2026 QAS Summary of Changes to ASHI Standards & Guidance

New disclaimer in section A:

A.1.3 The Standards are updated annually to reflect advancements in histocompatibility and immunogenetics practices or to include changes mandated by deeming organizations. The Standards in effect at the time a laboratory submits its accreditation application will be the standards applied at the time of its inspection, with the following exceptions:

A.1.3.1 Changes Mandated by CLIA: If updates to the CLIA regulations require a change to ASHI Standards, such a change will be effective at the time it is published in the Federal Register or when notified by CMS.

A.1.3.2. For other changes made to the ASHI Standards, the new standard will be enforced by the Accreditation Review Board one year after the revision is communicated to the ASHI-accredited laboratory community.

Re: A.1.3.2 - If a laboratory is compliant according to the latest version of the standard but would be noncompliant according to the previous version, the new standard will be applied immediately.

Updated Definitions:

~~**Category:** The type of testing performed in an accredited laboratory.~~

**changes were made to the definitions of test category, system and method, that also resulted in many changes made to those references throughout the document.

Test category: The high-level type of testing performed in an accredited laboratory.

Re: A.3 Test category - ASHI-defined test categories include, but are not limited to, immunogenetics, crossmatching, antibody testing, etc. A more comprehensive list can be found in the ASHI Accreditation Review Board Operations Manual.

Test method: ~~The specific assay utilized in determining a clinical result. In these standards, the terms method and technique are used interchangeably.~~ Test method or test methodology is the technology involved in one or more test systems to detect, identify or diagnose a clinical condition.

Re: A.3 Test method – ~~Because CMS allows a laboratory to utilize a specific test method once it has been validated and approved by the laboratory director, ASHI will no longer require laboratories to submit validation packets for individual testing methods. Test methods include but are not limited to CDC, SSOP, SSP, SBT, NGS and/or third generation sequencing, and Solid Phase Assays.~~ ASHI-defined test methods include, but are not limited to molecular typing, flow cytometry, complement dependent cytotoxicity, solid phase testing, etc. A more comprehensive list can be found in the ASHI ARB Operations Manual.

Test system: ~~The actual assay system utilized in determining results in a testing category.~~ The specific assay utilized in determining a clinical result. Test system, assay, and procedure are used interchangeably.

Re: A.3 Test system - ~~ASHI defined test systems include but are not limited to high or low resolution molecular typing, serological typing, flow cytometry, cellular methods, and complement dependent cytotoxicity.~~ Test systems (typically) involve analyzer(s), reagents and a procedure. Each test system must be validated according to ASHI standard D.4.1.5

Ungraded proficiency testing: Proficiency testing samples, or entire challenges, may be ungraded for many reasons, including the following: the laboratory submitted results after the cutoff date, the laboratory did not submit results, the laboratory did not complete the result form correctly, the laboratory's result was not graded due to lack of participant consensus, and/or the PT provider defined the challenge as "educational."

B.2.2 Laboratories making deletions or changes to any test category or test method must notify ASHI in writing no later than 6 months after the change. Laboratories seeking additional areas of accreditation for any test category must receive written approval from the Accreditation Review Board before beginning testing in that test category. ~~ASHI accredited laboratories seeking additional areas of accreditation, new categories, or test systems must notify the ASHI Accreditation Program in writing.~~ The expertise of the Director and Technical Supervisor must be approved by the ASHI Director Training Review and Credentialing Committee (DTRC) prior to the addition of any new area(s) of accreditation. ~~The ARB must approve the addition of new categories or test systems.~~

Re: B.2.2 – Consult the Accreditation Review Board operations manual for a list of test categories and test methods.

Removed C.2.3 standard & guidance (as duplicated in D.2.7 edits)

~~**C.2.3** For ungraded proficiency tests, the laboratory must review, evaluate and document an explanation of the cause for results that are not in concordance with ≥60% of participants.~~

~~**Re: C.2.2** - If a laboratory mis-assigns one DRB1 type in one sample and one DQB1 type in another sample with 5 samples in a send-out, performance is unsatisfactory (60%) for that assessment.~~

~~**Re: C.2.3** - Ungraded PT results must have documentation of review and corrective actions taken, if warranted (e.g., if the laboratory has a discordant result when the consensus ≥ 60%). Corrective action may also be warranted when a result was not graded because not enough laboratories have reported results (e.g., for *DQA1* typing).~~

Edited D.2.7 after ARB Discussion:

D.2.7 Evaluation of proficiency testing performance

D.2.7.1 The laboratory must review and evaluate, in a timely manner, the results obtained on all proficiency testing performed.

