

Suggested Modifications / Additions to the 2009 ASHI Standards

Current Standards	Suggested Modifications	Rationale
	<p>Verification typing: HLA typing performed on an independent sample (or, for a cord blood unit, from an attached segment or from the unit itself) with the purpose of verifying concordance of that typing assignment with the initial HLA typing assignment. Concordance does not require identical levels of resolution for the two sets of typing but requires the two assignments to be consistent with one another.</p>	<p>This definition replaces “confirmatory typing” in practice for the purpose of clarifying the intent of HLA typing of a second specimen and aligns ASHI standards with histocompatibility definitions with the European Federation of Immunogenetics, CAP, AABB, donor registries worldwide and Foundation for the Accreditation of Cellular Therapy (FACT).</p>
<p>D.5.2.2.19.2 It is recommended that each wipe test amplification be run without added DNA and with added DNA as a control for wipe test inhibition.</p> <p>D.5.2.2.19.3 If contamination and/or inhibition is detected, clean the area to eliminate the contamination or source of inhibition and document re-testing, as well as the measures taken to prevent future contamination.</p> <p>D.5.2.2.19.4 Document acceptable electrophoretic conditions used for each gel electrophoresis.</p>	<p>D.5.2.2.19.2 It is recommended that each wipe test amplification be run without added DNA and with added DNA as a control for wipe test inhibition.</p> <p>D.5.2.2.19.2 If contamination and/or inhibition is detected, clean the area to eliminate the contamination or source of inhibition and document re-testing, as well as the measures taken to prevent future contamination.</p> <p>D.5.2.2.19.3 Document acceptable electrophoretic conditions used for each gel electrophoresis.</p>	<p>The only inhibitor found by these wipe tests is bleach. If bleach is present it will also inhibit the spiked control. If either a contaminant or inhibitor is present, the solution is to clean the area with bleach. If water is used to remove the bleach, there is the risk of introducing a new contaminant. QAS wishes to open this for discussion among the ASHI membership.</p> <p>D.5.2.2.19.3 Numerical change.</p>
<p>D.5.2.12.7 Compare the current ABO/Rh group with previous records that are readily available. Any discrepancy found between the current results and the previous record must be resolved before transplantation.</p>	<p>D.5.2.12.7 Compare the current ABO/Rh group, <u>including sub group when applicable</u>, with previous records that are readily available. Any discrepancy found between the current results and the previous record must be resolved before transplantation.</p>	<p>Additional wording to include all aspects of ABO/Rh typing.</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>	<p>D.5.3.3.1.2 Repeat HLA typing of recipient using a new sample such that the individual’s HLA typing is <u>verified</u> 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 <u>verified</u> prior to stem cell collection. For unrelated donors, registry data is acceptable as the first of these two samples.</p>	<p>These changes align ASHI standards and histocompatibility definitions with the European Federation of Immunogenetics, CAP, AABB, donor registries worldwide and Foundation for the Accreditation of Cellular Therapy (FACT).</p>

<p>D.5.3.3.1.4 In the case of cord blood units, verify the HLA assignment using a sample obtained from a contiguous segment of the cord blood unit.</p>	<p>D.5.3.3.1.4 In the case of cord blood units, verify the HLA assignment using a sample obtained from a contiguous segment of the cord blood unit.</p> <p>D.5.3.3.1.4.1 Repeat typing for low-intermediate resolution assignments at HLA-A, B and high resolution HLA-DRB1, is usually sufficient to verify the HLA type.</p> <p>D.5.3.3.1.4.2 When the laboratory performs the verification typing, document that HLA assignments are concordant with previous HLA typing assignments.</p>	<p>New standards to address cord blood units.</p> <p>D.5.3.3.1.4.1 reflects HLA typing requirements in the 4th edition (January 2010) of <u>NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration</u>.</p>
<p>D.5.3.3.1 Laboratories performing testing for <u>blood, bone marrow and stem cell transplantation</u> must:</p> <p>D.5.3.3.1.4 Perform augmented testing (e.g. MLC, T cell precursor frequency, SNP analysis, typing of minor histocompatibility antigens) as appropriate for the transplant protocol and optimal donor selection.</p>	<p>Delete D.5.3.3.1.4</p>	<p>The intent of this standard is covered by D.5.3.1.1.1 thus D.5.3.3.1.4 is redundant.</p>
<p>E.6.1.2 Have laboratory training that includes any of the following:</p> <p>E.6.1.2.1 Completion of a clinical laboratory training program in an ASHI-accredited laboratory or an equivalent organization approved by HHS. This training may be included in the 60 semester hours listed in paragraph E.6.1.2.3 of this section.</p>	<p>E.6.1.2.1 Completion of a clinical laboratory training program in an ASHI-accredited laboratory or an equivalent organization approved by HHS. This training may be included in the 60 semester hours listed in paragraph <u>E.6.1.1.3</u> of this section.</p>	<p>Corrected standard number in reference.</p>