent blanks, RB1 EZ20-0358, RB1 EZ20-0359, RB1 EZ20-0360, and RB1_EZ20-0361, of large-volume extraction protocols. The technician for Batch 129 notified the technical leader and forensic biology management.

On October 27, 2020, the technician supervisor reviewed the data for the four reagent blanks and noticed three reagent blanks (RB1 EZ20-0358, RB1 EZ20-0360, and RB1 EZ20-0361) extracted by two different technicians all contained a 23 peak at D2S1338 and two of the reagent blanks (RB1 EZ20-0358 and RB1 EZ20-0360) contained a 13 peak at D8S1179. The technician supervisor notified the technical leader and forensic biology management.

Due to the similarity of peaks present in the same type of extraction protocols conducted by two different analysts, the technician supervisor questioned if an investigation into a reagent contamination would be appropriate next steps. After reviewing the associated data, the technical leader instructed to re-inject the reagent blanks and wait to investigate a reagent contamination until the results of the re-injection were reviewed.

On October 29, 2020, the technician supervisor reviewed the data for Batch 132 and observed a 23 allele peak at D2S1338 in reagent blank RB1_EZ20-0364. The technician supervisor notified the technical leader, assistant technical leader, interpretation supervisor, and forensic biology manager to review the data. Since it was the same peak activity observed in reagent blanks (RB1 EZ20-0358, RB1 EZ20-0360, and RB1 EZ20-0361) that were currently

slated for re-injected, an investigation into a possible reagent contamination was initiated by the forensic biology manager.
During the process of the investigation the assistant technical leader researched whether other laboratories were observing similar activity when using specific lot numbers of the G2 buffer and forwarded an email thread (containing the following lot number information: EZ1 kit/cartridges lot number 166027531, G2 lot number 166018574, G2 lot number 166012005, and ProK lot number 166020109) to the operations coordinator and the manager of logistics and equipment. The manager of logistics and equipment responded to the email specifying that she searched for the specific lot numbers in the reagent inventory sheet and that "HFSC does not have and has not ever received any of the questioned lots". Upon further investigation, it was discovered that G2 lot number 166018574 and G2 lot number 166012005 were part of the reagent inventory list at the time the manager of logistics and equipment searched the list.
In an interview with the manager of logistics and equipment, she acknowledged that although she remembers searching for these specific lot numbers in the reagent inventory spreadsheet, she did not find them at the time, but that she should have since all the information in the spreadsheet related to these lot numbers indicates they were there when she searched. While she has several ideas of what may have caused her to misidentify the lot numbers in the spreadsheet she is unsure of what actually occurred. In the process of trying to determine what could be improved to prevent this from re-occurring, she has created an ongoing addendum, for reagents that HFSC receives notifications on, to the reagent spreadsheet that would be searched quarterly. This would cover any reagents arriving since the previous search, as well as mitigating any previous searches that may have been affected by unnoticed filters.
On October 29, 2020 the technical leader contacted Qiagen informing them of the activity noticed in the reagent blanks and provided them with the lot numbers of the EZ1 kit, ProK, and G2 reagents. Qiagen provided the technical leader with the customer letter from August 2020, where customers were informed of three EZ1 DNA Investigator Kit lot numbers that were identified as being a potential source of an unknown DNA contaminant. One of the lots, lot # 166012738, was identified to have been used on batches 97-132.
On October 30, 2020, all potentially contaminated G2 buffer bottles were removed from the laboratory. On November 2, 2020, an email notification was sent to staff making them aware of the G2 Buffer contamination. No additional large-volume extractions took place between October 27, 2020, and November 2, 2020.
The technical leader reviewed all instances of activity in reagent blanks that utilized EZ1 Kit lot number 166012738.

All reagent blanks were determined to be acceptable for use except for the following:
Batch 2020-122: RB1_EZ20-0323, 2020-05166 sample 1.3.1.1; 2020-05167 sample 1.4.2.1; 2020-04982 sample 1.3.1.1; 2020-05751 sample 1.2.1; 2020-11428 sample 16.2.1; 2020-07677 samples 1.1.1, 2.1.1.1, 2.1.3.1, 2.2.1.1, 2.2.2.1, and 2.3.1.1. Batch 2020-129: RB1_EZ20-0358, 2018-14914 samples 4.1.1, 5.1.1, 7.1.1, and 8.1.1; 2020-12016 1.1.1.1, 1.2.1.1, and 1.3.1.1; 2020-12015 samples 1.1.1.1, and 1.2.1.1; 2020-11551 sample 15.2.1; 2020-12327 sample 1.1.1; and 2020-11223 sample 1.1.1. RB1_EZ20-0359, 2020-11900 sample 1.1; 2019-07258 samples 10.1.1, 10.2.1, 10.3.1, 10.4.1, 10.5.1, 10.6.1, 10.7.1, and 10.8.1; 2019-19045 samples 10.1.1, and 10.2.1; and 2020-11901 sample 1.1.1.1, and 1.2.1.1. RB1_EZ20-0360, 2020-12329 sample 1.1; 2020-12222 sample 1.1, 2016-13894 samples 13.2.1.1.1, and 13.2.2.1.1; 2020-08286 samples 18.3.1, 18.4.1, 18.6.1, 18.7.1, 18.8.1, 18.9.1; 2020-11428 samples 32.1.1, 51.1.1, and 52.1.1. RB1_EZ20-0361, 2020-12328 sample 1.1.1; 2020-12014 samples 1.1.1.1, and 1.2.1.1; 2020-05456 sample 1.1; 2020-12532 samples 2.1.1. and 3.1.1; 2020-08286 sample 18.2.1. RB1_EZ20-0364
There were instances where multiple reagent blanks were used on an EZ1 run to separate references of the same gender. Normal practice is to send the reagent blank with the highest quantification value forward for processing or if all reagent blanks are undetected, send the last reagent blank forward for processing. Although having one