D.2.7.1.1 The laboratory must document a corrective action for a proficiency testing challenge where the laboratory receives an incorrect result and include this in the accreditation application.

Re: D.2.7.1.1 - Further information on the requirements for these corrective actions can be found in the ARB operations manual.

D.2.7.1.2 The laboratory must provide evidence of review of any ungraded sample or challenge.

Re: D.2.7.1.2 - Ungraded samples or challenges do not require corrective action, but do require evidence that the results were reviewed by the director. Evidence of review should include the reason the sample was ungraded.

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2 new standards about outsourcing – one for SOT, one for HSC/BMT:

D.5.3.2.1.10 If testing is being outsourced, results must be documented and reviewed for discrepancies with previous results, if applicable.

D.5.3.3.1.7 If testing is being outsourced, results must be documented and reviewed for discrepancies with previous results, if applicable.

Virtual crossmatch clarifications – new guidance & edited standard:

Re: D.5.3.9.6 – This standard applies to Solid Organ and HSC/BM transplantation.

D.6.2.2.15 The virtual crossmatch analysis must be included on a report ~~used for final organ allocation must be documented~~, and must contain:

Re: D.6.2.2.15 – If retrospective physical crossmatch is performed and the result is inconsistent with the virtual crossmatch, the laboratory must notify the transplant program of the unexpected result and the investigation must be documented.

D.6.3.2.5 Any conditions that can potentially cause accidents determined to be attributable to inadequate laboratory space or to staff safety conditions must be documented, investigated. Corrective action must be taken, as needed, to prevent recurrence.

Added more guidance to **E.2.2.2**

Re: E.2.2.2 – For any change of ASHI Directorship, the laboratory/institution must submit a comprehensive coverage plan to the ARB, which must be approved by the ARB. This plan should include how they will fulfill the responsibilities of the Director, detailing coverage of all of their laboratories, such as:

i. delegated responsibilities must be clearly identified.
ii. person(s) to whom the responsibility is delegated must be identified.
iii. the amount of time and frequency of on-site availability.
iv. mechanisms to ensure that all delegated duties are properly performed.

E.2.2.20 Ensure that each member of the technical staff participates in continuing education relevant to his/her areas of responsibility in histocompatibility and/or immunogenetics testing at least to the level of the minimum requirements outlined by the ASHI Accreditation Review Board and copied below. A minimum of 50% of these hours must be directly related to the science and application of histocompatibility and/or immunogenetics testing.

E.2.2.20.1 Directors/Technical Supervisor: 50 hours per year
E.2.2.20.2 Clinical Consultants: 12 hours per year
E.2.2.20.3 General Supervisor: 27 hours per year
E.2.2.20.4 Technologists/technicians: 12 hours per year
E.2.2.20.5 Director in Training: 27 hours per year

New Guidance:

Re: E.2.2.20 - If technical staff performing functions for an ASHI accredited laboratory are not involved in histocompatibility testing, then the director should ensure that such staff are competent and meet the requirements of continuing education relevant to their work areas or specific duties. DNA extraction and quantification, serum separation, sample processing, serum aliquoting do not require histocompatibility continuing education.

The Director in Training may receive many "education" hours during the course of the training. However, at least 27 hours must be from seminars, workshops, lectures, etc. outside of the laboratory.

New Guidance:

Re: E.5 - A general supervisor in a high complexity laboratory must be accessible to testing personnel at all times testing is performed to provide on-site, telephone, or electronic support, and provides day-to-day supervision of personnel performing high complexity testing.

Added NEW standard to General Supervisor qualifications to match **CLIA § 493.1461**

E.5.1.2.6 Be qualified as testing personnel under **E.6.1.2.2** and have at least 3 years of laboratory training or experience in human immunogenetics, human histocompatibility, and/or human transplantation

immunology testing under the supervision of a director and/or technical supervisor of an ASHI-accredited or an equivalent ARB-approved laboratory.