Lab Dept:	**Chemistry**
Test Name:	**ALPHA-FETO PROTEIN (AFP) TUMOR MARKER**

General Information

Lab Order Codes:	AFPR
Synonyms:	Alpha-Fetoprotein (AFP) Tumor Marker, plasma or serum
CPT Codes:	82105 – Alpha-fetoprotein; serum
Test Includes:	AFP tumor marker level reported in ng/mL. If values are >40,000 ng/mL a reflex test will be forwarded for Mayo Medical Laboratories for confirmation.

Logistics

Test Indications:	Useful for the follow-up management of patients undergoing cancer therapy, especially for testicular and ovarian tumors and for hepatocellular carcinoma. Often used in conjunction with human chorionic gonadotropin.
Lab Testing Sections:	Chemistry – Performed on Minneapolis Campus
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 – 6 hours. If the specimen is referred to MML results will be available in 1-3 days.
Special Instructions:	Amniotic fluid should **not** be sent because this test is only used as a tumor marker. Diagnosis should be confirmed by other tests or procedures.

Specimen

Specimen Type:	Blood (amniotic fluid is not acceptable)
Container:	SST (Gold, marble or red)
Draw Volume:	3 mL blood
Processed Volume:	1 mL serum

Collection: Routine venipuncture

Special Processing: Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial. Store and ship at refrigerated temperatures. Forward promptly.

Patient Preparation: None

Sample Rejection: Mislabeled or unlabeled specimens; gross hemolysis

Interpretive

Reference Range:

Age:	**Range (ng/mL)**
0 – 1 month:	>2000
1 – 6 months:	9.8 – 1359.0
6 – 12 months:	0.4 – 103.1
1 – 19 years:	0.8 – 34.8
Adult:	<8.8

Note: Reference values are for non-pregnant subjects only; pregnancy may cause elevated AFP values. Range for newborns is not available, but concentrations over 100,000 ng/mL have been reported in normal newborns, and the values rapidly decline in the first 6 months of life.

Serum markers are not specific for malignancy and values may vary by method.

Interpretation:
Alpha-fetoprotein (AFP) levels may be elevated in association with a variety of malignancies or benign diseases.

Failure of the AFP value to return to normal by approximately 1 month after surgery suggests the presence of residual tumor.

Elevation of AFP after remission suggests tumor recurrence; however, tumors originally producing AFP may recur without an increase in AFP.

Results are not comparable with other methods or manufacturers.

Critical Values: N/A

Limitations:

This assay is intended only as an adjunct in the diagnosis and monitoring of AFP-producing tumors. The diagnosis should be confirmed by other tests or procedures. AFP is not recommended as a screening procedure for cancer detection in the general population. This test is not intended for the detection of neural tube defects. Higher values are found in newborns and pregnant women. Not useful in patients with pure seminoma or dysgerminoma.

Amniotic fluid should not be sent, because this test is only used as a tumor marker. This test is not the correct AFP test for pregnant patients.

This test is not intended for detection of neural tube defects. Higher values are found in newborns and pregnant women. Not useful in patients with pure seminoma or dysgerminoma.

Methodology:

Chemiluminescence MicroParticle Immunoassay, Abbott Diagnostics

References:

Abbott Architect AFP Product Insert, Abbott Laboratories, Abbott Park, IL. August 2019

CALIPER Reference Ranges, accessed 11/9/2020

Abbott Alinity AFP Calibrator Package Insert. Abbott Diagnostics, Abbott Park, IL, USA. August 2019

Updates:

11/16/2009: Plasma samples no longer accepted at Mayo. Send serum only.
7/8/2010: Specimen storage changed from frozen to refrigerated.
7/11/2017: Updated collection tube information.
5/15/2018: New method
9/7/2018: Updated for samples >40,000 ng/mL to be referred to MML.
11/6/2020: Updated for new Alinity analyzer.
11/9/2020: Reference interval update using CALIPER reference interval studies.
11/23/2020:Ref range update.