

Standard	Comment	QAS Response
<p>D.5.3.5.3 All UNOS histocompatibility laboratories that have the responsibility for listing candidates must use two independent source documents for ABO typing verification before they list that candidate</p> <p>New standard – D.5.3.1.1.6 Have a policy for verifying that each transplant candidate has been ABO typed on two separate occasions prior to listing on UNET, for laboratories that perform this function. “Two separate occasions” is defined as two samples, taken at different times, sent to the same or different labs.</p>	<p>D.5.3.1.1.6 Revision.</p> <p>The word "listing" may need better definition.</p> <p>Two separate entries (persons) are required to verify the ABO.</p> <p>The listing person may be a non-HLA person, while the verifying person may be an HLA person.</p> <p>The candidate can be listed and be pending, until a second person verifies the ABO that is "listed" is correct.</p> <p>Our lab verifies most, if not all new candidates, for ABO. However we check all newly listed candidates for HLA, antibody, unacceptables, as well as ABO with our records.</p>	<p>D.5.3.1.1.6 Have a policy 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>Would you consider changing “a policy” to “supporting documentation”?</p> <p>Rationale: Our lab is an Independent Lab that does the UNet entry for listing kidney, kidney/panc and panc patients. The Transplant Centers complete a form which requires they enter the results of each ABO typing. My lab enters the data into UNet. The policy for completing the form is in the Transplant Centers’ SOPs, rather than our lab, since UNOS Policy 3.1 states that the Transplant Center is responsible, not the lab. As an Independent Lab, we do not fit in the definition of a Transplant Center, since we are not in a hospital. Therefore, the required policy should be with the Center, and since we do the entry for them, we should only be required to document what they give us to enter.</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>The laboratory should have a policy in place outlining the labs rule in UNET data entry and its interactions with the transplant center.</p>
<p>D.5.3.3.1.1 Perform HLA typing at the level of resolution and including the loci that are required by hematopoietic stem cell donor registry and/or specific Transplant Program.</p>	<p>The level of resolution in bone marrow transplantation is a medical decision and, as such, it should be at the discretion of the clinicians performing the transplantation. Such medical decisions are beyond the scope of donor registries.</p> <p>Clinical standards of care are determined by</p>	<p>Donor registries and transplant programs have physicians and clinicians as part of their decision-making group. The standard requires that only the laboratory follow their specific program.</p>

	<p>practicing physicians in a scientific forum where clinical outcome data is shared openly and rigorously.</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 <u>final donor selection for both related and unrelated donor transplantation.</u></p>	<p>Would you consider a minimum definition of “HLA typing is confirmed”?</p> <p>Rationale: The term “HLA typing” is vague.</p> <p>If the intent is to verify that there was no sample switch, an abbreviated HLA typing (A,B,DR) may be sufficient. And I am hearing that many labs plan to do an abbreviated typing.</p> <p>If the intent is to verify that the initial recipient typing was <u>correct</u>, an HLA typing of all the loci initially tested AND at the same resolution as the initial seems necessary.</p>	<p>See Attachment A</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>D.5.3.3.1.3 Repeat HLA typing of a related or unrelated stem cell donor using a new sample such that the individual's HLA typing is confirmed prior to stem cell collection. For unrelated donors, registry data is acceptable as the first of these two samples.</p>	<ol style="list-style-type: none"> 1. A distinction must be made between the confirmation of the HLA type of a subject, on one hand, and the confirmation that a sample was actually drawn from the intended subject and not from anybody else, on the other hand. 2. Both the HLA type and the sample source must be confirmed. The two forms of confirmation must be carried out by independent testing or by simultaneous testing using a methodology that serves both purposes at the same time. Even if the same methodology is used to confirm both the sample source and the HLA type, the two forms of confirmation must be conceptually separated. 3. Whereas sample source confirmation requires matching test results obtained from two separate samples independently collected from the same individual, HLA type confirmation can be performed with only one sample. 4. Although sample source confirmation could be carried out performing HLA typing on separate independent samples, the discriminatory power of HLA typing between individuals is limited and a DNA fingerprinting methodology with higher 	

