



CA15-3 Fast Test Kit (Immunofluorescence Assay)

IF1081 for Getein 1100
IF5081 for Getein 1160
IF3081 for Getein 1180
IF2081 for Getein 1600
IF4081 for Getein 1200



Instructions for Use

INTENDED USE

Cancer Antigen 15-3 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cancer Antigen 15-3 (CA15-3) in serum or plasma samples. This test is utilized for the adjunctive diagnosis of breast cancer patients. For professional and laboratory use.

SUMMARY

CA15-3, a glycoprotein with a molecular weight of approximately 400kDa, is composed of intricate sugar chains and protein constituents. This particular antigen is commonly found in the luminal secretions of glandular cells, abstaining from entering the intricate pathways of circulatory system. However, when cells undergo a malignant transformation and their basement membrane becomes permeable, the presence of this antigen can be detected within the serums. It stands as a pervasive tumor marker, indispensable for auxiliary diagnosis and postoperative surveillance of breast cancer, as well as serving to vigilantly monitor the potential recurrence and metastasis of tumors. Its sensitivity proves lackluster in the early stages of breast cancer, but in the realm of metastatic breast cancer, its high positivity rate can ascend skyward, reaching an astonishing 80%. Nevertheless, it is crucial to acknowledge that the levels of CA15-3 can also surge due to various other factors, encompassing benign ailments (other breast diseases), pulmonary carcinoma, hepatic disorders, ovarian cancer, and an array of alike causes.

PRINCIPLE

CA15-3 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

CA15-3 monoclonal antibody binds with the CA15-3 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 CA15-3 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CA15-3 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the CA15-3 in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 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
CA15-3 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

*CA15-3 test card

A test card consists of: Fluorescence latex-labelled CA15-3 monoclonal antibody, CA15-3 monoclonal antibody and rabbit 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 main contains phosphate buffer (20 mmol/L), NaN3 (<0.1%).

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

-Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (<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 and plasma can be used as samples in the assay.
2. Heparin, sodium citrate and EDTA can be used as the

- anticoagulants for plasma. 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 at 2~8°C and 6 months at -20°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: **10 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 μ L of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μ L 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 (10 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 1600/Getein 1200 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1600/Getein 1200.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1600/Getein 1200 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 300 serum samples from apparently healthy individuals reveals that the entire dataset exhibits a non-normal distribution. Therefore, the 95th percentile for CA15-3 is estimated to be 26.2 U/mL, and the 99th percentile is estimated to be 34.5 U/mL using the percentile method.

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	1.5~300.0 U/mL
Lower Detection Limit	\leq 1.5 U/mL
Within-Run Precision	\leq 10%
Between-Run Precision	\leq 15%

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CA15-3 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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> 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 <i>instructions for use</i>
	Catalogue number		

Thank you for using CA15-3 Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

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