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March 21, 2022

Steven Kroll
Maryland State's Attorneys' Coordinator
3300 North Ridge Road, Suite 185
Ellicott City, MD 21043

Dear Mr. Kroll,

The Maryland Department of State Police (MDSP) was recently advised that a practice in our Forensic Sciences Division's (FSD) Blood Alcohol Analysis standard operating procedure has been deemed to no longer be an appropriate method. During a recent on-site visit by our accreditation body, the American National Standards Institute (ANSI) National Accreditation Board (ANAB), in October 2021, a non-conformance was issued to ISO/IEC 17025:2017 standard 7.2.1.1. The standard states, *"The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data."*

The method in question concerns the use of a single point generated calibration curve to perform quantitative analysis of blood alcohol samples. This method, which has been in practice by MDSP-FSD since 2011, was validated and implemented under the guidance and approval of the State Toxicologist and has always yielded successful proficiency test results. Furthermore, our accreditation body previously evaluated the method in both 2015 and 2019 without raising any concerns about the method, most likely because there historically have not been any standards requiring the use of a multi-point calibration curve. Based on this information, MDSP-FSD decided to challenge the finding. On December 22, 2021, the challenge was denied.

It is worth noting that a new ANSI/ASB Standard entitled "Standard for a Quality Control Program in Forensic Toxicology Laboratory" was approved in September 2021. While this new standard does require the use of a multi-point calibration curve, it was published just one month before our surveillance visit providing insufficient time to modify our method accordingly. In addition, it has not yet been approved by the Organization of Scientific Area Committees (OSAC) for Forensic Science, which is the body responsible for establishing forensic science standards for the federal government and setting best practices for the overall forensic community. Therefore, MDSP-FSD decided to file a level 2 challenge to be evaluated by an independent three-person panel.

On March 10, 2022, we were notified that, "The panel concludes that the use of a single point calibration, as delineated in their procedure, is not an appropriate method for establishing a calibration curve for determining quantitative values for forensic toxicology blood alcohol analyses. While single point calibration generated curves may be an acceptable scientific process for certain circumstances, it is not an appropriate method for forensic toxicology blood alcohol analysis." Because of this decision, MDSP-FSD will immediately cease in-house blood alcohol analysis. We will validate and implement a new procedure using a multi-point calibration curve as soon as possible, but until then, all blood alcohol cases will be outsourced to National Medical Services (NMS) in Horsham, PA.

We remain confident that our previous procedure yielded reliable results and have taken proactive measures to assure you of this. The data from a total of 744 samples that were originally analyzed using a single-point calibration curve were reanalyzed with a four-point calibration curve using NIST traceable standards that are routinely run with every batch of case samples as controls, rather than as calibrators. We found that 700 samples (94%) yielded no change in the reportable result. For the remaining 44 samples, differences between the original reportable measurement and the reanalyzed reportable measurement were no more than 0.01 g/dL and fell within the acceptable Uncertainty of Measurement as defined by COMAR. Moreover, there were no instances of the reanalysis causing a result to cross over the 0.08 g/dL legal threshold. To request the reanalysis results for a specific case, please contact our Toxicology Unit at msp.tox@maryland.gov.

The empirical data supports the notion that there is minimal significance to this issue; however, MDSP-FSD is committed to using best practices as well as being transparent with our customers, and therefore we are notifying you. Please pass along this letter to defense counsel as you see fit. If you have any questions regarding the circumstances of this letter, please contact me at 443-357-1301 or at daniel.katz@maryland.gov. Thank you for your attention to this matter.

Sincerely,

Daniel E. Katz
Director, MDSP-FSD

cc: Maryland Chiefs of Police Association
Maryland Sheriffs' Association