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.