MAYO CLINIC LABORATORIES

Test Definition: MAFP1

Alpha-Fetoprotein (AFP), Single Marker Screen, Maternal, Serum

Overview

Useful For

Prenatal screening for open neural tube defect

Special Instructions

- Second Trimester Maternal Screening Alpha-Fetoprotein / Quad Screen Patient Information

Highlights

This test is a screening assay to identify pregnancies that may have an increased risk for neural tube defects (NTD).

A screen-positive result indicates that the calculated alpha-fetoprotein multiple of the median (MoM) is 2.50 or greater and may indicate an increased risk for NTD.

A screen-positive result does not infer a definitive diagnosis of a NTD but indicates that further evaluation should be considered.

Method Name

Two-Site Immunoenzymatic (Sandwich) Assay

NY State Available

Yes

Specimen

Specimen Type

Serum

Necessary Information

In order to provide the best results, either answer the order entry questions or provide the required information using the Second Trimester Maternal Screening Alpha-Fetoprotein / Quad Screen Patient Information (T595).

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Do not collect specimen after amniocentesis as this could affect results.

2. Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Additional Information:

1. Collect blood between 15 weeks, 0 days and 22 weeks, 6 days.
2. Initial or repeat testing is determined in the laboratory at the time of report and will be reported accordingly. To be considered a repeat test for the patient, the testing must be within the same pregnancy and trimester, with interpretable results for the same test, and both tests are performed at Mayo Clinic.

Forms

1. If not ordering electronically, **Second Trimester Maternal Screening Alpha-Fetoprotein / Quad Screen Patient Information (T595) is required.**
2. If not ordering electronically, complete, print, and send a General Request (T239).

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	7 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Alpha-fetoprotein (AFP) is a fetal protein that is initially produced in the fetal yolk sac and liver. A small amount is produced by the gastrointestinal tract. By the end of the first trimester, nearly all AFP is produced by the fetal liver. The concentration of AFP peaks in fetal serum between 10 to 13 weeks. Fetal AFP diffuses across the placental barrier into the maternal circulation. A small amount also is transported from the amniotic cavity.

The AFP concentration in maternal serum rises throughout pregnancy, from the nonpregnancy level of 0.2 ng/mL to about 250 ng/mL at 32 weeks gestation. If the fetus has an open neural tube defect (NTD), AFP is thought to leak directly into the amniotic fluid causing unexpectedly high concentrations of AFP. Subsequently, the AFP reaches the maternal circulation, producing elevated serum levels. Other fetal abnormalities such as omphalocele, gastroschisis, congenital kidney disease, esophageal atresia, and other fetal distress situations (eg, threatened abortion and fetal demise) also may result in maternal serum AFP elevations. Increased maternal serum AFP concentrations also may be seen in multiple pregnancies and in unaffected singleton pregnancies in which the gestational age has been underestimated.

Lower maternal serum AFP concentrations have been associated with an increased risk for genetic conditions such as trisomy 21 (Down syndrome) and trisomy 18 (Edwards syndrome). Risks for these syndrome disorders are only provided with the use of multiple marker screening (QUAD1 / Quad Screen [Second Trimester] Maternal, Serum).

Measurement of maternal serum AFP values is a standard tool used in obstetrical care to identify pregnancies that may have an increased risk for NTD. The screen is performed by measuring AFP in maternal serum and comparing this value to the median AFP value in an unaffected population to obtain a multiple of the median (MoM). The laboratory has established a MoM cutoff of 2.5, which classifies each screen as either screen-positive or screen-negative. A screen-positive result indicates that the value obtained exceeds the established cutoff. A positive screen does not provide a diagnosis but indicates that further evaluation should be considered.

Reference Values

An alpha-fetoprotein (AFP) multiple of the median (MoM) <2.5 is reported as screen negative.
AFP MoM > or =2.5 (singleton and twin pregnancies) are reported as screen positive.

An interpretive report will be provided.

Interpretation

A screen-negative result indicates that the calculated alpha-fetoprotein (AFP) multiple of the median (MoM) falls below the established cutoff of 2.50 MoM. A negative screen does not guarantee the absence of neural tube defects (NTD).

A screen-positive result indicates that the calculated AFP MoM is 2.50 or greater and may indicate an increased risk for open NTD. The actual risk depends on the level of AFP and the individual's pretest risk of having a child with NTD based on family history, geographical location, maternal conditions such as diabetes and epilepsy, and use of folate prior to conception. A screen-positive result does not infer a definitive diagnosis of a NTD but indicates that further evaluation should be considered. Approximately 80% of pregnancies affected with an open NTD have elevated AFP MoM values greater than 2.50.

Follow up:
Upon receiving maternal serum screening results, all information used in the risk calculation should be reviewed for accuracy (ie, weight, diabetic status, gestational dating). If any information is incorrect the laboratory should be contacted for a recalculation of the estimated risks.

Screen-negative results typically do not warrant further evaluation.

