2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

HSC.21805 Histocompatibility Reagent Confirmation of Acceptability **Phase II**

New typing reagents are checked using suitable reference materials prior to use.

NOTE: Suitable materials for checking typing reagents include the use of previously typed cells or known archived DNA. Suitable materials for checking reagents for engraftment monitoring include the use of previously tested or archived admixtures.

Evidence of Compliance:

✓ Records of acceptability studies for new reagents prior to use

REFERENCES

1) 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):[42CFR493.1278(a)(3)].

HSC.21810 Specimen Handling - Typing/Screening Trays **Phase II**

If typing trays and antibody screening trays are prepared locally, the records indicate source, bleeding date, donor, identification, and available volume for sera and a means of identifying, locating and collecting fresh donor cells.

HSC.21835 Modified Reagent Use **Phase II**

If reagents are used in a manner different than manufacturer's instructions, there are records of validation studies.

Evidence of Compliance:

✓ Validation study data

CONTROLS

Inspector Instructions:

READ	• Sampling of QC policies and procedures • Sampling of lymphocyte preparation viability checks • Sampling of QC records
OBSERVE	• Control material (labeling)
ASK	• How do you determine when QC is unacceptable and corrective actions are needed? • What is your course of action when QC for compatibility testing is not acceptable?