

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 only.

INTENDED USE

The CA15-3 Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay 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.¹ It is derived from MUC1.² CA15-3 and associated CA 27-29 are different epitopes on the same protein antigen product of the breast cancer-associated MUC1 gene.

Elevated CA15-3, in conjunction with alkaline phosphatase (ALP), was found to be associated with an increased chance of early recurrence in breast cancer.³ Both CA15-3 and CA 27-29 may be elevated in patients with benign ovarian cysts, benign breast disease, and benign liver disease. Elevations may also be seen in cirrhosis, sarcoidosis and lupus. CA 15-3 is now being regarded as a reliable prognostic marker for breast cancer.

PRINCIPLES

The CA15-3 Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of CA15-3 in whole blood, serum or plasma. The membrane is pre-coated with anti-CA153 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.

MATERIALS

Materials provided

- Test cassettes
- Package insert
- Buffer
- Droppers

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND 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 specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
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 as packaged 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 (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 patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip 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 75 µL. 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 (S) of the test cassette.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing 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, specimens should be kept below -20 °C. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants.

DIRECTIONS FOR USE

Allow test cassettes, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

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 cassettes 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 cassettes, 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**

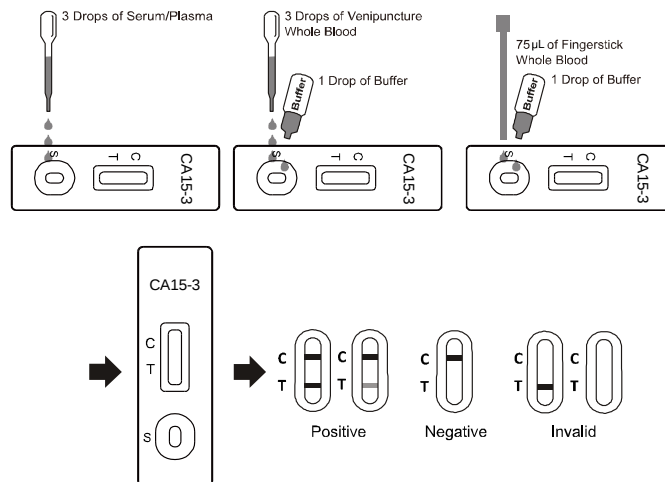
(approximately 40 µL), then start the timer. See illustration below.

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 specimen well (S) of the test cassettes, 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

(Please refer to the illustration above)

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

***NOTE:** The intensity of the color in 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: **One colored line appears in the control line region (C).** No colored line appears in the test region (T).

INVALID: **Control line fails to appear.** Insufficient 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 procedural 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 (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 increase in the concentration of CA15-3 can be determined by this qualitative test.
2. The CA15-3 Rapid Test (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. As 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. This CA15-3 Rapid Test is designed to work with hematocrit level between 25% and 65%. Performance of this test kit at a different hematocrit level can lead to erroneous results.

PERFORMANCE CHARACTERISTICS

Limitation of Detection

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

Sensitivity and Specificity

The CA15-3 Rapid Test (Whole Blood/Serum/Plasma) was compared with CA15-3 diagnostic kit (CMIA); the results indicate that CA15-3 Rapid Test (Whole Blood/Serum/Plasma) has a high sensitivity and specificity as follows.

CA15-3 Rapid Test (Whole Blood/Serum/Plasma)	Method	CMIA		Total Results
	Results	Positive	Negative	
		54	3	57
	Positive	2	238	240
	Negative	56	241	297
	Total Results			

Relative sensitivity: 96.4% (95%CI*: 87.7%–99.6%);

Relative specificity: 98.8% (95%CI*: 96.4%–99.7%);

Accuracy: 98.3% (95%CI*: 96.1%–99.5%).

*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of these specimens: negative, 30 U/mL CA15-3, 60 U/mL CA15-3 and 200 U/mL CA15-3. The negative, 30 U/mL CA15-3, 60 U/mL CA15-3 and 200 U/mL CA15-3 values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same specimens: negative, 30 U/mL CA15-3, 60 U/mL CA15-3 and 200 U/mL CA15-3. Three different lots of the CA15-3 Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, 30 U/mL CA15-3, 60 U/mL CA15-3 and 200 U/mL CA15-3 positive specimens. The specimens were correctly

identified >99% of the time.

Cross-reactivity

The CA15-3 Rapid Test (Whole Blood/Serum/Plasma) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG, anti-Rubella IgG, anti-CMV IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the CA15-3 Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

BIBLIOGRAPHY

1. Duffy MJ, Duggan C, Keane R, et al. (March 2004). "High preoperative CA 15-3 concentrations predict adverse outcome in node-negative and node-positive breast cancer: study of 600 patients with histologically confirmed breast cancer". Clin. Chem. 50 (3): 559–63.
2. Bearz A, Talamini R, Vaccher E, et al. (2007). "MUC-1 (CA 15-3 antigen) as a highly reliable predictor of response to EGFR inhibitors in patients with bronchioloalveolar carcinoma: an experience on 26 patients". Int. J. Biol. Markers. 22 (4): 307–11.
3. CA15-3 and alkaline phosphatase as predictors for breast cancer recurrence: a combined analysis of seven International Breast Cancer Study Group trials - Keshaviah et al. 18 (4): 701 - Annals of Oncology. 2007.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
	<i>In vitro</i> diagnostic medical device		Use-by date
	Temperature limit		Batch code
	Do not use if package is damaged		Manufacturer
	Catalogue number		Do not re-use



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