CA19-9 FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-CA199-001

A Fluorescence Immunoassay for the quantitative detection of Carbohydrate Antigen 19-9 (CA19-9) in human whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda CA19-9 FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Carbohydrate Antigen 19-9 (CA19-9) in whole blood, serum, or plasma as an aid in the diagnosis and treatment monitoring of pancreatic cancer and other gastrointestinal malignant tumours.

SUMMARY

Carbohydrate antigen 19-9 is a tumour marker related to pancreatic cancer, gallbladder cancer, colon cancer and gastric cancer, also known as gastrointestinal related antigen.[1] Normally, in the blood of healthy individuals or patients with benign diseases, the carbohydrate antigen 19-9 levels are very low.[2,3] Serum carbohydrate antigen 19-9 has a higher sensitivity and better specificity for pancreatic cancer, and its positive rate is between 85%-95%, and it decreases with the improvement of the condition after surgery. Therefore, it can be used as an auxiliary diagnostic index for pancreatic cancer, gallbladder cancer and other malignant tumors.[4,5] In patients with gastrointestinal malignancies, especially pancreatic cancer and gallbladder cancer, the level of carbohydrate antigen 19-9 is significantly higher, but the early diagnosis is of little value, and it is mainly used as an indicator of disease monitoring and predicting recurrence. In addition, some non-cancer conditions, such as acute pancreatitis, cholecystitis, hepatitis and non-malignant gastric and intestinal diseases can also lead to increased levels of carbohydrate antigen 19-9.[6]

PRINCIPLE

The CA19-9 FIA Rapid Test Device detects CA19-9 antigen based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains CA19-9 antigen, it attaches to the fluorescence microspheres-conjugated CA19-9 antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of CA19-9 antigen in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of CA19-9 antigen in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show CA19-9 antigen concentration in specimen.

REAGENTS

The test includes CA19-9 antibody conjugated to fluorescence microspheres and CA19-9 antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda CA19-9 FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 25 x foil wrapped CA19-9 test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (CA19-9)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

For Venipuncture Specimens

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

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

1. Turn on the Analyser. Then according to users' requirements, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. Follow the appropriate steps below for the chosen specimen type:
   - **a.** **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
     1. Pipette **20 µl of whole blood/serum/plasma** into the buffer tube.
     2. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
     3. Let the diluted specimen homogenise for approximately 1 minute. Diluted specimens should be used as soon as possible.
     4. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test cassette. Start the timer at the same time.
   - **b.** **<u>For finger-prick whole blood specimens:</u>**
     i. Wash hands with soap and warm water or clean finger with an

alcohol pad. Allow to dry.

ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.

iii. Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.

iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.

v. Using the provided capillary dropper and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 20 µl), *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then add to the specimen well (S) of the test cassette. Start the timer.

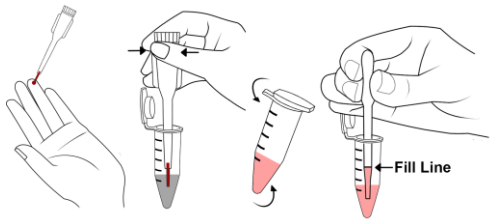

Figure 1

5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

INTERPRETATION OF RESULTS

The result of tests for CA19-9 is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
Linearity range of the Biopanda CA19-9 FIA Rapid Test is 2-2000 U/mL.

QUALITY CONTROL

Each Biopanda CA19-9 FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control 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

1. The Biopanda CA19-9 FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of CA19-9.
2. The Biopanda CA19-9 FIA Rapid Test Device will only indicate the presence of CA19-9 in the specimen and should not be used as the sole criterion for cancer diagnosis.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda CA19-9 FIA Rapid Tests are based on measuring the levels of CA19-9 in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
<37 U/mL	Healthy
≥37 U/mL	Risk of pancreatic and other gastrointestinal malignant tumours

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.
2. Assay Range and Detection Limit
- Assay Range: 2 - 2000 U/mL
- Minimum Detection Limit (Analytical Sensitivity): 2 U/mL

3. Linearity Range
2-2000 U/mL, R≥0.990
4. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 40 U/mL, 150 U/mL of CA19-9. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 40 U/mL, 150 U/mL of CA19-9. C.V. is ≤15%.
5. Interfering Substances
The following compounds have also been tested using the CA19-9 Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.
Triglyceride: 15 mg/mL Bilirubin: 0.2mg/mL
Ascorbic Acid: 2g/dL Hemoglobin:10 mg/mL
6. Method comparison
The product was evaluated with 127 clinical samples compared with commercial CLIA test kit. The correlation coefficient(r) is 0.9806.

REFERENCES

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3. Del Villano BC, Brennan S, Brock P, et al. Radioimmunometric assay for a monoclonal antibody-defined tumor marker, CA 19-9. Clin Chem. 1983 Mar; 29(3):549-52.
4. Glenn J, Steinberg WM, Kurtzman SH, et al. Evaluation of the utility of a radioimmunoassay for serum CA 19-9 levels in patients before and after treatment of carcinoma of the pancreas. J Clin Oncol. 1988 Mar; 6(3):462-8.
5. Willett CG, Daly WJ, Warshaw AL. CA 19-9 is an index of response to neoadjunctive chemoradiation therapy in pancreatic cancer. Am J Surg. 1996 Oct; 172(4):350-2.
6. Steinberg WM, Gelfand R, Anderson KK, et al. Comparison of the sensitivity and specificity of the CA19-9 and carcinoembryonic antigen assays in detecting cancer of the pancreas. Gastroenterology. 1986 Feb; 90(2):343-9.

Index of Symbols

	Manufacturer	Σ	Tests per kit	2	Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
4°C 30°C	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's CA19-9 FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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