Quality Division Use Only

Quality Tracking #:	2023-031	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	07/11/23	**Date of Incident:**	05/22/23

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2021-31855 2022-00618	130334421 006295322

Description of Non-conformance:

A Forensic Biology technician documented the incorrect volume of a reagent for an extraction.

Additional Information/Follow-Up:

While reviewing the data, the DNA analyst assigned to author case 2021-31855 noticed that the volumes of TE buffer and buffer ATL documented on the extraction worksheet would not have prepared enough diluted ATL master mix to perform the high-level extraction procedure.

For this type of high-level extraction, diluted ATL master mix is prepared using one-part buffer ATL diluted with two parts TE buffer. Based on the number of samples within this batch, the volume of the buffer ATL should have been 1800uL and the volume of TE buffer should have been 3600uL; however, the TE buffer was documented on the extraction worksheet as 2400uL.

The technician is no longer employed at the Houston Forensic Science Center but was contacted by the technical leader for an interview. The technician did not recall running out of diluted ATL master mix amid an extraction procedure and stated that she routinely prepares more master mix than required to ensure she has enough to perform the extraction.

Although it cannot be determined for certain whether the technician prepared the diluted ATL master mix using an incorrect volume of the TE buffer, if the incorrect documented volume had been used, this would have been discovered at the extraction step since the master mix would have been depleted before completing this process.

The Forensic Biology assistant manager reviewed the six high-level extractions performed by this technician in the past year since August 2022 and no other discrepancies in documented volumes were noted. In addition, the technician supervisor reviewed the 22 high-level extractions from all technicians in the past year since August 2022 and noted three other batches with minor discrepancies in the documented volumes, but the Forensic Biology section determined each discrepancy to be minimal and have no technical impact on the results.

The assistant manager, the technician supervisor, and a quality specialist reviewed the current process to determine if process changes would be warranted. In addition, the technician supervisor addressed this nonconformance at the technician meetings on July 27, 2023 and August 24, 2023 to allow technicians to contribute to the discussion.

From these meetings, the technicians articulated a need for consistency in their process of manually calculating how much diluted ATL master mix to prepare for an extraction. At the request of the technicians to eliminate any manual calculations and standardize the process among technicians, the technician supervisor created a table that depicts the volumes of TE buffer and buffer ATL to be used to prepare diluted ATL master mix based on the number of samples within a given extraction. This table was published as a controlled document on October 10, 2023 and posted in the laboratory as a reference guide.

Additionally, the previous verification process involved the verifier reviewing the extraction worksheet at the end of the process to ensure diluted ATL master mix reagent volumes were documented; however, there was not a verification step to verify the volumes were correctly documented on the extraction worksheet prior to preparing the diluted ATL master mix.

A new verification step will be introduced at the beginning of the process, before reagents are added to the samples. The technician assigned to prepare the extraction worksheet will record the volumes of TE buffer and buffer ATL to be used to prepare diluted ATL master mix based on the number of samples within a given extraction. A second technician will then verify the volumes are correctly documented on the extraction worksheet prior to preparing the diluted ATL master mix, and this verification will be documented on the extraction worksheet.

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:
For the cases affected, the technical leader reviewed and approved the generated data for interpretation and reporting purposes. **The report for case 2021-31855 was issued with the following report statement for the affected samples: "A quality incident occurred. Please see quality report 2023-031 for additional information."** **The report for case 2022-00618 was in the review process prior to the discovery of this incident and consequently issued 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 analyst assigned to the case was made aware and decided to not amend the report. An email about this notification was added to the case in LIMS for documentation purposes. In addition, a copy of this quality report will be added as a report in the case record.** **The technician supervisor detailed the new process and verification step for high-level extractions during the October 19, 2023 technician meeting. At the request of the technicians, an additional line item was included on the non-differential extraction worksheet checklist to further ensure that diluted ATL master mix reagent volumes have been documented on the extraction worksheet.**

Section Manager: Courtney Head **Date:** 11/02/23

Division Director: Amy Castillo **Date:** 11/02/23

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

Technical Leader: Cheron Maxwell **Date:** 11/01/2023

CODIS Administrator: Jennifer Clay **Date:** 11/01/2023

Quality Director: Jackeline Moral **Date Closed:** 11/02/23