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CA19-9 Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
CA19-9 Rapid Test Kit(Colloidal Gold)

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

INTENDED USE
The CA19-9 Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of CA 19-9 in human's whole blood, serum or plasma.

SUMMARY
CA19-9 (carbohydrate antigen 19-9, also called cancer antigen 19-9 or sialylated Lewis(a) antigen) is a tumor marker2 that is used primarily in the management of pancreatic cancer.
CA19-9 is an antigen defined by monoclonal antibody binding to CA19-9, the tumor surface marker Sialyl-Lewis A. CA19-9 was discovered in the serum of patients with colon cancer and pancreatic cancer in 1981 The main use of CA19-9 is to see whether a pancreatic tumor is secreting it; if that is the case, then the levels should fall when the tumor is treated, and they may rise again if the disease recurs.5 In people with pancreatic masses, CA19-9 can be useful in distinguishing between cancer and other diseases of the gland.16 Because of its rising and falling levels with treatment, CA 19-9 is used as a prognostic marker for pancreatic cancer.

PRINCIPLE
The CA19-9 Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of CA19-9 in Whole Blood, serum or plasma. The membrane is pre-coated with anti-CA19-9 on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-CA19-9. The mixture migrates upward on the membrane by capillary action to react with anti-CA19-9 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.

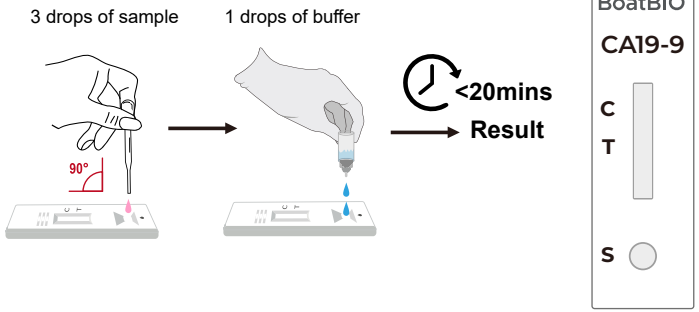
MATERIALS
Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer • Specimen collection containers •Centrifuge •Lancets (for fingerstick whole blood only) •Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

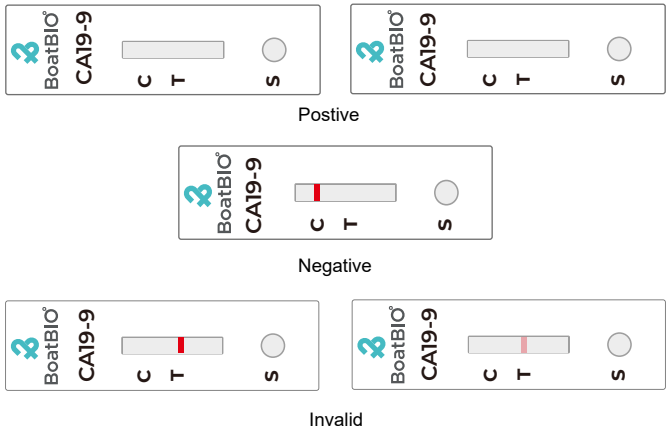
WARNINGS AND PRECAUTIONS
1 For professional in vitro diagnostic use only. Do not use after the expiration date.
2 Do not eat, drink or smoke in the area where the specimen or kits are handled.
3 Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological 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 CA19-9 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 75 pL. 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.
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.





Postive
Negative
Invalid

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 CA19-9 antigen present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
N**EGATIVE:** One colored line appears in the control 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 red 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 CA19-9 Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of CA19-9 antigen in whole blood, serum or plasma.
Neither the quantitative value nor the rate of increase in the concentration of CA19-9 can be determined by this qualitative test.
2. The CA19-9 Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of CA19-9 antigen in the specimen and should not be used as the sole criterion for the diagnosis/prognosis of Pancreatic 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 CA19-9 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 CA19-9 Rapid Test (Whole Blood/Serum/Plasma) can detect CA19-9 antigen as low as 40 U/mL.
Sensitivity and Specificity
The CA19-9 Rapid Test (Whole Blood/Serum/Plasma) was compared with CA19-9 diagnostic kit (ECLIA); the results indicate that CA19-9 Rapid Test (Whole Blood/Serum/Plasma) has a high sensitivity and specificity as follows.

Method		ECLIA		Total Results
CA19-9 Rapid Test (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	63	3	66
	Negative	2	225	227
Total Results		65	228	293

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, 40 U/mL CA19-9, 80 U/mL CA19-9 and 200 U/mL CA19-9. The negative, 40 U/mL CA19-9, 80 U/mL CA19-9 and 200 U/mL CA19-9 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, 40 U/mL CA19-9, 80 U/mL CA19-9 and 200 U/mL CA19-9. Three different lots of the CA19-9 Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, 40 U/mL CA19-9, 80 U/mL CA19-9 and 200 U/mL CA19-9 positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The CA19-9 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 CA19-9 Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed

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