

# reOpenTest

## COVID-19

### Antigen Rapid Test

(SALIVA)

#### 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 B-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.

##### Intend 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 posterior oropharyngeal saliva 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

Contains	COVG30S	COVG30X	COVG30C
Test Devices (Cassette sealed in foil pouch)	25	5	1
Buffers (400µL pack)	25	5	1
Extraction Tubes with Nozzle Cap	25	5	1
Saliva Collector (Paper cup)	25	5	1
Droppers	25	5	1
Instruction for Use	1	1	1
Tube Rack	1	0	0

#### Materials Required but not Provided

- Timer or watch.

#### 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°C) 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 foil pouch. **DO NOT FREEZE.**
- Direct swab specimens should be tested immediately after collection.

#### Warnings and Precautions

- For in vitro diagnostic use only. Please use it within the validity period. Do not reuse the test device and kit components.
- These instructions must be strictly followed by a trained healthcare professional to achieve accurate results.
- All users have to read the instruction prior to performing a test.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation of specimen and buffer. Clean up spills thoroughly using an appropriate disinfectant.
- 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.
- Do not open the foil pouch until instructed. Do not use the aluminum foil bag if it is damaged.
- Do not mix or interchange different specimens.
- Do not mix buffer of different lots or those for other products.
- Do not store the test kit in direct sunlight.
- To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
- To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.
- Do not dilute the collected swab with any solution except for the provided extraction buffer.
- 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.
- 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°C-30°C) 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.

**⚠ No eat, no drink, smoke, brush teeth or chew gum 30 minutes before testing.**

##### Sample collection

- Patient deep coughs **5 times** to generate oropharyngeal saliva  
**⚠ Make sure patient wear a face mask or when coughing cover his/her mouth and nose with a tissue and keep distance from other people.**
- Open the Saliva Collector, and gently spit collected oropharyngeal saliva into the **Saliva Collector**.  
**⚠ If not enough saliva has been collected, repeat the above sampling steps.**

##### Sample extraction

- Place an extraction tube in the tube rack, or the hole indexed on the box if it has.
- Hold the dropper vertically, draw the saliva specimen up from saliva collector to fill the first bubble of dropper, and transfer the specimen to the extraction tube.
- Unscrew the lid of a buffer pack to open, add all its buffer (approximately 400 µL) into the extraction tube.
- Close the nozzle cap of extraction tube firmly. Press Gently squeeze the extraction tube **15 times** to get the contents well mix.  
**⚠ Do not lay the tube down and avoid the fluid leaks.**
- Leave the extraction tube for **one minute**.

##### Detection operations

- Tear the sealed foil pouch along the incision and take the test device flat on a clean, dry surface.
- 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.**

- 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.

#### Limitations

- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- The performance of the COVID-19 Antigen Rapid Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test. False negative results may occur if a specimen is improperly collected or handled; False negative results may occur if inadequate extraction buffer is used (e.g., <4 drops); False negative results may occur if swabs are stored in their paper sheath after specimen collection.
- Positive test results do not rule out co-infections with other pathogens. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

#### Performance Characteristics

##### Performance evaluation

To evaluate posterior oropharyngeal saliva'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	Positive	Negative	Results
reOpenTest	Positive	146	2	159
	Negative	15	228	232
Total Result		161	230	391
Sensitivity = 90.68% (95% CI = 85.10% to 94.69%)				
Specificity = 99.13% (95% CI = 96.89% to 99.89%)				
Accuracy = 95.65% (95% CI = 93.13% to 97.45%)				

##### 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 4.46x10<sup>5</sup>TCID<sub>50</sub>/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 1.16x10<sup>4</sup>TCID<sub>50</sub>/ml.

##### Results of the limit of detection study

Concentration (TCID <sub>50</sub> /ml)	Number Positive / overall	Positive accordance
1.16x10 <sup>5</sup>	90/90	100%

##### Hook effect

In the investigation with heat-inactivated SARSCoV-2 virus, no Hook effect was found up to a concentration of 1x10<sup>5.6</sup>TCID<sub>50</sub>/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 x 10 <sup>5</sup> PFU/ml
2	Respiratory Syncytial Virus Type B	2.8 x 10 <sup>5</sup> TCID <sub>50</sub> /ml
3	Novel Influenza A/H1N1 Virus 2019	1 x 10 <sup>8</sup> PFU/ml

