The procedure manual contains specific instructions for test performance, preparation of reagents, control methods, specimen requirements, limitations of the method, and criteria for accepting/rejecting runs and reporting of results for each of the following procedures, as applicable:

1. **Lymphocyte isolation or identification, as applicable**
2. **HLA serologic typing**
3. **HLA molecular typing**
4. **Crossmatching-T cells**
5. **Crossmatching-B cells**
6. **Antibody screening and identification**
7. **Engraftment monitoring**
8. **ABO grouping**
9. **Complement titration**
10. **Environmental control**

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 2024): [42CFR493.1251(b)(1) and (8)].

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

READ	• Sampling of histocompatibility specimen collection/handling/tracking retrieval policies and procedures • Evaluation records (specimen collection containers/anticoagulants) for preservation of sample integrity
ASK	• What are the specimen acceptability criteria for each specimen type? • What is your course of action when you receive unacceptable/sub-optimal histocompatibility specimens? • How does your laboratory ensure preservation of antibody integrity in recipient sera?
DISCOVER	• Review records of unacceptable specimens and follow up. Determine if practice matches procedure.

HSC.20982 Specimen Collection Procedures Evaluation Phase II

The laboratory evaluates its specimen collection procedures to ensure that the anticoagulant/preservation medium in use does not contribute to analytic interference in the assays to be performed, and that it preserves sample integrity as necessary.

NOTE: This may be done through some combination of direct testing by the laboratory, review of the clinical literature, and evaluation of information from manufacturers. It does not mandate exhaustive testing by each laboratory.

Evidence of Compliance:

✓ Records of the evaluation of specimen collection procedures and anticoagulants in collection containers