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)].