HOTLINE: Effective May 18, 2020

New Test **3002062** **HLA Class I and II Panel (A,B,C,*DRB1, DRB345, DQA1, DQB1, DPA1, DPB1*) by Next Generation Sequencing** **HLA 11LOCI**

Methodology: Polymerase Chain Reaction (PCR)/Massively Parallel Sequencing
Performed: Varies
Reported: 8-15 days

Specimen Required: Collect: Lavender (K_2 EDTA). Also acceptable: Yellow (ACD Solution A).
Specimen Preparation: Transfer 4 mL whole blood to an ARUP Standard Transport Tube. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens collected in Yellow (ACD Solution B). Clotted, grossly hemolyzed, or heparinized specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Purpose: To identify HLA-A, -B, -C, -*DRB1*, -*DRB345*, -*DQA1*, -*DQB1*, -*DPA1*, and -*DPB1* allelic polymorphisms on specimens for transplant candidates and their donors.
Methodology: PCR followed by next generation sequencing of HLA-A, -B, -C, -*DRB1*, -*DRB345*, -*DQA1*, -*DQB1*, -*DPA1* and -*DPB1* loci.
Analytical Sensitivity & Specificity: >99 percent.
Limitations: Rare diagnostic errors can occur due to primer site mutations.
Test Results: Results are reported as HLA locus (A, B, C, *DRB1*, *DRB345*, *DQA1*, *DQB1*, *DPA1*, *DPB1*)* followed by the two-field (four digit) assigned allele.

Disclaimer Information:
HLA typing is performed by one or more of the following methodologies: next generation sequencing (NGS) and/or sequence specific probe hybridization (SSOP). The NMDP code provides possible rare alleles that cannot be ruled out. Additional unknown DNA polymorphisms could exist outside of the regions analyzed, the significance of which is not known.

This test was developed and its performance characteristics determined by the Histocompatibility& Immunogenetics laboratory at the University of Utah Health, and has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes; it should not be regarded as investigational or for research. The University of Utah Histocompatibility& Immunogenetics laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing. Performed at: Histocompatibility& Immunogenetics laboratory, University of Utah Health, 417 Wakara Way, Suite 3220, Salt Lake City, UT 84108.

CPT Code(s): 81382

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.