BIOCREDIT

COVID-19 Ag

CE IVD

One Step SARS-CoV-2 Antigen Rapid Test

CLEAN HANDS HEALTH

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 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. General recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing. Avoid close contact with anyone experiencing 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]

BIOCREDIT COVID-19 Ag is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in human nasopharynx. This test is for in-vitro professional diagnostic use and intended as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms. It provides only an initial screening test result and more specific alternative diagnosis methods should be performed in order to confirm COVID-19 infection.

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 4 hours prior to testing.

[Nasopharyngeal swab specimen]

To collect nasopharyngeal swab specimen, tilt the patient's head slightly backwards. Insert a nasopharyngeal swab horizontally into the nasal cavity until resistance is met at the level of the turbinate. Rotate the swab gently against the nasopharyngeal mucosa for 10 - 15 seconds. Remove the swab while making sure that the tip of the swab is wet.

* When collect the specimens, follow the Instruction for use thoroughly.

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 from the assay diluent tube. Immerse 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 against the tube. 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 is 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

1. Sensitivity and Specificity:

BIOCREDIT COVID-19 Ag has been evaluated comparing to PCR as reference at 3 different countries. The results are summarized in the following table:

Europe		PCR (After symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
BIOCREDIT COVID-19 Ag	Positive	24	0	96.0%	100.0%
	Negative	1	25		
Total		25	25		

South America		PCR (After symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
BIOCREDIT COVID-19 Ag	Positive	10	0	90.9%	100.0%
	Negative	1	109		
Total		11	109		

KOREA		PCR (After symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
BIOCREDIT COVID-19 Ag	Positive	12	0	80.0%	100.0%
	Negative	3	2		
Total		15	2		

Total		PCR (After symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
BIOCREDIT COVID-19 Ag	Positive	46	0	90.2%	100.0%
	Negative	5	136		
Total		51	136		

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 or if a poor quality specimen is tested.
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 with biosafety.
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. Do not use it beyond the expiration date.
10. Do not reuse.
11. Do not interchange or mix reagents of different lots.
12. A clinical decision should be made by physician after all clinical and laboratory findings have been evaluated.
13. Do not use the nasopharyngeal specimen in transport media.

Package

Refer to the outer packaging

Storage Condition

Store at 1~40℃.

RapiGEN

COVID-19 Ag

CLEAN HANDS HEALTH

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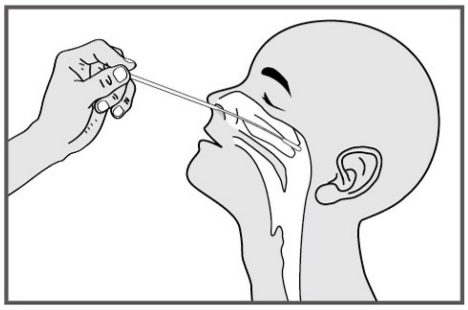
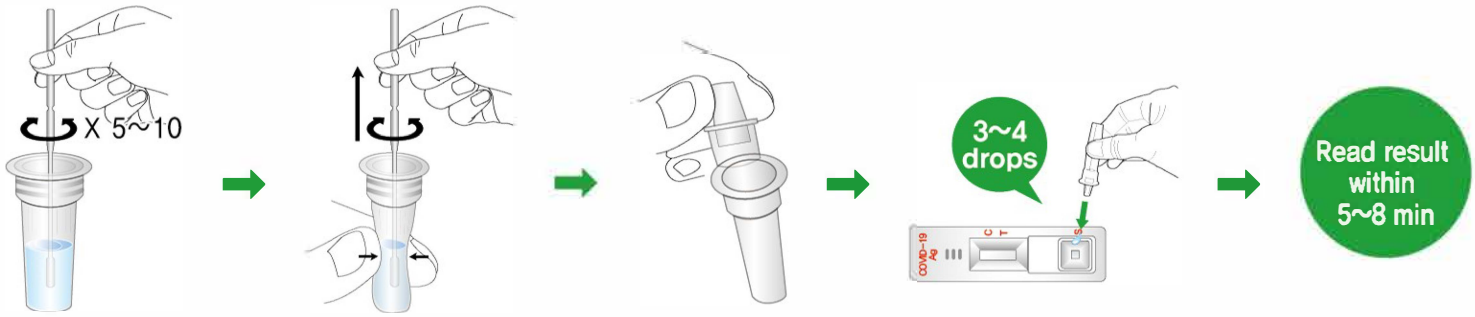
■ Specimen Collection

Nasopharyngeal Swab



① Tilt the patient's head slightly backwards.
② Insert a nasopharyngeal swab horizontally into the nasal cavity until resistance is met at the level of the turbinate.
③ Rotate the swab gently against the nasopharyngeal mucosa for 10 - 15 seconds.
④ Remove the swab while making sure that the tip of the swab is wet.

■ Assay Procedure



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

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

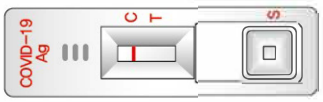
3 Take a filter cap from the pack and close the diluent tube securely.

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

5 Read the result within 5~8 minutes.

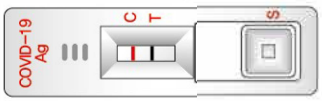
■ Interpretation of Results

Negative



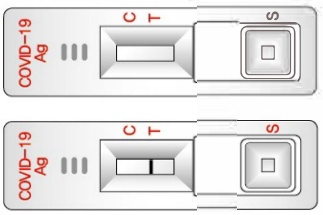
One red line "C" within the result window.

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.