MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: May 10, 2021
Effective Date: June 10, 2021

APOL1 Genotype, Varies

Test ID: APOL1

Useful for:
Determining an individual's *APOL1* genotype

This test is **not useful for** clinical management of individuals with *APOL1* risk genotypes.

This test alone is **not useful for** determining eligibility for donation or receipt of kidney allografts.

Method:
Real-Time Polymerase Chain Reaction (PCR) with Allelic Discrimination Analysis

Reference Values:
An interpretive report will be provided.

Specimen Requirements:
Multiple genotype tests can be performed on a single specimen after a single extraction.

Submit only 1 of the following specimens:

Specimen Type: Whole blood
Container/Tube: Lavender top (EDTA)
Specimen Volume: 3 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send specimen in original tube.
Specimen Stability Information: Ambient (preferred) 9 days/Refrigerated 30 days

Specimen Type: Saliva
Patient Preparation: Patient should not eat, drink smoke, or chew gum 30 minutes prior to collection.
Supplies: Saliva Swab Collection Kit (T786)
Specimen Volume: 1 Swab
Collection Instructions: Collect and send specimen per kit instructions.
Specimen Stability Information: Ambient 30 days

Specimen Type: Extracted DNA
Container/Tube: 2 mL screw top tube
Specimen Volume: 100 mcL (microliters)
Collection Instructions:
1. The preferred volume is 100 mcL at a concentration of 50 ng/mcL.
2. Include concentration and volume on tube.
Specimen Stability Information: Frozen (preferred)/Ambient/Refrigerated

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Varies	

Cautions:

This assay will not detect all variants associated with an increased risk for development or progression of a chronic kidney disease. Therefore, the absence of an *APOL1* risk genotype does not rule out the possibility that an individual is at an increased risk for development or progression of a chronic kidney disease.

Specific *APOL1* genotypes are associated with an increased lifetime risk for chronic kidney diseases. Currently, there are no guidelines for clinical management of individuals with *APOL1* risk genotypes.

The *APOL1* genotype of a kidney donor may be associated with worsened outcomes in the allograft recipient. However. this assay cannot predict or rule out the development or progression of a chronic kidney disease in an individual. Current guidelines advise that an individual's *APOL1* genotype alone should not determine eligibility for donation or receipt of kidney allografts.

Test results should be interpreted in the context of clinical findings, family history, and other laboratory data. Errors in the interpretation of results may occur if information given is inaccurate or incomplete.

Rare alterations may be present that could lead to false-negative or false-positive results. This assay does not identify less common apolipoprotein L1 alleles. Thus, an individual who appears to be homozygous for G1 or G2 may carry a rare allele that cannot be detected by this assay. If results obtained do not match the clinical findings, additional testing should be considered.

In rare cases, DNA variants of undetermined significance may be identified.

Samples may contain donor DNA if obtained from patients who received heterologous blood transfusions or allogeneic hematopoietic stem cell transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. For individuals who have received allogeneic hematopoietic stem cell transplantation, a pretransplant DNA specimen is recommended for testing.

CPT Code:

81479

Day(s) Setup: Monday through Friday

Analytic Time: 3 days; not reported on Saturday or Sunday

Questions

Contact Heather Flynn Gilmer, Laboratory Technologist Resource Coordinator at 800-533-1710.