INSTRUCTIONS FOR USE

ONE STEP TEST

Alpha-Fetoprotein (AFP)

Detection in Whole Blood / Serum / Plasma

Only for professional *in vitro* diagnostic use.

Product Code : TAFP01

AFP Test Device detects cancer marker Alpha-fetoprotein in human whole blood, serum and plasma.

BACKROUND INFORMATION

Alpha-Fetoprotein (AFP) is normally produced during fetal and neonatal development by the liver, yolk sac and in small concentrations by the gastrointestinal tract. By the second year of life, AFP concentrations decrease rapidly and thereafter only trace amounts are normally detected in serum. In general, normal adults have serum AFP concentrations of less than 10 ng/mL. Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other entodermal origin. AFP has also been used to detect early tumors in people at high risk for liver cancer. Studies of patients with large hepatic metastases or viral hepatitis also indicate slightly elevated or persistent AFP values. In areas where liver cancer is common, the use of AFP tests for screening has resulted in the detection of many tumors at an earlier stage. Detection of elevated AFP levels can also be used in the detection of fetal open neural tube defects.

INTENDED USE

AFP Test Device is a rapid immunochromatographic assay for qualitative detection of Alpha-fetoprotein in human whole blood / serum / plasma to aid diagnosis of hepatocellular carcinoma or fetal open neural tube defects.

REAGENTS

The test device contains AFP monoclonal antibody coated particles and AFP monoclonal antibody immobilized on the membrane.

METHOD

AFP Test Device is a rapid, qualitative, immunochromatographic assay for the detection of Alpha-fetoprotein in human whole blood / serum / plasma samples. Anti-AFP monoclonal antibodies are immobilized to "T" test area of the test. While performing the test; whole blood / serum / plasma sample dropped to the sample well reacts with the particles coated with anti-AFP monoclonal antibodies. This complex migrates to the other end of the membrane by capillary action. If there is AFP in the sample, it binds to anti-AFP monoclonal antibody in the "T" test area and creates a visible, colored signal that means the test result is positive. If the sample does not contain AFP, colored line does not appear in the "T" test area. This means the test result is negative. As a procedural control, a colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Hepatocellular Carcinoma or fetal open neural tube defects.
8. This test will indicate only the presence or absence of AFP in the sample, and should not be used as the only basis for the diagnosis of Hepatocellular Carcinoma or fetal open neural tube defects.

As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

For Whole Blood Samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

For Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.

For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

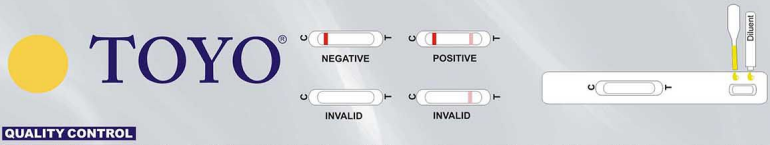
Kit components: Test devices, droppers, diluents and instructions for use.

Additional materials required but not provided: Sample collection tube, centrifuge and timer, lancet (for only fingerstick whole blood), heparinized dispensing bulbs and capillary tubes (for only fingerstick whole blood).

Additional materials recommended but not provided: Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials

TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and whole blood / serum /plasma samples to room temperature.
2. **For Whole Blood Samples:** Draw whole blood into dropper and put 2 drops (60 µl) into the sample well of the cassette. Immediately after, 1 drop (~40µL) of diluent is added into the sample well and allowed to soak in.
   For Serum / Plasma Samples: Draw serum / plasma into dropper and put 1 drop (30 µl) into the sample well of the cassette. Immediately after, 1 drop (~40µL) of diluent is added into the sample well and allowed to soak in.
   Avoid the formation of any air bubbles.
3. Depending on the AFP concentration in the sample, the test can react even in 5 minutes. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.



INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area, indicating that Alpha-fetoprotein does not exist.
Positive: Two colored lines are visible in "C" and "T" areas, indicating that Alpha-fetoprotein exists.
Low concentration of AFP may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Clinical Sensitivity, Specificity and Accuracy: The AFP Test Device has correctly identified a panel of specimens and has been compared to a leading commercial AFP EIA test using clinical specimens. The results are as below.

AFP Rapid Test Device - EIA test

Method		EIA		Total Results
	Results	Positive	Negative	
AFP Test Device	Positive	285	4	289
	Negative	2	400	402
Total Results		287	404	691

Cut-Off: 10ng/ml

Sensitivity: 99,3 %
+ Predictive V: 98,6 %
Specificity: 99 %
- Predictive V: 99,5 %

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. The AFP Test Device has been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

CROSS REACTIVITY

Specimens positive for HAMA, Carcinectomy and rheumatoid factor (RF) have been tested. No cross-reactivity was observed, indicating that the AFP Test Device has a high degree of specificity for Alpha-Fetoprotein.

INTERFERING SUBSTANCES

The AFP Test Device has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. In addition, no interference was observed in specimens containing up to 2.000 mg/dL Hemoglobin; up to 1.000 mg/dL Bilirubin; and up to 2.000 mg/dL human serum Albumin.

REFERANCES

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SYMBOLS USED

CE

Manufacturer

EC REP Authorized European Representative

Attention, see instruction for use

Consult instruction for use

IVD *In vitro* diagnostic medical device

Σ n Number of test

For single use only

Storage temperature

LOT Lot number

REF Catalog number

Expiry date