



### Quality Division Use Only

**Scientific Area Committee (SAC):**  **Subcommittee:**

**Standard/Guidelines Title**

**Date added to OSAC Registry**

**Can the Standard/Guidelines be followed in totality?**

**Please explain if the Standard/Guidelines and the applicable clauses that cannot be followed in their totality:**

Clause 4.4 “Laboratories shall meet the required scope and analytical sensitivity by testing internally, externally, or a combination of both.” The Toxicology performed validation studies to determine cross-reactivity for target analytes (Validation\_EIA\_Blood\_Eff 2021-03-02) and for additional analytes in the currently validated immunoassay screening method (Validation\_EIA\_Cross-Reactivity\_Eff. 2024-04-11). One analyte (lorazepam) did not meet the screening sensitivity requirements specified in ANSI ASB 120.

Table 1 – “Lorazepam: Blood Screen 15 ng/mL; Blood Confirmation 10 ng/mL”. The 04/11/2024 validation study determined that lorazepam reporting limit with BNZ-EIA based on % binding values is 25 ng/mL. The Toxicology confirmation method meets the sensitivity requirement for lorazepam.

**Compliance plan to achieve conformance to Standard/Guidelines:**

The Toxicology section did an extensive validation study to determine the cross-reactivity of non-target analytes by immunoassay (Validation\_EIA\_Cross-Reactivity\_Eff. 2024-04-11).

Toxicology intends to validate an LC-MS/MS targeted screening method with the goal of replacing the immunoassay screening method currently in use. Once validated, the LC-MS/MS screening method would meet the sensitivity requirements of ANSI ASB 120.

**Declaration of Compliance to OSAC Registry Standard/Guidelines:**

As of April 23, 2024, the Toxicology Section is compliant with all other recommendations listed in ANSI ASB 120 “Standard for Analytical Scope and Sensitivity of Forensic Toxicological Testing of Blood in Impaired Driving Investigations”.

**Technical Leader:**           N/A          

**Date:**           N/A          

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**Date:**           May 8, 2024          

**Division Director:**           Amy Castillo          

**Date:**           May 8, 2024          

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**Date:**           May 8, 2024