Rapid Response™

Carcinoembryonic Antigen (CEA) Test Strip
(Whole Blood/Serum/Plasma)

REF CEA-13S50 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ CEA Test Strip is a rapid visual immunoassay for the qualitative presumptive detection of human carcinoembryonic antigen (CEA) in human whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of various cancers.

Introduction

Carcinoembryonic antigen (CEA) is a tumor-associated antigen characterized as an oncofetal glycoprotein of approximately 200,000 molecular weight with Beta electrophoretic mobility, a single protein chain of about 800 amino acids, and 50-80% carbohydrate composition. CEA was first present as a specific antigen for adenocarcinoma of the colon. More recent studies have demonstrated CEA presence in a variety of malignancies, particularly those involving ectodermal tissues of gastrointestinal or pulmonary origin. Small amounts have also been demonstrated in secretions from the colonic mucosa. Additionally, CEA-like substances have been reported in normal bile from non-icteric patients. CEA testing can have significant value in the monitoring of patients. Persistent elevation in circulating CEA following treatment is strongly indicative of occult metastic and/or residual disease. A persistent rising CEA value may be associated with progressive malignant disease and poor therapeutic response. A declining CEA value is generally indicative of a favorable prognosis and good response to treatment. Measurement of CEA has been shown to be clinically relevant in the follow-up management of patients with colorectal, breast, lung, prostatic, pancreatic, ovarian, and other carcinomas. Follow-up studies of patients with colorectal, breast and lung carcinomas suggest that the preoperative CEA level has prognostic significance.

Principle

The Rapid Response™ CEA Test Strip detects human carcinoembryonic antigen (CEA) through visual interpretation of color development on the internal strip. CEA antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with CEA antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient CEA antigens in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- 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 tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink, or smoke in the area where the specimens and kits 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.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.

Materials

Materials provided

- Individually packed test Strips
- Disposable pipettes
- Product insert
- Buffer

Materials required but not provided

- Specimen collection container
- Centrifuge
- Timer

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- 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.

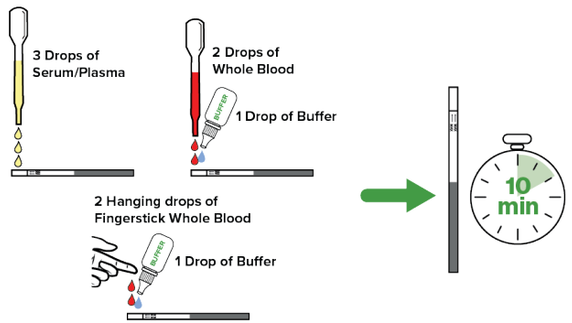
Collection and Storage of Specimens

- The Rapid Response™ CEA Test Strip is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35.6-46.4°F (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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- 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.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolyzed, heat treated and contaminated specimens may cause erroneous results.

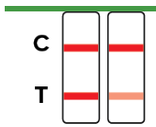
Test Procedure

Bring tests, specimens, buffer and/or controls to room temperature (59-86°F; 15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the Strip with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer **3 drops of serum/plasma specimen (approximately 75 µL)** to the sample pad of the strip and start the timer.
   OR
   Transfer **2 drops of whole blood specimen (approximately 50 µL)** to the sample pad with the provided disposable pipette, then add **1 drop of buffer** and start the timer.
   OR
   Allow **2 hanging drops of fingerstick whole blood specimen** to fall into the center of the sample pad on the strip, then add **1 drop of buffer** and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, you will see color move across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

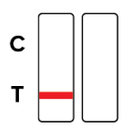


Results Interpretation



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not
produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response™ CEA Test Strip is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of human CEA. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The Rapid Response™ CEA Test Strip will only indicate the presence of human CEA in the specimen and should not be used as the sole criteria for the diagnosis of various cancers.
3. 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 rule out the possibility of cancer, as CEA may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics

Table: Rapid Response™ CEA Test Strip vs. EIA

		EIA		
		+	-	**Total**
Rapid Response™ CEA Test	+	246	3	249
	-	3	458	461
Total		249	461	710

Relative Sensitivity: 98.8% (96.5%-99.6%)*
Relative Specificity: 99.3%(98.1%-99.8%)*
Overall Agreement: 99.2% (98.2%-99.6%)*
*95% Confidence Interval

Bibliography

1. Reynoso, G., Chu. T.M., Holyoke, D., et al: Carcinoembryonic Antigen in Patients with Different Cancers; JAMA, Vol. 220, p. 361, 1972.
2. Zamcheck, N., Carcinoembryonic Antigen; Quantitative Variations in Circulating Levels in Benign and Malignant Digestive Tract Disease, Adv. Itern. Med., Vol. 19, p.143, 1974.
3. Gold, P., and Freedman, S.O., Specific Carcinoembryonic Antigens of the Human Digestive System, J. Exp. Med., Vol. 122, p. 467, 1965.
4. Lokich, J.J., Zamcheck, N., and Lowenstein, M., Sequential Carcinoembryonic Antigen Levels in the therapy of Metastatic Breast Cancer, Ann. Intern. Med., Vol. 89, p. 902, 1978.
5. Wanebo, H.J., Rao, B., Pinsky, C., et al Preoperative Carcinoembryonic Antigen Level assa Prognosis Indicator in Colorectal Cancer, N. Engl. J. Med., Vol. 299, p. 448, 1978.
6. Steward, A.M., Nixon, D., Zamcheck, N., and Aisenber, A., Carcinoembryonic Antigen in Breast Cancer Patients; Serum Levels and Disease Progress. Cancer, Vol. 33, p. 1246, 1974.
7. Skarin, A.T., Nixon, D., Zamcheck, N., et al Carcinoembryonic Antigen: Clinical Correlation and Chemotherapy for Metastatic Gastrointestinal Cancer. Cancer, Vol. 33, p. 1239, 1974.
8. Khoo, S.K., Warner, N.L., Lie, J.T. and Mackay, I.R., Carcinoembryonic Antigenic Activity of Tissue Extracts; A Quantitative Study of Malignant and Benign Neoplasms Cirrhotic Liver, Normal Adult and Fetal Organs. Cancer, Vol. 11, p. 68, 1973.
9. Coligan, J.E., Lautenschieger, J.T., Egar, M.L. and Todd, C.W., Isolation and Characterization of Cacinoembryonic Antigen, Immunochemistry Vol. 9, p. 377, 1972.

Glossary of Symbols

Consult instructions for use
Test per Kit
Do Not Reuse
Store between 35.6°F to 86°F
Use by
REF Catalogue #
LOT Lot Number
IVD For *in vitro* diagnostic use only

BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada
Technical Support: 1-888-339-9964