Deviation from Documented Procedures Form
BAC Whole Blood Control Deviation

Date of Deviation: January 4, 2024 – March 4, 2024

Type of Deviation: Procedural

Describe the Deviation:
Whole blood controls were tested for stability past the manufacturer's 45-day expiration date after opening. The following whole blood controls Levels 1 and 2 that were open past 45 days were added to batch runs in addition to unexpired controls in order to re-verify their concentration:

Whole Blood Ethanol Control Level 1 (S-22-031B and S-22-031C)
Lot Number: 2101199
Expiration Date: 2025-02-28

Whole Blood Ethanol Control Level 2 (S-23-5000)
Lot Number: 2110181
Expiration Date: 2026-03

The storage and stability of both whole blood controls states on the COAs as follows:

> *LiquiSPx Whole Blood Ethanol Control is stable until the expiration date on the package when stored unopened at 2-8° C and 45 days after opening when stored at 2-8° C. Discard any contaminated material. Microbial contamination is evidenced by an increase in turbidity and/or a characteristic odor.*

The acceptance criteria for re-verification was 5%. Both Toxicologists added at least one of the above listed whole blood control levels to their batch runs to test for stability. Notes whether re-verification criteria were met or failed are in each batch. S-22-031B and S-23-5000B were run in BAC_20240104_KB past 60 days. S-22-031B was not able to achieve the target. S-23-5000C was run in verification batch BAC_20240125_KB and able to achieve the acceptance criteria. S-22-031C was run in BAC_20240304_MH and able to achieve re-verification 60 days after opening.

> TOX-02-01 Ethanol Analysis Using Headspace Gas Chromatography
> *7.4 Whole Blood Controls (Blood QC A and Blood QC B)*
> *7.4.1 Blood QC A is a purchased control at a low ethanol concentration.*
> *7.4.2 Blood QC B is a purchased control at a high ethanol concentration.*
> *7.4.3 Storage:* ***Storage:*** *Refrigerator* ***Discard:*** *CRM expiration date*

> LOG-16-08 Standards, Controls, and Reagents
> *3.3.3 Reagents, stock solutions, reference material dilutions and chemicals used in the Laboratory shall be re-verified when it has exceeded its shelf life according to the guidelines in 3.5.2. Each shall be determined to still be suitable for its intended purpose. Upon successful re-verification, any material past the manufacturer's expiration may only be used for research and training purposes.*

BAC Whole Blood Control Deviation

Material used in casework cannot be expired. If acceptable re-verification is not achieved, the reagent or solution may not be used.
3.5.2 Re-verification based on the shelf-life of materials shall occur according to the guidelines below:
3.5.2.2 Purchased reagents that require refrigeration will be retested every three years, if not expired per the manufacturer.

Reason for Deviation:
This re-verification was to ensure stability and establish the extent of the shelf-life of the product from the manufacturer's 45-day expiration to 60 days after opening so that these whole blood controls may be used past the 45-day manufacturer's expiration in the future.

Laboratory Number(s) (if applicable): N/A

Brazoria County Sheriff's Office Crime Laboratory

Summer Swift — Evidence Technician — 4.19.2024 — Date

Melissa Henry — Toxicologist — 4/19/2024 — Date

Kayla M. Bayless — Toxicologist — 4/24/2024 — Date

Alexia Ventura — Quality Assurance Manager — 25 Apr. 2024 — Date

Laboratory Director — 25 April 2024 — Date