Quality Division Use Only

Quality Tracking #:	2022-012	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	02/03/22	**Date of Incident:**	02/03/22

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2022-00352	**22-5701-U2588A**

Description of Non-conformance:

A Forensic Biology technician inadvertently omitted a required negative control from a quantification plate.

Additional Information/Follow-Up:

While reviewing the quantification data for a proficiency test, the technician noted that the 7500 Real-Time PCR instrument software indicated there may be an issue with the negative control sample. Upon further investigation, the technician discovered that although the negative control was appropriately entered in the instrument software, there was no volume present in the negative control well of the quantification plate. The technician inadvertently omitted the required negative control from the manual quantification setup worksheet, and therefore did not add the negative control to the quantification plate. Because the negative control was not documented on the worksheet, the technician forgot to add the negative control to the well of the quantification plate.

The technician detailed her process for creating a manual quantification setup worksheet, which is consistent with the process for creating an automated quantification setup worksheet with the exception that the negative control is not automatically included on the manual quantification setup worksheet and must be manually entered into the worksheet. Although this is a standard practice, it has potential for oversight.

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:
Because the negative control was not included on the quantification plate, the results generated from the quantification plate were not used for interpretation and reporting purposes. A second quantification plate was created and included all samples and the required negative control. The negative control yielded expected results, and the results of the second quantification plate were used for interpretation and reporting purposes. A report was issued with the following statement: "A processing error occurred. See quality report 2022-012 for additional information." The Technician Supervisor addressed this nonconformance at the technician meeting on March 10, 2022 to clarify whether technicians are verifying the negative control in addition to verifying the sample order during quantification. Following the discussion, the technicians agreed to visually confirm the negative control on the worksheet when conducting a sample order verification for a manual quantification setup. In addition, the Technician Supervisor clarified that not all technicians place the physical DNA dilution buffer tube on their tube rack during setup. Therefore, the negative control should be listed on the manual quantification setup worksheet for the verifier to confirm, at a minimum, the presence of the negative control on the worksheet during the sample order verification. Because there have been no re-occurrences since incident 2022-012 occurred, this event was determined to be an isolated incident. In the meantime, the Operations Coordinator will investigate means to automatically add the negative control to the manual quantification setup worksheet.

Section Manager: Courtney Head **Date:** 01/10/23

Division Director: Amy Castillo **Date:** 01/18/23

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

Technical Leader: Cheron Maxwell **Date:** 12/28/2022

CODIS Administrator: Jennifer Clay **Date:** 01/04/2023

Quality Director: Erika Ziemak **Date Closed:** 01/18/23