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