Quality Division Use Only

Scientific Area Committee (SAC): Chemistry/Instrumental Analysis **Subcommittee:** Toxicology

Standard/Guidelines Title ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology

Date added to OSAC Registry 7/7/2020

Can the Standard/Guidelines be followed in totality? Yes

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

N/A

Compliance plan to achieve conformance to Standard/Guidelines:

After this standard was published onto the OSAC Registry several screening, confirmatory qualitative and quantitative validation studies were completed to conform to this standard. A series of LC-MS confirmatory quantitative and qualitative validation studies were completed. A full scan drug screen/qualitative confirmation (BSD) and quantitative carisoprodol/meprobamate (CAR) GC-MS methods, and an immunoassay screening method were also validated. Since the standard requires the evaluation of previously validated methods, the blood alcohol quantitative method was evaluated against the required validation parameters and an additional validation study was completed to conform to this standard.

Declaration of Compliance to OSAC Registry Standard/Guidelines:

As of June 30, 2021, the Toxicology Section is compliant with the requirements listed in "Standard Practices for Method Validation in Forensic Toxicology". This compliance date is when the last validation packets were signed and approved by both the Toxicology section and the Quality Division for the current immunoassay, GC, and LC methods as of July 7, 2021.

On March 24, 2021 the Toxicology Section incorporated the validation requirements from this standard into their sectional procedure (v3.5) under the following sections: 25. Validation of Quantitative Methods, 26. Validation of Reportable Qualitative Methods, 27. Validation of Immunoassay Using Commercial Kits, and 28. Validation of Screening Methods.

Technical Leader:	N/A	**Date:**	N/A
Section Manager:	Dayong Lee Digitally signed by Dayong Lee Date: 2021.07.08 09:57:50 -05'00'	**Date:**	
Division Director:	Amy Castillo Digitally signed by Amy Castillo Date: 2021.07.07 19:08:04 -05'00'	**Date:**	07/07/2021
Quality Director:	Erika Ziemak Digitally signed by Erika Ziemak Date: 2021.07.07 20:23:05 -05'00'	**Date:**	