



Quality Division Use Only

Quality Tracking #:	2020-001	Classification:	Incident
Non-Conformance Level:	N/A	Section:	Biology/DNA
Date of Discovery:	12/09/19	Date of Incident:	12/09/19

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2019-15960 2019-15688	124754219 121238819

Description of Non-conformance:

An analyst was preparing two separate master mixes for two differential protocols. While preparing the second master mix, the analyst noticed that instead of reaching for the ATL buffer, which was the next reagent needed in the protocol, the G2 buffer was accidentally grabbed. The analyst immediately stopped this master mix preparation but is unable to say with certainty as to if the first master mix preparation had been prepared using the correct reagent.

Additional Information/Follow-Up:

The analyst was working on two differential protocols. The first initial incubation master mix the analyst prepared was for worklist 15060. While the analyst began to prepare the initial incubation master mix for worklist 15062, she noticed she had grabbed the G2 Buffer, not the ATL Buffer needed. The analyst was able to stop the master mix preparation for 15062 but reached out to her supervisor to inform her of the slight concern that the G2 Buffer for the 15060 preparation could have been used.

The data for 15062 was not affected by this nonconformance because the analyst was able to stop the procedure and prepare a new master mix for these samples.

The technical leader at the time of this nonconformance reviewed the data that was generated for 15060 and recommended that all samples be re-extracted. Based on the data reviewed, re-extraction was determined to require consumption of all samples.



Actions Taken:

Permission to consume was requested for all samples.

Permission to consume has not been granted for case 2019-15688, the following statement was included on the report: "No results will be reported for this item due to a sample preparation error. Retesting will require the consumption of this item, which may not be conducted until permission to consume is received. See Quality Report #2020-001 for additional information."

Permission to consume was granted for case 2019-15960, the following statement was included on the report for the original portions: "No results will be reported for these items due to a sample preparation error. See Quality Report #2020-001 for additional information." The results from the second extraction were reported in accordance with the applicable standard operating procedures.

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

Section Manager: Courtney Head

Date: 08/13/20

Division Director: Amy Castillo

Date: 08/14/20

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

Technical Leader: Courtney Head

Date: 08/07/2020

CODIS Administrator: Jennifer Clay

Date: 08/13/2020

Quality Director: Erika Ziemak

Date Closed: 08/16/20