CA15-3 Rapid Test Kit (Colloidal Gold)

CE IVD

PRODUCT NAME
CA15-3 Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

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 MUC1,2CA15-3 and associated CA 27-29 are different epitopes on the same protein antigen product of the breast cancer-associated MUC1 gene.
Both CA15-3 and CA 27-29 may be elevated in patients with benign ovarian Elevated CA15-3, in conjunction with alkaline phosphatase (ALP), was found to be associated with an increased chance of early recurrence in breast cancer. 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.

PRINCIPLE
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.

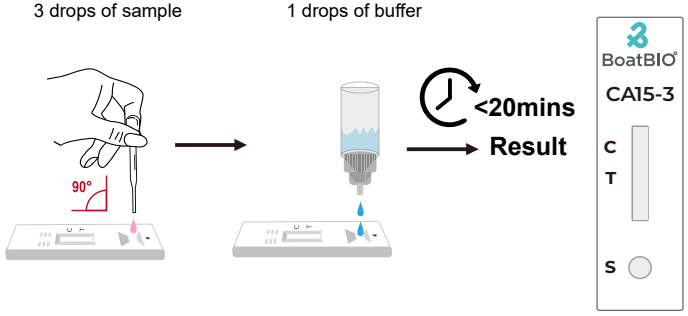
MATERIALS
Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer • Specimen collection containers •Centrifuge •Lancets (for fingerstick whole blood only) •Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

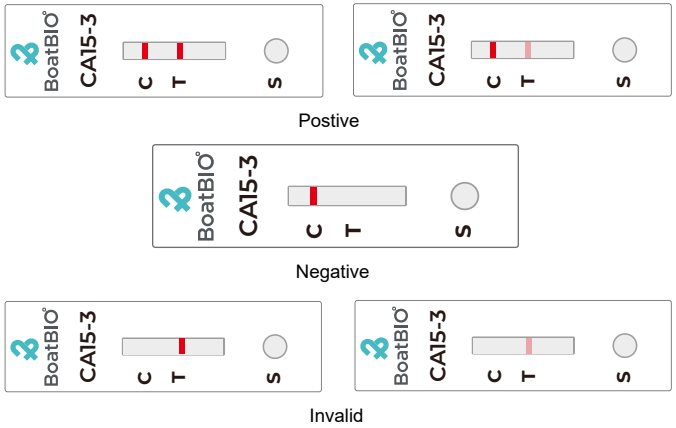
WARNINGS AND PRECAUTIONS
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against 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 Finqerstick 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 75p L. 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 devices.
• 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 anticoagulants.

DIRECTIONS FOR USE
Allow test devices, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.
1. Remove the Test devices 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 devices 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 devices, 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 devices, and add 1 drop of buffer (approximately 40 µL), then start the timer.
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 devices, 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 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 apparent 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 devices. 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
Detection Limitation
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.

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

Relative Sensitivity: 98.9%
Relative Specificity: 99.5%
Accuracy: 99.3%

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
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200 mg/dL
Bilirubin: 1g/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL
Hemoglobin 1000mg/dL
Oxalic Acid: 60mg/dL

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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