

HOTLINE: Effective May 17, 2021

New Test 3001593 MODY and Neonatal Diabetes Panel, Sequencing MODY NGS



Additional Technical Information



Patient History for MODY and Neonatal Diabetes

Methodology: Massively Parallel Sequencing

Performed: Varies
Reported: 3-6 weeks

Specimen Required: Collect: Lavender (EDTA) or Yellow (ACD Solution A or B).

Specimen Preparation: Transport 3 mL whole blood. (Min: 1.5 mL)

Storage/Transport Temperature: Refrigerated.

<u>Unacceptable Conditions:</u> Serum or plasma; grossly hemolyzed or frozen specimens.

Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Note: Genes tested: ABCC8*, APPL1, BLK, CEL*, EIF2AK3, FOXP3, GATA4, GATA6, GCK, HNF1A, HNF1B, HNF4A, INS, KCNJ11, KLF11,

NEUROD1, NEUROG3, PAX4, PDX1, RFX6, SLC19A2, WFS1, ZFP57

*CEL (NM_001807) exons 1, 8, 9, 11 are not sequenced due to technical limitations of the assay.

*ABCC8 (NM_001351295) partial exon 14 (Chr11:17449973-17450018) is not sequenced due to technical limitations of the assay.

CPT Code(s): 81403; 81404; 81405; 81406; 81479

New York DOH approval pending. Call for status update.

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