MAYO CLINIC LABORATORIES

Test Definition: FMT21

MaterniT21 Plus

Overview

Special Instructions

- Sequenom Test Requisition Form

Method Name

Circulating cell-free DNA is examined from maternal whole blood.

NY State Available

Yes

Specimen

Specimen Type

WB Streck

Specimen Required

**NOTE: Completed Sequenom Test Requisition form is required

A Core Option must be marked on TRF under MaterniT 21 PLUS test

If nothing indicated by client, mark option- Core (chr 21, 18, 13, sex)

Preferred evacuated tube: (1)10 mL Streck tube kit (MCL supply number T715).

Absolute minimum collection for analysis: (1) 10 mL in Streck tube

Collection instructions: Draw 1 tube of blood, 10 mL in special Streck tube kit (MCL supply number T715). Ship ambient.

REQUIRED:

1. Specimen MUST be received at MCL within 72 hours of collection.
2. Specimen collected NOT less than 9 weeks of gestation
3. Sequenom collection kit (MCL Supply T715)
4. Completed Sequenom Test Requisition form
5. Maternal Height (inches)
6. Maternal Weight (pounds)
7. Gestational Age (weeks)
8. Gestational Age (days)
9. Gestation (Number of fetuses)
10. Increased risk due to

Specimen Minimum Volume

10 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
WB Streck	Ambient	7 days	Streck Black/Tan top

Clinical & Interpretive

Clinical Information

The MaterniT21 PLUS test analyzes circulating cell-free DNA extracted from a maternal blood sample. The test is indicated for use in pregnant women with increased risk for chromosomal aneuploidy. Validation data on twin pregnancies is limited and the ability of this test to detect aneuploidy in a triplet pregnancy has not yet been validated.

DNA test results do not provide a definitive genetic risk in all individuals. Cell-free DNA does not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. These tests are not intended to identify pregnancies at risk for neural tube defects or ventral wall defects.

A patient with a positive test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative test result does not ensure an unaffected pregnancy. While results of this testing are highly accurate, not all chromosomal abnormalities may be detected due to placental, maternal or fetal mosaicism, or other causes. The health care provider is responsible for the use of this information in the management of their patient.

Reference Values

A final report will be provided

Performance

PDF Report

Referral

Day(s) Performed

Upon Receipt

Report Available

7 to 14 days

Performing Laboratory Location

Sequenom Center for Molecular Medicine LLC

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing and accredited by the College of American Pathologists (CAP).

CPT Code Information

81420

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FMT21	MaterniT21 Plus	Not Provided

Result ID	Test Result Name	Result LOINC® Value
Z3738	Result	Not Provided