



# 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  $\alpha$ 1-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.

Recommended anticoagulant

K<sub>2</sub> EDTA, K<sub>3</sub> EDTA, Sodium heparin

## STORAGE AND STABILITY

Component	Storage condition		
	Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C	20	Disposable

		months	
Detector tube	2 - 8 °C	20	Disposable
		months	

- 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™ III** **REF** FPRR037
  - ichroma™ M3** **REF** FPRR035
- ichroma™ Printer** **REF** FPRR007
- Boditech Tumor Control** **REF** CFPO-94
- 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

##### ► **ichroma™ Reader, ichroma™ II, ichroma™ M3**

##### Multi test mode/ Read now mode

- Transfer of sample (15 µL serum, plasma, control/30 µL whole blood) using a transfer pipette to a tube containing the detection buffer.
- 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.)
- Pipette out 75 µL of a sample mixture and load it into the sample well of the cartridge.
- Leave the Cartridge at room temperature for 15 minutes before inserting the cartridge into the holder.
  - ⚠ Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.**
- 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 is marked on the cartridge especially for this purpose.
- Press the 'Select' or Tap the 'START' button on the instrument for **ichroma™** tests to start the scanning process. (**ichroma™ M2** or **ichroma™ M3** is tested automatically after inserting.)
- The instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- Read the test result on the display screen of the instrument for **ichroma™** tests.

##### Single test mode/ Walk away mode

- The test procedure is same with "Multi test 1) - 3)".

- 2) Insert the cartridge into the 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 is marked on the cartridge especially for this purpose.
- 3) Press the 'Select' or Tap the 'START' button on the instrument for ichroma™ tests to start the scanning process.  
(ichroma™ M2 or ichroma™ M3 is tested automatically after inserting.)
- 4) The cartridge goes inside the Instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 15 minutes.
- 5) Read the test result on the display screen of the instrument for ichroma™ tests.

▶ **ichroma™ III**

- 1) The test procedure is same with "Single test 1) – 4)".

**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)	0.53 ng/mL
Limit of Detection (LOD)	0.90 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.
Hemoglobin	1000 mg/dL
Bilirubin, unconjugated	0.7 mM/L
Triglycerides	50 g/L
Ascorbic acid	0.3 mM/L
Glucose	1000 mg/dL

Biotin	3,500 ng/mL
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- 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	400
ALP	30
Tn-I	100
CK-MB	100
Myoglobin	100
Albumin	300

▪ **Precision**

- Single-site study

Repeatability (within-run precision)  
within-laboratory precision (Total precision)  
Lot to lot precision

3 Lots of **ichroma™ AFP** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

- Multi-site study

Reproducibility

1 Lot of **ichroma™ AFP** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

AFP [ng/mL]	Single-site study					
	Repeatability		Within-laboratory precision		Lot to lot precision	
	AVG	CV(%)	AVG	CV(%)	AVG	CV(%)
7.5	7.52	4.99	7.54	4.97	7.52	5.39
20	20.00	5.41	19.98	5.65	19.86	5.96
200	198.92	5.60	199.78	6.20	199.13	5.81

AFP [ng/mL]	Multi-site study		
	Reproducibility		
	AVG	SD	CV(%)
7.5	7.51	0.39	5.25
20	19.83	1.11	5.60
200	201.60	11.58	5.74

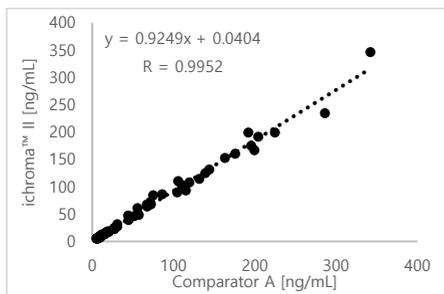
▪ **Accuracy**

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 (%)
200.0	193.75	198.59	205.81	199.38	100%
161.5	156.69	161.76	159.22	159.22	99%
123.0	120.31	127.23	121.04	122.86	100%
84.5	82.99	87.38	83.57	84.65	100%
46.0	46.28	46.04	44.51	45.61	99%
7.5	7.44	7.39	7.43	7.42	99%

▪ **Comparability**

AFP concentrations of 100 serum samples were quantified independently with **ichroma™ AFP** and comparator A as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R).



### REFERENCES

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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

For technical assistance, please contact:  
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