MAYO CLINIC LABORATORIES

# Test Definition: AFPA

Alpha-Fetoprotein, Amniotic Fluid

## Overview

### Useful For

Screening for open neural tube defects or other fetal abnormalities

Follow-up testing for patients with elevated serum alpha-fetoprotein results or in conjunction with cytogenetic testing

### Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| ACHE_ | Acetylcholinesterase, AF | Yes | No |

### Testing Algorithm

If alpha-fetoprotein is positive, then acetylcholinesterase will be performed at an additional charge.

### Special Instructions

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

### Method Name

AFPA: Immunoenzymatic Assay

ACHE_: Polyacrylamide Electrophoresis

### NY State Available

Yes

## Specimen

### Specimen Type

Amniotic Fld

### Necessary Information

**The following information is required:**

1. Estimated due date by ultrasound
2. Collection date
3. Gestational age must be between 13 and 24 weeks; 16 to 18 weeks preferred.

If not ordering electronically, provide information on Second Trimester Maternal Screening Alpha-Fetoprotein / Quad Screen Patient Information (T595) and send with specimen.

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

**Container/Tube:** Plain, plastic, screw-top tube
**Specimen Volume:** 0.75 mL
**Collection Instructions: Do not centrifuge.**

### Forms
Second Trimester Maternal Screening Alpha-Fetoprotein / Quad Screen Patient Information **(T595) is required.**

### Specimen Minimum Volume
0.5 mL

### Reject Due To
All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Amniotic Fld | Refrigerated (preferred) | 7 days | |
| | Ambient | 7 days | |

## Clinical & Interpretive

### Clinical Information
Alpha-fetoprotein (AFP) is a single polypeptide chain glycoprotein with a molecular weight of approximately 70,000 Da. Synthesis of AFP occurs primarily in the liver and yolk sac of the fetus. It is secreted in fetal serum, reaching a peak at approximately 13 weeks gestation, after which it rapidly declines until about 22 weeks gestation and then gradually declines until term. Transfer of AFP into maternal circulation is accomplished primarily through diffusion across the placenta. Maternal serum AFP levels rise from the normal non-pregnancy level of 0.20 ng/mL to about 250 ng/mL at 32 weeks gestation.

If the fetus has an open neural tube defect, AFP is thought to leak directly into the amniotic fluid, causing unexpectedly high concentrations of AFP. Other fetal abnormalities such as omphalocele, gastroschisis, congenital kidney disease, and esophageal atresia; and other fetal distress situations such as threatened abortion, prematurity, and fetal demise, may also show AFP elevations. Decreased amniotic fluid AFP values may be seen when gestational age has been overestimated.

### Reference Values
<2.00 multiples of median (MoM)

### Interpretation
A screening alpha-fetoprotein (AFP) cutoff level of 2.0 multiples of median (MoM), followed by acetylcholinesterase (AChE) confirmatory testing on positive results, is capable of detecting 96% of open spina bifida cases with a false-positive rate of only 0.06% in non-blood-stained specimens.

Acetylcholinesterase analysis is an essential confirmatory test for all amniotic fluid specimens with positive AFP results. Normal amniotic fluid does not contain AChE, unless contributed by the fetus as a result of open communication

between fetal central nervous system (eg, open neural tube defects) or, to a lesser degree, fetal circulation. All amniotic fluid specimens testing positive for AFP will have the AChE test performed. False-positive AChE may occur from a bloody tap, which may cause both elevated AFP and AChE levels.

### Cautions

This test is for screening only.

Increases in alpha-fetoprotein (AFP) are not specific for neural tube defects, and the test must be used in combination with other procedures, such as ultrasonography and acetylcholinesterase measurements.

Elevated AFP levels also can be caused by benign factors and incorrect gestational dating.

Negative results do not guarantee the absence of defects.

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. Clinical Laboratory Standards Institute (CLSI): Maternal Serum Screening: Approved Standard. 2nd ed. I/LA25-A2 CLSI; 2011
2. Cuckle H. Prenatal screening using maternal markers. J Clin Med. 2014;3(2):504-520. doi:10.3390/jcm3020504
3. Bernard JP, Cuckle HS, Bernard MA, Brochet C, Salomon LJ, Ville Y. Combined screening for open spina bifida at 11-13 weeks using fetal biparietal diameter and maternal serum markers. Am J Obstet Gynecol. 2013;209(3):223.e1-5

## Performance

### Method Description

The Access AFP (alpha-fetoprotein) 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. The chemiluminescent substrate Lumi-Phos530 is added to the reaction vessel and light generated by the reaction is measured by 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 multipoint calibration curve.(Package insert: Access AFP. Beckman Coulter Inc; 12/2021)

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available
2 to 19 days

### Specimen Retention Time
6 months

### 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
82106
82013 (if appropriate)

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| AFPA | Alpha Fetoprotein, AF | 58735-2 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 6739 | Collection Date | 58734-5 |
| 6740 | Last Menstrual Period (LMP) | 8665-2 |
| 24233 | EDD by LMP | 11779-6 |
| 24239 | GA at Collection by Scan | 11888-5 |
| 24240 | GA at Collection by Dates | 11885-1 |
| 24234 | GA Used | 21299-3 |
| 24241 | Results | 29595-6 |
| 24235 | Interpretation | 59462-2 |
| 24236 | Additional Comments | 48767-8 |
| 24237 | Follow up | 80615-8 |
| 24238 | General Test Info | 48767-8 |
| 9950 | Alpha Fetoprotein, AF | 1832-5 |

| | | |
|---|---|---|
| DAT15 | EDD by US Scan | 11781-2 |