EN

RAPID SARS-COV-2 ANTIGEN TEST CARD
（DEVICE FOR SELF–TESTING）

FOR THE QUALITATIVE ASSESSMENT OF SARS-CoV-2 VIRUS ANTIGEN
IN ANTERIOR NASAL(FRONT NOSE) SWAB SPECIMENS

For In Vitro Diagnostic Use Only

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is a one-step in vitro test based on immunochromatography. It aims to quickly and qualitatively determine the SARS-CoV-2 virus antigen in anterior nasal (front nose) swabs of individuals. Rapid SARS-CoV-2 Antigen Test Card is intended for infection detection. Rapid SARS-CoV-2 Antigen Test Card detects the SARS-CoV-2 nucleocapsid protein (N protein), and all known SARS-CoV-2 variants do not affect the product performance.

MODEL NUMBER

GMT102

INTRODUCTION

COVID-19 is an acute respiratory infectious disease. Currently, the individuals infected by the SARS-CoV-2 are the main source of infection. Based on the current epidemiological investigation, SARS-CoV-2 incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatographic lateral flow device using the principle of double antibody sandwich method. Anti-SARS-CoV-2 antibody was used as detection reagent. Goat anti rabbit antibody was used in the control line system. The colloidal gold-conjugated anti-SARS-CoV-2 antibody was dry-fixed on the test equipment. After adding the specimen, it will diffuse through the test strip through the capillary and migrate to re-water alloy conjugated complex. If it exists or exceeds the detection limit, the SARS-CoV-2 virus antigen will react with the gold conjugate complex to form particles, and the particles will continue to migrate along the test strip until the test area (T) captured by the immobilized antibodies. Anti-SARS-CoV-2 antibody forms a visible red line. If there is no SARS-CoV-2 virus antigen in the sample, there will be no red line in the test area (T). The gold conjugate complex will continue to migrate alone until it is captured by the antibody immobilized in the control zone (C) to form a red line, which indicates the validity of the test.

MATERIALS PROVIDED

1. Rapid SARS-CoV-2 Antigen Test Card
2. Sterilized swab
3. Extraction tube
4. Sample extraction buffer
5. Biohazard waste container
6. Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or timer, disinfectant

SPECIFICATION

1 test/package, 5 tests/package, 20 tests/package

STORAGE

1. Store and use the test device at 4℃ to 30℃, humidity range is 30% - 90%. Do not freeze.
2. Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3. The test device should remain in its original sealed pouch until ready for use.

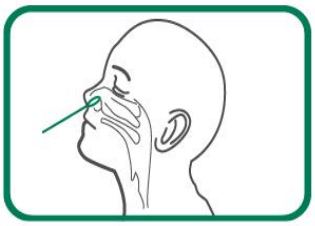
After opening, the test device should be used immediately. Do not reuse the device.
The kit is valid for 18 months.

PRECAUTIONS

1. If the packaging bag is damaged or the seal is broken, please do not use this product.
2. Before using this kit, please take off your hand jewellery and then wash hands with soap or an alcohol-based sanitiser.
3. The kit is suitable for people aged 18-70 to self-test. People aged 1 to 18 should be accompanied by adults to use this kit. Newborns under one year old are not suitable for the kit.
4. Please make sure to use the right amount of samples for testing. Too much or too little sample size may lead to biased results.
5. The used reagents should be discarded according to local regulations.
6. Improper humidity and temperature will adversely affect the test results.
7. If you accidentally touch the buffer with your eyes and skin, immediately flush eyes and skin with copious amounts of water. If you accidentally drink the buffer, immediately wash out mouth then call a physician.

SPECIMEN COLLECTION

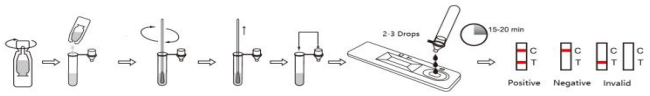
Correct specimen collection, storage, and transportation are critical to the performance of this test. Specimens should be tested as soon as possible after collection. For best test performance, please use the swab provided in the kit.



Anterior nasal (front nose) swab

1. Carefully insert the swab into the user's nostril. The swab tip should be inserted up to 2.5cm(1 inch) from the edge of the nostril.
2. Dab along the lining of the nostril and roll the swab several times.
3. Remove the swab from the nasal cavity.

