BIO TECHNOLOGY boditech

Tumor

ichroma™ AFP

INTENDED USE

ichroma™ 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 instrument for ichroma™ tests to show AFP concentration in sample.

COMPONENTS

ichroma™ AFP consists of 'Cartridges', 'Detection Buffer Tubes', an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human AFP at the test line, while rabbit IgG at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human AFP-fluorescence conjugate, anti rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-pack for the shipment

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- 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, ID chip and detection buffer) 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 incorrect test result(s).
- Do not reuse cartridges or detection buffer tubes. A detection buffer tube should be used for processing of one sample only. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with hemolysis and/or hyperlipidemia must not be used.
- Allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used detection buffer tubes, pipette tips and cartridges should be handled carefully and discarded 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.
- **ichroma™ AFP** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ AFP** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Sample type	Recommended anticoagulant
Plasma	K_2 EDTA K_3 EDTA Sodium heparin
Whole Blood	
Serum	Not applicable.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer dispensed in a tube is stable for 20 months if stored at 2-8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION 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(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result 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.

MATERIALS SUPPLIED

REF i-CHROMA AFP-25

Components of **ichroma™ AFP**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Box containing Detection Buffer tubes
  - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
- **ichroma™ Printer** REF FPRR007
- **Boditech AFP Control** REF CFPO-248

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ 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. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- 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 change of test values.

TEST SETUP

- Check the contents of **ichroma™ AFP**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube 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 ichroma™ tests.
  (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

<Multi mode>

1) Transfer of sample (15 µL serum, plasma, control/30 µL whole blood) using a transfer pipette to a tube containing the detection buffer.
2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Leave the sample-loaded cartridge at room temperature for 15 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
6) Tap the 'Start' button or press the 'Select' button on the instrument for ichroma™ tests to start the scanning process.
7) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
8) Read the test result on the display screen of the instrument for ichroma™ tests.

<Single mode>

1) Transfer of sample (15 µL serum, plasma, control/30 µL whole blood) using a transfer pipette to a tube containing the detection buffer.
2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Inserting the cartridge into the holder of the instrument for ichroma™ test. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
5) Tap the 'Start' button or press the 'Select' button on the instrument for ichroma™ tests.
6) The Instrument for ichroma™ tests will automatically start scanning the sample-loaded cartridge after 15 minutes.
7) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays AFP concentration of the test sample in terms of ng/mL.
- The cut-off (reference range): ≤10.9 ng/mL
- Working range : 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 **ichroma™ 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

- **Analytical sensitivity**

Limit of Blank (LOB)	0.79 ng/mL
Limit of Detection (LOD)	1.096 ng/mL
Limit of Quantitation (LOQ)	5 ng/mL

- **Analytical specificity**
  - Interference

There was no significant interference from these materials with the ichroma™ AFP test measurement.

Interference material	Conc.
Bilirubin	342 µmol/L
D-Glucose	1,000 mg/dL
Hemoglobin	2 g/L
L-Ascorbic acid	170 µmol/L
Triglyceride	37 mmol/L

- Cross-reactivity
  There was no significant cross-reactivity from these materials with the ichroma™ AFP test measurement.

Cross-reactivity material	Conc. (ng/mL)
CEA	500
PSA	100
ALP	30
Tn-I	100
CK-MB	100
Myoglobin	100
Albumin	300

- **Precision**
  - Between Lot
    One person tested ichroma™ AFP 1 DAY (2 times of day) of week, during 21 days in same place.
  - Repeatability (within-run precision)
    Repeatability of ichroma™ AFP was evaluated with some test result of 1 lot.
  - Total precision (within-run, between day)
    Total precision of ichroma™ AFP was evaluated with all test results of 1 lot.
  - Lot to lot precision
    Lot to lot precision was evaluated with test results of three different lots.

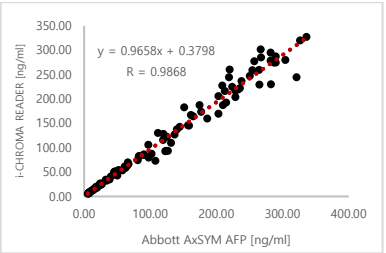
Conc. [ng/mL]	Mean [ng/mL]	Repeatability (within-run)		Total precision (within-laboratory precision)		Lot to lot precision	
		SD	CV (%)	SD	CV (%)	SD	CV (%)
10	9.73	0.66	6.7	0.68	6.9	0.73	7.48
20	19.73	1.39	7.1	1.41	7.1	1.36	6.87
100	100.3	5.19	5.2	5.38	5.3	5.36	5.34

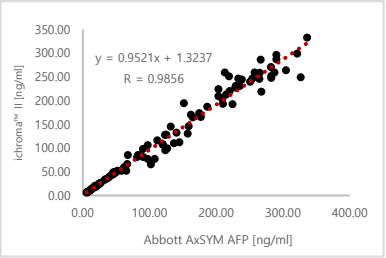
- Accuracy
  The accuracy was confirmed by testing with 3 different lots of **ichroma™ AFP**. The tests are repeated 10 times in each different concentration

AFP [ng/mL]	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
100	100.4	99.2	96.7	98.8	99%
82	81.51	85.65	84.12	83.76	102%
64	64.36	62.38	66.03	64.26	100%
46	44.54	45.04	46.51	45.36	99%
28	27.56	27.05	28.30	27.64	99%
10	10.00	9.90	10.36	10.09	101%

- **Comparability**
  AFP concentrations of 100 serum samples were quantified independently with **ichroma™ 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).

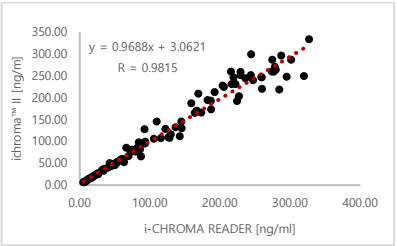
Instrument for Boditech Med.	Abbott AxSYM	
	linear regression	coefficient
i-CHROMA READER	Y=0.9658x + 0.3798	R=0.9868
ichroma™ II	Y=0.9521x + 1.3237	R=0.9856





- i-CHROMA READER VS ichroma™ II

linear regression	coefficient
Y=0.9688x + 3.0621	R=0.9815



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

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

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