

2009 Changes to 2008 ASHI Standards

2008 Standards	2009 Standards	Rationale for change	Guidance
new definition in 2009	Complaint means a written report made to ASHI that alleges noncompliance with ASHI Standards or with Federal and/or State laws and regulations.	New definition in 2009. The addition was an ASHI Accreditation Review Board (ARB) suggestion from the CMS Partner’s meeting.	
IMGT/HLA Sequence Database means specialist databases for sequences of the human Major Histocompatibility Complex and includes the official sequences for the WHO HLA Nomenclature Committee for Factors of the HLA System. The IMGT/HLA Sequence Database is part of the international ImMunoGeneTics project (IMGT). It is available at http://www.ebi.ac.uk/imgt/hla/ .	IMGT/HLA Sequence Database means a database for sequences of the human Major Histocompatibility Complex and includes the official sequences for the WHO HLA Nomenclature Committee for Factors of the HLA System. The IMGT/HLA Sequence Database is part of the international ImMunoGeneTics project (IMGT). It is available at http://www.ebi.ac.uk/imgt/hla/ .	Removed “specialist” before database and made “databases” singular.	
	Immediate Jeopardy means a situation in which the facility’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.	New definition in 2009. The definition was added because the term was added to D.6.3.2.6 .	
D.2.1.3 The laboratory must establish and follow written procedures for standard precautions as defined by CMS during collection, transport, storage and handling of blood and tissue specimens.	D.2.1.3 The laboratory must establish and follow written procedures for standard precautions as defined by the CDC or if applicable non-US equivalent during collection, transport, storage and handling of blood and tissue specimens.	Change made because CDC, not CMS, defines standard precautions in the U.S. Accommodation was made for laboratories outside of the U.S., that don’t fall under CMS or CDC guidance/requirements.	
D.2.3.1 The laboratory must establish and follow a written policy to ensure confidentiality of protected health information throughout all phases of the testing process, as	D.2.3.1 The laboratory must establish and follow a written policy to ensure confidentiality of protected health information throughout all phases of the testing process. US	Laboratories outside of the U.S., are not required to comply with the HIPAA final rule.	

<p>defined in the HIPAA Final Rule. [45CFR Parts 160 & 164]</p>	<p><u>laboratories must be in compliance with the HIPAA Final Rule. [45CFR Parts 160 & 164].</u></p>		
<p>D.4.1.5.2 Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results as applicable:</p>	<p>D.4.1.5.2 Each US laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results as applicable:</p>	<p>FDA clearance and approval are not relevant for laboratories outside of the U.S.</p>	
<p>D.5.2.2.9 For each new lot of kits:</p> <p>D.5.2.2.9.1 Perform parallel testing using the number of samples determined by the Director, or designee, for the size of the kit and frequency of use.</p> <p>D.5.2.2.9.2 When possible, include testing of alleles known to have demonstrated weak/false negative amplification with previous lots of the same kit.</p> <p>D.5.2.2.9.3 When possible, include testing of new primer/probe sets that have changed from the previous lot.</p> <p>D.5.2.2.10 Test each new shipment of kits to demonstrate that the integrity of the kits has not been compromised during shipment. This can be accomplished by:</p> <p>D.5.2.2.10.1 Testing with reference DNA samples and assessing the results or</p> <p>D.5.2.2.10.2 Testing with non-critical clinical samples and assessing the quality of the reactions and the ability to give a clear interpretation of the results or</p> <p>D.5.2.2.10.3 Testing the new lot or shipment in parallel with the old lot.</p>	<p>D.4.1.8.4.15 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.</p> <p><u>D.4.1.8.4.15.1 For each new lot, perform parallel testing with a previously approved lot or use appropriate reference material. The number of tested samples must be determined by the Technical Supervisor.</u></p> <p><u>D.4.1.8.4.15.2 For each new shipment, demonstrate that the reagents have not been compromised during shipment by testing at least one previously tested or reference sample to determine that the reagents perform as expected.</u></p>	<p>2008 Standards D.5.2.2.9 through D.5.2.2.10.3 were condensed and moved from: D.5.2 Methodology Standards to a more appropriate location: D.4.1.8 Control Procedures.</p> <p>D.5.2.2.9 through D.5.2.2.26 were renumbered to account for the Standards moved to D.4.1.8.</p>	<p>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.</p>

