

Deviation from Documented Procedures Form Lipomed 80 mg/dL ethanol standard solution recall

Dates of Deviation: 11/07/2023

Type of Deviation: Issue with Lipomed 80 mg/dL ethanol standard solution (Lot# 15122021-A)

Describe the Deviation:

An in-house 80 mg/dL control was made and verified by analyzing it in duplicate with a calibration curve and already established controls. The controls consisted of Cliniqua whole blood ethanol control level 1 and 2 and a Lipomed 400 mg/dL ethanol standard solution. This in-house control was previously referenced in a Toxicology deviation dated October 25, 2023. This control will be used in the analysis of fortified whole blood samples and unanalyzed proficiency samples to generate reviewable data for the upcoming Toxicology assessment in December.

Reason for Deviation:

The BCSO Crime Laboratory received an email from Lipomed stating that during retesting they found an impurity in lot# 15122021-A for the 80 mg/dL ethanol standard solution along with concentration variations. Lipomed sent an equivalent product from LGC (lot# 1-H111958WA). The lot was used in BAC_20231024_KB and the lot was not within 5% of the target concentration of 80 mg/dL. Lipomed was contacted about the contrary findings but has yet to respond to the inquiry.

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.

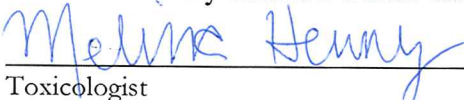
In order to have reviewable data available for the December assessment, the in-house control will serve as the Low QC for this sample. This deviation to TOX-02-00 section 7.2 will go into effect once all staff have signed to exclude the Quality Manager. The Quality Manager shall acknowledge the deviation on their return from leave.

Laboratory Number(s) (if applicable):

BCCL-22-0256 BCCL-22-1589 BCCL-23-0233

Additionally, fortified samples may be assigned a BCCL number to generate a reviewable laboratory report for the assessors. This will be determined at a future date.

Brazoria County Sheriff's Office Crime Laboratory



Toxicologist

11/07/2023
Date



Toxicologist

11/7/2023
Date



Quality Assurance Manager

20 Nov. 2023
Date



Laboratory Director

07 Nov 2023
Date

Approval Date: October 26, 2021
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