Evidence of Compliance:

- ✓ Defined criteria for screening recipient sera **AND**
- ✓ Records showing initial screening of recipient sera and all subsequent screening results

REFERENCES

1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR1278].

HSC.33475 Antibody Identification/Crossmatching **Phase I**

The laboratory performs antibody identification and crossmatching as defined by the transplantation programs supported by the laboratory (includes solid organ and hematopoietic progenitor cell transplantation).

MOLECULAR TESTING

If next generation sequencing (NGS) methods *are used for histocompatibility testing, the applicable requirements in the Molecular Pathology Checklist (eg, assay validation, quality control, specimen handling, NGS section) must be used in conjunction with the Histocompatibility Checklist for inspection.*

Inspector Instructions:

	• Sampling of molecular HLA typing policies and procedures • Specimen storage/handling procedure • Sampling of QC records • Sampling of HLA typing and hematopoietic progenitor cell engraftment reports for completeness • Sampling of the following records: molecular weight marker, in-house probe labeling validation, nucleic acid measurement, electrophoretic gel interpretation, and chimerism measurement
	• Raw data (eg, gel images, sequencer histograms, flow microbead fluorescence intensity histograms) • Current databases of known sequences for all alleles recognized by the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System (available) • Pre/post amplification areas (adequate physical separation)
	• What is your laboratory's process for assessing the quality (intactness) of high molecular weight DNA or RNA? • How does your laboratory avoid cross-contamination when performing amplification procedures? • How does the laboratory ensure the level of HLA typing resolution is adequate for each transplant service or registry supported (eg, allele-level resolution for hematopoietic progenitor cell transplants)?

GENERAL REQUIREMENTS FOR MOLECULAR TESTING

The requirements in this section are intended to apply to all molecular-based histocompatibility testing.