BIOCREDIT
COVID-19 Ag

IVD

One Step SARS-CoV-2 Antigen Rapid Test

■ Introduction

2019 novel coronavirus (2019-nCoV) is a single-stranded RNA coronavirus. Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by the 2019-nCoV. 2019-nCoV belongs to the Beta-coronavirus Genus, which also includes Severe Acute Respiratory Syndrome coronavirus (SARS-CoV, 2003) and Middle East Respiratory Syndrome coronavirus (MERS-CoV, 2012). Coronaviruses, 2019-nCoV consist of a four viral proteins named spike (S), envelope (E), membrane (M), and nucleocapsid (N).

Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

[Principle of test]

BIOCREDIT COVID-19 Ag is a lateral flow immunochromatographic assay that adopted dual color system. The test contains colloid gold conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test lines (T). If SARS-CoV-2 antigen is present in the specimen, a visible black band appears on the test lines (T) as antibody-antigen-antibody gold conjugate complex forms. The control line (C) is used for procedural control and should always appear if the test is performed correctly.

[Intended Use]

For the qualitative detection of SARS-CoV-2 antigen from Human nasopharynx

■ Kit Components

- Each test device sealed in a foil pouch with a desiccant
- Assay diluent tube
- Filter cap
- Sterilized swab for nasopharynx specimen collection
- Instructions for use

■ Specimen Collection and Storage

1. Specimen should be handled carefully as an infectious agent and should be collected by trained personnel.
2. As improper collection of the sample affects the test result significantly, handle with care.
3. More accurate results can be obtained if samples are collected from several parts.
4. Specimen should be tested as soon as possible upon collection. If the sample has to be stored, store the swab sample at 2~8℃ up to 12 hours or at −20℃ or below up to 24 hours.

   [Nasopharyngeal swab specimen]

   To collect nasopharyngeal swab specimen, gently insert a nasopharyngeal swab into the nasal cavity until the resistance is met at the level of the turbinate. Rotate softly and withdraw the swab. Make sure the tip of the swab is wet.

■ Assay Procedure

[PREPARATION]

1. Equilibrate kit components and specimen to room temperature before testing.
2. Do not break the seal of the foil pouch until ready to perform the test.

[TESTING]

1. Remove the aluminum seal of the assay diluent tube. Immerse both nasopharyngeal swab in the assay diluent and swirl the swabs 5~10 times while pressing the head against the bottom and side of the collection tube.
2. Withdraw the swab while pinching and squeezing. Dispose it with biosafety.
3. Close the assay diluent tube with a filter cap securely.
4. Remove the device from the foil pouch and place it on a flat and dry surface.
5. Invert the assay diluent tube and gently squeeze it to draw 3~4 drops (90~150㎕) into a sample well(S) of the device.

   * **Please ensure that an appropriate amount of specimen and assay diluent are used for testing. Too much or too little amount of specimen and/or assay diluent may lead to deviation of results.**
6. Read the result between 5~8 minutes.

   ☞Do not interpret the result after 8 minutes.

■ Interpretation of Results

[Negative]

The presence of only one red band at the control line (C) within the result window indicates a negative result.

[Positive]

Two bands appear; one red control line(C) and one black test line(T).

[Invalid]

If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.

Note: There is no meaning attributed to line color intensity or width.

■ Performance Characteristics

BIOCREDIT COVID-19 Ag has been evaluated with panel specimen by PCR. The results are summarized in the following table:

1. Sensitivity and Specificity:

		PCR (after symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
BIOCREDIT COVID-19 Ag	Positive	23	1	92.0%	98.0%
	Negative	2	49		
Total		25	50		

2. Precision

   Within-run and between run precision has been determined in triplicates of three lots using the following specimen panel: negative, low positive, medium positive and strong positive. All specimens are correctly identified 100% of the time.
3. Cross reactivity

   BIOCREDIT COVID-19 Ag has been tested with 20 potentially cross reacting microorganisms and viruses. The results showed that BIOCREDIT COVID-19 Ag had no cross-reaction with microorganisms and viruses except very weak cross reacting with SARS-coronavirus.
4. Interference

   BIOCREDIT COVID-19 Ag has been tested with 14 potentially interfering endogenous or exogenous substances. The results showed that BIOCREDIT COVID-19 Ag had no interference with endogenous or exogenous substances.

■ Limitations

1. A negative result can occur if the quantity of coronavirus present in the specimen is below the detection limits of the assay.
2. A negative test result cannot exclude a recent infection.

■ Precautions

1. For *in vitro* diagnostic use only.
2. The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Decontaminate and dispose of all specimens, reaction kit and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
5. Wear protective clothing, gloves and eye protection while handling specimens. Wash hands afterwards.
6. Repeated freeze-thawing specimen can cause false positive or false negative results.
7. Discard the solid waste by autoclaving at 121℃ for 1 hour.
8. The assay diluent contains less than 0.1% of sodium azide. In case of dermal or eye exposure, wash out thoroughly with running water and seek medical attention if necessary.
9. Decontaminate and dispose of all specimens, test device and potentially contaminated materials as if they were infectious waste in a biohazard container with biosafety.
10. Do not use it beyond the expiration date.
11. Do not reuse.
12. Do not interchange or mix reagents of different lots.
13. Other clinically available tests are required if questionable results are obtained. As with all other diagnostic test, a clinical decision should not be based on the results of this test, but should be made by physician after all clinical and laboratory findings have been evaluated.
14. In case the nasopharnygeal swab is immersed into UTM/VTM, the media should be diluted with assay buffer with 1:1 ratio. But, this dilution may lower sensitivity.

■ Package

Refer to the outer packaging

■ Storage Condition

Store at 1~40℃.

