CE
IVD

CEA Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
CEA Rapid Test Kit(Colloidal Gold)

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

INTENDED USE
The CEA Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of CEA in whole blood, serum or plasma to aid in monitoring of cancer patients.

SUMMARY
Carcinoembryonic Antigen (CEA) is a tumor-associated antigen characterized as an oncofetal glycoprotein. CEA is expressed in a variety of malignancies, particularly pulmonary or gastrointestinal tumors (e.g. colon cancer, liver cancer and lung cancer). CEA normally occurs in fetal gut tissue with detectable serum levels essentially disappearing after birth. Therefore, elevated levels of CEA can be of significant value in the diagnosis of primary carcinomas.
In addition to qualitative assessment, CEA testing plays an important role in the monitoring of cancer patients. Clinical evidence indicates that CEA levels can serve as predictive markers in both pre- and post-treatment cancer. Progressive elevation of CEA may signal tumor recurrence 3-36 months before clinical evidence of metastasis. Persistent elevation of circulating CEA following treatment is strongly indicative of occult metastatic and residual diseases and deficient therapeutic response.
The CEA Rapid Test utilizes a combination of anti-CEA antibody coated particles and anti-CEA antibodies to detect elevated levels of CEA in whole blood, serum or plasma. The minimum detection level is 5ng/ml.

PRINCIPLE
The CEA Rapid Test is a qualitative membrane based immunoassay for the detection of CEA in whole blood, serum or plasma. The membrane is pre-coated with anti-CEA antibodies on the test line region. During testing, the specimen reacts with the particle coated with anti-CEA antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-CEA antibodies on the membrane and generate a colored line. The presence of this colored line in the test line 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.

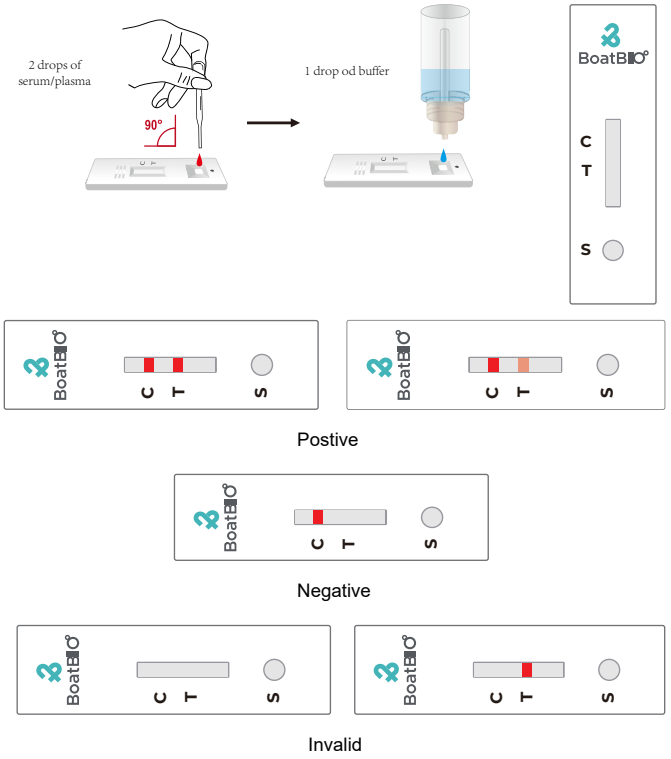
MATERIALS
Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer • Specimen collection containers •Centrifuge •Lancets (for fingerstick whole blood only) •Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

WARNINGS AND PRECAUTIONS
Please read all the information in this package insert before performing the test.
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test devices should remain in the sealed pouch until use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.
5. Do not eat, drink or smoke in the area where the specimens or kits are handled.
6. 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 or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.
NOTE: Once the canister has been opened, the remaining test(s) are stable for 90 days only.

SPECIMEN COLLECTION AND PREPARATION
• The CEA Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
• 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 50 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 area of the test devices.
• Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
• Position the patient's finger so that the drop of blood is just above the specimen area of the test devices.
• Allow 2 hanging drops of fingerstick whole blood to fall into the center of the bspecimen area on the test devicee, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
• Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
• Testing should be performed immediately after the specimens have been collected. 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. 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.
• 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.
If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test devices from the sealed pouch and use it as soon as possible.
2. Place the devices on a clean and level surface.
For Serum or Plasma specimen:
• Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well of test devices, then add 1 drop of buffer (approximately 40µL) and start the timer. See illustration below.
For Venipuncture Whole Blood specimen:
•Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50µL) to the specimen area, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.
For Fingerstick Whole Blood specimen:
• To use a capillary tube: Fill the capillary tube and transfer approximately 50µL of fingerstick whole blood specimen to the specimen area of test devices, then add 1 drop of buffer (approximately 40 µ L) and start the timer. See illustration below.
• To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µ L) to fall into the specimen area of test devices, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
POSITIVE:* Two distinct colored lines appear. One colored line should be in the vcontrol 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 CEA 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 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
A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1. The CEA Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of CEA in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in CEA concentration can be determined by this qualitative test.
2. The CEA Rapid Test will only indicate the presence of CEA in the specimen and should not be used as the sole criteria for the diagnosis of gastrointestinal tract tumors or other cancer.
3. The CEA Rapid Test cannot detect less than 5ng/ml of CEA in specimens.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional testing

using other clinical methods is recommended. A negative result does not at any time preclude the possibility of gastrointestinal tract tumors or other cancer.

EXPECT VALUE

The CEA Rapid Test has been compared with a leading commercial CEA EIA test. The correlation between these two systems is over 99%.

PERFORMANCE CHARACTERISTICS

The CEA Rapid Test has correctly identified a panel of specimens and has been compared to a leading commercial CEA EIA test using clinical specimens. The results show that the relative sensitivity of the CEA Rapid Test is 98.9%, and the relative specificity is 99.5%.

Method		EIA		Total Results
CEA Rapid Test	Results	Positive	Negative	
	Positive	188	2	190
	Negative	2	400	402
Total Results		190	402	592

Relative Sensitivity: 98.9% (95%CI*: 96.2%-99.9%) * Confidence Interval
Relative Specificity: 99.5% (95%CI*: 98.2%-99.9%)
Accuracy: 99.3% (95%CI*: 98.3%-99.8%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the AFP Rapid Test (Whole Blood /Serum /Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Specimens positive for HCV, HBV, HIV, AFP and Rheumatoid factor (RF) have been tested. No cross-reactivity was observed, indicating that the CEA Rapid Test has a high degree of specificity for Carcinoembryonic Antigen.

Interfering Substances

The CEA Rapid Test has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 30 mg/dL Bilirubin, 700 mg/dl Triglycerides and 1,700 mg/dl Total Lipids.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	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	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP **CMC MEDICAL DEVICES & DRUGS S.L**
Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Email - info@cmcmedicaldevices.com