

OneStep CEA RapiCard™ InstaTest (Whole Blood/ Serum/ Plasma)

REF 13060-1-44



Sensitivity	98.9 %
Specificity	99.5 %

A rapid test for the qualitative detection of Carcinoembryonic Antigen (CEA) in whole blood, serum or plasma. For professional in vitro diagnostic use only

INTENDED USE

The Cortez Diagnostics, Inc. CEA RapiCard™ InstaTest (Whole Blood/Serum/Plasma) 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 AND EXPLANATION

Carcinoembryonic Antigen (CEA) is a tumor-associated antigen characterized as an oncofetal glycoprotein.¹ 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.^{2,3} 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.⁴

The Cortez Diagnostics, Inc. CEA RapiCard™ InstaTest (Whole Blood/Serum/Plasma) 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.

TEST PRINCIPLE

The Cortez Diagnostics, Inc. CEA RapiCard™ InstaTest (Whole Blood/Serum/Plasma) 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 AND REAGENT

Reagent

The test cassette contains anti-CEA antibody coated particles and anti-CEA antibody coated on the membrane.

Materials provided

- Test cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Lancets (for finger whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

PRECAUTION

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test cassette should remain in the sealed pouch until use.

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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 until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Cortez Diagnostics, Inc. CEA RapiCard™ InstaTest (Whole blood/Serum/Plasma) 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 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 area of the test cassette.
- 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 cassette.
 - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette,

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.

ASSAY PROCEDURE

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 cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 25µL) to the specimen well of test Cassette, then add **1 drop of buffer** (approximately 40µL) and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen:

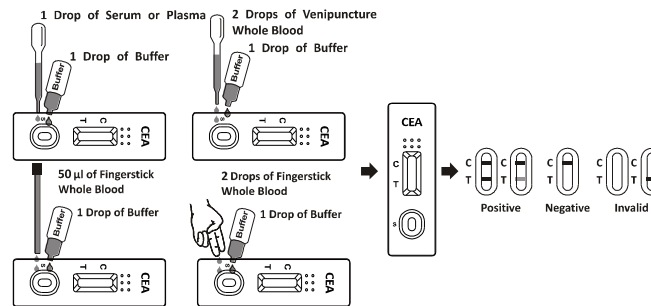
- Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50µL) to the specimen area, then add **1 drop of buffer** (approximately 40µL), and start the timer. See illustration below.

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 cassette, then add **1 drop of buffer**

(approximately 40µL) and start the timer. See illustration below.

- To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50µL) to fall into the specimen area of test cassette, then add **1 drop of buffer** (approximately 40µL) 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.



RESULTS

(Please refer to the illustration above)

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 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Cortez Diagnostics, Inc. CEA RapiCard™ (Whole Blood/Serum/Plasma) 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 RapiCard™ (Whole Blood/Serum/Plasma) is 98.9%, and the relative specificity is 99.5%.

Method	EIA		Total Results
	Results		
CEA RapiCard™	Positive	188	190
	Negative	2	402
Total Results		190	402

Relative Sensitivity: 98.9% (95%CI*: 96.2%-99.9%)

Relative Specificity: 99.5% (95%CI*: 98.2%-99.9%)

Accuracy: 99.3% (95%CI*: 98.3%-99.8%)

* Confidence Interval

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 CEA RapiCard™ (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 RapiCard™ (Whole Blood/Serum/Plasma) has a high degree of specificity for Carcinoembryonic Antigen.

Interfering Substances

The CEA RapiCard™ (Whole Blood/Serum/Plasma) 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

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 OF PROCEDURE


1. The Cortez Diagnostics, Inc. CEA RapiCard™ (Whole Blood/Serum/Plasma) 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 RapiCard™ (Whole Blood/Serum/Plasma) 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 RapiCard™ (Whole Blood/Serum/Plasma) 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.

EXPECTED VALUES

The Cortez Diagnostics, Inc. CEA RapiCard™ (Whole Blood/Serum/Plasma) has been compared with a leading commercial CEA EIA test. The correlation between these two systems is over 99%.

REFERENCE

1. Gold P and Freedman SO. Demonstration of Tumor-specific antigens in human colonic carcinomata by immunological tolerance and absorption. J. Exp. Med. 121:439, 1965.
2. Banjo C, Gold P, Freedman SO and Krupey J. Immunologically Active Heterosaccharides of the Carcinoembryonic Antigen (CEA) of the Human Digestive System, Nature, New Biol, 238,183, 1972.
3. Darcy DA, Turberville C, and Janes R. Immunological Study of Carcinoembryonic Antigen (CEA) and Related Glycoprotein, Br.J.Cancer, 28,147, 1973.
4. Phil Gold CC, and Goldenberg NA. The Carcinoembryonic Antigen (CEA): Past, Present, and Future. Perspectives in Colon and Rectal Surgery 9(2), 1996.

<p>ISO 13485 ISO 9001</p>  <p>Diagnostic Automation / Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
Date Adopted	2017-04-25
REF 13060-1-44	CORTEZ- OneStep CEA RapiCard™ InstaTest Whole Blood /Serum/ Plasma
EC REP	CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
Revision Date: 2015-03-19	