

## Deviation from Documented Procedures Form BAC Low QC Reference Material

**Dates of Deviation:** 02/26/2024

**Type of Deviation:** Establishing Target Concentration of NIST 0.08 % ethanol standard reference material

**Describe the Deviation:**

The typical Lipomed 80 mg/ dL standard was unavailable, so a NIST 0.08 % standard reference material was ordered. Standard operating procedure (SOP) TOX-02 dictates that the low quality control used in blood alcohol analysis be 0.08 g/ 100 mL with an uncertainty of  $\pm 5\%$ , which produces a tolerance of 0.076 g/ 100mL to 0.084 g/ 100mL. The 0.08% NIST standard ordered, SRM #2893a, established a certified value of 0.07663 g/ 100mL, with an uncertainty range of 0.07566 g/ 100 mL to 0.0776 g/100 mL. While the certified value of the NIST standard SRM #2893a is within the SOP requirement of 0.08 g/ 100 mL  $\pm 5\%$ , its uncertainty falls outside of the governing range. Due to this, the target concentration of this standard was established in-house by running a minimum of 12 replicates over more than one run to establish the mean. The batches for establishing the target were BAC\_20240125\_KB, BAC\_20240130\_MH, BAC\_20240214\_KB, BAC\_20240214\_MH, and BAC\_20240222\_MH. The in-house target concentration was established on February 22, 2024, to be 0.0778 g/ 100 mL  $\pm 5\%$ .

Future consideration will be given to the confining language of the listed high and low quality controls in TOX-02 SOP to include the certified value from a qualified provider.

**Reason for Deviation:**

Due to the current unavailability of Lipomed 80 mg/dL ethanol standard solution, a 0.08% ethanol water solution standard reference material was purchased from NIST. The certificate of analysis (COA) for the NIST 0.08 % standard reference material (SRM #2893a) states a certified value of  $0.07663 \pm 0.00097\%$ . The acceptance criteria for BCCL Ethanol Analysis of quality controls is based off a target concentration of 0.08 g/100 mL.

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

*7.2 Low Quality Control (Low QC) - 0.08 g/ 100 mL*

*7.2.1 The Low QC is a quality control from an external source. The contents of the vial may be transferred to a labeled container and capped.*

*13.0 Acceptance Criteria*

*13.2 Calibrators and Controls*

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

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

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**Laboratory Number(s) (if applicable):**

This will apply to batches run after February 22, 2024, that contain the NIST 0.08% SRM #2893a as the low quality control sample until Lipomed 80 mg/dL is available for purchase.

Applicable Analyst Melina Henry

Date 2/29/2024

Applicable Analyst Kayla M. Bayler

Date 2/29/2024

Quality Assurance Manager Allie Wint

Date 29 Feb. 2024

Laboratory Director Derek Deane

Date 02/29/2024