SPECIMEN PREPARATION



1. Add the sample extraction buffer into extraction tube, then place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the sample extraction buffer for 1 minute.**
2. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible.
3. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.

PROCEDURE

1. Open the pouch and remove the card. After opening, the test card must be used immediately.
2. Invert the extraction tube, and gently squeeze the extraction tube, add 2-3 drops of the test sample into the sample hole (S).
3. Read the result at **15-20 minutes**.

Note: The result after 20 minutes may not be accurate.

INTERPRETATION OF RESULT

Positive:

If two ribbons appear within 15-20 minutes, one ribbon appears in the control zone (C) and the other ribbon appears in the test zone (T), the test result is positive and valid. No matter how weak the color band is in the test area (T), the result should be considered positive. If there is a positive result, please go to professional testing institutions for recheck immediately. A positive result does not rule out simultaneous infection with other pathogens.

Negative:

If a ribbon appears in the control zone (C) within 15 to 20 minutes, but there is no ribbon in the test zone (T), the test result is negative and valid. A negative result does not rule out SARS-CoV-2 virus infection. You should consult with a doctor to determine the appropriate courses of action if you have symptoms.

Invalid result:

The test result is invalid if there is no colored band in the Control Zone (C) within 15-20 minutes. Please repeat the test with a new test device. If there are invalid results in multiple tests, it may indicate that the test performance is not good, please do not continue to use it.

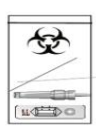
Note: Please do not take any decision of medical relevance without first consulting your medical practitioner.

DISPOSAL

1.Use a household bleach spray or a 70%-75% alcohol spray to disinfect used product components and other place contacted with the sample (e.g. used fragment of the tabletop, timer surface).

2.Place all the components in the provided plastic biohazard waste container. Seal the bag and throw it away.

3.Wash the hands thoroughly.



QUALITY CONTROL

The control zone is for internal reagent and procedure control. It will appear if the test is performed correctly and the reagent is reactive.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection (LoD) of Rapid SARS-CoV-2 Antigen Test Card was determined based on the performance evaluation studies performed with a virus strain and a recombinant nucleocapsid protein. LoD was confirmed in the table below.

Item	Limit of Detection
SARS-CoV-2, Recombinant nucleocapsid protein	100 pg/mL

Cross Reactivity

The cross-reactivity of Rapid SARS-CoV-2 Antigen Test Card was evaluated with above list . None of the microorganisms tested in the following table produced positive results.

Microorganisms	Concentrations	Microorganisms	Concentrations
Humanes Coronavirus 229E	1.6×10^5 $TCID_{50}$/mL	*Haemophilus Influenzae Type B*	10^4 CFU/vial
Humanes Coronavirus OC43	1.6×10^5 $TCID_{50}$/mL	*Streptococcus pyogenes*	10^4 CFU/vial
Humanes Coronavirus NL63	$1.6\times10^3$$TCID_{50}$/mL	*Streptococcus pneumoniae*	4.25×10^5 CFU/mL
Humanes Coronavirus HKU1	$1.6\times10^5$$TCID_{50}$/mL	*Bordetella pertussis*	4.8×10^6 CFU/mL
MERS Coronavirus	$8.9\times10^4$$TCID_{50}$/mL	*Mycoplasma pneumoniae*	3.0×10^6 CFU/vial
SARS Coronavirus	$1.6\times10^5$$TCID_{50}$/mL	*Chlamydia pneumoniae*	9.1×10^6 CFU/mL
Adenovirus typy5	$1.6\times10^5$$TCID_{50}$/mL	*Legionella pneumoniae*	3.9×10^5 CFU/mL
Human metapneumovirus (hMPV)	$1.6\times10^5$$TCID_{50}$/mL	*Staphylococcus aureus*	$>10^4$ CFU/vial
Human Parainfluenza virus type 1	$8.9\times10^5$$TCID_{50}$/mL	*Staphylococcus epidermidis*	$>10^4$ CFU/vial
Human Parainfluenza virus type2	$1.0\times10^5$$TCID_{50}$/mL	*Candida albicans*	5×10^6 CFU/mL
Human Parainfluenza virus type3	$1.6\times10^5$$TCID_{50}$/mL	*Enterovirus A* CV-A10	$1.6\times10^5$$TCID_{50}$/mL
Human Parainfluenza virus type4a	$1.6\times10^3$$TCID_{50}$/mL	*Enterovirus B Echovirus 6*	$1.6\times10^5$$TCID_{50}$/mL
Human Parainfluenza virus type4b	$5.0\times10^5$$TCID_{50}$/mL	*Enterovirus C* CV-A21	$1.6\times10^5$$TCID_{50}$/mL
Influenza A Virus (H1N1)	$5.2\times10^5$$CEID_{50}$/mL	*Dengue Virus Type-1*	$1.6\times10^5$$TCID_{50}$/mL
Influenza A Virus (H3N2)	$2.0\times10^6$$TCID_{50}$/mL	*Dengue Virus Type-2*	$1.6\times10^5$$TCID_{50}$/mL
Influenza B Virus (Yamagata)	$2.0\times10^6$$TCID_{50}$/mL	*Dengue Virus Type-3*	$1.6\times10^5$$TCID_{50}$/mL
Influenza B Virus (Victoria)	$1.8\times10^5$$CEID_{50}$/mL	*Dengue Virus Type-4*	$1.6\times10^5$$TCID_{50}$/mL
Enterovirus EV71	$1.6\times10^5$$TCID_{50}$/mL	*Mycobacterium tuberculosis*	2.0×10^6 CFU/mL
Respiratory syncytial virus A	$2.8\times10^5$$TCID_{50}$/mL	*Pseudomonas aeruginosa*	2.0×10^6 CFU/mL
Rhinovirus 16	$>5\times10^3$$TCID_{50}$/mL	*pooled human nasal washes*	N/A

