CHEM.DXI.ASSAY.1.0 DXI AFP (AFPTM)

PRINCIPLE

Alpha-fetoprotein (AFP) is a single chain glycoprotein with a molecular mass of approximately 70,000 daltons. (1) AFP is highly similar to albumin, and together, both proteins constitute the two major proteins in fetal circulation. Production of AFP occurs primarily in the fetal liver and yolk sac, and to a lesser degree in other organs. (2) AFP is first detected in the fetal circulation approximately 30 days after conception. (3) After reaching a peak concentration at 12-15 weeks gestation, levels gradually diminish until birth. By 2 years of age, only trace levels of AFP can be detected in normal individuals. (4) Elevated AP levels reappear in adults in certain malignant disease and pregnancy.

The Access AFP assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel along 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 a different antigenic site on the same 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 vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of AFP in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

OWNERS

Manager, Regional Chemistry

RELATED DOCUMENTS

CHEM.DXI.1.0 DXI Operating Procedure

SPECIMEN

A. Specimen Type
    1. Serum
B. Specimen Stability
    1. Room Temperature (15-30°C) – 8 hours
    2. Refrigerated (2-8°C) – 48 hours
    3. Frozen (≤-20°C) ->48 hours or for shipment
C. Special Instructions
    1. Thaw specimens only once.

REAGENTS

A. The reagent is ready to use.
B. Store upright and refrigerate at 2-10°C.
C. Refrigerate at 2-10°C for a minimum of two hours before use on the instrument.

D. Stable until the expiration date on the label when stored at 2-10°C.
E. Stable at 2-10°C for 28 days after initial use.
F. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading onto the instrument.
G. Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
H. For in vitro diagnostic use.
I. Handle all reagents with caution and avoid contact with skin, eyes, or mouth. Refer to the Method Manual for any known toxicity.

EQUIPMENT

Beckman Coulter Access UniCel DxI 600

CALIBRATION

A. An active calibration curve is required for all tests.
B. Calibration is required every 28 days for Access AFP.
C. Calibrators are Ready to Use.
D. Store upright at 2-10°C.
E. Mix contents by gently inverting before use
F. Stable until the expiration date stated on the label when stored at 2-10°C.
F. Refer to calibration card for exact concentrations.
G. Refer to the appropriate system manual and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

A. Refer to CHEM.QC.REGIONAL.2.0 Quality Control Testing Intervals for QC Testing Intervals for appropriate control materials and testing intervals.
B. Refer to CHEM.QC.REGIONAL.1.0 Regional Chemistry laboratory Quality Control for criteria on accepting/rejecting patients based on control results.
C. Refer to CHEM.QC.REGCHEM.2.2 QC PREP and STABILITY

PROCEDURE

A. See, DxI Operating Procedure, CHEM.DXI.1.0 for specific details.
B. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

DILUTIONS

A. for auto or manual dilution refer to CHEM.DXI.1.2 for specific details.

The DxI system onboard dilution feature automates the dilution process, using predefined assay sample and the Wash Buffer/ Sample Diluent volumes, allowing samples to be quantitated. Results Reported by the system are adjusted for dilution.

REPORTING RESULTS

Refer to, CHEM.DXI.1.1 for Test Codes, AMR, CRR, Critical and Normal Ranges

RESULT ENTRY

A. Sunquest
1. OEM or MEM
2. Worksheet: DXI
3. Method: DXI
4. Test Code: AFPTM

B. Toplab
1. Enter results in Toplab using Toplab Common Pathway: 3,3,1
2. Toplab Worklist: DXI1
3. Test Code: 237

C. If HIS or LIS systems are not functional, see the Computer Downtime CHEM.LIS.5.0 procedure.

PROCEDURE NOTES

Use 250 µL of sample for each determination run with the DXI system.

LIMITATIONS

A. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interferes with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.

B. The Access AFP results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests and other appropriate information. Elevated concentrations may be observed in non-neoplastic conditions including ataxia, telangiectasia, heredity tyrosinemia, nonmalignant hepatic disease (such as acute viral hepatitis, chronic active hepatitis and cirrhosis) and pregnancy. Not all teratocarcinomas of germ cell origin produce AFP. Therefore, the Access AFP assay is not intended for the diagnosis of, or for screening for testicular cancer.

REFERENCES

A. Beckman Coulter Access Immunoassay Systems AFP Assay Procedure (A86472E) 2014