Ultrasound is recommended to confirm dates for NTD screen-positive results. If ultrasound yields new dates that differ by at least 7 days, a recalculation should be considered. If dates are confirmed, high-resolution ultrasound and amniocentesis (including amniotic fluid AFP and acetylcholinesterase measurements for NTD) are typically offered.

Cautions

Race, weight, smoking, multiple fetus pregnancy, and insulin-dependent diabetes (IDD) may affect marker concentrations. Black mothers tend to have higher alpha-fetoprotein (AFP) levels but lower risk of neural tube defects and are assigned to a separate AFP median set. Multiple of the medians (MoM) are adjusted for maternal weight (to account for dilution effects in heavier mothers). The AFP is adjusted upward in IDD to account for lower values in

diabetic pregnancies. Smoking results in higher second trimester maternal serum AFP. MoM are adjusted accordingly to account for serum AFP differences in smokers.

The screen results are dependent on accurate information for gestation, race, IDD, and weight. Inaccurate information can lead to significant alterations in the estimated risk. In particular, erroneous assessment of gestational age can result in false-positive or false-negative screen results. Because of its increased accuracy, the determination of gestational age by ultrasound is recommended, when possible, rather than by last menstrual period.

A screen-negative result does not guarantee the absence of fetal defects. A screen-positive result does not provide a diagnosis but indicates that further diagnostic testing should be considered (an unaffected fetus may have screen-positive result for unknown reasons).

Valid measurements of AFP in maternal serum cannot be made after amniocentesis.

Triplet and higher multiple pregnancies cannot be interpreted.

Each center offering maternal serum screening to patients should establish a standard screening protocol, which provides pre- and post-screening education and appropriate follow-up for screen-positive results.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Christensen RL, Rea MR, Kessler G, Crane JP, Valdes R Jr. Implementation of a screening program for diagnosing open neural tube defects: selection, evaluation, and utilization of alpha-fetoprotein methodology. Clin Chem. 1986;32(10):1812-1817
2. American College of Obstetricians and Gynecologists: Practice Bulletin No. 163: Screening for Fetal Aneuploidy. Obstet Gynecol. 2016;127(5):e123-137
3. Zhang J, Lambert-Messerlian G, Palomaki GE, Canick JA. Impact of smoking on maternal serum markers and prenatal screening in the first and second trimesters. Prenat Diagn. 2011;31(6):583-588
4. Yarbrough ML, Stout M, Gronowski AM. Pregnancy and its disorders. In: Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018:1655-1696

Performance

Method Description

Alpha-fetoprotein (AFP) values are compared to the median value for the unaffected population at a given gestational age and the multiple of the median is obtained and classified as either screen-positive or screen-negative. The Access AFP assay is a 2-site immunoenzymatic sandwich assay. A sample is added to a reaction vessel with mouse monoclonal anti-AFP alkaline phosphatase conjugate and paramagnetic particles coated with a second mouse monoclonal anti-AFP

antibody. The AFP in the sample binds to the immobilized monoclonal anti-AFP on the solid phase while, at the same time, the monoclonal anti-AFP-alkaline phosphatase conjugate reacts with different antigenic sites on the sample AFP. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then the chemiluminescent substrate Lumi-Phos*530 is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the amount of AFP in the sample. The amount of analyte in the sample is determined by means of a stored multipoint calibration curve.(Instruction manual: Access AFP. Beckman Coulter, Inc; 2024)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
4 to 6 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
82105

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MAFP1	AFP Single Marker SCRN, Maternal, S	48802-3

Result ID	Test Result Name	Result LOINC® Value

IDD	Insulin dependent diabetes	44877-9
IVFP	IVF pregnancy	47224-1
MULTF	Number of Fetuses	55281-0
10356	INTERPRETATION	49092-0
10248	Additional comments	48767-8
10357	RECOMMENDED FOLLOW UP	80615-8
10358	GENERAL TEST INFORMATION	62364-5
7058	Recalculated Maternal Serum Screen	32399-8
3009	Specimen collection date	33882-2
7823	Maternal date of birth	21112-8
7834	Calculated age at EDD	43993-5
26717	Maternal Weight	29463-7
26718	Maternal Weight	29463-7
10054	EDD by U/S scan	11781-2
7753	EDD by LMP	11779-6
7203	GA on collection by U/S scan	11888-5
7204	GA on collection by dates	11885-1
7830	GA used in risk estimate	21299-3
10351	AFP	83073-7
113146	Results Summary	32399-8
113147	Neural tube defect risk estimate	48803-1
113148	AFP MoM	23811-3
RACE1	Patient race	21484-1
SMKNG	Current cigarette smoking status	64234-8
CHOR_	Number of Chorions	92568-5
PRNTD	Prev Pregnancy w/ Neural Tube Defect	53827-2
PTNTD	Patient or father of baby has a NTD	53827-2
INTL	Initial or repeat testing	77202-0
DRPHN	Physician Phone Number	68340-9