



REFERENCES

- 1) Bray RA, Nolen JD, Larsen C, et al. Transplanting the highly sensitized patient: The emory algorithm. *Am J Transplant.* 2006 Oct;6(10):2307-15. doi: 10.1111/j.1600-6142.2006.01521.x. Epub 2006 Aug 25. PMID: 16939516.
- 2) Jackson AM. The Virtual Crossmatch: An Essential Tool for Transplanting Sensitized Patients. *Clin Transpl.* 2014;131-6. PMID: 26281137.

RED CELL TYPING

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of blood type/antibody screen policies and procedures • Sampling of current typing sera/reagent package inserts, for consistency with written procedures • Sampling of typing sera/reagent cell reactivity/anti-D QC records • Sampling of patient records with forward and reverse grouping • Record retention policy • Sampling of historical record checks
	<ul style="list-style-type: none"> • If there has been an instance where the ABO and Rh typing results were not in agreement with the patient's historical record, further evaluate the laboratory's responses, corrective actions and resolutions

HSC.29877 Reagent Handling - Red Cell Typing Reagents

Phase II

Typing sera and reagent cells are used according to the manufacturer's instructions; or, if alternative procedures are used, validation records confirm that they perform as intended.

NOTE: Testing methods used for ABO, Rh and antibody screening that are different from the manufacturer's instructions, are acceptable provided they are not prohibited by the manufacturer, have been demonstrated to be satisfactory, or, for laboratories subject to US regulations, have been approved by the Centers for Biologics Evaluation and Research (CBER).

Evidence of Compliance:

- ✓ Records of validation if instructions have been modified

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 24);[42CFR493.1271(a)(1)]

HSC.29885 Package Inserts/Manufacturer's Instructions - Red Cell Typing

Phase II



Current package inserts/manufacturer's instructions are available for the red cell typing reagents used by the laboratory.

NOTE: The laboratory must have a procedure that assures that:

- The most current manufacturer's instructions/package inserts are in use
- The relevant procedures are updated when changes to the instructions occur.

Although it is not required to retain discontinued instructions, the laboratory must have a process to obtain expired package inserts from the manufacturer, if requested.

HSC.29893 Forward/Reverse Typing

Phase II



For each patient, red blood cells are tested with anti-A, anti-B, and anti-D, and serum/plasma is tested using A1 and B reagent red cells.