PROFICIENCY TESTING

Inspector Instructions:

	• Are proficiency testing samples tested with the same cut-offs for clinical HLA antibody determination as clinical specimens? • Are proficiency testing samples for HLA antigens tested to the same level of resolution as clinical specimens?
	• Select a representative clinical report from each service area. Compare the extent of reporting for the relevant proficiency testing sample.

HSC.10475 PT Extent of Testing **Phase II**

Proficiency testing specimens are tested to the same extent as clinical specimens.

NOTE: Proficiency testing samples must be tested using the most comprehensive testing algorithm or pathway applied to patient samples. For example, if a laboratory has a written procedure that calls for both low and high-resolution HLA analysis for a certain patient population, then all PT samples are tested to the highest resolution level.

Evidence of Compliance:

✓ Comparison of patient and proficiency testing work records demonstrating identification to the same extent

QUALITY MANAGEMENT

PROCEDURE MANUAL

Inspector Instructions:

	• Representative sample of procedures for completeness. Current practice must match contents of procedures.

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

HSC.20200 Procedure Manual **Phase II**

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