reOpenTest CE IVD

COVID-19 Antigen Rapid Test

(USE NASAL SWAB)

About the Test

Introduction

The Coronavirus disease (SARS-CoV-2), also known as the COVID-19 virus, is an acute respiratory infectious disease. The SARS-CoV-2 is a β-coronavirus, which is an enveloped non-segmented positive-sense RNA virus. Currently it is spread by human-to-human transmission via droplets or direct contact, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the 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. The availability of a cost-effective, rapid point-of-care diagnostic test is critical to enable healthcare professionals to aid in the diagnosis of patients and prevent further spread of the virus. Antigen tests will play a critical role in the fight against COVID-19.

Intent of Use

The reOpenTest COVID-19 Antigen Rapid Test is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. The reOpenTest COVID-19 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

Test Principle

The reOpenTest COVID-19 Antigen Rapid Test contains a membrane strip, which is pre-coated with immobilized anti-SARS-CoV-2 antibody on the test line and mouse monoclonal anti-chicken IgY on the control line. Two types of conjugates (human IgG specific to SARS-CoV-2 Ag gold conjugate and chicken IgY gold conjugate) move upward on the membrane chromatographically and react with anti-SARS-CoV-2 antibody and pre-coated mouse monoclonal anti-chicken IgY respectively. For a positive result, human IgG specific to SARS-CoV-2 Ag gold conjugate and antiSARS-CoV-2 antibody will form a test line in the result window. Neither the test line nor the control line is visible in the result window prior to applying the patient specimen. A visible control line is required to indicate a test result is valid.

Materials Provided

- 1 Test device with desiccant in individual foil pouch
- 1 Buffer in individual pack of 400μL
- 1 Extraction tube with Nozzle cap
- 1 Anterior nasal swab
- 1 Instruction for use

Materials Required but not Provided

- Timer or watch

Quality Control

External Negative and Positive Controls are not supplied with this test kit. However, external positive and negative controls should be tested in accordance with good laboratory practice to confirm the test procedure and to verify proper test performance. Additional testing may be required according to guidelines or local, state, and/or nation regulations or accrediting organizations. The SARS-COV-2 Ag External Control Kit can be purchased separately. Please contact reOpenTest or your distributor for information on purchasing these controls.

Storage and Stability

- Store the test kit at temperature, 2°C to 30°C (36°F to 86°F), out of direct sunlight. When stored in refrigerator, all kit components must be brought to room temperature (15-30℃) for a minimum of 30 minutes prior to performing the test. Do not open the sealed pouch before components come to room temperature.
- Shelf-Life is 23 months, Kit contents are stable until the expiration date printed on the outer box and poil pouch. ***DO NOT FREEZE***.
- *Direct swab specimens should be tested immediately after collection.*

Warnings and Precautions

1. For in vitro diagnostic use only. Please use it within the validity period. Do not reuse the test device and kit components.
2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results.
3. All users have to read the instruction prior to performing a test.
4. Do not eat or smoke while handling specimens.
5. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
6. Avoid splashing or aerosol formation of specimen and buffer.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e. swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
9. Do not open the foil pouch until instructed. Do not use the aluminum foil bag if it is damaged.
10. Do not mix or interchange different specimens.
11. Do not mix buffer of different lots or those for other products.
12. Do not store the test kit in direct sunlight.
13. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
14. The provided sterilized swabs in the package should be used only for nasal specimen collection.
15. To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.
16. Do not dilute the collected swab with any solution except for the provided extraction buffer.
17. The buffer contains <0.1% Proclin300 as preservative, may be toxic if ingested. When disposed of through a sink, or comes in contact with the skin or eyes, flush with a large volume of water.
18. There is desiccant inside the aluminum foil bag. ⚠ ***DO NOT EAT***.

