CE IVD

CEA

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF

IF1051 for Getein1100
IF3051 for Getein1180
IF2051 for Getein1600

INTENDED USE

CEA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of carcinoembryonic antigen (CEA) in serum or plasma samples. This test can be used as a tumor marker to monitor colorectal carcinoma treatment and follow-up. But CEA test is not reliable for diagnosing cancer or as a screening test for early detection of cancer.

SUMMARY

CEA is a glycosylated molecule with a molecular weight of approximately 180,000 Daltons. CEA, like AFP, belongs to the group of carcino-fetal antigens that are produced during the embryonic and fetal period. The CEA gene family consists of about 17 active genes in two subgroups. The first group contains CEA and the nonspecific cross-reacting antigens (NCA); the second group contains the pregnancy-specific glycoproteins (PSG).
CEA is normally produced in gastrointestinal tissue during fetal development, but the production stops before birth. Consequently, CEA is usually present at very low levels in the blood of healthy adults. Slight to moderate CEA elevations can also occur in 20-50% non-malignant diseases of the intestine, the pancreas, the liver, and the lungs (i.e. liver cirrhosis, chronic hepatitis, pancreatitis, ulcerative colitis, Crohn's Disease). Smoking can also lead to elevated CEA values and needs to be taken into account when interpreting CEA levels.
CEA determinations are not recommended for cancer screening in the general population and CEA concentrations within the normal range do not exclude the possible presence of a malignant disease. The main indication for CEA determinations is to monitor colorectal carcinoma treatment, to identify recurrences after treatment or surgical resection and to aid in staging and assessing metastasis.

PRINCIPLE

This test uses a CEA antibody I conjugated with fluorescence latex and another CEA antibody II coated on the test line. After sample has been applied to the test strip, the fluorescence latex-labelled CEA antibody I binds with the CEA antigen in sample and forms marked antibody-antigen complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by CEA antibody II. The fluorescence intensity of the test line increases in proportion to the amount of CEA antigen in the sample.
Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of CEA antigen in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein CEA test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein CEA test cards
User manual: 1 piece/box Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled CEA antibody I, the test line is coated with another CEA antibody II and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent at 0~30°C with a valid period of 24 months.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should follow by local regulations.
8. Carefully read and follow the user manual to ensure an appropriate test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME(for Getein1100/Getein1180) : ***100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

9. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.

10. Enter testing interface of Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table, horizontally placed.
13. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample port on the test card.
14. ***Reaction time: 15 minutes.*** Insert the test card into Getein 1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

15. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
16. Put the sample diluent at the correct position in Getein1600.
17. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein-1100/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1180/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 5 times.

EXPECTED VALUE

The expected normal value for CEA was determined by testing serum samples from 1000 apparently healthy individuals. The 95th percentile of the concerntration for CEA is 4.7 ng/mL.(The probability that CEA value of a normal person below 4.7 ng/mL is 95%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0 ng/mL-500.0 ng/mL
Lower Detection Limit	≤ 2.0 ng/mL
Within-run Precision	≤ 10%
Between-run Precision	≤ 15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	1000 mg/dL	20 mg/dL

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CEA Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing CEA Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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