

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

**Dates of Deviation:** 10/25/2023

**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 will be made and verified by analyzing it in duplicate with a calibration curve and already established controls. These controls will consist of Cliniqua whole blood ethanol control level 1 and 2 and a Lipomed 400 mg/dL ethanol standard solution. After successful verification of the in-house control, a proficiency test (PT) sample due October 30, 2023 (BCCL-2023-1491\_001) will be analyzed using the in-house control and the previously mentioned established controls.

**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.

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.*

Since the PT sample is due October 30, 2023, 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-23-1491

**Brazoria County Sheriff's Office Crime Laboratory**

Melina Henry  
Toxicologist

10/25/2023  
Date

Kayla M. Bayler  
Toxicologist

10/25/2023  
Date

Ari Wuth  
Quality Assurance Manager

20 Nov. 2023  
Date

Derek Sanders  
Laboratory Director

25 Oct 2023  
Date

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

Issuing Authority: Upper Management  
Authorized for Distribution by Laboratory Director