MAYO CLINIC LABORATORIES

NEW TEST

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

Cytochrome P450 *3A5* Genotype, Varies

Test ID: 3A5Q

Useful for:
Aids in optimizing treatment with tacrolimus and other drugs metabolized by cytochrome P450 3A5

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

Advisory Information:
Testing is available as the single gene assay (this test) and as a part of a psychotropic or focused pharmacogenomics panel.

If multiple pharmacogenomic genotype testing is desired, order PGXQP / Focused Pharmacogenomics Panel, Varies.

If genotype testing for psychotropic medications is desired, order PSYQP / Psychotropic Pharmacogenomics Gene Panel, Varies.

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:

Rare variants may be present that could lead to false-negative or false-positive results. If results obtained do not match the clinical findings (phenotype), additional testing could be considered.

Samples may contain donor DNA if obtained from patients who received non-leukoreduced 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.

CYP3A5 genetic test results in patients who have undergone liver transplantation may not accurately reflect the patient's CYP3A5 status.

This method may not detect all variants that result in altered CYP3A5 activity. Therefore, absence of a detectable variant does not rule out the possibility that a patient has altered CYP3A5 activity due to other *CYP3A5* variants that cannot be detected with this method. Furthermore, when 2 or more variants are identified, the cis-/trans- status (whether the variants are on the same or opposite chromosomes) is not always known.

Drug-drug interactions and drug-metabolite inhibition must be considered.

Drug-metabolite inhibition can occur, resulting in inhibition of CYP3A5 catalytic activity.

CPT Code:

81231-CYP3A5

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.