

FILE DEFINITION TEST CHANGE

Notification Date: July 1, 2025 Effective Date: July 31, 2025

Focused Pharmacogenomics Panel, Varies

Test ID: PGXQP

Explanation: On the effective date, the Test Algorithm will be updated to include an additional reflex test when necessary. Additionally, the Specimen Required, Days Performed, and Times Performed sections will be updated as indicated below.

Current Testing Algorithm

If a specimen requires follow-up for *CYP2D6*, then reflex testing will be performed as appropriate at an additional charge.

For more information see <u>CYP2D6 Comprehensive</u> <u>Cascade Testing Algorithm</u>.

New Testing Algorithm

If a specimen requires follow-up for *CYP2D6*, then reflex testing will be performed as appropriate at an additional charge.

For cord blood specimens, maternal cell contamination testing may be performed at an additional charge.

For more information see <u>CYP2D6 Comprehensive Cascade</u> Testing Algorithm.

Current Reflex Tests				
Test ID	Reporting Name	Available Separately	Always Performed	
2D61Z	CYP2D6 Full Gene Sequence	No (Bill Only)	No	
2D62Z	CYP2D6 GEN CYP2D6-2D7 Hybrid	No (Bill Only)	No	
2D63Z	CYP2D6 GEN CYP2D7-2D6 Hybrid	No (Bill Only)	No	
2D64Z	CYP2D6 Nonduplicated Gene	No (Bill Only)	No	
2D65Z	CYP2D6 5' Gene DUP/MLT	No (Bill Only)	No	
2D66Z	CYP2D6 3' Gene DUP/MLT	No (Bill Only)	No	

New Reflex Tests				
Test ID	Reporting Name	Available Separately	Always Performed	
2D61Z	CYP2D6 Full Gene Sequence	No (Bill Only)	No	
2D62Z	CYP2D6 GEN CYP2D6- 2D7 Hybrid	No (Bill Only)	No	
2D63Z	CYP2D6 GEN CYP2D7- 2D6 Hybrid	No (Bill Only)	No	
2D64Z	CYP2D6 Nonduplicated Gene	No (Bill Only)	No	
2D65Z	CYP2D6 5' Gene DUP/MLT	No (Bill Only)	No	
2D66Z	CYP2D6 3' Gene DUP/MLT	No (Bill Only)	No	
MATCC	Maternal Cell Contamination, B	Yes	No	

Current Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Whole blood

Container/Tube:

Preferred: Lavender top (EDTA)

Acceptable: None 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) 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.

Additional Information: Due to lower

concentration of DNA vielded from saliva, testing cannot proceed to reflex testing for 2D6 sequencing and will stop after initial testing is complete.

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. Provide concentration of DNA and volume on tube.

Specimen Stability Information: Frozen (preferred) 1 year/Ambient/Refrigerated

New Specimen Required

Patient Preparation: A previous hematopoietic stem cell transplant from an allogenic donor will interfere with testing. For information about testing patients who have received a hematopoietic stem cell 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:**

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.

2. 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 Collection Kit (T786) Specimen Volume: 2 Swabs

Collection Instructions: Collect and send specimen per kit

instructions.

	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 interrogated will be noted in the report. Alternatively, additional specimen may be required to complete testing. Specimen Type: Extracted DNA Container/Tube: Preferred: Screw Cap Micro Tube, 2 mL with skirted conical base 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.
Current Days Performed	New Days Performed
Monday through Friday	Varies
Current Times Performed	New Times Performed
8 a.m.	Varies

Questions

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