DNA-free reagent blank provides evidence of DNA-free reagents used on the associated samples, it is noted that reagents blanks that did not proceed beyond quantification in the reference EZ1 runs were not evaluated for possible contamination.

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

N/A

Actions Taken:

In the email communication with the Qiagen representative in October 2020, the technical leader asked to be added to the email notification list and the Qiagen representative confirmed her addition.
Quality and forensic biology management held a discussion to assess the reason why the letter sent by Qiagen in August 2020 was not known about until October 2020. From the conversation, the forensic biology manager identified that because many of the emails she receives from Qiagen are advertisement-based; she only realized in hindsight that she did not read this email as she assumed it was an advertisement.
The forensic biology manger had a conversation with the Qiagen representative on March 1, 2022, to determine what types of email notification lists exist. The forensic biology manager asked the Qiagen representative to include the technical leader, assistant technical leader, operations coordinator, technician supervisor, and the logistics manager to the Qiagen customer email distribution. The Qiagen representative confirmed these HFSC staff members were now part of the email notifications list.
The Qiagen representative informed the forensic biology manager that global communications for Qiagen is based out of Europe and any communication that comes from the global headquarters is posted to an outward facing website and he takes on the responsibility of gathering important communication and sending it to his customers in the Southwest region.
Moving forward everyone in the email notification list will forward messages to the technical leader to help her identify information of importance.
The above reagent blanks were re-injected and re-amplified and still contained activity. The technical leader reviewed the data and concluded the following:
For case 2020-05166, the report was issued with the following statement for sample 1.3.1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will

be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-05167, the report was issued with the following statement for sample 1.4.2.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-04982, the report was issued with the following statement for sample 1.3.1 (which includes sample 1.3.1.1): The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-05751, the report was issued with the following statement for sample 1.2 (which includes sample 1.2.1): The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-11428, the report was issued with the following statement for sample 16.2.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-07677, the report was issued with the following statement for samples 1.1.1, 2.1.1.1, 2.1.3.1, 2.2.1.1, 2.2.2.1, and 2.3.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2018-14914, the report was issued with the following statement for samples 4.1.1, 5.1.1, 7.1.1, and 8.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12016 the report was issued with the following statement for samples 1.1.1.1, 1.2.1.1, and 1.3.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12015 the report was issued with the following statement for samples 1.1.1.1, and 1.2.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-11551 the report was issued with the following statement for sample 15.2.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. See Quality Report 2020-097.
For case 2020-12327 the report was issued with the following statement for sample 1.1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-11223 the report was issued with the following statement for sample 1.1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Please contact the analyst for more information. See Quality Report 2020-097.

For case 2020-11900 the report was issued with the following statement for sample 1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2019-07258 the report was issued with the following statement for samples 10.1.1, 10.2.1, 10.3.1, 10.4.1, 10.5.1, 10.6.1, 10.7.1, and 10.8.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2019-19045 the report was issued with the following statement for samples 10.1.1, and 10.2.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-11901 the report was issued with the following statement sample 1.1.1.1, and 1.2.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12329 the report was issued with the following statement for sample 1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12222 the report was issued with the following statement for sample 1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2016-13894 the report was issued with the following statement for samples 13.2.1.1.1, and 13.2.2.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-08286 the report was issued with the following statement for samples 18.2.1 18.3.1, 18.4.1, 18.6.1, 18.7.1, 18.8.1, 18.9.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-11428 the report was issued with the following statement for samples 32.1.1, 51.1.1, and 52.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12328 the report was issued with the following statement for sample 1.1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. Please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12014 the report was issued with the following statement for samples 1.1.1.1, and 1.2.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-05456 the report was issued with the following statement for sample 1.1: The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will

be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2020-097.
For case 2020-12532 the report was issued with the following statement for samples 2.1.1. and 3.1.1: The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2020-097.

	Courtney Head		07/08/22
Section Manager:		**Date:**	
Division Director:	Amy Castillo	**Date:**	07/14/22

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

Technical Leader:	Cheron Maxwell	**Date:**	06/27/2022
CODIS Administrator:	Jennifer Clay	**Date:**	07/07/2022
Quality Director:	Erika Ziemak	**Date Closed:**	07/14/22