	<p>discriminatory power is preferable.</p> <p>5. HLA type confirmation must meet these criteria:</p> <p>5.1. Each allele assignment at each locus must be confirmed with two independent methodologies. Confirming HLA typing with the same method as used in the original typing does not do, even if performed in different labs.</p> <p>5.2. Homozygosity at the PCR amplification level, that is, when one PCR product provides no evidence of having more than one sequence, special measures must be in place to rule out the possibility of allele drop out or preferential amplification. These measures must include the amplification of the same sequence area with a different set of PCR primers.</p> <p>5.3. The efforts to confirm HLA typing must be a function of the allele association between loci and the allele frequency in various ethnic groups. The rarer the allele association or the more infrequent an allele in a given ethnic group, the greater the efforts to confirm the typing.</p> <p>6. HLA type and the sample source must be confirmed in both donor and recipient prior to final donor selection. This holds good for related and unrelated donor transplantation.</p> <p>The proposed change is self explanatory.</p>	
	<p>D.5.3.3.1.3 requires repeat HLA typing of a related or unrelated stem cell donor using a new sample such that the individuals HLA typing is confirmed prior to stem cell collection.</p> <p>While this will not be an issue with unrelated</p>	

	<p>donors it may introduce some logistic issues with related donors from out of town if we have to defer collection until the repeat test is back. Could ASHI consider changing this standard to:</p> <p>D.5.3.3.1.3 requires repeat HLA typing of a related or unrelated stem cell donor using a new sample such that the individuals HLA typing is confirmed prior to the recipient starting their conditioning regimen.</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-accredited or approved laboratory.</p>	<p>Suggest Changing (for consistency with Standard E.2.1.3.1):</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 <u>or combined anatomic/clinical</u> 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-accredited or approved laboratory.</p>	<p>QAS accepts suggested change to be consistent with CFR 493.</p>
<p>E.2.1.4.2 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 maximum of 2 of 4 years of post-doctoral experience.</p>	<p>I don't agree that this change should be made. It would very much dilute the intent of the original standard since <u>bench</u> experience can be very limited, without involving any test interpretation at all, and is not similar to supervisory experience. Moreover, UNOS requirements would continue to be far more stringent (requiring 4 years of post-doctoral experience) and ASHI has an obligation to enforce UNOS requirements.</p>	
<p>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 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>Suggest Changing (for consistency with Standard E.3.1.3.1):</p> <p>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 <u>or combined anatomic/clinical</u> 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-accredited or approved laboratory.</p>	<p>QAS accepts suggested change to be consistent with CFR 493.</p>
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	<p>The deletion of the phrase “or a residency in clinical and/or anatomic pathology or other related medical specialty”, will bring the ASHI standard for training and/or experience of Technical Supervisors of Histocompatibility laboratories in line with CAP and the Federal (CLIA) standards: (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility;</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>E.3.1.4.2 Use of pre-doctoral experience as if were post-doctoral.</p> <p>I know this will become an ASHI standard but it remains a bad idea. I am not aware of any profession (MD, DVM, engineer) that considers a pre-degree job in the same field as equivalent to post-degree training. This is another endeavor by ASHI to simplify requirements for technicians who go on to earn a PHD as opposed to holding to a higher benchmark. I expect it will be viewed that way by our professional medical colleagues.</p>	<p>Prior to a candidate sitting for the ABHI Diplomate Exam, each candidate is qualified to sit by the ABHI Board on an individual basis. The standard is written that pre-doctoral work <u>may</u> be credited, not <u>will be</u> credited.</p>
	<p>It is an elementary fact of propositional logic that the disjunction includes the conjunction, and</p>	<p>All documents are reviewed by ASHI’s Publications Committee.</p>

	<p>therefore saying “and/or” is the same as saying simply “or”. If the concern is distinguishing between the inclusive disjunction from the exclusive disjunction, plain standard English is very clear about that: a simple “or” stands for the inclusive disjunction and phrases build with an “either .. or” structure stand for the exclusive disjunction. Using “and/or” in a document of professional standards should be discouraged.</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>1. STR Chimerism study is regulated and predominantly performed by molecular pathology laboratory and not general Immunology. So, either has to be omitted from the above standards or be written under a different paragraph stating "CMS requirements in molecular Pathology".</p> <p>2. CMS requirement for technical supervisors in virology or flow performing CD34 is not MD or Ph.D. Any technologists with 6-12 months experiences in virology or phenotyping such as CD34 can be technical supervisors. However, ASHI requirement for Technical Supervisor is MD or Ph.D. and I believe the change of standards requiring 6-12 months training or experience in those area for MD or Ph.D. is over killing requirement. CD34 is performed using a kit and can be learned in less than one week. Similarly, a MD or Ph.D. with experiences in molecular testing can learn all those virology tests, which are performed by kits and do not require interpretation, in one week. The above comments are based on my experiences inspecting molecular Pathologies for CAP.</p> <p>ASHI requiring MD or Ph.D. for TS does not have to have the CMS length of training or experience. Therefore, Standards must add if TS used for those areas is not MD or Ph.D., has to have so much training.</p>	<p>ASHI sought deemed status for testing that HLA labs were doing in addition to histocompatibility testing. CMS responded that inclusion of chimerism analysis falls under general immune testing.</p>