

**CEA****Fast Test Kit****(Immunofluorescence Assay)**

IF1051 for Getein 1100  
 IF5051 for Getein 1160  
 IF3051 for Getein 1180  
 IF2051 for Getein 1600  
 IF4051 for Getein 1200

**Instructions for Use**

by 5-6 times, it indicates a poor prognosis.

**PRINCIPLE**

CEA Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After sample has been applied to the test strip, the fluorescence-labelled CEA monoclonal antibody binds with the CEA 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 another CEA monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CEA antigen in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CEA in sample be detected quantitatively.

**APPLICABLE DEVICE**

Getein 1100 Immunofluorescence Quantitative Analyzer  
 Getein 1160 Immunofluorescence Quantitative Analyzer  
 Getein 1180 Immunofluorescence Quantitative Analyzer  
 Getein 1600 Immunofluorescence Quantitative Analyzer  
 Getein 1200 Immunofluorescence Quantitative Analyzer

**CONTENTS**

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
CEA test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

\*CEA test card

A test card consists of: Fluorescence-labelled CEA monoclonal antibody, CEA monoclonal antibody.

\*\* Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 1.0 mL contained in each tube consists of:

- Phosphate buffer (20 mmol/L), NaN<sub>3</sub> (<0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer (20 mmol/L), NaN<sub>3</sub> (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

**Note:**

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".

2. Do not mix or interchange different batches of kits.

**STORAGE AND STABILITY****Realtime stability:**

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

**In-use stability:**

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

- For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, 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.

**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 instructions for use 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.

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 Getein 1100/Getein 1160/Getein 1180): 100 µL.

**TEST PROCEDURE**

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.

2. Test kit and sample should be brought to room temperature before testing.

**For Getein 1100:**

1. Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.

2. Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details).

3. Remove the test card from the sealed pouch before use. Horizontally place the test card.

4. Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port "S" on the test card.

5. Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

**For Getein 1160/Getein 1180:**

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.

2. Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details)

3. Remove the test card from the sealed pouch before use. Horizontally place the test card.

4. Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port "S" on the test card.

5. Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

**For Getein 1200/Getein 1600:**

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.

**INTENDED USE**

CEA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of carcinoembryonic antigen (CEA) in serum or plasma samples. The test is used clinically as an aid in the diagnosis and management of cancer patients. For professional and laboratory use only.

This test can NOT be used to guide the diagnosis of pair trisomy 21.

**SUMMARY**

CEA is a glycosylated molecule with a molecular weight of approximately 180,000 Daltons. CEA (Carcinoembryonic Antigen) is synthesized by epithelial tissues of the fetal gastrointestinal tract, pancreas, and liver cells. Typically, the levels of CEA increase during the first six months of pregnancy and become very low in the serum after birth. CEA is a non-organ-specific tumor-associated antigen, and tumors that secrete CEA are mostly located in hollow organs such as the gastrointestinal tract, respiratory tract, and urinary tract.

Normally, CEA is metabolized by the gastrointestinal tract, but in the presence of tumors, CEA enters the blood and lymphatic circulation, causing abnormally high serum CEA levels. This results in elevated serum CEA in patients with various types of tumors mentioned above.

Clinically, when CEA exceeds 60 µg/L, it can be seen in colon cancer, rectal cancer, gastric cancer, and lung cancer. Elevated CEA levels indicate the presence of residual or progressive lesions. For patients with lung cancer, breast cancer, bladder cancer, and ovarian cancer, serum CEA levels significantly increase, mostly indicating tumor infiltration, with about 70% being metastatic cancers. Generally, CEA levels return to normal 6 weeks after surgical resection; otherwise, it suggests the presence of residual tumor. If the CEA concentration continuously increases or its value exceeds the normal range

- Put the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

**Notes:**

- It is required to perform “SD card” calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the test card and the sample insertion are correct and complete.

**RESULTS**

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

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

**LIMITATIONS**

- 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.
- Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

**EXPECTED VALUE**

The expected normal value for CEA was determined by testing serum samples from 1000 apparently healthy individuals. The 95th percentile of CEA is 4.7 ng/mL.

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
Limit of Detection	≤ 2.0 ng/mL
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

**REFERENCES**

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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 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/ European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using CEA Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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