ALPHA FETAL–PROTEIN (AFP) DEVICE

(2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADAFP1	20 Tests

Intended Use:
The AFP Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of alpha fetal-protein (AFP) in human whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of various cancers.

Summary:
Alpha fetoprotein (AFP) is a single chain glycoprotein with a molecular weight of approximatively 70,000. It is produced by the fetal yolk sac and proximal structures of the liver and gastrointestinal tract. In the human fetus, AFP is a major serum protein which reaches a level of several milligrams per milliliter at week 12 of gestation and then drops to trace concentration in the normal non pregnant adult. The clinical value of AFP as a tumor marker was not immediately appreciated because the assays used for quantitation were not sensitive enough to detect the nanogram amounts associated with early disease. As more sensitive radioimmune assays became available, the utility of AFP as a tumor marker became increasingly apparent. Significant increases are observed in malignant tumours in childhood, such as hepatoblastomas and nephroblastomas, and in hepatocellular carcinoma and certain testicular tumours in adults. Less commonly, malignant tumours of the gastro¬intestinal tract and other organ systems with massive hepatic metastases are associated with increased concentrations of AFP in serum or plasma. AFP levels should be measured at presentation and monitored during treatment and they are very useful in diagnosis and in evaluating the effectiveness of therapy.

Test Principle:
The AFP Rapid Test Device (Whole Blood/Serum/Plasma) detects alpha fetal-protein (AFP) through visual interpretation of colour development on the internal strip. AFP antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with AFP antibodies conjugated to coloured particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient AFP antigens in the specimen, a coloured band will form at the test region of the membrane. The presence of this coloured band indicates a positive result, while its absence indicates a negative result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Disposable pipettes
Buffer
Package Insert
Materials not provided: Timer, Specimen collection container, Centrifuge

Precautions:
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Reagent Preparation and Stability:

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

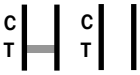
Specimen Collection and Storage:
- The AFP Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Assay Procedure:
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Transfer 3 drops of whole blood/serum/plasma to the specimen well (S) of the device with the provided disposable pipette, and start the timer.
   OR
   Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen well (S) of the test device, and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
3. If the test fails to migrate across the membrane after 1 minute, add 1 drop of buffer to the specimen well (S).
4. Wait for the coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1. The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Controls:

- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The AFP Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of AFP. No meaning should be inferred from the colour intensity or width of any apparent bands.
2. The AFP Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of AFP in the specimen and should not be used as the sole criteria for the diagnosis of various cancers.
3. 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 rule out the possibility of cancer, as AFP may be present below the minimum detection level of the test.

As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics:

Table:AFP Rapid Test vs. EIA

Relative Sensitivity:
>99.2% (97.9%-99.8%)*
Relative Specificity:
>98.8% (97.5%-99.5%)*
Overall Agreement:
>99.0% (98.1%-99.5%)*

***95% Confidence Interval**

		AFP Rapid Test		
		+	-	Total
EIA	+	482	4	486
	-	7	562	569
		489	566	1055

References:

1. Gitlin D, Perricelli A, Gitlin GM. Synthesis of α-Fetoprotein by Liver, Yolk Sac, and Gastrointestinal Tact of the Human Conceptus. Cancer Res. 32: 979, 1972.
2. Gitlin D. Normal biology of α-fetoprotein. Ann N Y Acad Sci. 259:7-16, 1975.
3. Davids, Jacobs, et al. Laboratory test handbook, Lexi-Comp Inc, 1996, 4th Edition: 73.
4. Abelev GI. Alpha-fetoprotein in ontogenesis and its association with malignant tumors. Adv. Cancer Res. 14: 295-358, 1971.
5. Ding-Shinn C, Juei-Low S. Serum Alphafetoprotein in Hepatocellular Carcinoma. Cancer. 40(2):779-783, 1977.
6. Nasser J. The Role of Biologic Tumor Markers in Testicular Cancer. Cancer. 45(7):1755-1761,1980.
7. Bock J. Current Issues in Maternal Serum Alpha-Fetoprotein Screening. Clinical Chemistry. 97(4)541-554, 1992.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	2	Do not reuse

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