4	Seasonal influenza A H1N1	1 x 10 <sup>5</sup> PFU/ml
5	Influenza A H3N2	1 x 10 <sup>5</sup> PFU/ml
6	Influenza A H5N1	1 x 10 <sup>5</sup> PFU/ml
7	Influenza B Yamagata	1 x 10 <sup>5</sup> PFU/ml
8	Influenza B Victoria	1 x 10 <sup>5</sup> PFU/ml
9	Rhinovirus	1 x 10 <sup>5</sup> PFU/ml
10	Adenovirus 3	5 x 10 <sup>1.5</sup> TCID <sub>50</sub> /ml
11	Adenovirus 7	2.8 x 10 <sup>5</sup> TCID <sub>50</sub> /ml
12	EV-A71	1 x 10 <sup>5</sup> PFU/ml
13	Mycobacterium tuberculosis	1 x 10 <sup>5</sup> Bacteria/ml
14	Mumps virus	1 x 10 <sup>5</sup> PFU/ml
15	Human coronavirus 229E	1 x 10 <sup>5</sup> PFU/ml
16	Human coronavirus OC43	1 x 10 <sup>5</sup> PFU/ml
17	Human coronavirus NL63	1 x 10 <sup>5</sup> PFU/ml
18	Human coronavirus HKU1	1 x 10 <sup>5</sup> PFU/m
19	Parainfluenza virus 1	7.3 x 10 <sup>5</sup> PFU/m
20	Parainfluenza virus 2	1 x 10 <sup>5</sup> PFU/ml
21	Parainfluenza virus 3	5.8 x 10 <sup>5</sup> PFU/ml
22	Parainfluenza virus 4	2.6 x 10 <sup>5</sup> PFU /ml
23	Haemophilus influenzae	5.2 x 10 <sup>5</sup> CFU/ml
24	Streptococcus pyogenes	3.6 x 10 <sup>5</sup> CFU/ml
25	Streptococcus pneumoniae	4.2 x 10 <sup>5</sup> CFU/ml
26	Candida albicans	1 x 10 <sup>5</sup> CFU/ml
27	Bordetella pertussis	1 x 10 <sup>5</sup> Bacteria/ml
28	Mycoplasma pneumoniae	1.2 x 10 <sup>5</sup> CFU/ml
29	Chlamydia pneumoniae	2.3 x 10 <sup>5</sup> IFU/ml
30	Influenza B Victoria	1 x 10 <sup>5</sup> PFU/ml
31	Legionella pneumophila	1 x 10 <sup>5</sup> Bacteria/ml
32	Influenza A H3N2	1 x 10 <sup>5</sup> PFU/ml
33	Influenza A H5N1	1 x 10 <sup>5</sup> PFU/ml
34	Influenza B Yamagata	1 x 10 <sup>5</sup> PFU/ml
35	Influenza B Victoria	1 x 10 <sup>5</sup> PFU/ml
36	Rhinovirus	1 x 10 <sup>5</sup> PFU/ml

#### Interfering Substances

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

No.	Substance	Concentration
1	Dexamethasone	0.8mg/ml
2	Rebetol	4.5µg/ml
3	Orange juice	100%
4	Mucin	50µg/ml
5	Relenza	282ng/ml
6	Mouthwash	2%
7	Flunisolide	6.8ng/ml
8	Tamiflu	1.1µg/ml
9	Caffeine	1mg/ml
10	Mupirocin	12mg/ml
11	Tobramycin	2.43mg/ml
12	Oxymetazoline	0.6mg/ml
13	Tea	33.3mg/ml
14	Phenylephrine	12mg/ml
15	Milk	11.2%
16	Coke	/
17	Toothpaste	/

#### 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 LightCycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

reOpenTest

# COVID-19 Antigen Rapid Test

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

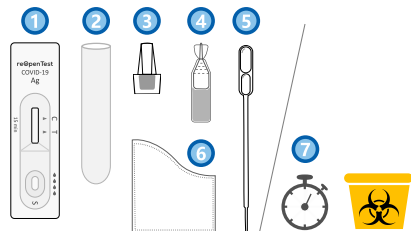
## Preparation

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

**△ No eat, no drink, smoke, brush teeth or chew gum 30 minutes before testing.**

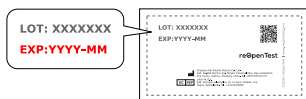
**2. Open the package and make sure the test kit has all components.**

- ① Test device (with desiccant in individual foil pouch)
- ② Extraction Tube with ③ Nozzle Cap
- ④ Buffer (400µL pack)
- ⑤ Dropper ⑥ Saliva Collector

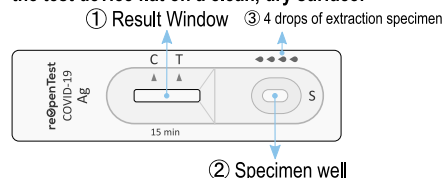


⑦ timer or watch is required but not provided.

