HSC.29495 Crossmatch **Phase II**

The laboratory defines the patient sera and donor cells utilized for final crossmatch testing.

NOTE: Cellular targets for transplant crossmatches must include donor T-cells, and may include donor B-cells when appropriate.

REFERENCES
1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(e)].

HSC.29682 Specimen Handling **Phase II**

Patient samples for crossmatch testing are used undiluted, and kept frozen for a defined time post-transplantation.

REFERENCES
1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

HSC.29869 Final Crossmatch Results Availability **Phase II**

The laboratory defines criteria for availability of final crossmatch results for renal transplant patients (before transplantation) and for presensitized extrarenal transplant patients.

NOTE: Laboratories supporting solid organ transplants must be capable of performing prospective crossmatches and must have a written policy describing in what situations pre- or post-transplant crossmatching is performed for all types of solid organ transplants. Results of the final crossmatch must be available before a kidney transplant is performed. The policy for presensitized extrarenal transplant patients must describe if and when crossmatches are performed. Crossmatches may be physical or virtual crossmatches as defined in the policy.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(e)].
2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

HSC.29874 Virtual Crossmatch **Phase II**

The eligibility criteria and process used to perform a prospective virtual crossmatch are defined for each transplant program the laboratory serves.

NOTE: The laboratory must define the following, as applicable:
1. *Patient eligibility criteria (eg, sensitization level)*
2. *Sample date eligibility criteria*
3. *Evaluation of known sensitizing events since the last sample date*
4. *Requirement for recipient solid phase antibody testing and donor molecular HLA typing*
5. *Description of antibody interpretation (eg, consideration of locus, cutoff value, cross-reactivity, epitome, etc.) utilized in the virtual crossmatch*
6. *Situations requiring additional testing (eg, donor high resolution typing, DPA1 typing, up-to-date antibody testing)*
7. *Process for reporting the virtual crossmatch results.*

The virtual crossmatch eligibility criteria and procedure must be addressed within each transplant program agreement.

If a prospective physical crossmatch is performed, the above eligibility criteria are not applicable.

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.