Interference

1. Microorganism

Rapid SARS-CoV-2 Antigen Test Card has detected common microbial samples. The results show that up to the listed concentrations, these microorganisms have no effect on the specificity of the assay.

Microorganisms	Concentrations	Microorganisms	Concentrations
Humanes Coronavirus 229E	1.6×10^5 $TCID_{50}$/mL	*Haemophilus Influenzae Type B*	10^4 CFU/vial
Humanes Coronavirus OC43	1.6×10^5 $TCID_{50}$/mL	*Streptococcus pyogenes*	10^4 CFU/vial
Humanes Coronavirus NL63	$1.6\times10^3$$TCID_{50}$/mL	*Streptococcus pneumoniae*	4.25×10^5 CFU/mL
Humanes Coronavirus HKU1	$1.6\times10^5$$TCID_{50}$/mL	*Bordetella pertussis*	4.8×10^6 CFU/mL
MERS Coronavirus	$8.9\times10^4$$TCID_{50}$/mL	*Mycoplasma pneumoniae*	3.0×10^6 CFU/vial
SARS Coronavirus	$1.6\times10^5$$TCID_{50}$/mL	*Chlamydia pneumoniae*	9.1×10^6 CFU/mL
Adenovirus typy5	$1.6\times10^5$$TCID_{50}$/mL	*Legionella pneumoniae*	3.9×10^5 CFU/mL
Human metapneumovirus (hMPV)	$1.6\times10^5$$TCID_{50}$/mL	*Staphylococcus aureus*	$>10^4$ CFU/vial
Human Parainfluenza virus type 1	$8.9\times10^5$$TCID_{50}$/mL	*Staphylococcus epidermidis*	$>10^4$ CFU/vial
Human Parainfluenza virus type2	$1.0\times10^5$$TCID_{50}$/mL	*Candida albicans*	5×10^6 CFU/mL
Human Parainfluenza virus type3	$1.6\times10^5$$TCID_{50}$/mL	*Enterovirus A* CV-A10	$1.6\times10^5$$TCID_{50}$/mL
Human Parainfluenza virus type4a	$1.6\times10^3$$TCID_{50}$/mL	*Enterovirus B Echovirus 6*	$1.6\times10^5$$TCID_{50}$/mL
Human Parainfluenza virus type4b	$5.0\times10^5$$TCID_{50}$/mL	*Enterovirus C* CV-A21	$1.6\times10^5$$TCID_{50}$/mL
Influenza A Virus (H1N1)	$5.2\times10^5$$CEID_{50}$/mL	*Dengue Virus Type-1*	$1.6\times10^5$$TCID_{50}$/mL
Influenza A Virus (H3N2)	$2.0\times10^6$$TCID_{50}$/mL	*Dengue Virus Type-2*	$1.6\times10^5$$TCID_{50}$/mL
Influenza B Virus (Yamagata)	$2.0\times10^6$$TCID_{50}$/mL	*Dengue Virus Type-3*	$1.6\times10^5$$TCID_{50}$/mL
Influenza B Virus (Victoria)	$1.8\times10^5$$CEID_{50}$/mL	*Dengue Virus Type-4*	$1.6\times10^5$$TCID_{50}$/mL
Enterovirus EV71	$1.6\times10^5$$TCID_{50}$/mL	*Mycobacterium tuberculosis*	2.0×10^6 CFU/mL
Respiratory syncytial virus A	$2.8\times10^5$$TCID_{50}$/mL	*Pseudomonas aeruginosa*	2.0×10^6 CFU/mL
Rhinovirus 16	$>5\times10^3$$TCID_{50}$/mL	*pooled human nasal washes*	N/A

