Introduction: The Commissioners of the Accreditation Review Board (ARB) are often asked questions from accredited laboratories on interpretation of ASHI Standards. In an effort to share as much information with our laboratories as possible, we are excited to launch this new feature in the monthly ASHI News publication.

We would like to thank outgoing region 10 Commissioner Anne Marie Pichotta for creating this concept and region 3 Commissioner Dr. Cathy Gebhart for contributing the Q&A for the first edition, highlighting some common questions we receive on the ARB.

1) Q: Can you provide clarification on standards for External Controls (D.4.1.8.3 & D.4.1.8.4)?

   A. The revised standard's wording makes it clear that this standard applies to all assays, not just assays where a control is provided by a manufacturer in a kit. This means that any assay, including lab-developed assays such as flow cytometric crossmatch, will need separate controls, if a control is used to calculate results for the assay. This also applies regardless of how the controls are used; if the value of a control is used in any way to calculate results (such as calculating cutoff, or as part of a standard curve), a separate control is needed. Put another way, if a control is used to calculate the results of a test, it is a calibrator and not a control, and separate controls need to be run.

   The QAS committee has shared the proposed edits to the standards (to be approved by the ASHI Board & CMS):

   D.4.1.8.3 Controls as Calibration Materials: Controls ~~provided by manufacturers in a test kit~~ are considered to be calibration materials if they are used to calculate the cutoff value of a test or a patient test result.

   D.4.1.8.4 Testing of Additional External Controls: If ~~the manufacturer's instructions include a formula which uses the positive and/or negative~~ controls ~~included in the kit~~ are used to determine the cutoff value of a test or a patient test result, additional external ~~positive and/or negative~~ controls must also be tested.

2) Q: A patient typed as A*02:26. There isn't a WHO assigned serologic type for this allele. What should I assign as the serologic equivalent?
   A: You must assign the serologic type by following your laboratory's written policy for assignment of serologic equivalents outside of WHO terminology (D.6.2.2.11.1).

3) Q: We perform SSP and SSO typing, are we required to perform proficiency testing (PT) using these assays, even though they are not our primary testing methods?
   A: No, you are not required to perform PT on all typing methods. PT should be tested to the highest resolution level used in the laboratory (see Guidance for C.1.1). All other typing methods must be correlated twice per year in accordance with D.6.3.1.

4) Q: Temperature probes are not available for our real-time PCR instrument. If the amplification plots of controls are acceptable on runs, is that sufficient demonstrate that the appropriate target temperatures are achieved (D.4.1.7.4)?
   A: Function checks using spectral and normalization calibration trays must be performed every six months.

5) Q: We have three Laboratory Directors. Do we have to document competency assessment for them?
   A: Competency assessment does not need to be performed for CLIA laboratory directors unless they perform patient testing. Competency assessment is required for all non-CLIA directors (see guidance for D.2.6.3)