RECORDS

The records listed below must be kept to the extent of services provided by the laboratory.

Inspector Instructions:

	• Record retention policy • Sampling of stored specimen inventory records/log • Sampling of transplant donor and recipient records • Verification of patient data policy (interval of review is defined) • Sampling of patient histocompatibility data review and verification • Sampling of policies and procedures for donor confidentiality
	• How does your laboratory resolve inter-laboratory HLA typing discrepancies? • How do you store results for comparison with subsequent reports?
	• Review all records of a sampling of patient and donor histocompatibility results and reports to ensure completion of all steps in the process from specimen requisitions to final disposition. Determine if records provide an adequate audit trail of all activities.

HSC.21316 Record and Material Retention - Histocompatibility **Phase II**

A copy of each final report, all records of results, reagent lots, gel images, *in situ* hybridization slides, and histograms used for interpretation and determination of test results are retained in compliance with existing laws.

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.21332 Stored Specimen Log **Phase II**

A log of all stored specimens is maintained to enable prompt retrieval for further testing.

Evidence of Compliance:

✓ Electronic or paper inventory log of stored specimens

*****NEW** 12/26/2024***

HSC.21340 Laboratory Records **Phase II**

Methods, instruments, and reagent lot and shipment numbers used for processing and analyzing each specimen (or batch of specimens) can be identified and traced in the laboratory's records.

RECIPIENT AND DONOR INFORMATION RECORDS