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:

READ	• 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
DISCOVER	• 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.

NOTE: The ABO/Rh type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping. Discrepancies between cell and serum groups must be resolved before ABO group is assigned.

Evidence of Compliance:

✓ Logs or computer records with forward and reverse grouping

HSC.29901 A1 Red Cell Subgrouping **Phase II**

There is evidence of the specificity of A1 subgroup testing in the ABO system to distinguish A1 from other red cell subgroups.

NOTE: If the organ donor has been transfused with red blood cells in the past three months, ABO subgroup typing must be performed on a pretransfusion sample. This is due to the possibility of misinterpretation of ABO subgroup typing.

HSC.29909 Antisera/Reagent Red Cell QC **Phase II**

There are records of acceptable reactivity and specificity of typing sera and reagent red cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer's instructions for daily quality control are followed.

NOTE: Unless manufacturer's instructions state otherwise, the following apply:

- *Typing reagents, including antisera (eg, anti-D, anti-K, anti-Fy(a)) and reagent red cells must be checked for reactivity and specificity on each day of use. Typing antisera must be checked with known positive and negative cells; reagent red cells must be checked with known positive and negative antisera.*
- *Each cell used for antibody screening must be checked each day of use for reactivity of at least one antigen using antisera of 1+ or greater avidity.*
- *Anti-IgG reactivity of antiglobulin reagents may be checked during antibody screening and crossmatching.*

This checklist requirement can be satisfied by testing one vial of each reagent lot each day of testing.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7171 [42CFR493.1256]

HSC.29925 Historical Record Check - Red Cell Typing **Phase II**

ABO, Rh, and antibody screen test results are compared with results of the same tests performed previously to detect discrepancies.

Evidence of Compliance:

✓ Records of historical result comparisons

HSC.29941 Results Reporting - ABO Antibody Titers **Phase I**

The laboratory defines how to perform and interpret ABO antibody titers.

HSC.29949 Anti-D Controls **Phase II**

Appropriate control(s) are used for anti-D testing.

NOTE: If an anti-D reagent contains a potentiating diluent, the appropriate control is the diluent alone. Controls used must be consistent with the manufacturer's instructions.