Rapid CEA Whole Blood Test
CEA-WB0405

A Rapid Chromatographic Immunoassay for the Detection of Carcinoembryonic Antigen (CEA) in whole blood.

Summary and Explanation
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 prostate.

Test Principle
The CEA whole blood test device is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of CEA in whole blood. The test device contains a test strip of a porous material embedded with two key test reagents, a movable colloidal gold labeled antibody at the conjugate zone, and an immovable antibody at the test zone. A blood separation membrane at the sample well is capable of separating plasma from blood cellular components. The plasma migrates through the absorbent area separation membrane at the sample well is capable of separating plasma from blood cellular components. The plasma migrates through the absorbent area.

CEA present in the specimen is bound by antibody-gold conjugate forming an antibody-antigen complex. This complex migrates to the test zone (T) of the strip, where an anti-CEA antibody immobilized to the membrane captures it forming a pink coloured line. The result of the labeled reagent and the sample migrate to the control (C) zone of the strip, where the gold conjugate is captured by an immobolized antibody, producing a pink coloured control line even in the absence of CEA. If the patient sample contains an elevated level of cardiac CEA, the test line (T) will appear colored with its intensity stronger or equal to that of the 5ng/ml CEA standard. Both the intensity of the test line and the speed of the appearance will increase with increased concentration of CEA in the patient’s sample.

Specimen Collection and Preparation
Circulation blood is collected from a finger tip or an ear using a sterile lancet. The blood can be transferred to the device using a transfer pipette, a capillary tube, or let it naturally drip off the finger tip to the sample well of a cassette.

Storage and Handling
- Store the Test kit at room temperature.
- Wear disposable gloves while handling specimens and thoroughly wash hands afterwards.
- All patient samples should be handled as if they are potentially infectious.

Test Procedure
1. Open the foil pouch, remove cassette and place the device on a level surface.
2. Add 1 drop (40ul) whole blood sample to the sample well of a cassette.
3. Add 3 drops (5ul) of test buffer to the sample well.
4. Read the test result at 15 minutes.

Interpretation of Test Results
Read the result 15 minutes after application of the specimen.

a. POSITIVE: A visible pink-red line presents at the test (T) area of the device, which indicates the CEA level in the blood sample is equal to or above 5 ng/ml.
b. NEGATIVE: Only a control line presents at the control (C) area.
c. INVALID: If there is no pink-red color band visible in the control window, then the test result is invalid. It is recommended that the specimen be retested.

If an invalid test result is obtained, it is recommended that the specimen be retested.

References