1) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.

REAGENTS

Inspector Instructions:

	• Reagent inventory log • Sampling of procedures for reagent and patient sample storage and handling • Sampling of typing/screening tray records for completeness • Validation studies for modified reagents
	• What are your laboratory's criteria for mixing components from one lot number of reagent kit with components from another lot number of kit? • How do you ensure that all reagents are acceptable and in date? • How does your laboratory manage and control reagent inventory?

Additional requirements are in the REAGENTS section of the All Common Checklist.

HSC.21612 Reagent Tracking **Phase II**

The laboratory records the reagent lot numbers and shipments used for each assay.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1): 1038 [42CFR493.1256(a)]

HSC.21675 Reagent Kit Components **Phase II**

Combinations of reagents from different lots are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service.

Evidence of Compliance:

✓ Records of checks performed on combinations of reagents from different lots

*****REVISED** 12/26/2024***

HSC.21800 Reagent and Specimen Storage **Phase II**

Optimal storage conditions for reagent and specific types of patient specimens are defined and followed.

NOTE 1: Written procedures must include storage and retention requirements for specific types of patient specimens, including lymphocytes, RNA, DNA, and sera.

NOTE 2: Use of continuous monitoring and alert systems and back-up storage plans must be specified as applicable.

Evidence of Compliance:

✓ Records of storage and retention at defined conditions

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)(1) and (a)(2)].

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?