Test Procedure

(Please follow the figure on reverse)

Preparation

- ☐ Allow the test kit and its components to reach room temperature (15℃-30℃) prior to testing for 30 minutes.
- ☐ Make sure the test kit has all components.
- ☐ Look at the expiration date (EXP) of the kit box or foil pouch. If the expiration date has passed, use another kit.
- ☐ Ensure foil pouch is intact. Do not use the test if there is visible damage to the foil pouch.
- ☐ Please read the instruction carefully before beginning.

Sample collection

1. Use dedicated swab for specimen collection.
2. Open swab package at stick end. Take swab out, DO NOT touch or press on swab tip.
3. Tilt head back and gently insert swab tip (usually 1.5cm to 2.5cm) until it is fully inside the nostril and meet resistance.
4. Rub swab tip around inside of nose cavity at least 5 times or more for 15 seconds to make sure collect a good sample.
5. Remove swab and repeat in another nostril.
   ⚠ It is important to swab both side of nostrils; Some discomfort is expected – if experiencing sharp pain, try another nostril.

Sample extraction

1. Place the extraction tube in the tube rack, or the hole indexed on the box if it has.
2. Unscrew the lid of a buffer pack to open, add all its buffer (approximately 400 μL) into an extraction tube.
3. Insert the swab specimen in the extraction tube, Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least **15 times** and then squeeze out the swab by squeezing the extraction tube with fingers.
4. Break the swab at the breakpoint and close the nozzle cap of extraction tube firmly.
   ⚠ Do not lay the tube down and avoid the fluid leaks.
5. Leave the swab in the extraction tube for one minute.

Detection operations

6. Tear the sealed foil pouch along the incision and take the test device flat on a clean, dry surface.
7. Reverse the specimen extraction tube, holding the tube upright, drop **4 drops** (approximately 100 μL) slowly into the **"S"** well and start timing. ⚠ Caution: Avoid making bubble when dropping. Never pour the sample over the test cassette.
8. Observe the results showed within **15-20 minutes**.
   ⚠ **DO NOT use the result after 20 minutes.**

Interpretation of results

- ***Positive (+)***: Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).
  ⚠ *Caution: The T line can be very faint. Any pink/gray line visible here indicates a positive result when the result is valid.*
- ***Negative (-)***: Only a red line appears in the quality control area (C), and no line appears in the test area (T).
- ***Invalid***: No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged.

Performance Characteristics

Performance evaluation

To evaluate nasal swabbing specimen's diagnostic performance, COVID-19 positive samples from 161 people and COVID-19 negative samples from 230 people were introduced into this study.

reOpenTest COVID-19 Antigen Rapid Test Results

Method		PCR		Total Results
	Results	Positive	Negative	
reOpenTest	Positive	157	2	159
	Negative	4	228	232
Total Result		161	230	391

Sensitivity = 97.52% (95% CI = 93.76% to 99.32%)
Specificity = 99.13% (95% CI = 96.89% to 99.89%)
Accuracy = 98.47% (95% CI = 96.69% to 99.43%)

Detection limit

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which around 95% of all (genuinely positive) replicates test positive. Heat-inactivated SARS-CoV-2 virus with an initial concentration of $1.15x10^7 TCID_{50}$/ml (tissue culture infection dose of 50%) was transferred to negative samples and serially diluted. Each dilution was tested in triplicate with the reOpenTest COVID-19 Antigen Rapid Test. The detection limit of the coronavirus antigen rapid test is $5.75x10^2 TCID_{50}$/ml.

Results of the limit of detection study

Concentration ($TCID_{50}$/ml)	Number Positive / overall	Positive accordance
$5.75x10^2$	200/200	100%

Hook effect

In the investigation with heat-inactivated SARSCoV-2 virus, no Hook effect was found up to a concentration of $4.6x10^5 TCID_{50}$/ml.

