

Incident / Corrective Action Plan Form Internal Audit: BAC Analysis

Incident/Corrective Action Number: 2024-15

Date of Discovery: May 29, 2024

Incident Date(s): May 29, 2024

Section: Toxicology

Reported By: Quality Assurance Manager

Classification: Incident

Incident Type: Procedural

Description of Non-Conformity: A number of nonconformances were found during the 2024 Internal Audit, one of which was seen during the direct observation of the analyst completing BAC_20240529_KB batch. I did not observe the DI water control used to monitor potential contamination from the environment uncapped during the entire preparation process.

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

7.5.1 The DI water control is used to monitor potential contamination from the environment throughout the sampling process. It consists of 100 μ L of DI water added to a headspace vial and left uncapped for the duration of the sampling process. Internal standard is added at the end of sampling.

11.3 Prepare DI water control and leave open for the duration of the sampling process. After sampling is completed, add internal standard, cap, and crimp.

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.

Root Cause Analysis: As the auditor, I did not observe the DI water control open during the sampling process. When interviewing the analyst, they claimed to have left it open. Being that the observation report was not discussed and signed until August 2, 2024, it could have been either party's misremembering.

Level of Non-Conformity: N/A

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Level of Non-Conformity Determination and its Impact on Casework: The work product was not affected. There were no ethanol peaks in the DI water control.

Preventive Action(s): N/A

Proposed Corrective Action(s): N/A

Timeframe for Corrective Action(s): N/A

Kayla M. Bayle / Toxicology
Applicable Analyst / Discipline

8/26/2024
Date

Allia Wirth
Lab Quality Manager

29 Aug. 2024
Date

Derek Sear
Laboratory Director

29 Aug 2024
Date