AFP

infinosis™

Alpha Fetoprotein (FIA)

REF: IN067710 Σ **25**

Intended use
The infinosis™ AFP is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of alpha fetoprotein (AFP) in human serum or plasma. The assay is useful in the diagnosis of thyroid or pituitary disorders. For professional use only.

Summary
References[1-3]
AFP is a glycoprotein with a molecular weight of between 65,000 and 70,000 Daltons including 4% of carbohydrate during fetal development, AFP maintains high levels in the serum and drops to very low levels throughout the remainder of life.AFP is elevated in the malignant diseases of hepatocelluar, testicular nonseminomatous origin, and occasionally of other endodermis origin AFP may be slightly elevated or persisted in the patients with large hepatic metastases or viral hepatitis. AFP measurement is widely accepted as tumor marker and for monitoring .the therapeutic effectiveness of hepatocellular cancer and nonseminomatous testicular cancer. The highest AFP concentration appears in the amniotic fluid in the earliest stages of pregnancy, and diminishes in concentration through the remainder of the pregnancy. Elevated AFP levels in the amniotic fluid were found in fetus with open neural tube defects, e. g. spinal bifida or anencephaly also were found in fetus with severe fetal hemolytic disease, omphalocele, esophageal atresia, congenital nephrosis, intrauterine death, or fetal bleeding into the amniotic fluid. For diagnostic purpose, ultrasonography and acetyicholinesterase measurement should be performed in conjunction with the measurement of AFP.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-AFP antibody binds to AFP antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and AFP are captured to anti-AFP antibody that has been immobilized on test strip.
More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for infinosis™ tests to show AFP concentration in the sample.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- AFP control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ AFP should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ AFP assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Storage and stability
- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **50 µL** of sample (Human plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- AFP has a low clinical sensitivity and specificity as a tumor marker. Clinically an elevated AFP value alone is not of diagnostic value as a test for cancer and

IVD

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should only be used in conjunction with other clinical manifestations (observations) and diagnostic parameters. AFP levels are known to be elevated in a number of benign diseases and conditions including pregnancy and non-malignant liver diseases such as hepatitis and cirrhosis.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Calculation
The analyzer automatically calculates the analyte concentration of each sample either in IU/mL or ng/mL.

Conversion factor: IU/mL x 1.21 = ng/mL

Measuring range
1.0-400 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as <1.0 ng/mL. Values above the measuring range are reported as >400 ng/mL.

Lower detection limit
1.0 ng/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 18).

Expected values
Male and female: <8.5 ng/mL (97-98%)
Approximately 97-98% of the normal healthy population has AFP levels less than 8.5ng/ml.[4] In high-risk patients, AFP values between 100-350 ng/ml suggest hepatocellular carcinoma. Concentrations over 350 ng/ml usually indicate the disease.
Values for AFP for a normal, healthy population and pregnant women, during gestation cycle, are given below. The values depicted below represent limited in house studies in concordance with published literature.[5,6,7]

Median values during Gestation	
Gestation (week)	AFP (ng/mL)
15	39.20
16	42.45
17	51.26
18	60.88
19	74.87
20	82.98
21	89.78

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by using 10 tests in the same batch to test with AFP control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with AFP control, CV ≤ 20%

Method comparison
A comparison of the Porrima AFP assay (y) with the Roche Elecsys AFP assay (x) using 96 clinical samples gave the following correlations:
Linear regression
y = 1.0075x + 0.091
r = 0.9574
The sample concentrations were between approx. 3.0 and 560 ng/mL.

Functional sensitivity
1.2 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References
1. Ruosiahti, E., H. Pihko, and M.Seppaia.Transpiant Rev.20:38-60,1974.
2. Sliver, H.K.B., P. Goid, S. Feder, S.O. Freeman and J. Shuster. Proc. Natl. Acad.Sci.USA 70:526-530,1973
3. Braunstein, G.D., K.R. McIntire, and T.A. Walaman. Cancer 32:1065-1068, 1973.
4. Li D, Mallory T, Satomura S, "AFP; a new generation of tumor marker for hepatocellulor carcinoma", Clin Chem Acta, 313, 15-9 (2001).
5. Canick JA, Rish S. 'The accuracy of assigned risks in maternal serum screening', Prenatal Diagnosis; 18:413-415 (1998).
6. NIH State-of-the Science Conference Statement on Management of Menopause-Related Symptoms. NIH Consensus State Sci Statements. Mar 21-23; 22(1), 1-38 (2005).
7. Tietz NW, ED: Clinical Guide to Laboratory Tests 3rd Ed, Philadelphia, WA Saunders Co (1995).

Symbols

IVD In vitro diagnostic medical device	2°C 30°C Temperature limit	 Consult instructions for use	REF Catalog number
LOT Batch code	 Date of manufacture	 Use-by date	Σ Contains sufficient for <n> tests
 Manufacturer	 Do not re-use	 Do not use if package is damaged and consult instructions for use	

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