



CA125 Fast Test Kit (Immunofluorescence Assay)

IF1079 for Getein 1100
IF5075 for Getein 1160
IF3075 for Getein 1180
IF2079 for Getein 1600
IF4079 for Getein 1200



Instructions for Use

INTENDED USE

CA125 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cancer Antigen 125 (CA125) in serum, plasma or whole blood samples. The test is indicated for use as an aid in the detection of ovarian carcinoma. For professional and laboratory use.

SUMMARY

CA125 is an antigen recognized by monoclonal antibodies generated by immunizing mice with ovarian serous cystadenocarcinoma cells, and it is also hybridized with myeloma cells. Due to the presence of certain mucin-like molecular characteristics in its amino acid sequence, it is named CA125. CA125 has a high detection rate in the serum of patients with non-mucinous epithelial ovarian tumors. It is not expressed in normal ovarian epithelial cells (in adults and fetuses). Ovarian cancer accounts for about 20% of gynecologic tumors, with an incidence rate of 15/100,000. CA125 can be detected in amniotic fluid and the body cavity epithelial cells of fetuses. It can also be present in the epithelial cells of the fallopian tubes, endometrium, and cervix in adults. Certain benign gynecologic diseases can cause elevated CA125 levels, such as ovarian cysts, ovarian endometriosis, endometriosis, uterine fibroids, and cervical inflammation. Although CA125 is a non-specific marker, it remains the most important biomarker for the diagnosis and prognosis of ovarian tumor patients.

PRINCIPLE

CA125 Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled CA125 monoclonal antibody binds with the CA125 in sample

and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another CA125 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CA125 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the CA125 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
CA125 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*0.4 mL/tube	25*0.4 mL/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

*CA125 test card

A test card consists of: Fluorescence latex-labelled CA125 monoclonal antibody, CA125 monoclonal antibody and goat anti-mouse IgG antibody.

** Sample diluent

(1)Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.4 mL contained in each tube consists of:

-Sample diluent contains phosphate buffer (20 mmol/L), Na₃ (<0.1%).

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

-Sample diluent contains phosphate buffer (20 mmol/L), Na₃ (<

<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600)

***Other Materials required for Getein 1200/Getein 1600:

- (1) Box with pipette tips (96 tips/box),
- (2) 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 the 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. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
6. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma and whole blood can be used as samples in the assay.
2. Heparin, sodium citrate can be used as the anticoagulants for

- plasma and whole blood. Do not use hemolysis specimens.
3. This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
 4. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
 5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

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 "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 4) Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well 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 or click on "Start" icon. 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" on the analyzer according to the sample type (see the instructions of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally

- placed.
- Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
 - 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 displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Place 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 and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

LIMITATIONS

- The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	400 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	500 mg/dL

EXPECTED VALUE

Statistical analysis of the results from measurements of 500 serum samples from apparently healthy individuals reveals that the entire dataset exhibits a non-normal distribution. Therefore, the 95th percentile for the CA 125 is estimated to be 35.0 U/mL. The reference ranges for plasma and whole blood samples are the same as those for serum samples. It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0~500.0 U/mL
Lower Detection Limit	≤2.0 U/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CA125 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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		

Thank you for using CA125 Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

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