2. Interfering substances

Rapid SARS-CoV-2 Antigen Test Card has tested samples containing interfering substances. The results show that up to the listed concentrations, these substances have no effect on the specificity of the assay.

Substances	Concentrations	Substances	Concentrations
Whole Blood	4% v/v	Homeopathic(Alkalol)	10% v/v
Mucin	0.5% w/v	nasal Drops(Phenylephrine)	15% v/v
Tobramycin	0.0004% w/v	Afrin(Oxymetazoline)	15% v/v
Ricola (Menthol)	0. 15% w/v	Nasal Spray (Cromolyn)	15% v/v
Mupirocin	1% W/V	Fluticasone Propionate	5% v/v
Tamiflu (Oseltamicir Phosphate)	0.5% w/v	Zicam	5% v/v
Azelastine	0.25% w/v	Saline（Nasal sprays）	2% v/v
D-panthenol	0.5% w/v	Sore Throat Phenol Spray	15%V/V
Chloraseptic	0.15% (W/V)	Nasogel (NeilMed)	5% (V/V)

Accuracy

The accuracy of Rapid SARS-CoV-2 Antigen Test Card was established using 604 anterior nasal (front nose) swabs collected from patients suspected of COVID-19. The following table summarizes the accuracy of Rapid SARS-CoV-2 Antigen Test Card compared with RT-PCR.

RAPID SARS-CoV-2 Antigen Test Card	RT-PCR		
	Positive	Negative	Total
Positive	180	1	181
Negative	20	403	423
Total	200	404	604

The sensitivity was 90% (95%CI:84.979%～93.784%).

The specificity was 99.752% (95%CI:98.629%～99.994%).

The accuracy was 96.523% (95%CI:94.734%～97.835%).

95%CI (CI:Confidence Interval) means that a certain range is credible.

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 virus antigen in anterior nasal (front nose) swab specimens. This assay cannot determine the exact concentration of SARS-CoV-2 virus antigen.
2. It is very important to collect specimens correctly. If this procedure is not followed, incorrect results may be obtained. Improper specimen collection, storage of samples or repeated freezing and thawing can cause inaccurate results.
3. If the antigen level in the sample is below the detection limit of the test, a negative test result may appear.
4. A negative test result cannot exclude other potential non-SARS-CoV-2 virus infections . If SARS-CoV-2 is suspected, a negative result should be confirmed by molecular diagnosis.
5. A positive test result cannot exclude co-infection with other pathogens.
6. The Rapid SARS-CoV-2 Antigen Test Card can detect active and inactive SARS-CoV-2 particles. Rapid SARS-CoV-2 Antigen Test Card that quickly detects the presence of SARS-CoV-2 depends on the antigen load and may not be related to other diagnostic methods performed on the same sample.
7. The kit has been verified using various cotton swabs. Using other swabs may result in false negative results.
8. Users should test specimens as soon as possible after specimen collection and within one hours after specimen collection.

EXPLANATION FOR SYMBOLS

IVD	For in vitro diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
4-30°C	Store between 4-30°C		Use by	2	Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer				Consult Instructions For Use
	Biological risks	CE 1434			The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC

INSTRUCTION APPROVAL AND REVISION DATE

Approval date：November 14, 2020

Revision date：November 31th, 2021

EC REP **Lotus NL B.V.**

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IVD CE 1434