The antibody reagents (anti IgG, IgM, IgA, etc.) are used at a selected dilution for optimal sensitivity and class specificity.

HSC.31178 Positive Crossmatch Results Cut-off **Phase II**

The cut-off for positive crossmatch results is determined by testing an appropriate number of sera from non-alloimmunized individuals and established for all pertinent target cells (T-cells, B-cells, etc.).

Evidence of Compliance:

✓ Records for the validation of the positive cut-off

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.31552 HLA Class II Antibody Procedure **Phase II**

The procedure for HLA Class II antibodies readily separates Class I from Class II specificity.

HLA ANTIBODY SCREENING

Inspector Instructions:

READ	• Sampling of HLA antibody screening policies and procedures, including protocol for screening for each organ transplanted or hematopoietic progenitor cell recipient and the frequency of such screening • Agreement for reflex testing using more sensitive screening method, if applicable • Sampling of antibody identification QC records • Sampling of initial and subsequent recipient sera screening records
ASK	• What is your laboratory's course of action for antibody identification/crossmatching for high risk patients? • How does the laboratory determine cutoffs for identification of HLA antibody based on the clinical programs supported? • How does the laboratory determine the assignment of unacceptable antigens for organ transplantation?

HSC.32487 Immunizing Event **Phase II**

There is a system to record any potential immunizing event that could cause sensitization in a patient.

NOTE: There must be a policy that encourages timely blood sample collection at 14 days after the potential immunizing event in a patient. This new sample should be available for use in antibody screening and crossmatch studies.

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(c)].
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.32674 HLA Antibody Detection **Phase II**