Cross reactivity

The following organisms were examined for cross-reactivity. Samples that tested positive for the following organisms were found negative when tested with the reOpenTest COVID-19 Antigen Rapid Test:

No.	Potential Cross-Reactant	Concentration
1	Respiratory Syncytial Virus Type A	$5,5 \times 10^7$ PFU/ml
2	Respiratory Syncytial Virus Type B	$2,8 \times 10^5$ $TCID_{50}$/ml
3	Novel Influenza AH1N1 Virus 2019	1×10^6 PFU/ml
4	Seasonal influenza A H1N1	1×10^5 PFU/ml
5	Influenza A H3N2	1×10^6 PFU/ml
6	Influenza A H5N1	1×10^6 PFU/ml
7	Influenza B Yamagata	1×10^5 PFU/ml
8	Influenza B Victoria	1×10^6 PFU/ml
9	Rhinovirus	1×10^6 PFU/ml
10	Adenovirus 3	$5 \times 10^{7.5}$ $TCID_{50}$/ml
11	Adenovirus 7	$2,8 \times 10^6$ $TCID_{50}$/ml
12	EV-A71	1×10^5 PFU/ml
13	Mycobacterium tuberculosis	1×10^3 Bacteria/ml
14	Mumps virus	1×10^5 PFU/ml
15	Human coronavirus 229E	1×10^5 PFU/ml
16	Human coronavirus OC43	1×10^5 PFU/ml
17	Human coronavirus NL63	1×10^6 PFU/ml
18	Human coronavirus HKU1	1×10^6 PFU/m
19	Parainfluenza virus 1	$7,3 \times 10^5$ PFU/m
20	Parainfluenza virus 2	1×10^6 PFU/ml
21	Parainfluenza virus 3	$5,8 \times 10^6$ PFU/ml
22	Parainfluenza virus 4	$2,6 \times 10^6$ PFU /ml
23	Haemophilus influenzae	$5,2 \times 10^6$ CFU/ml
24	Streptococcus pyogenes	$3,6 \times 10^6$ CFU/ml
25	Streptococcus pneumoniae	$4,2 \times 10^6$ CFU/ml
26	Candida albicans	1×10^7 CFU/ml
27	Bordetella pertussis	1×10^4 Bacteria/ml
28	Mycoplasma pneumoniae	$1,2 \times 10^6$ CFU/ml
29	Chlamydia pneumoniae	$2,3 \times 10^6$ IFU/ml
30	Influenza B Victoria	1×10^6 PFU/ml
31	Legionella pneumophila	1×10^4 Bacteria/ml
32	Influenza A H3N2	1×10^6 PFU/ml
33	Influenza A H5N1	1×10^6 PFU/ml
34	Influenza B Yamagata	1×10^5 PFU/ml
35	Influenza B Victoria	1×10^6 PFU/ml
36	Rhinovirus	1×10^6 PFU/ml

Interfering Substances

The following substances, which occur naturally in respiratory samples or which can be artificially introduced into the nasal cavity or the nasopharynx, were examined with the coronavirus antigen rapid cassette test in the concentrations listed below and classified as not impairing performance.

No.	Substance	Concentration
1	Human blood (EDTA)	20% (v/v)
2	Mucin	5 mg/ml
3	Oseltamivir phosphate	5 mg/ml
4	Ribavirin	5 mg/ml
5	Levofloxacin	5 mg/ml
6	Azithromycin	5 mg/ml
7	Meropenem	5 mg/ml
8	Tobramycin	2 mg/ml
9	Phenylephrine	20% (v/v)
10	Oxymetazoline	20% (v/v)
11	0.9% sodium chloride	20% (v/v)
12	A natural, calming ALKALOL	20% (v/v)
13	Beclomethasone	20% (v/v)
14	Hexadecadrol	20% (v/v)
15	Flunisolide	20% (v/v)
16	Triamcinolone	20% (v/v)
17	Budesonide	20% (v/v)
18	Mometason	20% (v/v)
19	Fluticasone propionate	20% (v/v)
20	Fluticasone	20% (v/v)

Repeatability & Reproducibility

Repeatability & Reproducibility of reOpenTest COVID-19 Antigen Rapid Test was established using in-house reference panels containing negative specimens and a range of positive specimens. There were no differences observed within-run, between-run, between-lots, between-sites, and between-days.

