

INTENDED USE

The Finecare™ CEA Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA System (Model No.: FS-112/FS-113/FS-205) for quantitative determination of carcino-embryonic antigen in human whole blood, serum or plasma.

The test is used as an aid in the evaluation of therapeutic efficiency, prognosis and recurrence monitoring for carcinoma.

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

SUMMARY

Carcino-embryonic Antigen (CEA), a cell-surface 200 KD glycoprotein, is normally produced during the development of a fetus 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. Arising CEA level indicates progression or recurrence of the cancer.

PRINCIPLE

The Finecare™ CEA Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ CEA Rapid Quantitative Test uses a sandwich immunodetection method. When sample is added into the sample well of the Test Cartridge, the fluorescence-labeled detector CEA antibodies on the sample pad bind to CEA antigens in blood specimen and they form immune

complexes. As the complexes migrate on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibodies and CEA are captured to CEA antibodies that have been immobilized on test strip. Thus the more CEA antigens in blood specimen, the more complexes accumulated on test strip. Signal intensity of fluorescence of detector antibodies reflect the amount of captured CEA.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Carefully follow the instructions and procedures described in this insert.
3. Lot number of all the test components (Test Cartridge, ID Chip and Detection Buffer) must match with each other.
4. Do not interchange the test components from different lots or use the test components beyond the expiration date printed on package.
5. The Finecare™ CEA Rapid Quantitative Test kit is only operated in Finecare™ FIA System. Tests should be applied by professionally trained staff working in certified laboratories and clinics at which the sample(s) is taken by qualified medical personnel.
6. The Test Cartridge should remain in its original sealed pouch until use. Do not use the Test Cartridge if the pouch is damaged or already opened.
7. A Detection Buffer vial and Pipette Tip should be used for processing one sample only. Similarly a Test Cartridge should be used for testing one processed sample only. Both the Detection Buffer vial as well as the test cartridge should be discarded after single use.
8. The Test Cartridge and Finecare™ FIA System should be used away from vibration and/or magnetic field. During normal usage, the Test Cartridge may produce minor vibrations which should be regarded as normal.
9. Do not smoke, eat, or drink in the areas where specimens or test reagents are being handled.
10. Blood specimens, used Test Cartridges, Pipette Tips and Detection Buffer vials are potentially infectious. They should be handled carefully and disposed of by an appropriate method in accordance with relevant local regulations.

11. The Finecare™ CEA Rapid Quantitative Test should not be used as absolute evidence of the presence or the absence of carcinoma. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test should be applied on a routine basis but not in emergency situations.

MATERIAL

Material Provided

Components of Finecare™ CEA Rapid Quantitative Test:

- Test Cartridge in a sealed pouch with desiccant 25
- ID Chip 1
- Detection Buffer 25
- Pipette Tip 25
- Leaflet with Instructions for Use 1

Material Required But Not Provided

- Finecare™ FIA System
- Transfer Pipette Set (100 µL size)
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

STORAGE AND STABILITY

1. Store the test kit at 4 °C~30 °C up to the expiration date printed on package.
2. If removed from refrigerator, allow the test kit for 30 minutes to return to room temperature before testing.
3. Do not remove the Test Cartridge from the pouch until use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen with a blood collection tube which contains suitable anticoagulant. (EDTA, Heparin, Sodium Citrate)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged period. If the specimens are not tested immediately, they should be kept at 2 °C~8 °C.
3. It is not suitable to test the whole blood specimen which have been kept at 2 °C~8 °C for more than 2 days.

For Serum and Plasma:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen. If you need to collect plasma, use a blood collection tube which contains suitable anticoagulant (EDTA, Heparin, Sodium Citrate).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis. Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged period. Specimens should be kept at 2 °C~8 °C for up to 7 days. For long time storage, specimens should be kept below -20 °C.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolytic specimens can be used.

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA System Operation Manual. Test should be performed at room temperature.

Step 1: Preparation

Before testing, activate "use" in setting then save it. Ensure that the lot number of the Test Cartridge matches ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA System.

