First Romanian rapid tests manufacturer !

rev1

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"See Now" CEA CassetteTest Serum/ Plasma

CE

For in vitro Diagnosis Use
Product Code: SN 3.4

INTENDED USE

The *"See Now"* Carcinoembryonic antigen (CEA) is an *in vitro* qualitative test for the rapid detection of CEA in human serum samples. This test is for the qualitative detection of human CEA in serum or plasma at or above the cutoff level of 5 ng/mL to help in the diagnosis of colorectal, breast, lung and pancreas cancers. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

.PRINCIPLE

Carcinoembryonic Antigen (CEA) is a cell-surface 200-kd glycoprotein. Increased levels of CEA are observed in more than 30% of patients with cancer of the lung, liver, pancreas, breast, colon, head or neck, bladder, cervix, and prostrate. It is intended for professional use as an aid in monitoring the effectiveness of therapy of many cancers.

The *"See Now"* CEA test device is a chromatographic immunoassay which utilizes monoclonal antibodies to selectively detect CEA in serum or plasma with a high degree of sensitivity. When the sample is added, CEA 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 then captured by the marker-specific antibodies immobilized on the membrane. Red color lines will appear on the test zone if CEA 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 Device, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

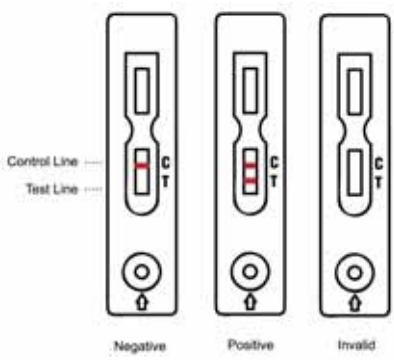
SPECIMEN PREPARATION

- 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 the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is make with an arrow on the testing device.
- 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



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 15-25ºC 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

- 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 device 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.