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

HSC.21350 Clinical Transplant Registries and Transplant Data Retention **Phase II**

The institution participates in and retains records of patient and donor transplant information in the United Network for Organ Sharing (UNOS) Clinical Transplant Registry or its equivalent.

NOTE: The laboratory and/or transplant coordinator must retain records on transplant recipients, including a history of prior transfusion, pregnancy, and prior transplants as well as HLA antibody history, date of transplant(s) and outcome. In addition, there must be records of donor and recipient age, race, sex, ABO, and HLA types. The source of the donor organ or donor hematopoietic stem cells must be recorded. This information can be retained as part of an institutional registry.

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.21366 Record Review **Phase II**

There are records of periodic review and verification of patient histocompatibility data.

NOTE: Histocompatibility tests performed for organ transplantation (HLA typing, HLA antibody sensitization, unacceptable antigens during prior transplants or sensitization, and any pretransplant screening results) must be reviewed and verified when patients are placed on organ waiting lists. Changes or additions to the waiting lists must be verified. These records must be readily available for review and retained for at least two years.

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.

****REVISED** 12/26/2024***

HSC.21382 Discrepancy Resolution **Phase II**

The laboratory has a defined process to resolve HLA typing discrepancies within and between laboratories.

NOTE: There must be records of the steps taken to resolve discrepancies.

This requirement applies to HLA testing performed by all testing methods, including next generation sequencing.

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) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.

HSC.21390 Donor Confidentiality **Phase II**

The laboratory ensures confidentiality of all donor records, including releasing or sharing donor information for clinical purposes.

NOTE: For example, if identifiable donor information will be shared with the recipient, appropriate donor informed consent must be obtained, donor information must be redacted, or other appropriate action taken.

Refer to the Laboratory General Checklist for specific requirements on patient privacy and patient data accessibility.

REFERENCES