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

HSC.20985 Extracted Nucleic Acid Specimens **Phase II**

If extracted nucleic acid is accepted as a specimen type, the laboratory ensures that isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS. This policy is clearly displayed to ordering clients.

NOTE: All clinical testing must be performed in CLIA-certified laboratories or laboratories meeting equivalent requirements (refer to GEN.41350 and MOL.35840). This includes all components of testing that may impact the quality of the test result, including isolation or extraction of nucleic acids. Laboratories may choose to have referring clients formally attest that extracted nucleic acid submitted for testing has been isolated or extracted in an appropriately qualified laboratory.

Evidence of Compliance:

- ✓ Written statement on the test requisition, test catalog, or policy available to referring clients stating that the laboratory only accepts isolated or extracted nucleic acids for which extraction or isolation is performed in an appropriately qualified laboratory

HSC.20988 Specimen Integrity - Flow Cytometry **Phase II**

The laboratory has a defined process to evaluate the integrity of flow cytometry specimens.

NOTE: The yield of lymphocytes from blood samples is affected by a number of factors. If specimens are not processed immediately after collection, the laboratory should verify that its anticoagulant, holding temperature and preparation method maintain specimen integrity. Selective loss of cell subpopulations and/or the presence of dead cells may lead to spurious results. Routine viability testing is not necessary on specimens of whole blood that are analyzed within 24 hours of drawing. Analyses on older samples are possible if the laboratory has verified the absence of statistical differences between the fresh and aged specimen phenotype fractions being evaluated.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline.* 2nd ed. CLSI Document H42-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2007.

HSC.21050 Recipient Sera **Phase II**

The most appropriate recipient sera are employed for final crossmatching or final selection of donor.

NOTE: There must be a written policy defining an appropriate specimen to utilize in transplantation or final donor selection that takes into consideration the potential recipient's past pregnancies, past transplants, recent blood transfusions, and sensitization history. The specimens must have been properly handled and appropriately stored to preserve antibody integrity.

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.

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

HSC.21130 Specimen Storage **Phase II**

Stored specimens are retained in a way which allows for prompt retrieval for further testing.

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(a)(2)].

RESULTS REPORTING

Inspector Instructions:

	• Sampling of patient reports for completeness, use of appropriate nomenclature, and review prior to release • Sampling of referral laboratory accreditation records
	• How are urgent results communicated?

HSC.21250 Patient Reports **Phase II**

Patient results are reported in a legible, easy to interpret format that clearly indicates the test method and delineates the clinical implications of the results.

NOTE: For patient test results that include an interpretative analysis narrative or statement, the name of the individual(s) responsible for the interpretation must be included.

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

HSC.21275 Final Report **Phase II**

The final report includes the following:

- **Summary of the methods used**
- **Loci tested**
- **Objective findings***
- **Limitations of the methods, when applicable**
- **Interpretation.**

NOTE: For donor registries, aggregate reports may be provided for a group of donors.

When performing testing by next generation sequencing (NGS), the loci tested are not required to be listed on the report.

** For high resolution HLA typing, there is no need to list unresolved non-common, intermediate, or well-documented (CIWD version 3.0.0) alleles or G and P group alleles or codes if stated in the report, client agreement, or client request in writing.*

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) Hurley CK, et al. Common, intermediate and well-documented HLA alleles in world populations: CIWD version 3.0.0. *HLA.* 2020;95(6):516-531.

HSC.21277 Nomenclature **Phase II**