

AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS LABORATORY ACCREDITATION BOARD

October 20, 2015

Vincent J. M. Di Maio, M.D. Presiding Officer Texas Forensic Science Commission 1700 North Congress Avenue, Suite 445 Austin, Texas 78701

Delivered via electronic mail to: vincent dimaio@yahoo.com

Dear Dr. Di Maio:

The purpose of this correspondence is to respond to the questions you presented in your September 29, 2015 letter to ASCLD/LAB. As I prepare to respond to your questions, I want to assure you that the overriding intent of ASCLD/LAB is to ensure, to the extent reasonable and practical, that test results issued by ASCLD/LAB accredited laboratories are accurate, reliable and do not exceed the limitations of the validated methods on which those test results are based. I believe that ASCLD/LAB and the Texas Forensic Science Commission share common goals in that respect.

1. Is it the intention of ASCLD/LAB to require laboratories to test hundreds of possible combinations of DNA mixtures as part of an extensive validation study (e.g., four person mixtures with ratios such as 1:1:1;1, 1:1:2:1, 1:2:1;3, 9:3:1:1, ... at 1 ng total, 500 pg total, 250 pg total, etc.)? Based on well-established principles of molecular biology and allele stacking, we do not consider an extensive study to be necessary, reasonable or practical.

The simple answer is "No," it was not and is not the intent of ASCLD/LAB to require laboratories to test hundreds of possible combinations. Our intent is clarified in our response to Question #2 below. We understand that no laboratory can do a study that accounts for all possible mixture contribution combinations

2. If the above is not the intention of ASCLD/LAB, then can we assume the intention is a careful verification of current DNA mixture protocol performance with a fewer number of mixtures containing two or more known contributors sufficient to determine whether laboratory protocols are effective?

Your assumption is correct. We expect all ASCLD/LAB accredited laboratories to use validated methods that produce accurate and reliable results and that test results are not being reported outside the limitations of the laboratory's validated method(s). That is true for every forensic science discipline we accredit and is not a unique expectation for the Biology/DNA discipline.

Each laboratory accredited in the DNA category of testing needs to be able to provide ASCLD/LAB assessment teams with objective evidence that the laboratory's approved mixture interpretation and reporting protocol produces accurate and reliable results when used by any reporting analyst in the laboratory. The objective evidence provided must clearly demonstrate that the accuracy and reliability of the mixture interpretation protocol has been evaluated using known mixed samples or

profiles which represent the range of mixture profiles being interpreted and reported by the laboratory. To use your words, "verification of current DNA mixture protocol performance" is an accurate characterization of what ASCLD/LAB expects.

If the "verification of current DNA mixture protocol performance" fails to confirm the accuracy or reliability of the approved protocol in place, then ASCLD/LAB expects the accredited laboratory to restrict the limit of its reporting to what is verifiable. Any interpretation or reporting of results in the range that cannot be verified must cease and not be reinstated until more extensive validation is completed.

3. What is the intention with regard to relatives (*e.g.*, should non-contributor relatives be assessed against a multi-person test mixture)?

There was no intent by ASCLD/LAB to address the impact of a relative on a mixture. We encourage this discussion and research to continue within the DNA community.

4. If relatives are intended in the ASCLD/LAB requirements, how many mixtures should be tested to understand the capabilities and limitations of a laboratory's interpretation protocol?

Please see the response to question #3.

As a recognized accrediting body working in accordance with accepted international standards, ASCLD/LAB is prohibited from serving as both an accrediting body and a consultant to the laboratories we accredit. For that primary reason, ASCLD/LAB has moved away from providing specific examples to laboratories of corrective actions or examples of conformance with accreditation requirements. I acknowledge the request you made for "a few examples of how laboratories may successfully fulfill the requirements" but, for the reason just stated, specific examples are not included in this response. Suffice it to say that if an ASCLD/LAB accredited laboratory is reporting results for mixtures with more contributors than what was included in the laboratory's original validation, then we expect the laboratory's "verification of current DNA mixture protocol performance" to represent and verify the effectiveness of the protocol for the range being reported.

Please feel to let me know if you have additional questions. As always, the leadership of ASCLD/LAB values our cooperative relationship with the Texas Forensic Science Commission and we look forward to continuing to work to together on matters of mutual interest.

Sincerely,

John K. Neuner
Executive Director
ASCLD/LAB

cc: ASCLD/LAB Board of Directors
Pamela Bordner, ASCLD/LAB Chief Operating Officer
Lynn Robitaille Garcia, General Counsel, Texas Forensic Science Commission