Change in Instrumentation/Methodologies: AFP Tumor Marker

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective August 2, 2021, Clinical Pathology Laboratories is pleased to announce a change in instrumentation/ methodology and reference range for AFP Tumor Marker with transition to the Roche Cobas electrochemiluminescence immunoassay (ECLIA) method. Previously, Serum AFP Tumor testing was performed on the Beckman Coulter DxI by paramagnetic particle chemiluminescent immunoassay.

Alpha fetoprotein, an albumin-like glycoprotein with a molecular weight of 70000 daltons, is formed in the yolk sac, fetal/neonatal and regenerating liver cells, and the fetal gastrointestinal tract. 70-95 % of patients with primary hepatocellular carcinoma have elevated AFP values. Assessment of AFP levels are essential for classifying and following certain germ cell neoplasms.

Validation studies with the prior method show strong correlation with a negative bias of 19% that is accommodated by a reference interval adjustment. With the change in reference interval and method, the laboratory will retain the prior method and will archive tested specimens for 30 days to facilitate reestablishment of a baseline if clinically indicated. Additionally, the following note will be applied to communicate this change:

> *Note: New methodology is Roche Cobas chemiluminescent immunoassay associated with reference interval change. Specimen is retained in laboratory for 30 days for comparative testing if clinically required. Please contact laboratory to reassess with prior method.*

Changes in reporting:

Assay	Test Code	Prior Reference Range	New Reference Range	Notes
AFP Tumor Marker	2625	Males and Non Pregnant Females ≤ 9.0 ng/mL	Males and Non Pregnant Females ≤ 8.3 ng/mL. Reference interval has not been specifically assessed for neonates, infants and children.	Reporting Range: 0-2 Years: Not Given 3-150 Years: ≤ 8.3 ng/mL

Order Unit Codes and Test Names:	**2625 AFP, Tumor Marker**
Specimen Requirements:	2 mL serum. Allow sst tube to clot in an upright position for at least 30 minutes, then centrifuge sample within 2 hours of collection. Refrigerate. *Do not collect samples from patients receiving therapy with high biotin doses (>5 mg/day) until at least 8 hours following the last biotin administration.*
Other Acceptable Specimen Requirements:	2 mL serum from a plain top tube. Allow sample to clot in an upright position for at least 60 minutes, then centrifuge sample and transfer serum to a plastic transport tube within 2 hours of collection. Clearly label tube as serum from a plain top tube. *Do not collect samples from patients receiving therapy with high biotin doses (>5 mg/day) until at least 8 hours following the last biotin administration.*
Transport Temperature:	Refrigerated
Stability (collection to initiation of testing):	Room Temperature 15-25°C: 7 days Refrigerated 2-8°C: 7 days Frozen (-15) - (-25)°C: 1 month
Performed:	Monday through Friday / PM Shift
Analytic Time:	1 day
CPT Code:	82105

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