**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:**



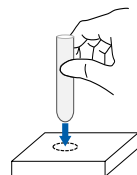
**Scan to test and report**

Support: <http://reopentest.com/ifu>

IVD

## Test Procedure

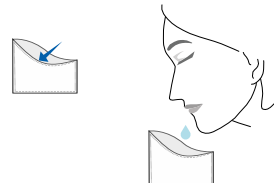
**5.** Place the extraction tube in the tube rack, or the hole indexed on the box if it has.



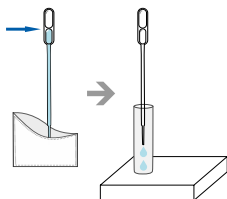
**6.** Deep coughs **5 times** to generate **posterior oropharyngeal saliva**.  
△ Make sure patient wear a face mask or when coughing cover his/her mouth and nose with a tissue and keep distance from other people.



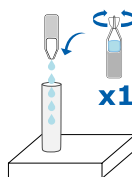
**7.** Open the Saliva Collector, and gently spit collected **oropharyngeal saliva** into the Saliva Collector.  
△ If not enough oropharyngeal saliva has been collected, repeat the above sampling steps.



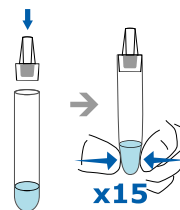
**8.** Hold the dropper vertically, draw the saliva specimen up from saliva collector to fill the first bubble of dropper, and transfer the specimen to the extraction tube.



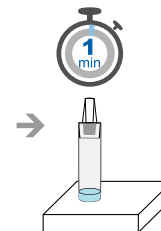
**9.** Unscrew the lid of a buffer pack to open, add all its buffer (approximately 400 µL) into the extraction tube.



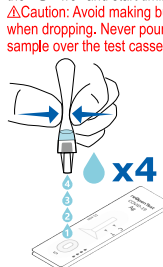
**10.** Close the nozzle cap of extraction tube firmly. Press Gently squeeze the extraction tube **15 times** to get the contents well mix.  
△ Do not lay the tube down and avoid the fluid leaks.



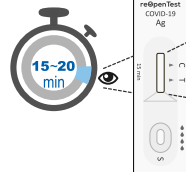
**11.** Leave the swab in the extraction tube for **one minute**.



**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.

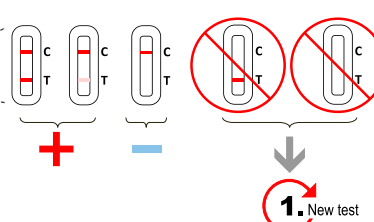


**13.** Keep the cassette on a flat surface for **15 minutes**, and then observe result within 5 minutes, **positive result may come slowly**.



**20+ min.**

△ Do NOT use result after 20 minutes.



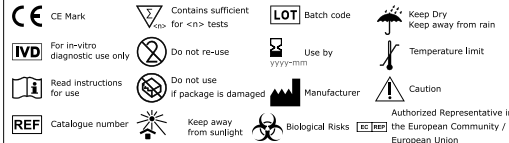
**1. New test**

## Disposal

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

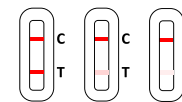


## Symbols Reference



## 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.



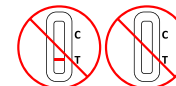
It is very likely patient has COVID-19 and it is important to be under the care of the healthcare provider. It is likely patient will be asked to isolate himself/herself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (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** COVG30S: 25Tests/Kit  
COVG30X: 5Tests/Kit  
COVG30C: 1Test/Kit

**reOpenTest**

## ORDER / SERVICE

1. Contact reOpenTest's distributors or
2. Visit reOpenTest website: <http://www.reopentest.com>
3. E-mail: [service@reopentest.com](mailto:service@reopentest.com)

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