

The purpose of the new patient safety standard D.5.3.3.1.2 requiring a new sample be typed is to ensure the correct typing for patient and donor is used for bone marrow and stem cell transplant purposes. Incidences of sample switches are rare; reported as 0.1 to 0.3 % in transfusion medicine (Arch.Path Lab Med 130, 1196; 2006; Vox Sang 85, 40-47, 2003) and reported case in Human Immunol; 2006. While the low incidence shows the dedication to quality work the result of an error (GVH or graft loss) is dire for the patient.

The new standard brings ASHI standards in alignment with EFI standards (I1.000 and I2.000) and FACT standard for Cord Blood Units B2.1.2.16. The change was initiated by a committee of QAS members. The change was put to the ASHI membership for public comment and adopted by the ASHI board in January of 2009, and subsequently reviewed and approved by CMS. Compliance with the standard is required January 1, 2010. The majority of public comment has been in favor of the new standard.

There are several sources of sample errors; (1) mislabel or sample switch at collection; (2) sample switch or laboratory error during laboratory procedures; (3) sample switch or typographical error at the time of reporting.

The EFI standards require A, B and DR loci be typed to confirm an HLA typing. QAS has left this up to the discretion of the laboratory and its director. Each transplant program has different safety measures in place. What is appropriate for one laboratory may not be necessary for another. Some have commented that they use a low resolution screen and high resolution typing on a second confirmatory sample.