Manufactured by RapiGEN,INC.
2F, 25, Heungan-daero, Gunpo-si, Gyeonggi-do, 15809, Republic of Korea
TEL : +82-31-427-4677 FAX : +82-31-427-4678 Email : info@rapigen-inc.com www.rapigen-inc.com

I-H073A-E00(2020.04.03)

RapiGEN

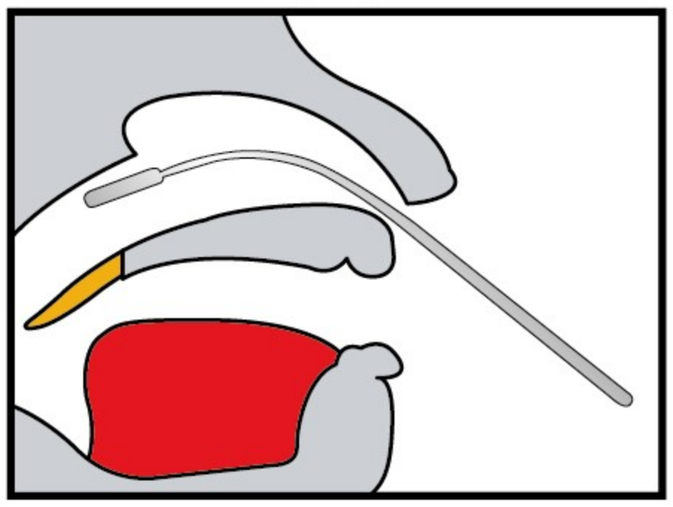
BIOCREDIT COVID-19 Ag

Cat.No. G61RHA20

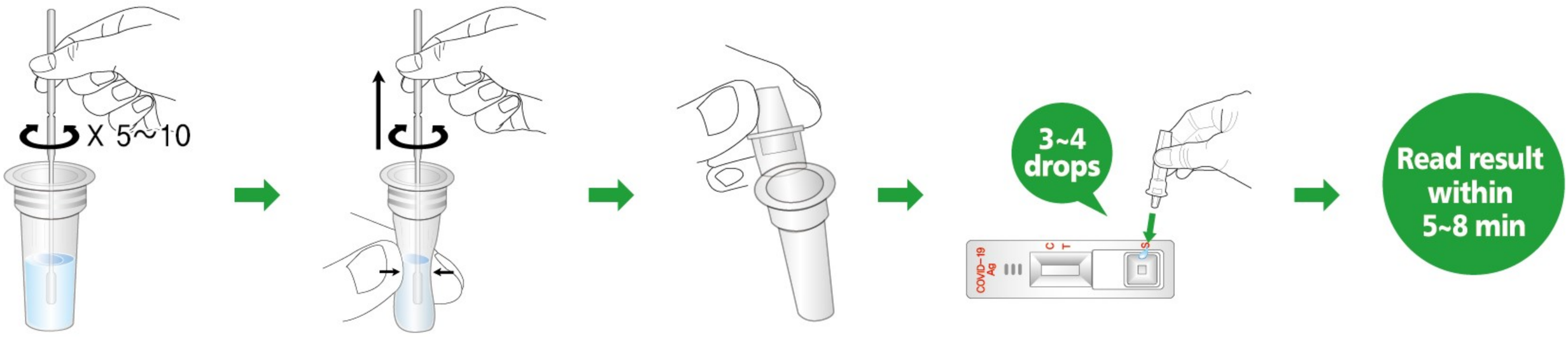
One Step SARS-CoV-2 Antigen Rapid Test

■ Specimen Collection

Nasopharyngeal Swab



■ Assay Procedure



1 Insert the swab specimen and swirl the swab 5~10 times.

2 Remove the swab while gently squeezing the head of the swab.

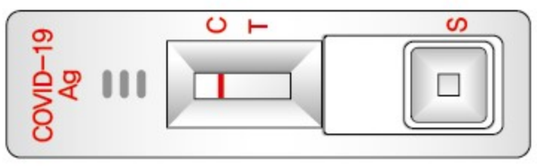
3 Close the assay diluent tube with a filter cap securely.

4 Invert the assay diluent tube and gently squeeze it to draw 3~4 drops (90~150μℓ) into a sample well on the device.

5 Read the result within 5~8 minutes.

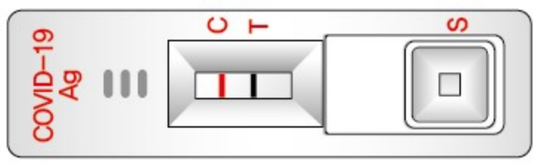
■ Interpretation of Results

Negative



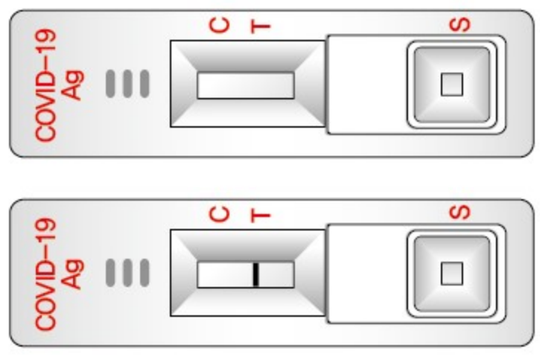
One **red** line "C" within the result window.

Positive



Two bands ; **black** "T" test line and **red** "C" control line within the result window.

Invalid



No "C" line within the result window.
It is recommended that the specimen be retested.

CE EC REP MT Promedt Consulting GmbH
Altenhofstrasse 80. 66386 St.Ingbert, Germany
Tel : +49-6894-581020 Fax : +49-6894-581021 Email : info@mt-procons.com www.mt-procons.com

I-H073A-E00(2020.04.03)