<p>D.5.1.2.1 The laboratory must have a system to identify, assess, and document patient test results that appear inconsistent with the following relevant criteria, when available:</p> <p>D.5.1.2.1.1 Patient age.</p> <p>D.5.1.2.2 Sex.</p> <p>D.5.1.2.3 Diagnosis or pertinent clinical data.</p> <p>D.5.1.2.4 Distribution of patient test results.</p> <p>D.5.1.2.5 Relationship with other test results.</p>	<p>D.5.1.2.1 The laboratory must have a system to identify, assess, and document patient test results that appear inconsistent with the following relevant criteria, when available:</p> <p>D.5.1.2.1.1 Patient age.</p> <p>D.5.1.2.1.2 Sex.</p> <p>D.5.1.2.1.3 Diagnosis or pertinent clinical data.</p> <p>D.5.1.2.1.4 Distribution of patient test results.</p> <p>D.5.1.2.1.5 Relationship with other test results.</p>	<p>Numbering corrected.</p>	
<p>D.5.2.2.27 When applicable, interpret data using the IMGT/HLA or other appropriate nucleotide sequence database. The database that is used must be updated at least every six months.</p>	<p>D.5.2.2.25 When applicable, interpret data using the IMGT/HLA or other appropriate nucleotide sequence database. The database that is used must be updated at least every twelve months.</p>	<p>To provide vendors and laboratories more time to address the impact of changing/updating the databases.</p> <p>D.5.2.2.9 through D.5.2.2.26 were renumbered in 2009 to account for the Standards moved to D.4.1.8.</p>	
	<p>D.5.3.1.1.6 Have a policy with supporting documentation for verifying that each transplant candidate has been ABO typed on two separate occasions prior to the addition of patient to the UNET deceased donor waitlist. "Two separate occasions" is defined as two samples, taken at different times, sent to the same or different labs.</p>	<p>New Standard added to reflect UNOS policies. D.5.3.5.3 from the 2008 Standards was deleted as it is redundant to this standard.</p>	<p>The responsibility of verification and the supportive evidence that two ABO types are performed prior the listing of recipient in UNET needs to be documented</p> <p>The laboratory may not be the party responsible for listing but documentation must be available upon request.</p>
<p>D.5.3.3.1.2 Repeat HLA typing of recipient using a new sample such that the individual's HLA typing is confirmed prior to:</p> <p>D.5.3.3.1.2.1 Final donor selection for related donor transplantation</p>	<p>D.5.3.3.1.2 Repeat HLA typing of recipient using a new sample such that the individual's HLA typing is confirmed prior to final donor selection for both related and unrelated donor transplantation.</p>	<p>The condensed Standard allows more flexibility in the timing of confirmatory typing for recipients with unrelated donors. Formal registry searches do not need to be delayed for repeat typing of recipient.</p>	<p>The laboratory must have a policy that defines how this is met. For initial or confirmatory testing, it is acceptable for a lower resolution typing to be performed on one of the samples as long as documentation exists that the results of both samples correlate.</p>

<p>D.5.3.3.1.2.2 The initiation of a formal registry search and unrelated donor selection</p>			<p>For recipients and related donors, typing results reported by another laboratory using a different sample is acceptable as the first of these two samples with documentation that the results correlate.</p>
<p>D.6.2.6.8.1 The individual parentage/relationship index for each genetic system reported <u>based on validated calculations using appropriate allele or haplotype frequencies and considering mutation rates, if applicable.</u></p>	<p>D.6.2.6.8.1 The individual parentage/relationship index for each genetic system reported based on validated calculations using appropriate allele or haplotype frequencies and considering mutation rates, if applicable.</p>	<p>Underline removed.</p>	
<p>D.6.3.2.3 The laboratory must document all corrective actions taken when test systems do not meet the laboratory's verified or established performance specifications which include, but are not limited to:</p>	<p>D.6.3.2.3 The laboratory must document all corrective actions taken when test systems do not meet the laboratory's verified or established performance specifications which include, but are not limited to:</p>	<p>Comma removed.</p>	
<p>D.6.3.2.6 The laboratory must have a policy to address sentinel events that includes immediate reporting to the ASHI Accreditation Program, with appropriate and complete documentation and investigation of the event.</p>	<p>D.6.3.2.6 The laboratory must have a policy to address sentinel events/immediate jeopardy situations that includes immediate reporting to the ASHI Accreditation Program, with appropriate and complete documentation and investigation of the event.</p>	<p>Immediate jeopardy situations were added to the Standard requiring a laboratory policy to address sentinel events.</p>	
<p>E.2.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical and/or anatomic pathology or other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-</p>	<p>E.2.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical or combined anatomical/clinical pathology or other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-</p>	<p>The Standard was revised to require a combined anatomical/clinical pathology residency to be consistent with CFR 493.</p>	

