

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:

READ 	<ul style="list-style-type: none"> • Sampling of patient reports for completeness, use of appropriate nomenclature, and review prior to release • Sampling of referral laboratory accreditation records
ASK 	<ul style="list-style-type: none"> • 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**