Summary of Proposed Revisions to the 2017 Standards
November 2018

The following revisions are proposed to the 2017 ASHI Standards.

The following changes were made to A.3 Definitions:

Reflex Testing: Confirmatory or additional laboratory testing that is automatically ~~requested~~ performed by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.

Re: C.1.1 - One Primary Method per analyte is to be used for all samples in a Proficiency Testing (PT) challenge. All other Methods must be correlated according to D.6.3.1. PT samples must be tested and reported according to a patient testing algorithm (highest volume, most complex or primary method used during the PT testing event). Exception: For HLA typing analysis, all PT samples are to be tested to the highest resolution level (by locus) used in the lab.

Re: C.1.4.2 – If the laboratory patient specimen testing procedures normally require reflex, distributive, or confirmatory testing at another location, the laboratory should test the proficiency testing sample as it would a patient specimen only up to the point it would refer to a second laboratory and no further. Please refer to the ARB Operations Manual section IV. Proficiency Testing (PT) Requirements (part H),

D.2.3.2 The t~~T~~est results (including electronic records access and electronic record distribution) must be released only to the: tested patient; authorized representative; ordering physician and/or provider; the individual responsible for using test results, and the laboratory that initially requested the test.

Re: D.2.3.2 - The laboratory must have a written policy for reporting and distributing results (including electronic distribution). Reports with results derived from more than one individual must not be released unless consent is received from all individuals reflected in the report. ~~The laboratory must have a written policy for reporting and distributing results (including electronic distribution). Patients or their authorized representatives are now entitled to receive laboratory results directly from the laboratory.~~

D.2.6 Personnel ~~technical~~ competency assessment

D.2.6.1.1 Establish and follow written policies and procedures to assess and document ~~technical~~ competency of staff ~~and, if applicable, consultant competency~~ at least annually.

~~**RE: D.2.6.1.1** - Competency assessments must be performed on individuals serving as clinical consultants, technical supervisors and/or general supervisors based on their regulatory~~

~~responsibilities including specific responsibilities designated to them. Competency assessment does not need to be performed for laboratory directors unless they perform patient testing. Additionally, if the laboratory director fulfills additional roles such as technical supervisor, clinical consultant, and/or general supervisor, no competency assessment is required for these roles unless they perform patient testing. Please note that competency assessment is required for the roles of Technical Supervisor, Clinical Consultant, and General Supervisor when someone other than the laboratory director fills these positions.~~

D.2.6.2 For ~~personnel performing testing~~ testing personnel, the evaluation must include documentation of competency for the following as applicable:

D.2.6.3 Document the performance of individuals with responsibilities in the role of Technical Supervisor, Clinical consultant and/or General Supervisor who are not listed as the CLIA laboratory director annually.

Re: D.2.6.3 Competency assessment does not need to be performed for CLIA laboratory directors unless they perform patient testing. Additionally, if the CLIA laboratory director fulfills additional roles such as technical supervisor, clinical consultant, and/or general supervisor, no competency assessment is required for these roles unless they perform patient testing. Please note that competency assessment is required for the roles of Technical Supervisor, Clinical Consultant, and General Supervisor when someone other than the CLIA laboratory director fills these positions.

D.2.6.3.1 All laboratory director responsibilities which are delegated to the clinical consultant, technical supervisor, or general supervisor must be in writing and included in the competency assessment.

D.2.6.3.2 Competency assessment for the Technical Supervisor should include the responsibilities listed in E.3.2

D.2.6.3.3 Competency assessment for the Clinical Consultant should include the responsibilities listed in E.4.2

D.2.6.3.4 Competency assessment for the General Supervisor should include the responsibilities listed in E.5.2

D.4.1.8.3 ~~The control procedures must:~~ 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.

Re: D.4.1.8.3 The Laboratory Director/Technical Supervisor is responsible for the determination of what control materials to use in the laboratory. Inspectors will ensure that the laboratory is following its own established policies, specifically its Quality Control (QC) procedures.

D.4.1.8.4 ~~The laboratory must:~~ 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 to determine the cutoff, additional external positive and/or negative controls must also be tested.

D.4.1.8.5 The control procedures must:

D.4.1.8.5.1 Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

D.4.1.8.5.2 Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance, environmental conditions, and variance in operator performance.

D.4.1.8.6 The laboratory must:

D.4.1.8.6.1 For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in this section.

D.4.1.8.6.2 Perform the following at least once each day that specimens are assayed or examined:

D.4.1.8.6.2.1 For each quantitative procedure, include two control materials of different concentrations.

D.4.1.8.6.2.2 For each qualitative procedure, include a negative and positive control material.

D.4.1.8.6.2.3 If reaction inhibition is a significant source of false negative results, include a control material capable of detecting the inhibition.

D.4.1.8.6.3 For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured (e.g., molecular weight markers).

D.4.1.8.6.4 Perform control material testing before resuming patient testing when a complete change of reagents is introduced, major preventive maintenance is performed, or any critical part that may influence test performance is replaced.

D.4.1.8.6.5 Over time, rotate control material testing among all operators who perform the test.

D.4.1.8.6.6 Test control materials in the same manner as patient specimens.

D.4.1.8.6.7 When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

D.4.1.8.6.8 Establish or verify the criteria for acceptability of all control materials.

D.4.1.8.6.9 When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

D.4.1.8.6.10 The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

D.4.1.8.6.11 Statistical parameters for locally obtained control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

D.4.1.8.6.12 Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting test results.

D.4.1.8.6.13 The laboratory must document all control procedures performed.

D.4.1.8.6.14 If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

D.4.1.8.6.15 Laboratories must adhere to their policy for quality control of each lot and shipment of reagents. Reference material must be used for quality control whenever possible.

D.4.1.8.6.15.1 For each new lot, perform parallel testing with a previous lot or use appropriate reference material. The number of tests must be determined by the Technical Supervisor.

D.4.1.8.6.15.2 For each new shipment, demonstrate that the reagents have not been compromised during shipment by testing at least one previously tested or noncritical sample to determine that the reagents perform as expected

Re: D.4.1.8.6.15.2 - Note: These standards indicate that testing of new shipments of a lot previously in use does not have to be as extensive as testing of new lots.

D.4.1.8.7 Laboratories performing nucleic acid testing must have written criteria or protocols for preventing DNA contamination using physical and/or biochemical barriers for assays involving amplification of templates.

Re: D.5.2.2.12. Specific amplification products can be assessed by other means like product coverage (NGS) or internal controls of each amplified product (SSO).

Re: D.5.2.2.24 - Independent review is defined as validated software analysis or review by a qualified individual of the software output. The data output results must be reviewed by a qualified individual before release. ~~Automated analysis by validated software alone is sufficient for hematopoietic cell donor registry testing only.~~

Re: D.5.2.11.2

- During validation, laboratories should establish procedures to assess the potential impact of barcode sequences on the efficiency of the enrichment method~~,~~ when the barcode is part of a primer. When barcodes are incorporated after target enrichment, fidelity of the barcoding method to identify a particular sample needs to be monitored (e.g., by rotating control samples with different barcode sequences).
- During validation, laboratories should establish procedures to identify potential allele dropouts and preferential amplifications, and if necessary adjust the software program to detect preferential amplification levels

D.6.2.2.12 A list of all ambiguous allele**s** ~~combinations~~ when 2 field (or more) typing is reported.