

Additional Changes to the 2009 ASHI Standards; December 2010. These changes once approved by the ASHI board and publications will become effective when the current CMS review is completed.

New:

D.6.3.1.3. If testing subject to CLIA regulation is referred, the subcontracting laboratory must be certified by CLIA to perform the referred testing. All testing subject to CLIA regulation may only be referred to a laboratory that is CLIA certified; ASHI accreditation alone is not sufficient.

D.6.3.1.4. Labs outside of the U.S. may refer samples for immunogenetics, histocompatibility and/or transplantation immunology testing to ARB approved (e.g. EFI accredited) laboratories that meet ASHI accreditation requirements, but are not following CMS regulations because they are not testing samples from U.S. patients.

D.6.3.1.5. Referring laboratories must keep on file the following:

D.6.3.1.5.1. A copy of the subcontracting laboratory's accreditation documentation for the testing performed; AND

D.6.3.1.5.2. A copy of the testing laboratory's report.

Old:

D.6.3.1.3 If immunogenetics, histocompatibility and/or transplantation immunology testing is referred, the subcontracting laboratory must be accredited by ASHI or CLIA or ARB approved (for laboratories outside the U.S.) to perform the referred testing. The referring laboratory must keep on file the following:

D.6.3.1.3.1 A copy of the subcontracting laboratory's accreditation documentation for those test systems

D.6.3.1.3.2 A copy of the testing laboratory's report.

New

D.2.9.3 New procedures and changes in procedures must be approved, signed and dated by the current CLIA designated Laboratory Director, the ASHI designated Laboratory Director and relevant Technical Supervisor before use.

Old

D.2.9.3 New procedures and changes in procedures must be approved, signed and dated by the current laboratory Director and relevant Technical Supervisor.