MAYO CLINIC LABORATORIES

Test Definition: FFMSS

Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT

Overview

Useful For

Helpful to identify pregnancies at increased risk of having a child with Down Syndrome (DS), open neural tube defects (ONTD) and trisomy 18 (T18). This test is not diagnostic.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
FPATI	Patient Information	No	Yes
FMAS1	Maternal Screen INT-1	No	Yes

Special Instructions

- PATIENT HISTORY FOR MATERNAL SERUM TESTING

Method Name

Quantitative Chemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Specimen #1 collection must occur between 10 weeks, 0 days and 13 weeks, 6 days gestation. (If gestational age is based on Crown-Rump length (CRL), the specimen must be collected when the CRL is between 32.4 - 83.9 mm)

Draw blood in a plain red-top tube(s), serum gel tube is acceptable. Spin down and send 0.5 mL serum refrigerated in a plastic vial.

Separate from cells ASAP or within 2 hours of collection.

Note:
Submit with order: Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient was diabetic at the time of conception, if there is a known family history of neural tube defects, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if the patient is taking valproic acid or

carbamazepine (Tegretol), if this is a repeat sample, and the age of the egg donor if in vitro fertilization.

In addition to the above:
If a NT measurement is performed: the date of ultrasound, the CRL measurement, the nuchal translucency (NT) measurement and the name and certification number of the sonographer is required. NT must be measured when the CRL is between 38-83.9mm.

Or

If no NT measurement is performed: a due date or CRL measurement with the date of ultrasound is required.

The NT measurement must also be performed by an ultrasonographer that is certified by one of the following agencies: Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR).

Specimen Minimum Volume
0.3 mL

Reject Due To

Hemolysis	Mild reject/Gross reject
Other	Plasma

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Ambient	72 hours	
	Refrigerated (preferred)	14 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information
This test combines a first- and second-trimester specimen to screen low-risk pregnancies for Down syndrome (DS), open neural tube defects (ONTD) and trisomy 18 (T18).

Collection of two blood samples is required for this test. A first trimester ultrasound to measure the fetal nuchal translucency (NT) is optional (see special instructions).

Patient demographics and analyte/ultrasound measurements are used to calculate multiple of the median (MoM) values for each of the laboratory analytes and the NT. The pattern of the MoM values is used to calculate post-test risks of ONTD, DS and T18.
Markers used for assessment of risk include first-trimester PAPP-A with or without NT and second-trimester AFP, hCG, unconjugated estriol (uE3) and dimeric Inhibin A.

A DS risk of 1 in 110 or worse is reported as abnormal. This risk cutoff predicts a detection rate of 87 percent at a screen positive rate of 1.0%.

A T18 risk of 1 in 100 or worse is reported as abnormal. This risk cutoff predicts a detection rate of 90 percent at a screen positive rate of <0.5%.

ARUP uses a singleton AFP MoM cut off of >or= 2.5. If the interpretation is "high AFP," there is an increased risk of an ONTD in the pregnancy. This cutoff value predicts a detection rate of 80% at a screen positive rate of 1.5%. High AFP also occurs in unrecognized twin pregnancies and with underestimated gestational age.

Pregnancies at an increased risk for ONTD with an AFP MoM <2.5, but a risk of 1 in 250 or worse, are also reported as abnormal. This is usually due to a family history of ONTD, the use of certain seizure medications by the patient during pregnancy, or the presence of maternal insulin-dependent diabetes, any of which increases a patients risk for ONTD.

An increased risk of congenital steroid sulfatase deficiency or Smith-Lemli-Opitz syndrome (uE3 <or= 0.14 MoM) and poor fetal outcome (hCG >or= 3.5 MoM) is reported as "see note".

Reference Values

An interpretive report will be provided.

Part 2 must be completed in order to receive an interpretable result.

If the second specimen is not received for sequential screening, the results are uninterpretable and no maternal risk will be provided.

Interpretation

The first specimen of an integrated Maternal Serum Screening is used to measure PAPP-A. A second sample must be submitted for a final interpretive report. Acceptable date ranges to draw the second samples will be provided in the Integrated-1 report. Final interpretive report will be available when the second specimen test results are complete.

Cautions

A screen interpreted as “normal” misses approximately 15% of Down Syndrome, 20% of open neural tube defects and 10% of trisomy 18 cases.

Abnormal results require follow-up with targeted ultrasound, genetic counseling and consideration of fetal diagnostic testing.

Performance

Method Description

PAPP-A is pregnancy associated plasma protein A and is a sequential immunoenzymatic assay that uses two monoclonal antibodies and external calibrators.

AFP and hCG are both measured using a non-competitive immunoassay that uses one antibody to capture the protein to a solid phase, another antibody to detect the protein, and external calibrators.

The estriol assay is a solid phase competitive immunoassay that uses an anti-estriol polyclonal antibody, labeled estriol, a solid phase antibody directed against the estriol antibody, and external calibrators.

Inhibin-A is measured using a non-competitive microtiter immunoassay that uses a detection antibody to subunit *α*, a capture antibody to inhibin subunit *B*A, and external calibrators.

Calculation of post-test risks uses a multivariate log Gaussian model. Risk estimates for DS and T18 are influenced strongly by maternal age.

PDF Report
No

Day(s) Performed
Sunday through Saturday

Report Available
6 to 10 days

Performing Laboratory Location
ARUP Laboratories

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.

CPT Code Information
84163

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FFMSS	Maternal Serum Screen INT, Sp-1	Not Provided

Result ID	Test Result Name	Result LOINC® Value
Z5958	PAPP-A Maternal	48407-1
Z5959	Nuchal Translucency (NT)	12146-7

Z5960	Nuchal Translucency (NT), Twin B	12146-7
Z5961	Maternal Screen Interpretation	49586-1
Z5962	Maternal Age At Delivery	21612-7
Z5963	Maternal Weight	29463-7
Z5964	Estimated Due Date	11778-8
Z5965	Gestational Age Calculated at Coll.	18185-9
Z5966	Dating	21299-3
Z5967	Number of Fetuses	11878-6
Z5968	Maternal Race	21484-1
Z5969	Smoking	64234-8
Z5970	Family History of Aneuploidy	32435-0
Z5971	Specimen	19151-0
Z5972	Crown Rump Length	11957-8
Z5973	Crown Rump Length, Twin B	11957-8
Z5974	Sonographer Certification Number	49089-6
Z5975	Sonographer Name	49088-8
Z5976	Ultrasound Date	34970-4
Z5977	Best date to draw sample nmb 2 by	33882-2
Z5978	EER Maternal Serum, Integrated, Sp1	11526-1