Reference

- Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4 [J]. Journal of clinical microbiology 42(4): 1564-1569.
- Smith, A.B., Mock, V., et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

EN

reOpenTest

COVID-19 Antigen Rapid Test

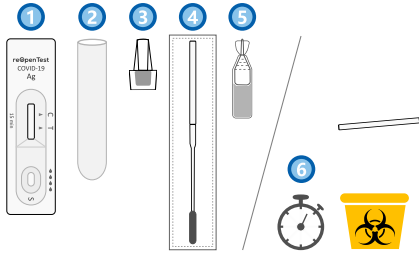
In vitro diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)

Preparation

1. Allow the test kit and its components to reach room temperature (15°C-30°C) prior to testing for 30 minutes.

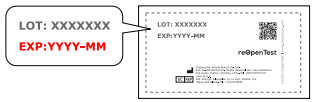
2. Open the package and make sure the test kit has all components.

① Test device (with desiccant in individual foil pouch)
② Extraction Tube with ③ Nozzle Cap
④ Swab (sealed in bag)
⑤ Buffer (with 400μL pack)

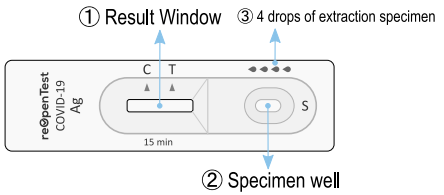


⑥ timer or watch is required but not provided.

3. Look at the expiration date (EXP) of the kit box or foil pouch. If the expiration date has passed, use another kit.



4. Ensure foil pouch is intact. Do not use the test if there is visible damage to the foil pouch. Open foil pouch and look for the following ① to ③, and take the test device flat on a clean, dry surface:



Scan to test and report

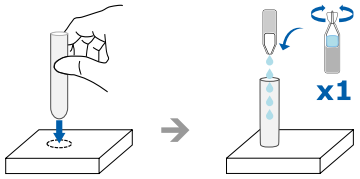
Support: http://reopentest.com/guide

IVD

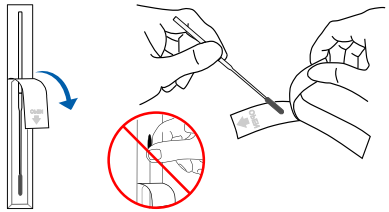
Test Procedure

5. Place the extraction tube in the tube rack, or the hole indexed on the box if it has.

6. Unscrew the lid of a buffer pack to open, add all its buffer (approximately 400 μL) into an extraction tube.

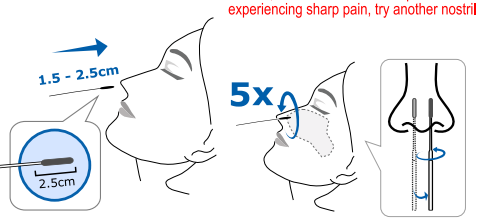


7. Use dedicated swab for specimen collection. Open swab package at stick end. Take swab out.
⚠ DO NOT touch or press on swab tip.



8. Tilt head back and gently insert swab tip (usually 1.5cm to 2.5cm) until it is fully inside the nostril and meet resistance.

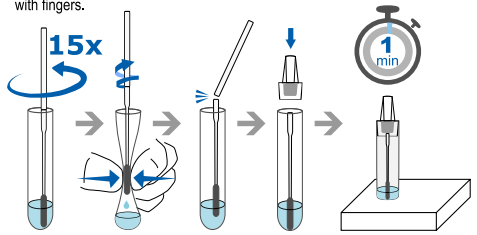
9. Rub swab tip around inside of nose cavity at least 5 times or more for 15 seconds to make sure collect a good sample. Remove swab and repeat in another nostril.
⚠It is important to swab both side of nostrils; Some discomfort is expected – if experiencing sharp pain, try another nostril.



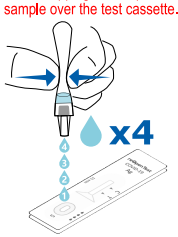
10. Insert the swab specimen in the extraction tube, Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least **15 times** and then squeeze out the swab by squeezing the extraction tube with fingers.

