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**

The HLA antigen and allele assignments and their written designation conform to the current World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System for histocompatibility antigens.

*NOTE: For example: Phenotype is HLA-A1,2; B51,B44; Cw3; DR1,4; DR53; DQ4,8. Genotype is HLA-A*01:01, *02:01; HLA-B*51:07, B*44:03, HLA-C*03:01; HLA-DRB1*01:01, DRB1*04:01; DRB4*01:01; DQB1*04:01, DQB1*03:02. Haplotypes should not be assigned unless all haplotypes can be identified, uniquely, by pedigree analysis. For example, solid organ transplant typings are reported as antigens compatible with UNOS/OPTN requirements and hematopoietic progenitor cell transplant typings are reported at the allele level compatible with National Marrow Donor Program (NMDP) requirements.*

All genotype and phenotype designations must also conform to WHO Nomenclature Committee for Factors of the HLA System recommendations. The laboratory must maintain a list of antigens and alleles defined by the reagents used.

Evidence of Compliance:

- ✓ Appropriate antigen and allele assignments to support the transplant program

REFERENCES
1) http://www.ebi.ac.uk/imgt/hla
2) Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1278(b)(1)].

HSC.21281 Accreditation of Referral Laboratories — Phase II

Outside referral laboratories are accredited by appropriate histocompatibility agencies. US laboratories are CLIA certified or meet equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

NOTE: Laboratories that are members of the United Network for Organ Sharing (UNOS) may only refer histocompatibility testing to other laboratories that are OPTN-approved.

Refer to GEN.41350 for additional information on requirements for referral laboratory selection.

Evidence of Compliance:

- ✓ Records verifying referral laboratory certification/accreditation in histocompatibility

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.21287 Result Review — Phase II

All laboratory results (excluding reports from outside referral laboratories) have two levels of independent review, including review by the section director (technical supervisor) or designee prior to release.

NOTE: The initial review may be performed by validated automated analysis or by a qualified individual. The data output results must be reviewed by a qualified individual before release.

Evidence of Compliance:

- ✓ Records of result review

HSC.21295 Critical Reporting — Phase I

The laboratory communicates critical findings when test results meet defined criteria (eg, an unexpected positive crossmatch or development of a de novo donor-specific antibody).

Evidence of Compliance:

- ✓ Records of critical report communications