

Incident / Corrective Action Plan Form

BAC ISTD Recovery

Incident/Corrective Action Number: 2024-06

Date of Discovery: July 16, 2024

Incident Date(s): June 26, 2024

Section: Toxicology

Reported By: Toxicologist

Classification: Incident

Incident Type: Procedural

Description of Non-Conformity:

The second Blood QC A in batch BAC_20240626_KB had internal standard recoveries for both FID1 and FID2 outside of the $\pm 10\%$ range of the average area count of the calibrators. Per TOX-02-01, section 13.4, this is acceptable because internal standard recovery only pertains to case samples and not controls.

TOX-02-01 Ethanol Analysis Using Headspace Gas Chromatography-Flam
Ionization Detection

9.0 Verification of Whole Blood Controls and Internal Standard

9.2 Internal Standard

9.2.1 Prepare two negative samples with the newly prepared internal standard. These samples should be added to the end of a casework run.

9.2.2 Compare the area of the new internal standard to the area of the current internal standard in the negative control. The internal standard area of the newly prepared lot should be within $\pm 20\%$ of the current lot.

13.0 Acceptance Criteria

13.4 Internal Standard

13.4.1 Internal standard recovery for case samples shall be within 10% of the average internal standard area of the calibrators.

Root Cause Analysis:

The standard operating procedure only dictates the area of any newly prepared internal standard be within $\pm 20\%$ of the current lot. The new internal standard lot met the acceptance criteria of being within $\pm 20\%$ of the previous lot.

Level of Non-Conformity: Incident

Level of Non-Conformity Determination and its Impact on Casework: N/A

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Preventive Action(s): Further consideration will be given in revising the SOPs to include limits on controls.

Proposed Corrective Action(s): N/A

Timeframe for Corrective Action(s): N/A

Melina Henry Toxicology
Applicable Analyst / Discipline

7/30/2024
Date

Kayla M. Bayler Toxicology
Applicable Analyst / Discipline

8/1/2024
Date

Allen Winters
Lab Quality Manager

6 Aug. 2024
Date

Derek Waters
Laboratory Director

20 Aug 2024
Date