Quality Division Use Only

Quality Tracking #:	2022-042	**Classification:**	Corrective Action
Non-Conformance Level:	Class II	**Section:**	Toxicology
Date of Discovery:	07/04/22	**Date of Incident:**	05/16/22

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2022-03066 2022-03067	FTC-A-2022-01 FTC-A-2022-02

Description of Non-conformance:

The quantitative results for two items in a confirmatory Toxicology proficiency test (PT) were inconsistent with the PT provider's consensus report. These items contained a correctly identified analyte that was lower than the acceptance criteria. The other analytes contained in these samples were correctly identified and were within the acceptance criteria.

Additional Information/Follow-Up:

The quantitative results for morphine in FTC-01 (2022-03066) and for delta-9-THC in FTC-02 (2022-03067) were lower than the acceptance criteria and were deemed by the PT provider as "unacceptable". The PT provider statistically determines the limits of acceptability range based on the reported results from the participating laboratories and grades the participant based on their qualitative and quantitative reported results.

Morphine was reported as 39.0 ng/mL and the acceptability range determined by the PT provider was 82.3 through 170.3 ng/mL. Delta-9-THC was reported as 8.1 ng/mL and the acceptability range determined by the PT provider was 14.8 through 29.6 ng/mL.

The other analytes contained in these samples were correctly identified and were within the acceptance criteria.

Summary of Root Cause Analysis:
Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

Based on the results obtained from the re-analysis and from the independent laboratory, the original analysis was satisfactorily completed and neither the methods nor the original analysts had poor precision. The cause for this lower-than-expected results were attributed to the instability of the analytes in the sample and the time delay between the date of receipt and date of confirmatory analysis.

Actions Taken:

Both samples were re-analyzed by an independent analyst using the same method and drug controls. The re-analysis results for 2022-03066 were still comparable to the original analysis (morphine 39.87 ng/mL), and the results for 2022-03067 were lower than the original analysis (delta-9-THC 3.69 ng/mL). The QC logs were also reviewed by the section to ensure there was no systemic bias present in the performance of the drug assay method.

In addition, the same samples were outsourced to an independent laboratory for the corresponding drug assay analysis. The results of the outsource laboratory for 2022-03066 were also consistent with the original and the re-analysis values (40 ng/mL). The results of the outsource laboratory for 2022-03067 were even lower than the re-analysis analysis (2.3 ng/mL). The results from the independent laboratory demonstrated that there were no issues associated to the analytical methods and were related to the samples. Upon initial receipt, the samples were maintained in the section's evidence freezer.

Upon looking at the date that these samples were analyzed it was noted that these two cases were received by the laboratory on March 10, 2022. The confirmatory analysis for 2021-03066 was performed on April 21, 2022, and for 2021-03067 on March 31, 2022. The reason for the delay in analyzing these items was because the Toxicology section schedule for running confirmatory assays for casework are spread out and distributed throughout the month. One analyst prepares batch samples and runs one type of assay a day per instrument. Assays are alternated throughout the weeks, so all types of confirmatory assays are completed as a way to make casework a more efficient process.

As means to prevent this from re-occurring, the section made several process changes when confirmatory blood proficiency test samples are received. The blood PT cases rather than being screened by several analysts, will be screened at the same time by one assigned analyst. Depending on the screening results, the confirmatory drug assays that screened positive will be given priority in the analytical workflow schedule. In addition, several changes were also made in the receipt and inception process. The Quality Division notifies via email the Logistics Department, CS/CM Division, and the Toxicology section when Toxicological PT samples are scheduled to be shipped and their intended receipt date. This notification: 1) helps the Logistics Department know when personnel is needed to receive these samples, 2) prompts the Toxicology section to assign analysts to these samples, and 3) notifies CS/CM of PT samples that need to be prioritized and entered in their accessioning workflow. The Quality

Division after notifying these sections pre-assigns a forensic case numbers and pre-prints case labels so the PT samples can be quickly re-packaged and transferred to CS/CM's evidence refrigerator upon their receipt by HFSC.

These process changes were tested with another round of blood confirmatory PT samples (FTC-B-2022) issued from the same PT provider*. The results for the PT samples associated to that PT round were deemed satisfactory by both the PT provider and HFSC's Toxicology management. These process changes created an effective receipt and inception process that helps in the evaluation of the quality and performance of the Toxicology section technical methods. Proficiency tests is a reliable tool for laboratories to use to effectively evaluate the quality of their analytical results. The process changes made for this type of submission were done with the intent of evaluating the performance of the Toxicology section technical processes and methods. While these changes were determined to be effective to allow the Toxicology section to confirm the appropriateness of their validated methods for drug confirmation analysis using proficiency test samples, similar changes cannot be made to the Toxicology section's casework workflow because they are not sustainable as a routine practice. There is a known inherent risk involved in drug analyses due to variations in analyte stability and/or sample conditions that may affect the reported concentration in casework samples.

***NOTE: This corrective action remained open until the FTC-B-2022 PT samples were tested and their results were evaluated by the PT provider. The Toxicology section and the Quality Division wanted to determine if the process changes denoted above helped in the evaluation of their technical methods.**

	Dayong Lee		10/17/22
Section Manager:		**Date:**	
Division Director:	Amy Castillo	**Date:**	10/24/22

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

Technical Leader:	N/A	**Date:**	N/A
CODIS Administrator:	N/A	**Date:**	N/A

Quality Director:	Erika Ziemak	**Date Closed:**	10/28/22