



# SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)

## User Manual



IF1095 for Getein1100  
IF2095 for Getein1600

### INTENDED USE

SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* qualitative detection of SARS-CoV-2 neutralizing antibody in serum, plasma or whole blood samples. The test is only used for professional and laboratory use, not for home testing.

### SUMMARY

SARS-CoV-2 has four structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N) proteins. The trimeric spike protein (S) is responsible for the fusion between viral and target cell membranes to initiate the infection. It is consisted of two fragments: the virus binding fragment S1 and the fusion fragment S2. It is found that the binding through the virus binding domain to the cell surface receptor, angiotensin converting enzyme 2 (ACE2), and further proteolytic cleavage on the S2 fragment triggers the dissociation of S1 and irreversible refolding of S2 into a post fusion conformation. These structural rearrangements finally lead to the endocytosis of virus into host cells.

SARS-CoV-2 neutralizing antibody is a protective soluble protein secreted by adaptive immunizing cells after inoculation with SARS-CoV-2 vaccine or infection with SARS-CoV-2. These antibodies can specifically bind with virus RNA binding domain (RBD) to block the binding of RBD with angiotensin-converting enzyme 2

(ACE2) on human cells surface, thus prevent the virus or its genetic material into the human cell and virus infection. Therefore, SARS-CoV-2 neutralizing antibody testing can be used as a aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, it should not be used to diagnose acute SARS-CoV-2 infection.

### PRINCIPLE

The SARS-CoV-2 neutralizing antibody in human serum, plasma or whole blood is detected by immune competition method.

When the sample does not contain SARS-CoV-2 neutralizing antibody, the fluorescence latex labeled RBD moves under chromatography and forms fluorescence latex-labeled compound with ACE2 receptor protein coated on the test line. When the sample contains SARS-CoV-2 neutralizing antibody, the SARS-CoV-2 neutralizing antibody in the sample can bind competitively with the ACE2 receptor protein coated in the test line, and the fluorescence latex labeled RBD cannot or form a small amount of fluorescence latex labeled complex at the test line. The fluorescence intensity of the test line varies inversely with the concentration of SARS-CoV-2 neutralizing antibody in human blood.

### CONTENTS

#### 1. A kit for Getein1100 contains:

Package specifications: 25 tests/box.

- 1) Getein SARS-CoV-2 Neutralizing Antibody test card in a sealed pouch with desiccant
- 2) Whole blood buffer: 1 bottle/box
- 3) User manual: 1 piece/box
- 4) SD card: 1 piece/box
- 5) Disposable pipet

#### 2. A kit for Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

- 1) Sealed cartridge with 24/48 Getein SARS-CoV-2 Neutralizing Antibody test cards

2) 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

**Note: Do not mix or interchange different batches of kits.**

#### 3. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a fluorescence latex pad (coated with recombinant SARS-CoV-2 RBD), nitrocellulose membrane with two test lines (T line coated with mixed anti-human IgM and IgG antibody), the control line (coated with anti-recombinant protein tag protein), absorbent paper and liner.

#### 4. Sample diluent/whole blood buffer composition:

Phosphate buffered saline, protein stabilizer and surfactant.

### APPLICABLE DEVICE

Getein1100 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.

For test card of Getein1100: Use the test card 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 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.

Store the sample diluent/whole blood buffer at 0–30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2–8°C for better results.

### PRECAUTIONS

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

### SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma** or **whole blood** samples. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after whole blood collection. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2–8°C. For long-term storage, samples should be stored below -20°C and avoid repeated freeze-thawcycles (whole blood sample may be stored up to 3 days at 2–8°C).
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing.
4. Do not use heat-inactivated samples or hemolysis samples.
5. SAMPLE VOLUME (for Getein1100): **100 µl**.

**TEST PROCEDURE**

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.
4. Perform "SD card" calibration when necessary.
5. Enter testing interface of Getein1100.
6. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
7. Put the test card on a clean table, horizontally placed.
8. Using sample transfer pipette, deliver 100 µl of sample into the sample port on the test card(for whole blood sample, one drop of whole blood buffer must be added after loading 100 ul sample on the test card).
9. Reaction time: **15 minutes**. Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

10. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
11. Place the sample diluent at the correct position of Getein1600.
12. 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.
3. Make sure the test card insertion is correct and complete.

**TEST RESULTS**

1. Getein1100/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/ Getein1600.
2. The test result is displayed numerically in terms of inhibition rate for SARS-CoV-2 neutralizing antibody. The reaction voltage value of each sample was obtained through the experiment to calculate the inhibition rate: Inhibition rate = (1- sample voltage value/critical value) × 100%
3. The interpretation of the results can be referred to the following table:

Display	Judgement
≥30%	SARS-CoV-2 neutralizing antibodies detected
<30%	No SARS-CoV-2 neutralizing antibodies detected
Invalid Test	Test invalid, repeat the test (some procedural error or malfunction of test cards and/or analyzers).

4. It is recommended that each laboratory establish its own expected values for the population it serves.

**LIMITATIONS**

1. The test is for *in vitro* diagnostic use only.
2. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

**DESCRIPTION OF SYMBOLS USED**

The following graphical symbols used in or found on the test kit 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		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community
	CE mark		Do not use if package is damaged
	Catalogue number		

Thank you for purchasing SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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