Test Definition: FMSS2

Maternal Serum Screen INT, Sp-2

Overview

Useful For

Helpful to identify pregnancies at increased risk of having a child with Down syndrome (trisomy 21), Open Neural Tube Defect (ONTD, spina bifida) and trisomy 18 (T18). This test is not diagnostic.

The patient information provided with the Integrated, Specm1 will be used to calculate the risks for this report.

Method Name

Quantitative Chemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Specimen must be drawn between 14 weeks, 0 days and 24 weeks, 6 days gestation (based on the CRL). Recommended time for maternal serum screening is 16 to 18 weeks gestation. Acceptable date ranges to draw the second samples will be provided in the Integrated-1 report.

Draw blood in a plain red-top tube(s), serum gel tube is acceptable. Spin down and send 3 mL of serum refrigerated in a plastic vial.

Separate from cells ASAP or within 2 hours of collection.

This test requires that a previous first trimester specimen, Maternal Serum Screening, Integrated, Specimen #1, PAPP-A, NT (ARUP test ID: 3000147), has been performed.

Specimen Minimum Volume

1 mL

Reject Due To

Hemolysis	Mild reject; Gross reject
Lipemia	NA
Icterus	NA
Other	Plasma

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	365 days	

Specimen Type	Temperature	Time	Special Container
	Ambient	72 hours	

Clinical and 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 for 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 cutoff 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 patient's priori 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.

Interpretation

An interpretive report will be provided.Â See clinical information sections. 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.

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 *a*, 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) and Time(s) Test Performed

Sunday - Saturday

Analytic Time

2 - 4 days

Maximum Laboratory Time

4 - 8 days

Performing Laboratory Location

ARUP Laboratories

Fees and 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 Regional Manager. For assistance, contact Customer Service.

CPT Code Information

81511

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FMSS2	Maternal Serum Screen INT, Sp-2	Not Provided

Result ID	Test Result Name	Result LOINC Value
Z5170	Patient's AFP	1834-1
Z5171	MoM for AFP	20450-3
Z5172	Patient's uE3	2250-9
Z5173	MoM for uE3	20466-9
Z5174	Patient's hCG, 2nd Trimester	19080-1
Z5175	hCG MoM, 2nd Trimester	20465-1
Z5176	Patient's DIA	23883-2
Z5177	MoM for DIA	35738-4
Z5178	PAPP-A Maternal	32046-5
Z5179	MoM for PAPP-A	32123-2
Z5180	Nuchal Translucency (NT)	12146-7
Z5181	MoM for NT	49035-9
Z5182	Nuchal Translucency (NT), Twin B	12146-7
Z5183	MoM for NT, Twin B	49035-9
Z5184	Maternal Screen Interpretation	49586-1
Z5185	Maternal Age At Delivery	21612-7
Z5186	Maternal Weight	29463-7
Z5187	Estimated Due Date	11778-8
Z5188	Gestational Age for Second Specimen	18185-9
Z5189	Dating	21299-3
Z5190	Number of Fetuses	11878-6
Z5191	Maternal Race	21484-1
Z5192	Insulin Req Maternal Diabetes	44877-9
Z5193	Smoking	64234-8
Z5194	Family Hx Neural Tube Defect	8670-2
Z5195	Family History of Aneuploidy	32435-0
Z5196	Specimen	19151-0
Z5197	Crown Rump Length	11957-8
Z5198	Crown Rump Length, Twin B	11957-8
Z5199	Sonographer Certification Number	49089-6
Z5200	Sonographer Name	49088-8
Z5201	Ultrasound Date	34970-4
Z5202	EER Maternal Serum, Integrated, Sp2	11526-1