REFERENCES

1. Bates SE. Clinical applications of serum tumor markers. Ann Intern Med 1991;115:623-38.
2. Kuusela P, Haglunk C, Roberts PJ. Comparison of a new tumour marker CA 242 with CA 19-9, CA 50 and carcinoembryonic antigen (CEA) in digestive tract diseases. Br J Cancer 1991;63:636-40.
3. Nilsson O, Johansson C, Glimelius B, et al. Sensitivity and specificity of CA242 in gastro-intestinal cancer. A comparison with CEA, CA50 and CA 19-9. Br J Cancer 1992;65:215-21.
4. Barillari P, Bolognese A, Chirletti P, et al. Role of CEA, TPA, and CA 19-9 in the early detection of localized and diffuse recurrent rectal cancer. Dis Colon Rectum 1992;435:471-6.
5. Camuñas J, Enriquez JM, Devesa JM, et al. Value of follow-up in the management of recurrent colorectal cancer. Eur J Surg Oncol 1991;17:530-5.
6. Moertel CG, Fleming TR, Macdonald JS, Haller DG, Laurie JA, Tangen C. An evaluation of the carcinoembryonic antigen (CEA) test for monitoring patients with resected colon cancer. JAMA 1993;270:943-7.
7. Chevinsky AH. CEA in tumors of other than colorectal origin. Semin Surg Oncol 1991;7:162-6.

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Carcinoembryonic Antigen (CEA) ELISA

Catalog No.: CE236T (96 Tests)

INTENDED USE

The Calbiotech, Inc. CEA ELISA Kit is intended for the quantitative measurement of CEA in human serum. **For Research Use Only. For professional use only. Not for use in diagnostic procedures.**

SUMMARY AND EXPLANATION

CEA is a heavily glycosylated cell surface glycoprotein involved in intercellular adhesion. It is part of the immunoglobulin superfamily. Research applications include cell signaling studies, epithelial biology, glycoprotein characterization, and its role as a molecular marker in epithelial cell transformation models.

PRINCIPLE OF THE TEST

The CEA is a solid phase sandwich ELISA method. The samples, and anti-CEA-HRP/Biotin conjugate are added to the wells coated with Streptavidin. CEA in the patient's sample forms a sandwich between two specific antibodies to CEA. Unbound protein and HRP conjugate are washed off by wash buffer. Upon the addition of the substrate, the intensity of color is proportional to the concentration of CEA in the samples. A standard curve is prepared relating color intensity to the concentration of the CEA.

MATERIALS PROVIDED	96 Tests
1. Microwells coated with Streptavidin	12x8x1
2. CEA Standard: 7 vials (ready to use)	0.5ml
3. CEA Control: 2 vials (ready to use)	0.5ml
4. CEA Enzyme Conjugate: 1 bottle (ready to use)	12ml
5. TMB Substrate: 1 bottle	12ml
6. Stop Solution: 1 bottle (ready to use)	12ml
7. 20X Wash Concentrate: 1 bottle	25ml

MATERIALS NOT PROVIDED

1. Distilled or deionized water
2. Precision pipettes
3. Disposable pipette tips
4. ELISA reader capable of reading absorbance at 450nm
5. Absorbance paper or paper towel
6. Graph paper

STORAGE AND STABILITY

1. Store the kit at 2 - 8° C.
2. Keep microwells sealed in a dry bag with desiccants.
3. The reagents are stable until the expiration of the kit.
4. Do not expose test reagents to heat, sun, or strong light.

WARNINGS AND PRECAUTIONS

Potential biohazardous materials:

1. The standards contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.
2. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
3. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
4. It is recommended that standards, control and serum samples be run in duplicate
5. Optimal results will be obtained by strict adherence to this protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from this may yield invalid data.

SPECIMEN COLLECTION HANDLING

This assay is designed for use with human serum or plasma samples obtained in compliance with applicable laws, regulations, and institutional policies. Handle and store samples using procedures appropriate for research use. Samples may be stored refrigerated (2–8 °C) for up to seven days, or frozen (–20 °C or below) for up to six months. Avoid repetitive freeze–thaw cycles.

REAGENTS PREPARATION

1. Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

ASSAY PROCEDURE

Prior to assay, allow reagents to stand at room temperature (20-25°C).
Gently mix all reagents before use.

1. Place the desired number of coated strips into the holder
2. Pipet 25 µl of CEA standards, control and patient specimens into designated wells.
3. Add 100 µl of ready to use enzyme conjugate to all wells. Shake for (10-30) sec.
4. Cover the plate and incubate for 60 minutes at room temperature.
5. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbent paper towels.
6. Add 100 µl of TMB substrate to all wells.
7. Incubate for 15 minutes at room temperature.
8. Add 50 µl of stop solution to all wells. Shake the plate gently to mix the solution.
9. Read absorbance on ELISA Reader at 450 nm within 15 minutes after adding the stopping solution.

CALCULATION OF RESULTS

The standard curve is constructed as follows:

1. Check CEA standard value on each standard vial. This value might vary from lot to lot. Make sure you check the value on every kit. See example of the standard attached.
2. To construct the standard curve, plot the absorbance for the CEA standards (vertical axis) versus the CEA standard concentrations (horizontal axis) on a linear graph paper. Draw the best curve through the points.
3. Read the absorbance for controls and each unknown sample from the curve. Record the value for each control or unknown sample.

Example of Standard Curve

	OD 450 nm	Conc. ng/mL
Std 1	0.017	0
Std 2	0.101	5
Std 3	0.183	10
Std 4	0.451	25
Std 5	0.872	50
Std 6	1.437	100
Std 7	2.710	250

LIMITATIONS OF THE TEST

1. Do not use sodium azide as preservative. Sodium azide inhibits HRP enzyme activities.