Finecare™

CEA(Carcinoembryonic Antigen) Rapid Quantitative Test

Catalog No. W226

INTENDED USE

The Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test along with Finecare™ FIA Meter is intended for in-vitro quantitative determination of CEA in human whole blood, serum, or plasma.

-Fluorescence immunoassay
-Evaluation of therapeutic efficiency and prognosis and recurrence monitoring for carcinoma

For in vitro diagnostic use only. For professional use only.

SUMMARY

CEA (Carcinoembryonic Antigen), a cell-surface 200 KD glycoprotein, is normally produced during the development of a fetus but disappears or becomes very low in the blood of healthy adults because the synthesis of this protein ceases before birth. However, increased levels may be present in colorectum, gastric area, breast, ovary, liver, lung, pancreas, biliary and medullary thyroid carcinoma, as well as in some benign conditions like smoking, inflammatory bowel disease, chronic gastritis, peptic ulcer, cirrhosis, hepatitis and pancreatitis. CEA is often used to monitor patients with cancers, especially colorectal carcinoma, after surgery to measure the response to therapy and whether the disease is recurring. When the CEA level is abnormally high before surgery or other treatments, it is expected to fall back to normal after following successful surgery to remove carcinoma. A rising CEA level indicates progression or recurrence of the cancer.
Normal reference range: < 5 ng/mL.
Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test is based on fluorescence immunoassay technology.
The Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test uses a sandwich immunofluorescence detection method. When sample is added to the sample well of the test cartridge, the fluorescence-labeled CEA antibodies bind to CEA antigens in blood specimen. As the sample mixture migrates on the nitrocellulose membrane of test strip by capillary action, the complexes of detector antibody and CEA are captured by CEA antibody that has been immobilized on test strip. Thus, the more CEA antigen exists in blood specimen, the more complexes will be accumulated on test strip. Fluorescence signal intensity of detector antibody reflects the amount of captured CEA and Finecare™ FIA Meter shows the CEA concentrations in blood specimen. The default results unit of Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test is displayed as XXX ng/mL from Finecare™ FIA Meter. The working range and the detection limit of the CEA Test system are 1-500 ng/mL and 1 ng/mL.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with ID Chip # that is inserted into the equipment.
5. The Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. Test cartridge contaminated by blood or other liquid must not be inserted into FIA meter, otherwise the meter might be contaminated or damage.
8. High working temperature should be avoided, buffer stored in low temperature should be balanced to room temperature for a couple of minutes before use.
9. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded normal.
10. Use separate clean pipette tips and detector buffer vials for different specimens.
11. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
12. Use of fresh blood specimen is recommended. Please do not use sample with obvious appearance of hemolysis or blood clot which might interfere with the test causing wrong result.
13. The Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test should not be used as an absolute evidence. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25
Leaflet with instructions for use	

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (100 µL size)
3. Specimen Collection Containers
4. Alcohol Pads
5. Centrifuge (for Plasma/serum only)
6. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4℃～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test Cartridge at 4℃～30℃, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.
For Whole Blood Collected by Venipuncture:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 2 days.

For Serum and Plasma:
1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the test. The test should be operated in room temperature.
Step1: Preparation
Before testing, activate “use” in setting then save it. Check/insert ID Chip onto the equipment.
Step2: Sampling
Draw 75 µL of whole blood, serum or plasma with a transfer pipette and add it to the buffer tube.
Step3: Mixing
Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.
Step4: Loading
Take 75 µL of sample mixture and load it onto the sample well of the Test Cartridge.
Step5: Testing
1. Finecare™ FIA meter:
Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 15 minutes later, choose the sample type, then the result will show in the display and print out when click “Print”.
Quick test: Put the Test Cartridge on the operation platform. 15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Test”.
Choose the sample type, then the result will show in the display and print out when click “Print”.

2. Finecare™ multi-channel FIA meter:
   Insert the Test Cartridge onto the Test Cartridge Holder. 15 minutes later, choose the sample type, then the result will show in the display and print out when click “Print”.
   Please refer to the **Operation** in user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test Cartridge contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The results of Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If CEA test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some components in blood from individual and epitopes from some non-specific adhesion components in blood which are similar to these fluorescent labeled antibodies.
4. The false negative results may come from some unknown substance blocking epitope adhering antibodies, unstable or degenerated CEA that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. Other factors may interfere with Finecare™ CEA(Carcinoembryonic Antigen) Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same batch were tested with CEA control, mean and Bias% were calculated, Bias% was within 10%

Assay Range and Detection Limit

- **Assay Range**: 1-500 ng/mL
- **Detection Limit:** 1ng/mL

Linearity

A serial concentration of CEA controls were tested, the Correlation Coefficient (R) is ≥ 0.99.

Precision

Intra-Lot Precision
Within-run precision has been determined by using 10 replicates to test with CEA control. C.V. is ≤ 15%.

Inter-Lot Precision
Between-run precision has been determined by using 3 replicates for each of 3 lots to test with CEA control. C.V. is ≤ 15%.

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IVD In Vitro Diagnostic Use	See Instruction for Use	Expiry Date
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
4°C 30°C Store between 4～30℃		

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