accredited or approved laboratory.	accredited or approved laboratory.		
E.2.1.4.2 If a candidate has relevant pre-doctoral experience supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.	E.2.1.4.2 If a candidate has relevant pre-doctoral experience supervising and/or performing high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.	Suggestion from the ASHI Director Training Review Committee. This change will allow experience gained as a histocompatibility technologist and/or histocompatibility supervisor to be considered for credit toward 2 of the 4 years of post-doctoral training experience for Director.	
E.2.2.15 Provide appropriate consultation and supervision to assure the accurate testing and reporting of test results for all aspects of services provided by the laboratory. Ensure that the laboratory employs a sufficient number of laboratory personnel with the appropriate qualifications as described in sections E.5 and E.6 of this document.	E.2.2.15 Provide appropriate consultation and supervision to ensure accurate testing and reporting of test results for all aspects of services provided by the laboratory. Ensure that the laboratory employs a sufficient number of laboratory personnel with the appropriate qualifications as described in sections E.5 and E.6 of this document.	Grammatical correction.	
E.2.2.20 Ensure that the technical staff participates in continuing education relevant to histocompatibility and/or immunogenetics testing at least to the level of the minimum requirements outlined by the ASHI Accreditation Review Board.	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	Some members of the technical staff may not perform, or be responsible for, every test performed in the laboratory. The revision requires continuing education specific to the area(s) of responsibility.	
E.3.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical and/or anatomic pathology or	E.3.1.4.1 Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field, or a residency in clinical or combined	The Standard was revised to be consistent with CFR 493.	

<p>other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory.</p>	<p><u>anatomic/clinical pathology</u> or other related medical specialty, and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory.</p>		
<p>E.3.1.4.2 If a candidate has relevant pre-doctoral experience supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.</p>	<p>E.3.1.4.2 If a candidate has relevant pre-doctoral experience supervising <u>and/or performing</u> high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience.</p>	<p>Suggestion from the ASHI Director Training Review Committee. This change will allow experience gained as a histocompatibility technologist and/or histocompatibility supervisor to be considered for credit toward 2 of the 4 years of post-doctoral training experience for Technical Supervisor.</p>	
<p>E.3.1.6 For laboratories performing General Immunology Testing (e.g., platelet antigen typing, platelet antibody identification and crossmatching; chimerism analysis; immunophenotyping; immune function testing; non-HLA polymorphic allele typing), the Technical Supervisor must meet the CMS requirements in general immunology which include one year of laboratory training or experience in high complexity testing within the specialty of diagnostic immunology, <u>if the testing is performed by facilities using ASHI accreditation to meet CLIA requirements.</u></p>	<p>E.3.1.6 For laboratories performing General Immunology Testing (e.g., platelet antigen typing, platelet antibody identification and crossmatching; chimerism analysis; immunophenotyping; immune function testing; non-HLA polymorphic allele typing), the Technical Supervisor must meet the CMS requirements in general immunology which include one year of laboratory training or experience in high complexity testing within the specialty of diagnostic immunology.</p>	<p>The phrase “if the testing is performed by facilities using ASHI accreditation to meet CLIA requirements” is redundant. As stated in this standard, the Technical Supervisor must meet CMS requirements.</p>	
	<p>E.3.1.7 For laboratories performing Virology Testing (e.g., NAT testing for HIV-RNA, HCV – RNA, HBV –</p>	<p>New Standard. Added for laboratories using ASHI accreditation for virology testing.</p>	

	DNA for deceased organ donors), the Technical Supervisor must meet the CMS requirements in virology which include one year of laboratory training or experience in high complexity testing within the specialty of microbiology with a minimum of 6 months of laboratory training or experience in high complexity testing within the subspecialty of virology		
	E.3.1.8 For laboratories performing Syphilis Serology Testing (e.g., the RPR (flocculation test), the Treponemal Test (EIA) for deceased organ donors), the Technical Supervisor must meet the CMS requirements in syphilis serology which include one year of laboratory training or experience in high complexity testing within the specialty of diagnostic immunology.	New Standard. Added for laboratories using ASHI accreditation for syphilis serology testing.	
E.6.2.3.7.1 Testing personnel qualified under E.6.1.3.4 or E.6.1.3.5 may only perform testing under direct supervision, except for those testing personnel performing high complexity testing before 1/19/1993.	E.6.2.3.7.1 Testing personnel qualified under E.6.1. <u>2</u> .4 or E.6.1. <u>2</u> .5 may only perform testing under direct supervision, except for those testing personnel performing high complexity testing before 1/19/1993.	Standards numbers revised/corrected to reflect current numbering of previous standards.	