

PROFICIENCY TESTING

Inspector Instructions:

 ASK	<ul style="list-style-type: none"> • 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?
 DISCOVER	<ul style="list-style-type: none"> • 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:

 READ	<ul style="list-style-type: none"> • Representative sample of procedures for completeness. Current practice must match contents of procedures.
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****REVISED** 12/26/2024**

HSC.20200 Procedure Manual

Phase II