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Tumor

AFIAS AFP

INTENDED USE

AFIAS AFP is a fluorescence Immunoassay (FIA) for the quantitative determination of Alpha Feto Protein (AFP) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of primary hepatocellular carcinoma and non seminomatous testicular cancer.

For *in vitro* diagnostic use only.

INTRODUCTION

Alpha-fetoprotein (AFP) is a α1-globulin family of human plasma proteins and a glycoprotein with a molecular weight approximately 70 kDa. AFP is produced primarily in the liver of developing fetus. It can be found in maternal blood and in amniotic fluid since it is secreted into fetal serum. A great increase of AFP concentration in several malignant diseases mostly is primary hepatocellular carcinoma and non-seminomatous testicular cancer. Some 70-90% of patients with primary hepatocellular carcinoma and nonseminomatous testicular cancer have been observed to have high levels of AFP. High concentration of AFP also have been found in a limited number of patients diagnosed with various diseases such as gastrointestinal tract cancer, viral hepatitis, chronic active hepatitis, alcoholic cirrhosis, and adenocarcinomas of lung, pancreas, and gall bladder. Since AFP is well known to be an important prognostic indicator of non-seminomatous testicular cancer, its most definitive role is on monitoring post-treatment clinical status and the post therapeutic evaluation of patients.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by the instrument for AFIAS tests to show AFP concentration in sample.

COMPONENTS

AFIAS AFP consists of 'Cartridge', 'Pipette tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has two components, a detector part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human AFP at the test line, while rabbit IgG at the control line.
- Detector part contains anti human AFP-fluorescence conjugate, anti rabbot IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- **AFIAS AFP** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used pipette tips, and cartridges should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **AFIAS AFP** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS AFP** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **EDTA** should be avoided.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-27

Components of **AFIAS AFP**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette Tip (Zipper bag) 24
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS AFP**.
Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Tumor marker Control** REF CFPO-94
- **Boditech Tumor marker Calibrator** REF CFPO-106

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS AFP** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Serum or plasma sample stored frozen at -20 °C for 3 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the components of the **AFIAS AFP** as described below. : Cartridge, pipette tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS tests 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

1) Take 100 µL of sample with a pipette and dispense it into the sample well on the cartridge.
2) Insert the cartridge into the cartridge holder
3) Insert a tip into the tip hole of the cartridge.
4) Tap the 'START' icon on the screen.
5) The test result will be displayed on the screen after 15 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays AFP concentration of the test sample in terms of ng/mL.
- Reference range: ≤ 10.9 ng/mL
- The working range of the **AFIAS AFP** is 5-350 ng/mL.

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 not provided with **AFIAS AFP**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

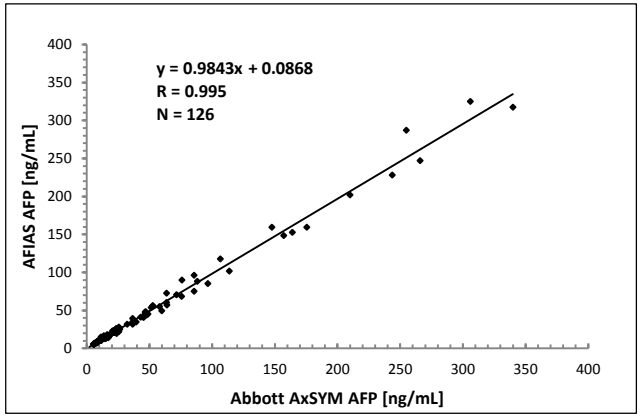
PERFORMANCE CHARACTERISTICS

- **Specificity**
  There, in test samples, are biomolecules such as hemoglobin, bilirubin, triglyceride, ascorbic acid, glucose, CEA, PSA, ALP, Troponin I, CK-MB, Albumin, and myoglobin in higher concentration than their normal physiological levels. But this doesn't interfere with the **AFIAS AFP** test measurements, nor occurs any significant cross-reactivity.

- **Precision**
  The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **AFIAS AFP.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentrations.

AFP	Intra-assay			Inter-assay		
[ng/mL]	Mean	SD	CV (%)	Mean	SD	CV (%)
20	20.51	1.11	5.41	20.66	1.09	5.25
80	79.81	3.49	4.37	82.20	2.55	3.11
175	179.27	4.42	2.46	180.18	5.23	2.90

- **Comparability**
  AFP concentrations of 126 serum samples were quantified independently with **AFIAS AFP** and Abbott AxSYM System as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y = 0.9843X + 0.0868 and R = 0.995 respectively.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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CE