Commissioner's Corner
October 2023
Leslie Mayfield – Region 10 Commissioner

QUESTION: When does a lab need to perform a validation and submit it for review and what needs to be included in order to make the review/ sign off process smooth?

ANSWER: Validations are the foundation of the ASHI accreditation process and all new test systems or categories must be validated and submitted to your commissioner for review. New methods of previously approved systems must be validated and available for onsite inspection. However, these not required to be submitted to your commissioner. All the required pieces for a top-notch validation packet can be found in Appendix I of the ARB Ops Manual under the corresponding Validation Guideline. The most common mistake we see is when a lab submits the application packet but forgets to include the Validation Guideline and does not adequately address the performance specifications. A comprehensive Summary and Interpretation of the Validation should be compiled by the Director or Technical Supervisor. The purpose of the validation and how it is to be used in your laboratory, as well as a step-by-step procedure, QC procedures and QA monitoring, Equipment Calibration data, and enrollment in a PT program should also be included in the packet. To avoid this common mistake, the Performance Specifications should address and summarize the accuracy, precision, sensitivity, specificity, range of results, normal values and limitations of the assay. Each of these points is required to be clearly detailed, including an explanation of any outlying data or underperformance within the assay. To round out a stellar validation packet, be sure to include your training checklist and the competency documentation of all the hard-working techs that are now trained to perform this test. Of course, if help is needed in locating the Validation Guideline or if you have questions always reach out to your commissioner, and they will direct you in the right direction.