# CEA Rapid Quantitative Test

**Catalog No.BT2401**

## INTENDED USE

The Biotime CEA (Carcinoembryonic antigen) Rapid Quantitative Test along with Biotime FIA Analyzer is intended to quantify the concentration of CEA in human serum or plasma by fluorescence immunoassay. It is used as a detection of disease monitoring of tumor patients after radiation therapy or surgery.
-Fluorescence immunoassay
-Tumor disease
For in vitro diagnostic use only. For professional use only.

## SUMMAR

Carcinoembryonic antigen (CEA), whose encoding gene locates at chromosome 19, is an acid glycoprotein (AAG) with a molecular weight of 22kD. It is an embryonic carcinogenic antigen, which mainly comes from stomach, intestines and blood of fetuses; as well as it is found in intestinal, pancreatic and liver tissues of normal human of low content. As the formation of CEA is inhibited after birth, it is hard to detect the CEA in normal human blood. CEA, secreted by cancer cells with loss of polarity, enters the blood and lymph resulting in the increase of its level. The level increases in rectal colon cancer patients, while it falls after resection of the tumor successfully or by endogenous factors[1-2].

## PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the CEA in the sample and the mouse anti-CEA monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with CEA specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of CEA in human serum or plasma.
The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of CEA in human serum or plasma.

## PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should beavoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

## MATERIAL

**Material Provided**
1. Test Cartridge 25 tests/kit
2. SD Card 1 pierce/kit
3. Detection buffer 25 tubes/kit
4. Instructions for use 1 copy/kit

**Material Required But Not Provided**
1. Biotime FIA Analyzer
2. Pipette (range 5-50μL and 10-100μL size)
3. Specimen Collection Containers
4. Timer

## STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

## SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum or plasma specimen.
2. The specimen collection container shall be immune tube or pro-coagulant tube for serum and EDTA-K2 anticoagulant tube for plasma.
3. The collecting of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for 7 days，or at -20℃ for 6months. Samples must be recovered to the room temperature before tests.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

## TEST PROCEDURE

Please refer to the operation manual of Biotime FIA Analyzers for details.
The test should be operated at room temperature(~25℃).
**Step 1: Preparation**
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
**Step 2: Sampling**
Take 20μL of plasma or serum with pipette and add it to the buffer tube.
**Step 3: Mixing**
Mix well the specimen with buffer by tapping or inverting the tube.
**Step 4: Loading**
Take 80μL of sample mixture and load it into the well of Test Cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
**Step 5: Testing**
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

## REFERENCE INTERVAL

Normal Reference Value: <5.0ng/ mL

## INTERPRETATION OF TEST RESULTS

1. If the concentration of CEA is higher than reference value, the physiological change and the stress response should be ruled out first. If the concentration of CEA is actually abnormal, the test result should be used with other clinical information, such as medical history, symptoms, other tests and clinical performance.
2. The result is appropriate for the reference value by our method only.
3. Other factors may cause test result inaccurate including the technology, the operation and the sample.

## LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma.
2. The human anti-mouse antibody (HAMA) may emerge from the patient who had accepted the mouse-derived single anti-immune drug. Although the test kit eliminates the influence of the antibody through special method, the evaluation of the result should still be careful when facing the conditions mentioned above[3].
3. The test result is only an auxiliary diagnosis for doctors, if the test result is not sin accordance with clinical assessment, the further test is needed.

## PERFORMANCE CHARACTERISTICS

**Accuracy**
CEA control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations were within ±15%.
**Assay Range and Detection Limit**
**Assay Range**: 0.5-500.0ng/mL
**The Lowest Detection Limit**: 0.5ng/mL
**Linearity**
A serial concentration of CEA control at 1.0-500.0ng/mL were tested, the Correlation Coefficient(R) is ≥ 0.9900.
**Precision**
**Intra-Lot Precision**
Intra-lot precision was determined by testing of CEA reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
**Inter-Lot Precision**
Inter-lot precision was determined by testing of CEA reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 15%.
**Specificity**
The concentration of CEA is not greater than 1.00ng/mL when the concentration of human serum albumin is 100.0ng/mL.
The concentration of CEA is not greater than 1.00ng/mL when the concentration of LCA 99 is 400.0IU/mL.
The concentration of CEA is not greater than 1.00ng/mL when the concentration of LCA 125 is 500.0IU/mL.
**Hook effect**
There is no Hook effect when the level is 100000.0ng/mL.

## SYMBOLS

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| REF | Catalogue number | IVD | In vitro diagnostic medical device |
| LOT | Batch code | | Consult instructions for use |

| | | | |
|---|---|---|---|
| | Date of manufacture | | Keep dry |
| | Use-by date | | Keep away from sunlight |
| | Manufacturer | 2℃ 8℃ | Store at 2-8℃ |
| | Do not re-use | 2℃ 30℃ | Store at 2-30℃ |
| EC REP | Authorized representative in the European | CE | CE mark |

## BIBLIOGRAPHY OF SUGGESTED READING

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3. Hansen JH, et al. HAMA Interference with Murine Monoclonal Antibody-Based Immunoas says[J].J of Clin Immunoassay,1993,16:294-299.

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