DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria, IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at

"DIAQUICK" CEA Cassette

(Human Carcinoembryonic Antigen)

for whole blood, serum or plasma samples

REF

Content

Z06030

- 30 cassettes individually packed, disposable pipette, buffer sufficient for 30 tests (30 x Ref. No: Z06030B)
- 1 package insert

For in vitro diagnostic use only

GENERAL INFORMATION

Method	sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	4-30°C
Sample	whole blood, serum, plasma
Results	after 5 minutes, do not read after 20 minutes
Sensitivity	5 ng/ml

INTENDED USE

The „DIAQUICK" CEA Cassette is a rapid, chromatographic immunoassay for the qualitative determination of human carcinoembryonic antigen (CEA) in human whole blood, serum or plasma.

CLINICAL SIGNIFICANCE

Carcinoembryonic antigen (CEA) is a tumor associated antigen characterized as an oncofetal glycoprotein of approximately 200,000 Da 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 metastatic and/or residual disease. A persistent rising CEA value may be associated with a 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. CEA testing is not recommended as a screening procedure to detect cancer in the general population; however, use of the CEA test as an adjunctive test in the prognosis and management of cancer patients is widely accepted.

TEST PRINCIPLE

The „DIAQUICK" CEA Cassette (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 in 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.

WARNINGS AND PRECAUTIONS

1. For *in vitro* use only.
2. Do not use kit beyond the expiration date.
3. Do not open the foil pouch until ready to perform the test.
4. Patient samples may contain infectious agents; properly handle and dispose of all used reaction devices in the biohazard container.
5. Apply appropriate measures to handle potentially infectious materials.

STORAGE

Store the test kit at 4-30°C up to the expiration date stated on the label .

SAMPLE COLLECTION AND PREPARATION

- The "DIAQUICK" CEA Cassette (whole blood/serum/plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Venipuncture Whole Blood specimens**:

  Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- 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 well (S) 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 well (S) of the test cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test cassette, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- 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 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. 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.

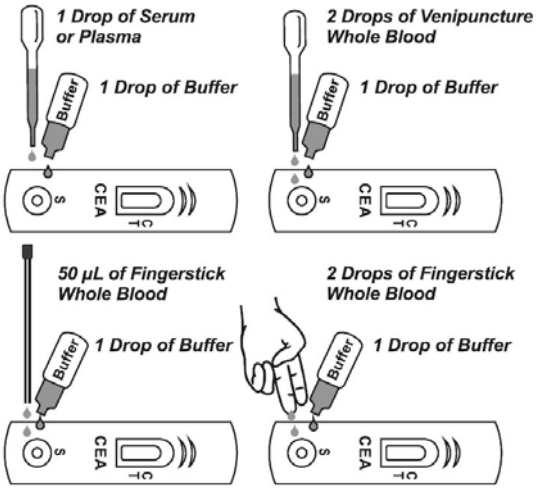
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.

   For **Serum or Plasma specimens**: Hold the dropper vertically and **transfer 4 drops of serum or plasma** (approximately 100 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.

   For **Venipuncture Whole Blood specimens**: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.

   For **Fingerstick Whole Blood specimens**:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood** to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.
   - To use hanging drops: **Allow 2 hanging drops of fingerstick whole blood** (approximately 50 µL) to fall into the center of the specimen well (S) on the test cassette, 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 10 minutes.** Do not interpret the result after 20 minutes.

DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria, IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at



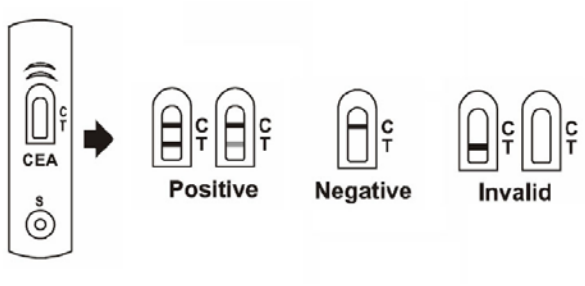
INTERPRETATION OF RESULTS

Positive Result:
Two rose-pink colored bands appear in the result window, one in the control line region "C" and one in test line region "T". A positive result indicates that CEA is present in the sample with a concentration of 5 ng/ml or higher.

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 line region (T) should be considered positive.

Negative Result:
One rose-pink colored band appears in the control line region "C" with no apparent colored band in the test line region "T". The CEA level of the specimen is below the 5 ng/ml detection sensitivity of the test.

Invalid Result:
A total absence of colored bands in the two regions is an indication of a procedural error and/or that reagent deterioration has occurred. Add additional drops of sample to the sample pad. If there is still no color band appearing the test should be voided. The result should be considered as invalid.



QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE PROCEDURE

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The „DIAQUICK" CEA Cassette (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 sensitivity of the "DIAQUICK" CEA Cassette (whole blood/serum/plasma) is 98.7%, and the specificity is 99.2%.

Method		EIA		Total Results
„DIAQUICK" CEA Cassette	Results	Positive	Negative	
	Positive	154	3	157
	Negative	2	390	392
Total Results		154	393	549

Relative Sensitivity: 98.7% (95.4%-99.8%)* Relative Specificity: 99.2% (97.8%-99.8%)*
Accuracy: 99.1% (97.9%-99.7%)* * 95% 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 „DIAQUICK" CEA Cassette (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 „DIAQUICK" CEA Cassette (whole blood/serum/plasma) has a high degree of specificity for Carcinoembryonic Antigen.

Interfering Substances
The „DIAQUICK" CEA Cassette (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.

BIBLIOGRAPHY

1. Rexnoso, 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. Intern. Med., Vol. 19, p.143, 1974,
3. Gold, P., and Freeman, 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 Assay 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.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.
7. 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.
8. Coligan, j.E., Lautenschieger, J.T., Egar, M.L. and Todd, C.W., Isolation and Characterization of Carcinoembryonic Antigen, Immunochemistry Vol. 9, p. 377, 1972.