

Deviation from Documented Procedures Form Continued Use after Notification of Impure Lipomed 80 mg/dL Ethanol Standard Solution

Dates of Deviation: 11/09/2023 – 12/01/2023

Type of Deviation: Procedural; Continued use after notification of impure Lipomed 80 mg/dL ethanol standard solution (Lot# 15122021-A)

Describe the Deviation:

The BCSO Crime Laboratory is using an 80 mg/dL ethanol standard solution from Lipomed (lot# 15122021-A), despite a notification from Lipomed that their recent retesting found an impurity and concentration variations. The BCSO Crime Laboratory was able to run the 80 mg/dL ethanol standard solution in batch BAC_20231109_KB and it successfully meet acceptance criteria. In order to have reviewable data available for the December assessment, the original 80 mg/dL ethanol standard solution from Lipomed will serve as the Low QC.

TOX-02-00 Ethanol Analysis Using Headspace Gas Chromatography-Flame Ionization Detection

"7.2 Low Quality Control (Low QC) – 0.080g/100mL

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.

LOG-16-08 Standards, Controls, and Reagents

"3.2 Controls

3.2.1 For Laboratory procedures calling for the use of control samples, a reputable sample shall be used or prepared. The quality of any reference material or control shall be verified or confirmed before use and may require periodic verifications. If acceptable testing is not achieved the reference materials or controls shall not be used in casework."

Reason for Deviation:

The BCSO Crime Laboratory received an 80 mg/dL ethanol standard solution from Lipomed (lot# 15122021-A). The standard was verified to meet the acceptance criteria of being within 5% of the target concentration of 80 mg/dL throughout validation of the BAC.M method completed October 4, 2023. On October 23, the laboratory was notified that Lipomed found an impurity along with concentration variations in their latest rescheduled testing. Lipomed sent a replacement product from LGC (lot# 1-H111958WA). However, the lot did not meet the acceptance criteria of being within 5% of the target concentration of 80 mg/dL in BAC_20231024_KB. Lipomed was contacted about the contrary findings but has yet to respond to the inquiry. An in-house 80 mg/dL control was made and verified by analyzing it in duplicate with a calibration curve and already established controls on October 26, 2023. This in-house control was previously referenced in a Toxicology deviation dated October 25, 2023. However, when the in-house control was run again in order to generate reviewable data for the upcoming Toxicology assessment in December, it failed to meet the acceptance criteria. Since the original 80 mg/dL ethanol standard solution from Lipomed (lot# 15122021-A) repeatedly met the acceptance criteria during the validation, it was decided that it would be used. The lot was verified again in duplicate in batch BAC_20231109_KB.

This deviation will go into effect once all staff have signed to exclude the Laboratory Director. The Laboratory Director shall acknowledge the deviation upon their return from leave.

Laboratory Number(s) (if applicable):

This will apply to batches run the remainder of November 2023 in order to generate reviewable data for the ANAB assessment scheduled December 4-6, 2023, for the re-addition of Toxicology

Approval Date: October 26, 2021
Effective Date: October 26, 2021

Issuing Authority: Upper Management
Authorized for Distribution by Laboratory Director

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to our scope of accreditation. So long as acceptance criteria is still met, the original Lipomed 80 mg/dL ethanol standard solution (lot# 15122021-A) will continue to be used for training and research purposes.

Brazoria County Sheriff's Office Crime Laboratory

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Toxicologist

11/13/2023
Date

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11/13/2023
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Approval Date: October 26, 2021
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