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"See Now" AFP Strip Test CE

Serum/ Plasma

For in vitro Diagnosis Use
Product Code: SN 3.1

INTENDED USE

The *"See Now"* human alpha-fetoprotein (AFP) Test is a colloidal gold-antibody complex immunoassay. It is used for *in vitro* qualitative determination of AFP in serum or plasma at or above the cutoff of 25 ng/ml. It is intended for professional use as an aid in the diagnosis of primary hepatocellular carcinomas, testicular teratocarcinomas, and neural tube defects (NTD). This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

.PRINCIPLE

Alfa-fetoprotein (AFP) is a major protein in fetal circulation during early life. It is mainly synthesized and secreted from liver and yolk sac. It is a glycoprotein with molecular weight between 65,000 and 70,000 and contains 4% carbohydrate. Serum AFP has been shown to increase in various disease states, including hepatic primary and metastatic tumors, germ cell tumors, hepatitis, and cirrhosis. AFP also is found at an elevated level in amniotic fluid and maternal serum in the case of neural tube defects (25ng/ml).

"*See Now*" AFP test is a chromatographic immunoassay which utilizes monoclonal antibodies to selectively detect AFP in serum with a high degree of sensitivity. When the sample is added, AFP molecules in the specimen can be captured by specific antibodies conjugated to colloidal gold. Through capillary action, the antigen-antibody-gold complexes are migrated along the nitrocellulose membrane and captured by the marker-specific antibodies immobilized on the membrane. Red color lines will appear on the test zone if AFP presents in the specimen. Antibody-gold complexes will be captured in the control zone (C) where goat anti-mouse IgG is immobilized. To serve as an internal process control, a control band was designed to indicate that the test is performed properly, and should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

MATERIALS SUPPLIED

- Test Strip, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

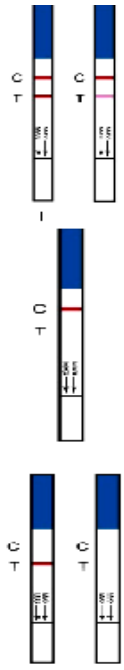
SPECIMEN PREPARATION

- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test strip with patient or control identification
- Immerse the strip into the sample tube with the arrow end pointing towards the specimen. Let it stay immersed until you see liquid traveling up past the MAX word.
- Take the strip out after a minimum of 10 seconds. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface
- Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the results. Do not read the results after 30 minutes.

INTERPRETATION OF RESULTS



Positive: Two colored lines should be observed. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to indicate proper performance of the device. The color intensity of the test line may be weaker or stronger than that of the control line.

Negative: The control line appears in the test, but the test line is not visible.

Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

LIMITATION OF PROCEDURE

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

QUALITY CONTROL

Although the testing strip contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.