**CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma)**

**Package Insert**

A rapid test for the qualitative detection of CA 15-3 in human’s whole blood, serum or plasma.

For professional in vitro diagnostic use.

**INTENDED USE**

The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunosay for the qualitative detection of CA15-3 in human’s whole blood, serum or plasma.

**SUMMARY**

CA15-3, for Carcinoma Antigen 15-3, is a tumor marker for many types of cancer, most notably breast cancer. It is derived from MUC1. CA15-3 and associated CA 27-29 are different epitopes of various common antigenic products of mucin gene family. Elevated CA15-3, in conjunction with alkaline phosphatase (ALP), was found to be associated with an increased chance of early recurrence in breast cancer. CA15-3 is most often used in patients with benign ovarian cysts, benign breast disease, and benign liver elevations. Elevated CA15-3 is now being regarded as a reliable prognostic marker for breast cancer.

**[PRINCIPLE]**

The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of CA15-3 in human’s whole blood, serum or plasma. The membrane is pre-coated with anti-CA15 antibody on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-CA15-3. The mixture migrates upward on the membrane by capillary action to react with anti-CA15-3 on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The test cassette contains anti-CA15-3 particles and anti-CA15-3 coated on the membrane.

**[PRECAUTIONS]**

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimen materials with care. Dispose of used specimens according to local regulatory requirements.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

**[STORAGE AND STABILITY]**

Store at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.

**DO NOT FREEZE**

Do not use beyond the expiration date.

**[SPECIMEN COLLECTION AND PREPARATION]**

- **The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.**

- To collect Fingerstick Whole Blood specimens:
  - Wash the hand with soap and warm water or with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertips of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 75μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
  - Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolysed specimens can be used.

- **Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. For long-term storage, the specimens should be kept below -20 °C. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested within 1 hour of collection.**

- **Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.**

- **If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of infectious materials.**

- **EDTA K2, Hepes sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants.**

**[MATERIALS]**

- **Materials provided**
  - Test Cassette
  - Droppers
  - Package Insert
  - Buffer (10mL)
  - **Materials required but not provided**
    - Specimen Collection Containers (1 per test)
    - Centrifuge (For plasma samples only)
    - Timer
    - Lancets (for fingerstick whole blood only)
    - Heparinized Capillary Tubes and Dispensing Bulb (for fingerstick whole blood only)

**[DIRECTIONS FOR USE]**

允 test allows the detection of CA 15-3 antigen in whole blood, serum or plasma.

1. Remove the Test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test cassette on a clean and level surface.

For **Serum or Plasma** specimens:

Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 μL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.

**For Venipuncture Whole Blood** specimens:

Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 μL) to the specimen well (S) of the test cassette, and add 1 drop of buffer (approximately 40 μL) then start the timer. See illustration below.

**For Fingerstick Whole Blood** specimens:

To use a capillary tube: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the test cassette, then add 1 drop of buffer (approximately 40 μL) and start the timer. See illustration below.

3. Wait for the colored line is appeared. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

**Note:** It is suggested not to use the buffer, beyond 6 months after opening the vial.

**[INTERPRETATION OF RESULTS]**

**POSITIVE:** Two distinct colored lines appeared. One colored line should be in the control region (C) and another colored line should be in the test region (T).

**NEGATIVE:** No color change of the test line region (T) will vary depending on the concentration of CA15-3 antigen present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

**NEGATIVE:** No colored line appears in the control line region (C). No apparent colored line appears in the test region (T).

**INVALID:** Control line fails to appear. Insignificant specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**[QUALITY CONTROL]**

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedure technique.

Control standards are not supplied with this kit; however, 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]**

1. The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of CA15-3 antigen in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of change in concentration of CA15-3 can be determined by this test.

2. The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of CA15-3 antigen in the specimen and should not be used as the sole criterion for the diagnosis/prognosis of breast cancer.

3. With all diagnostic tests, all results must be considered with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested.

5. The CA15-3 Rapid Test Cassette to work with hematoctrit level between 25% and 65%. Performance of this test kit at a different hematoctrit level can lead to erroneous results.

**[PERFORMANCE CHARACTERISTICS]**

**Detection Limitation**

The CA15-3 Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect CA15-3 antigen as low as 30 U/mL.