

## Incident / Corrective Action Plan Form

### BAC ISTD Recovery

**Incident/Corrective Action Number:** 2024-17

**Date of Discovery:** August 30, 2024

**Incident Date(s):** August 29, 2024 and September 16, 2024

**Section:** Toxicology

**Reported By:** Toxicologist

**Classification:** Incident

**Incident Type:** Procedural

**Description of Non-Conformity:**

Both the last Blood QC A in batch BAC\_20240829\_KB and the third Blood QC A in batch BAC\_20240916\_MH had internal standard recoveries for both FID1 and FID2 outside of the  $\pm 10\%$  range of the average area count for controls. 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.*

*13.2.4 Negative, air blank, and DI water controls shall be clear of significant peaks of interest (i.e., area counts  $>10\%$  of the LOQ). All other quality controls shall meet acceptance criteria to report ethanol quantitatively.*

*13.2.5 If the concentration of a calibrator does not meet acceptance criteria, non ethanol case sample results may be reported. If a control does*

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*not meet acceptance criteria, the batch may be partially acceptable.  
Control failures will be handled on a batch by batch basis.*

**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

**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

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Applicable Analyst / Discipline

9/23/2024  
Date

*Melvin Henry Toxicology*  
Applicable Analyst / Discipline

9/23/2024  
Date

*Ari White*  
Lab Quality Manager

27 Sept. 2024  
Date

*Dave Dean*  
Laboratory Director

27 Sept 2024  
Date