

Incident / Corrective Action Plan Form TOX BAC Instrument Verifications

Incident/Corrective Action Number: 2024-16

Date of Discovery: August 27, 2024

Incident Date(s): January 25, 2024, January 30, 2024, August 20, 2024

Section: Toxicology

Reported By: Toxicologist

Classification: Incident

Incident Type: Procedural

Description of Non-Conformity: Both Toxicologist forgot to fill out the LAB-TOX-12 Verification of Quantitative Methods when performing the August 2024 instrument verifications. They were not filled in at the time of verification or mentioned in review. The Lead Toxicologist had completed her verification earlier in the month on August 7th, but did not complete and sign LAB-TOX-12 until August 19th. The other Toxicologist started her verification batch on August 20, 2024. It was upon her verification batch being returned for correction and the review of LAB-TOX-08 BAC Verification Summary Worksheet of previous verifications that she realized she had overlooked the completion of LAB-TOX-12. It was then that the verification summaries were completed.

The error needing correcting in the reviewed Toxicologist's batch was the documented internal standard range being outside of the accepted 10% on LAB-TOX-08. The Toxicologist then went back to view previous verification batches to verify the acceptance criteria was being met. The spreadsheet was thought to have calculated the internal ratio range for FID1 and FID2 to be within 10% but was found to be calculating 20%. All batches were reviewed and corrected. Batches from January 25th and 30th were corrected manually while the batch from August 20th was corrected electronically.

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

5.1 Verifications shall be performed after any maintenance, repair, or changes in the method parameters, excluding changes made to data acquisition. Changes made to data acquisition shall require a validation to be performed. The verification run must meet acceptance criteria defined in 5.4.4. If the acceptance criteria is not met, appropriate actions will be taken to remedy the issue. Verification runs shall be documented in the maintenance log.

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5.4 A major or minor verification shall be performed dependent upon the extent of the maintenance, repair or changes made to the method.

5.4.4 Verification acceptance criteria will be as follows:

5.4.1.1 Bias: % bias $\leq 5\%$ for target concentrations >0.05 g/100mL

5.4.1.2 Within-run precision: %CV $\leq 10\%$

5.4.1.3 Between-run precision (major verifications): %CV $\leq 10\%$

13.0 Acceptance Criteria

13.2.3 Average ethanol concentrations from FID1 and FID2 ≤ 0.05

g/100mL shall be within 10% of the target concentration. Average ethanol concentrations from FID1 and FID2 >0.05 g/100mL shall be within 5% of the target concentration.

Root Cause Analysis: Both Toxicologist forgot to fill out the Verification of Quantitative Methods, LAB-TOX-12. It was also not caught in review. The Lead Toxicologist also failed to remember to notify the other Toxicologist that she noticed an issue during her performed verification with the calculated acceptance criteria for the internal standard area count.

Level of Non-Conformity: N/A

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

Casework was not affected. The internal standard calculated during the verification process does not have any effect on the internal standard calculation when analyzing cases. Due to not stating the acceptance criteria of the internal standard area count to be the same acceptance criteria used during casework, a note will be made in past verifications if the calculated internal standard is outside of the 10% acceptance criteria. It will not be re-run since the calibrators and controls are known values.

Preventive Action(s):

1. TOX-02 Ethanol Analysis Using Headspace Gas Chromatography has been updated so that the same 10% acceptance criteria for internal standard regarding casework will also be applied to verification.
2. The cells calculating the acceptance criteria for the IS area count in LAB-TOX-08 BAC Verification Summary Worksheet has been updated from 20% to 10%.
3. LAB-TOX-08 BAC Verification Summary Worksheet has been updated to include an initials and date line for when the verification excel is completed.
4. LAB-TOX-12 Verification of Quantitative Methods has been updated so that anywhere it says validation be changed to verification.

Proposed Corrective Action(s): N/A

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Timeframe for Corrective Action(s): N/A

Kayla M. Baylor / Toxicology

Applicable Analyst / Discipline

11/4/2024

Date

Melina Henry / Toxicology

Applicable Analyst / Discipline

11/4/2024

Date

Alvin Winter

Lab Quality Manager

5 Nov. 2024

Date

Derek S. [Signature]

Laboratory Director

5 Nov 2024

Date