CA 15-3 Rapid Test

Catalogue Number: RAPG-CA153-001

Please read this manual carefully before operating to ensure proper use.

TEST KIT DESCRIPTION

The Biopanda CA 15-3 Rapid Test qualitatively detects CA 15-3 in human whole blood, serum and plasma samples. The test is intended for professional use to help detect CA 15-3.

SUMMARY

Carcinoma Antigen 15-3 (CA 15-3), is a tumour marker for many types of cancer, most notably breast cancer.[1] It is derived from MUC1.[2] CA 15-3 and associated CA 27-29 are different epitopes on the same protein antigen product of the breast cancer-associated MUC1 gene.

Elevated CA 15-3, in conjunction with alkaline phosphatase (ALP), was found to be associated with an increased chance of early recurrence in breast cancer.[3]

Both CA 15-3 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.

PRINCIPLE

The Biopanda CA 15-3 Rapid Test is a qualitative, lateral flow immunoassay for the detection of CA 15-3 in whole blood, serum or plasma. The membrane is pre-coated with anti-CA15-3 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 laterally along the membrane by capillary action to react with anti-CA15-3 on the membrane and generates a coloured line. The presence of this coloured line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 20 x foil wrapped cassette with dropper and desiccant
- 1 x buffer tube
- 1 x product insert

STORAGE AND STABILITY

Store the kit between 2-30^{o}C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

PRECAUTIONS

Follow these instructions for the best results:

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- Samples may be potentially infectious and should be handled with standard biosafety procedures.
- Ensure the test kit is at room temperature before running the test.
- Keep the cassette inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Tests that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test to ensure quality controlled testing.

SAMPLE COLLECTION AND PREPARATION

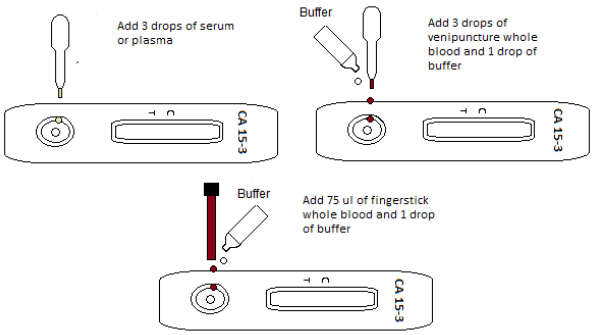
- The Biopanda CA 15-3 Rapid Test can be performed using whole blood, serum and plasma specimens.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol 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 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.

TEST PROCEDURE

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 specimen well (S) of the test cassette, then **add 1 drop of**

buffer (**approximately 40 µl**) and start the timer. See illustration below.

3. Wait for the coloured line is appeared. The result should be read **at 10 minutes.** Results read after **20 minutes** are considered invalid.



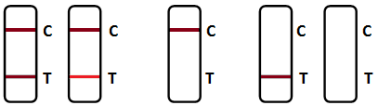
TEST RESULTS

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

***NOTE**: The intensity of the colour in the test line region (T) will vary depending on the concentration of CA 15-3 antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS OF THE PROCEDURE

1. The Biopanda CA 15-3 Rapid Test is for *in vitro* diagnostic use only. This test should be used for detection of CA 15-3 antigen in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of CA 15-3 can be determined by this qualitative test.
2. The Biopanda CA 15-3 Rapid Test will only indicate the presence of CA 15-3 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 CA 15-3 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 Biopanda CA 15-3 Rapid Test can detect CA 15-3 antigen as low as 30 U/ml.

SENSITIVITY AND SPECIFICITY

The Biopanda CA 15-3 Rapid Test was compared with CA 15-3 diagnostic kit (CMIA); the results indicate that CA 15-3 Rapid Test has a high sensitivity and specificity as follows.

Method		CMIA		Total Result
Biopanda CA 15-3 Rapid Test	Results	Positive	Negative	
	Positive	54	3	57
	Negative	2	238	240
Total Result		56	241	297

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 CA 15-3, 60 U/ml CA 15-3 and 200 U/ml CA 15-3. The negative, 30 U/ml CA 15-3, 60 U/ml CA 15-3 and 200 U/ml CA 15-3 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 CA 15-3, 60 U/ml CA 15-3 and 200 U/ml CA 15-3. Three different lots of the Biopanda CA 15-3 Rapid Test have been tested over a 3-day period using negative, 30 U/ml CA 15-3, 60 U/ml CA 15-3 and 200 U/ml CA 15-3 positive specimens. The specimens were correctly identified >99% of the time.

CROSS-REACTIVITY

The Biopanda CA 15-3 Rapid Test 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 Biopanda CA 15-3 Rapid Test 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

REFERENCES

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.

Thank you for purchasing Biopanda's CA 15-3 Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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