Quality Division Use Only

Quality Tracking #:	2019-093	**Classification:**	Corrective Action
Non-Conformance Level:	Class II	**Section:**	Biology/DNA
Date of Discovery:	12/19/19	**Date of Incident:**	12/19/19

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2019-15791 2018-01072 2019-16726 2019-17242 162982506 2019-16197 2017-23560 2019-15610 2019-16456 2018-19611 2019-16333 2019-16973 2019-17496 2019-16976 2018-14468 2019-15606 2019-17645	121782019 008131018 131064919 127416419 162982506 121581419 159901017 117329919 111909319 149679718 124918719 132881419 127602719 133971819 118041718 119343919 100818419

Description of Non-conformance:

An expired reagent was used during three low-level evidence extraction procedures. The reagent was used within twenty-four hours after expiration.

Additional Information/Follow-Up:

Because the affected samples were low level samples, re-portioning and re-extracting would likely require consumption. In order to avoid the needless consumption of evidence, a study was designed to determine the potential effect of using the expired cRNA reagent. The outcome of this study was used to determine whether the resulting casework data could be used for interpretation/reporting purposes. Known liquid blood was used to minimize any variability within the test samples. The blood was serially diluted to 1:10, 1:100, 1:1,000 and 1:10,000. Each dilution was then aliquoted into six tubes. Three of the tubes were then incubated overnight using the expired cRNA and the other three were incubated using non-expired cRNA. All samples (24 in total) were then extracted using the same extraction protocol used on the casework samples. All samples were then quantified and the quantification results for each concentration was averaged. The averaged quantification results for the samples using the expired cRNA were compared to those of the non-expired cRNA. Before the study was performed the parameters for accepting/using the casework data were established; if the average concentration from samples extracted with the expired cRNA were greater than the lower bound of one standard deviation of the non-expired cRNA this would support the use of the casework data with the expired cRNA for interpretation/reporting purposes. For the 1:10 dilutions, the expired cRNA quantified lower than the non-expired cRNA but was within one standard deviation of the non-expired cRNA. For the 1:100 dilution, the expired cRNA quantified higher than the non-expired cRNA. For the 1:1,000 dilutions the expired cRNA quantified lower than the non-expired cRNA but was within one standard deviation of the non-expired cRNA. Based on the results from this study, the data associated with the use of expired cRNA was approved for interpretation and reporting by the Technical Leader. Re-extraction, which would require consumption of the items tested, remains an option should it be requested.

Actions Taken:
As a result of this nonconformance, analysts are now required to have the reagent information verified by the verifying analyst before using reagents on casework. An email was sent on February 10, 2020 reminding technicians of the change in the verifying step. In addition, subsequent observations conducted by a quality specialist after the change in the workflow process confirmed technicians are verifying the expiration date, lot number and QC date before processing any samples. Reports associated with this nonconformance have the following report statement: "A sample preparation error occurred with this item. See Quality Report #2019-093 for additional information.

Summary of Root Cause Analysis: Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.
After reviewing documentation and interviewing multiple analysts, it was determined there was no requirement within the extraction procedure that dictated when analysts should review reagents for expiration dates, lot numbers and QC dates. This resulted in the analyst making an assumption that the reagents she was using were still within the expiration period and only after use in casework did she observe that this specific reagent had expired the day before.

Section Manager: Courtney Head **Date:** 12/17/20

Division Director: Amy Castillo **Date:** 12/21/20

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

Technical Leader: Cheron Maxwell **Date:** 12/03/2020

CODIS Administrator: Jennifer Clay **Date:** 12/10/2020

Quality Director: Erika Ziemak **Date Closed:** 01/08/21