Step 2: Sampling

Draw 75 µL of whole blood or serum or plasma with a transfer pipette and add into the Detection Buffer tube.

Step 3: Mixing

Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading

Pipette 75 µL of sample mixture and load it into the sample well of the Test Cartridge.

Step 5: Testing

There are two test modes for Finecare™ FIA System, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA System for details.

- a) **For Standard Test mode:** Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System right after adding sample mixture to the sample well. Press “**Test**” to start testing. (Apply to FS-112, FS-113 and FS-205)
- b) **For Quick Test mode:** Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 15 minutes. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System. Press “**Test**” to start testing. Finecare™ FIA System will start scanning the sample-loaded Test Cartridge immediately. (Apply to FS-112 and FS-113)

Results are displayed on main screen or be printed by press “**Print**”.

Discard the used Test Cartridge according to local regulations and procedures after released from Finecare™ FIA System.

INTERPRETATION OF RESULTS

The Finecare™ FIA System calculates CEA test results automatically and displays the exact concentrations of CEA on the screen as form of XXX.X ng/mL. For further information, please refer to the Operation Manual for the Finecare™ FIA System.

Normal reference value: ≤5.0 ng/mL

Note: Recommend that each laboratory formulates its own reference range according to actual situation.

QUALITY CONTROL

Each Finecare™ CEA Rapid Quantitative Test Cartridge contains internal control that satisfies routine quality control requirements. This internal control is performed each time when a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA System. An invalid result from the internal control causes an error message on Finecare™ FIA

System 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 test procedure, precautions and interpretations of results for this test must be followed when testing.
3. The results of Finecare™ CEA Rapid Quantitative Test should be evaluated with all available clinical and laboratory data.
4. The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of CEA antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
5. Other factors may interfere with Finecare™ CEA 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

A comparative study is tested for 223 clinical samples in using Finecare™ CEA Rapid Quantitative Test and the Roche CEA Reagent Kit. The Correlation Coefficient (R²) is 0.979.

Assay Range and Detection Limit

- **Assay Range:** 1~500 ng/mL
- **Detection Limit (Analytical Sensitivity):** 1 ng/mL

Cross-Reactivity

The following substances do not interfere with the CEA test results at the indicated concentrations: PSA at 100 ng/mL and AFP at 1000 ng/mL.

Linearity

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

Precision

Intra-Lot Precision:

Determined by using 10 Test Cartridges in the same batch to test with CEA control. C.V. is ≤15%.

Inter-Lot Precision:

Determined by using 3 Test Cartridges in 3 random and continuous batches to test with CEA control. C.V. is ≤20%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Anonymous.Carcinoembryonic antigen:its role as a marker in the manage-ment of cancer.Summary of an NIH consensus statement[J].Lancet,1981,282:373-375.
2. Anonymous.Clinical practice guidelines for the use of tumor markers in breast and colorectal cancer[J].J Clin Oncol,1996,14:2843-2877.
3. Graham RA,Wang S,Catalano PJ,et al.Post surgical surveillance of colon cancer:preliminary cost analysis of physician examination,CEA testing,chest X-ray and colonoscopy[J].Ann Surg,1998,228:59-63.
4. Moertel CG,Fleming TR,Macdonald J,et al. An evaluation of the carcinoembryonic antigen(CEA)test for monitoring patientswith resected coloncancer[J].JAMA,1993,270:943-947.

INDEX OF SYMBOLS

	See Instruction for Use		Tests per Kit		Manufacturing Date
	In Vitro Diagnostic Use		Expiry Date		Do not reuse
	Store between 4 ~ 30 °C		Batch Number		Catalog #
	Keep away from Sunlight		Keep Dry		Authorized Representative
	Manufacturer				

 Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

  Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel, Belgium



物料编码及项目名称：1.5.2.3.04830 说明书 新（飞测CEA定量检测试剂）英文

尺寸规格：340*125mm

颜色：黑色

设计师：许广添

材质：80克铜版纸

申请人：周梦琳

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