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?

DISCOVER

- Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory procedure for corrective action

HSC.21850 Daily Controls **Phase II**

The laboratory performs positive and negative controls daily, using positive controls for specific cell types (T cells, B cells, etc.), where available.

NOTE: Positive and negative controls must be run with each test procedure where appropriate. This must include daily positive controls for specific cell type (T cells, B cells, etc.), as well as appropriate antibody isotypes as needed for each assay. This must also include one positive control serum that is historically reactive to all Class I and/or Class II positive cells at the same dilutional titer as appropriate for the methodology utilized.

Evidence of Compliance:

✓ Records of control results

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7168 [42CFR493. 1256(d)(3)(iii)]

HSC.21950 Viability Checks **Phase II**

Viability checks on lymphocyte preparations are performed by recording negative control results or by performing and recording a separate test each time they are used.

NOTE: For cytotoxicity procedures, cell viability after initial incubation should be greater than 80% in the negative control well.

Evidence of Compliance:

✓ Records of viability checks on lymphocyte preparations

HSC.22070 Compatibility Testing Controls **Phase II**

The laboratory includes control material for each phase of compatibility testing.

NOTE: Results of patient testing must not be reported until control values are reviewed and found acceptable.

HSC.22140 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient/client samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:

✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7166 [42CFR493. 1256(d)(8)]