Quality Division Use Only

Quality Tracking #:	2023-011	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	02/07/23	**Date of Incident:**	07/07/22

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2021-25659 2015-09939 2022-01852 2021-33863 2021-24465 2020-00802 2021-35254 2021-35281 2022-05064 2013-05298 2021-30588 2019-09245 2020-07022 2022-07531 2022-12813 2022-04971 2021-25345 2021-35281	065962121 091272515 019027422 152443021 056742121 007044120 166627921 165661621 052651122 008276613 SWIPE TEST 2021 063547519 068883020 082510822 144304822 047125122 063494421 165661621

Description of Non-conformance:

An expired internal lane size standard was used in the processing of two batches of Forensic Biology casework. The Technical Leader reviewed the internal lane size standard data for each sample and control and determined that the data was acceptable based on the predefined acceptance criteria for this standard.

Additional Information/Follow-Up:

During the final step of the laboratory DNA process, case samples undergo DNA fragment analysis by capillary electrophoresis (CE) using a genetic analyzer instrument. In this process, the internal lane standard is added to all samples and controls processed on the plate. The internal lane standard, although important to this part of the process, is not considered a critical reagent per FBI QAS standard. Critical reagents are those that require testing on known samples before use on forensic or casework reference samples. The internal lane standard fragments are used by the GeneMapper ID-X software to generate a sizing curve that calculates the base-pair size of the peaks present in the analyzed case samples and controls. Because the internal lane standard fragments are of a known base-pair value, the GeneMapper ID-X software has predefined acceptance criteria parameters that an internal lane standard must meet to be deemed as acceptable. When these criteria are not met the software will flag the sample/control for either review by the analyst or as failed.

In addition to the internal lane standard acceptance criteria, both the allelic ladder and the positive control have additional acceptance criteria. Both the allelic ladder and the positive control utilize the internal lane standard to generate base pair sizes of their peaks. If the sizing of the peaks is incorrect due to a bad internal lane standard, then the acceptance criteria for the allelic ladder and the positive control does not pass.

While reviewing a case, a DNA reporting analyst discovered that the internal lane size standard (LIZ, Lot # 01151014) expired December 18, 2022, had been used in the processing of Batch 61 on December 21, 2022. The DNA analyst notified the Technician Supervisor, Production Lead, and Technical Leader.

The DNA analyst confirmed that the expired standard had been disposed and was no longer available in the laboratory. The Technician Supervisor at the time (now Assistant Manager) reviewed all batches and trays processed after the expiration date of the internal lane size standard and identified that this standard had been used in the processing of Batch 52 on December 20, 2022. No other batch runs were identified as part of this review.

Technicians are required to have the reagent expiration date, lot number, and QC date verified by a second analyst before using reagents on casework. Although the verification process checked that the reagent information was correctly transcribed, the technicians and the verifying analysts inadvertently failed to connect that the transcribed date was in the past and the standard had expired days prior.

The Technical Leader reviewed the data generated from each batch and determined the data could be used for interpretation and reporting purposes. The positive control and allelic ladder contain all the appropriate allele calls which is indicative of a passing internal lane sizing standard, and the internal lane sizing standard for every sample and control produced results as expected with no unusual peak morphology.

The Operations Coordinator at the time (now Assistant Technical Leader) contacted the vendor technical support for guidance in respect to the expiration date assigned to the internal standard. The vendor was able to confirm that the standard would be expected to perform as intended beyond its expiration date as long as the standard is stored properly, protected from light, and handled in a manner to not introduce contaminants.

The Quality Division is tracking this notification as an incident because there was no technical impact to these cases.

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:
The Technician Supervisor communicated the discrepancy to all DNA reporting analysts via email on February 8, 2023, and directed analysts to notify the Technical Leader and herself if the analysts are currently reporting a case or have released a report associated to the identified batches and/or the expired standard. **Two cases, 2013-05298 and 2015-09939, were issued prior to the discovery of this incident and consequently without a report statement. Although it is not required to amend an issued report for the sole purpose of adding a report statement, the DNA analysts assigned to the cases were made aware and decided to not amend the reports. An email about this notification was added to the cases in LIMS for documentation purposes. The other cases associated with the affected batches will be reported with the following report statement: "A sample preparation error occurred. Please see quality report 2023-011 for additional information."** **The Operations Coordinator and Logistics and Equipment Manager monitor reagents in the Forensic Biology section. To increase the visibility of expiring reagents the Operations Coordinator created a calendar reminder for the beginning of each month to prompt the Logistics and Equipment Manager and himself to identify the reagents set to expire soon (next two months) and manage the disposal of those reagents before their expiration date, thus minimizing the likelihood of reoccurrence of this incident. This calendar reminder and action is meant to be a more proactive approach to monitor expiring reagents.** **In addition, the Technician Supervisor addressed this nonconformance at the February 23, 2023 technician meeting to remind technicians and verifying analysts to not only ensure the correct transcription of dates but to check that the reagents have not expired when verifying this information before use in casework.**

Section Manager: Courtney Head **Date:** 04/30/23

Division Director: Amy Castillo **Date:** 04/30/23

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

Technical Leader: Cheron Maxwell **Date:** 04/28/2023

CODIS Administrator: Jennifer Clay **Date:** 04/29/2023

Quality Director: Jackeline Moral **Date Closed:** 05/01/23