11. Break the swab at the breakpoint and close the nozzle cap of extraction tube firmly.

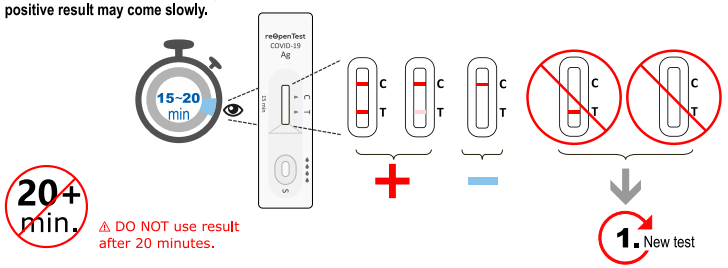
Leave the swab in the extraction tube for one minute.



12. Reverse the specimen extraction tube, holding the tube upright, drop **4 drops** (approximately 100 μL) slowly into the **"S"** well and start timing.
⚠Caution: Avoid making bubble when dropping. Never pour the sample over the test cassette.



13. Keep the cassette on a flat surface for **15 minutes**, and then observe result within 5 minutes, **positive result may come slowly.**



⚠ DO NOT use result after 20 minutes.

Disposal

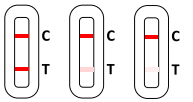
After test is completed, place the test unit in plastic disposal bag and dispose all test kit materials in trash.

Symbols Reference

CE Mark	Contains sufficient for <n> tests	LOT Batch code	Keep Dry Keep away from rain
IVD For in-vitro diagnostic use only	Do not re-use	Use by yyyy-mm	Temperature limit
Read instructions for use	Do not use if package is damaged	Manufacturer	Caution
REF Catalogue number	Keep away from sunlight	Biological Risks	EC REP Authorized Representative in the European Community / European Union

Read Results

Corona Positive (+): Two red lines appear. One is in the test area (T) and the other is in the quality control area(C).
⚠Caution: The T line can be very faint. Any pink/gray line visible here indicates a positive result when the result is valid.

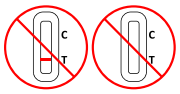


It is very likely patient has COVID-19 and it is important to be under the care of the healthcare provider. It is likely patient will be asked to isolate himself/herself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive). Please contact the healthcare provider to determine how best to care for patient based on the test results along with medical history and patient's symptoms.

Corona Negative (-): Only a red line appears in the quality control area (C), and no line appears in the test area (T).

A negative result means the virus that causes COVID-19 was not found in the sample. If patient took this test while patient has symptoms, a negative test result usually means that patient's current illness was not caused by COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means patient could possibly still have COVID-19 even though the test is negative. If this is the case, the healthcare provider shall consider the test result with all other aspects of patient's history such as symptoms and possible exposures to decide how to care for patient. It is important to work with the healthcare provider to help patient understand the next steps he/she should take.

Invalid: No red line displays in the quality control area (C). This means something with the test did not work properly. If the test result is invalid, it will need to retest with **a new test** or consult a healthcare professional.



REF COVG10C

reOpenTest

ORDER / SERVICE
1. Contact reOpenTest's distributors or
2. Visit reOpenTest website: http://www.reopentest.com
3. E-mail: service@reopentest.com

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Manufactured for:
Hangzhou Fenhe Technology Co., Ltd.
Add: Room 312, Bldg 1-1, No.560, Yueming Road, Xixing Street, Binjiang District, Hangzhou 310052, China. Tel: +86-15381046223

Manufactured by:
Zhejiang Anji Saianfu Biotech Co., Ltd.
Add: 2nd Floor, No 3 Factory, No 489 WenYun Road, TangPu Industrial Park, Dipu Subdistrict, Anji County, HuZhou City, ZheJiang Province, China.
Tel / Fax: +86-0571-87763175

EC REP **Lotus NL B.V.**
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. Tel: +31644168999