HOTLINE: Effective May 20, 2019

New Test Available Now **3001053** **Red Blood Cell Antigen Genotyping** **RBC GENO**

Additional Technical Information

Methodology: Polymerase chain reaction followed by fluorescent probe ligation and detection
Performed: Sun-Sat
Reported: 7-14 days

Specimen Required: Collect: Lavender (EDTA)
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum; collection of specimen in sodium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Interpretive Data:
Background Information for Red Blood Cell Antigen Genotyping:
Characteristics: Erythrocyte alloimmunization may result in hemolytic transfusion reactions or hemolytic disease of the fetus and newborn (HDFN). Clinical presentation is variable and dependent upon the specific antibody and recipient factors.
Incidence: Erythrocyte alloimmunization occurs in up to 58% of sickle cell patients, up to 35% in other transfusion-dependent patients, and in approximately 0.8% of all pregnant women.
Inheritance: Typically co-dominant for red blood cell (RBC) antigens, autosomal recessive for hemoglobin S (HbS).
Cause: Antigen-antibody mediated red-cell hemolysis between donor/recipient or transferred maternal antibodies.
Variants Tested: See the "Additional Technical Information" document.
Clinical Sensitivity: >99% for c (RH4), C (RH2), e (RH5), E (RH3), k (KEL2), K (KEL1), Jka (JK1), Jkb (JK2), Fya (FY1), Fyb (FY2), M (MNS1), N (MNS2), S (MNS3), s (MNS4). Unknown for Kpa (KEL3), Kpb (KEL4), Jsa (KEL6), Jsb (KEL7), Lua (LU1), Lub (LU2), Dia (DI1), Dib (DI2), Coa (CO1), Cob (CO2), Doa (DO1), Dob (DO2), Joa (DO5), Hy (DO4), LWa (LW5), LWb (LW7), Sc1 (SC1), Sc2 (SC2), U (MNS5), V (RH10), VS (RH20), Hemoglobin S (HbS).
Methodology: Immucor PreciseType™ HEA Molecular BeadChip which is FDA-approved for clinical testing. Predicted phenotypes are reported for each antigen and HbS based on the variants tested.
Analytical Sensitivity and Specificity: >99% for c (RH4), C (RH2), e (RH5), E (RH3), k (KEL2), K (KEL1), Jka (JK1), Jkb (JK2), Fya (FY1), Fyb (FY2), M (MNS1), N (MNS2), S (MNS3), s (MNS4). Unknown for Kpa (KEL3), Kpb (KEL4), Jsa (KEL6), Jsb (KEL7), Lua (LU1), Lub (LU2), Dia (DI1), Dib (DI2), Coa (CO1), Cob (CO2), Doa (DO1), Dob (DO2), Joa (DO5), Hy (DO4), LWa (LW5), LWb (LW7), Sc1 (SC1), Sc2 (SC2), U (MNS5), V (RH10), VS (RH20), Hemoglobin S (HbS).
Limitations: Only the targeted variants will be interrogated. Rare nucleotide changes leading to altered or partial antigen expression and null phenotypes may not be detected by this assay. This assay does not assess for RhD nor is it designed to diagnose sickle cell disease. Patients who have had hematopoietic stem cell transplants may have inconclusive results on this test. Abnormal signal intensities may result in indeterminate genotyping results for all tested antigens/HbS.

CPT Code(s): 0001U

New York DOH approval pending. Call for status update.

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