

### FILE DEFINITION TEST CHANGE

Notification Date: June 3, 2025 Effective Date: July 3, 2025

# Cytochrome P450 3A4 Genotype, Varies

Test ID: 3A4Q

**Explanation:** On the effective date, the test algorithm will be updated to include a reflex test when necessary. Additionally, the Useful For, Specimen Required, and Times Performed sections will be updated as indicated below.

#### **Current Useful For**

Aids in determining therapeutic strategies for drugs that are metabolized by cytochrome P450 3A4, including atorvastatin, simvastatin, and lovastatin

This test is **not useful for** managing patients receiving fluvastatin, rosuvastatin, or pravastatin since these drugs are **not** metabolized appreciably by CYP3A4.

#### **New Useful For**

Aids in determining therapeutic strategies for drugs that are metabolized by cytochrome P450 3A4, including quetiapine

This test is **not useful for** managing patients receiving fluvastatin, rosuvastatin, or pravastatin since these drugs are **not** metabolized appreciably by CYP3A4.

#### **Current Algorithm**

None

#### **New Algorithm**

For any cord blood specimen that is received, maternal cell contamination testing may be performed at an additional charge.

#### **Current Reflex Tests**

None

New Reflex Tests			
Test ID	Reporting Name	Available Separately	Always Performed
MATCC	Maternal Cell Contamination, B	Yes	No

#### **Current Specimen Required**

Multiple genotype tests can be performed on a single specimen after a single extraction. See Multiple Genotype Test List in Special Instructions for a list of tests that can be ordered together.

#### **New Specimen Required**

**Patient Preparation:** A previous hematopoietic stem cell transplant from an allogenic donor or a liver transplant will interfere with testing. For more information about testing patients who have received a hematopoietic stem cell or liver transplant, call 800-533-1710.

#### Submit only 1 of the following specimens:

Specimen Type: Whole blood

Container/Tube: Lavender top (EDTA)

**Specimen Volume:** 3 mL Collection Instructions:

Invert several times to mix blood.
 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: One 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

#### 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 whole blood specimen in original tube. **Do not** 

aliquot.

**Specimen Stability Information**: Ambient (preferred) 4 days/Refrigerated 4 days/Frozen 4 days

Additional Information:

- 1. Specimens are preferred to be received within 4 days of collection. Extraction will be attempted for specimens received after 4 days, and DNA yield will be evaluated to determine if testing may proceed.
- 2. To ensure minimum volume and concentration of DNA is met, the requested volume must be submitted. Testing may be canceled if DNA requirements are inadequate.

Specimen Type: Cord blood

Container/Tube: Lavender top (EDTA)

**Specimen Volume**: 3 mL Collection Instructions:

1. Invert several times to mix blood.

 Send cord blood specimen in original tube. Do not aliquot.
 Specimen Stability Information: Ambient (preferred) 4 days/Refrigerated 4 days/Frozen 4 days

#### **Additional Information:**

- 1. Specimens are preferred to be received within 4 days of collection. Extraction will be attempted for specimens received after 4 days, and DNA yield will be evaluated to determine if testing may proceed.
- 2. To ensure minimum volume and concentration of DNA is met, the requested volume must be submitted. Testing may be canceled if DNA requirements are inadequate.
- 3. While a properly collected cord blood sample may not be at risk for maternal cell contamination, unanticipated complications may occur during collection. Therefore, maternal cell contamination studies are recommended to ensure the test results reflect that of the patient tested and are available at an additional charge. Order MATCC / Maternal Cell Contamination, Molecular Analysis, Varies on the maternal specimen.

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: 2 Swabs

Collection Instructions: Collect and send specimen per kit

instructions.

Specimen Stability Information: Ambient (preferred) 30

days/Refrigerated 30 days

Additional information: Saliva specimens are acceptable but not recommended. Due to lower quantity/quality of DNA yielded from saliva, some aspects of the test may not perform as well as DNA extracted from a whole blood sample. When applicable, specific gene regions that were unable to be

8 a.m.	Varies
Current Times Performed	New Times Performed
Current Times Performed	Acceptable: Matrix tube, 1 mL Collection Instructions:  1. The preferred volume is at least 100 mcL at a concentration of 75 ng/mcL.  2. Include concentration and volume on tube. Specimen Stability Information: Frozen (preferred) 1 year/Ambient/Refrigerated Additional Information: DNA must be extracted in a CLIA-certified laboratory or equivalent and must be extracted from a specimen type listed as acceptable for this test (including applicable anticoagulants). Our laboratory has experience with Chemagic, Puregene, Autopure, MagnaPure, and EZ1 extraction platforms and cannot guarantee that all extraction methods are compatible with this test. If testing fails, one repeat will be attempted, and if unsuccessful, the test will be reported as failed and a charge will be applied. If applicable, specific gene regions that were unable to be interrogated due to DNA quality will be noted in the report.  New Times Performed
	Specimen Type: Extracted DNA Container/Tube: Preferred: Screw Cap Micro Tube, 2mL with skirted conical base
	interrogated will be noted in the report. Alternatively, additional specimen may be required to complete testing.

## Questions

Contact Michelle Raths, Laboratory Resource Coordinator at 800-533-1710.