

# Rapigen BIOCREDT COVID-19 Ag Home Test Nasal

## ENGLISH

**Intended Use**  
**BIOCREDT COVID -19 Ag Home Test Nasal** is a rapid chromatographic immunoassay intended for the qualitative detection of nucleocapsid (N) protein antigen from SARS-CoV-2 in individuals with or without symptoms or other epidemiological reasons to suspect COVID -19 infection. This test is authorized for home use with self-collected direct nasal (nares) swab samples from individuals collected nasal swab.

### Principle of Test

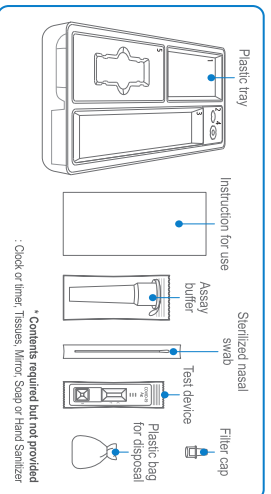
BIOCREDT COVID-19 Ag Home Test Nasal is a lateral flow immunochromatographic assay that adopted dual color system. The test contains colloid gold conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test line (T). If SARS-CoV-2 antigen is present in the specimen, a visible black band appears on the test line (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.

### Test preparation

1. Prepare a flat and dry surface such as a desk. Clean the prepared area.
2. Wash your hands with soap or hand sanitizer for 30 seconds, then dry them off.
3. If you use more than one test, you will need to clean the table and wash your hands after each test.
4. Make sure you have all the components required to use this kit. If there is any missing or damaged part, do not use the kit.

### Components provided

Plastic tray, Sterilized nasal swab, Filter cap, Assay diluent, Test device, Instruction for use, Plastic bag for disposal.



**Components required but not provided**  
 Clock or timer, Tissues, mirror, soap or hand sanitizer.

### Specimen collection using Nasal swab

1. Gently blow your nose into a tissue 3 times to remove foreign substances.
2. Wash hands clean with soap or hand sanitizer, wear gloves (not included).
3. Take out the assay buffer tube from the aluminum pouch located at (1) and remove the lid. That contains a colorless liquid.
4. Insert the assay buffer tube into the tube fixing hole (2).
5. Take out the swab in (3). Open the closed wrapper and take out the swab by holding the handle. Don't touch the soft, fabric tip of the swab with your hands.
6. Gently insert the swab into the nostril. Collect sample from nasal wall by rotating the swab in a circular path 10 times against the nasal wall. Slowly remove the swab.
7. Repeat above procedure to the opposite nostril.
8. Take out the tube placed in (2), insert the swab into tube and immerse the entire tip of swab into the assay buffer. Rotate the swab about 10 times with the head in contact with the bottom and wall of the tube.
9. After collecting the specimen, place the swab inside the tube and break the swab stick at the break point, and the tip of the swab is inserted into the tube. Throw the broken plastic handle away in a plastic bag for disposal.
10. Take out the filter cap of (4) and press the cap tightly on to the tube to avoid any leaks (Do not separate the combined filter cap from the assay diluent tube.).
11. Place the assay buffer tube in the tube fixing hole (2).

### Test Procedure

1. Take the test device out of the aluminum pouch located in (5) and lay it on the fixing frame (5).
2. Take out the tube from the tube fixing hole (2) and mix by gently insert 10 times.
3. Hold the tube vertically and apply 3 drops of assay buffer into the sample well (5).
4. Check the results after 15 to 30 minutes.

### Interpretation

Result	Representation	Interpretation
Negative		One red control line "C" in results window
Positive		Two stripes, black test line "T" and a red control line "C" in the window results.
Invalid		There is no control line in the results window "C". It is recommended that the sample be retested

\* Even if the test line is faint should be interpreted as a positive result.

1. Look at the results window of the test device and check if there is a red line next to control line C or a black line next to test line T.
2. Negative result: The appearance of only the red line in control line C indicates negative result.  
 [A negative test result means that the SARS-CoV-2 antigen that causes COVID-19 was not found in your specimen. This does not mean that you are not infected with COVID-19, so if symptoms develop, persist or become more severe, consult your healthcare professional.]
3. Positive result: The appearance of the control line C and test line T indicates positive result.  
 [An antigen of the COVID-19 virus has been found in your specimen, which means that you are very likely infected with COVID-19. It is very unlikely that this test can give a positive result that is wrong (false positive result). You should self-isolate to avoid spreading the virus to others, and consult a healthcare professional as soon as possible.]
4. Invalid result: If the control line C does not appear or only test line T is appeared, the results are invalid.  
 [Check if there are any problems with the usage method, and contact the place of purchase if you have any questions.]

### Disposal

1. After completing the test, throw all used parts of the kit into the plastic bag for disposal.
2. Dispose of all samples and materials used to perform the test in accordance with all local, state, and national regulations.

### Clinical Performance

The clinical trial of BIOCREDT COVID-19 Ag Home Test Nasal, developed as a personal COVID-19 corona test kit, was conducted prospectively for men and women between the ages of 19 and 74 in South Korea. The individual used the test and medical device to read the result and compared it with the result of the confirmed molecular diagnostic conducted by the expert.

As a result of the performance evaluation, the sensitivity and specificity of BIOCREDT COVID-19 Ag Home Test Nasal were analyzed as 93.15% (95% CI: 84.76% ~ 97.74%) and 100% (95% CI: 97.81% ~ 100%). There were no cases of invalid in the entire test.

### Clinical sensitivity and specificity

BIOCREDT COVID-19 Ag Home Test Nasal	Reference Test		
	Positive	Negative	Total
Sensitivity	68	0	68
Specificity	5	215	220
	Total 73 215 288		

Positive predictive value	100% (215/215) [95% CI: 98.30% ~ 100%]
Negative predictive value	97.73% (215/220) [95% CI: 94.86% ~ 99.07%]

### Sensitivity for symptom

Symptom	Positive	Negative	Sensitivity
Symptomatic	47	1	97.92%(47/48) [95% CI: 87.53%-99.89%]
Asymptomatic	21	4	84.00%(21/25) [95% CI: 63.08%-94.74%]
Total	68	5	93.15%(68/73) [95% CI: 84.76%-97.74%]

### Sensitivity for symptom onset days

Period symptom	Positive	Negative	Sensitivity
0-3	12	0	100%(12/12) [95% CI: 69.87%-100%]
4-7	35	1	97.22%(35/36) [95% CI: 83.79%-99.85%]
Total	47	1	97.92%(47/48) [95% CI: 87.53%-99.89%]

1. Be sure to read and understand the instruction for use.
2. All kit components must be brought to room temperature (15-25 °C) for a minimum of 30 minutes prior to performing the test.
3. Do not store the test kit in direct sunlight and freezer. If you have children, keep them out of reach.
4. One kit is used by one person and it must not be reused. Also, do not use on animals.
5. Do not eat or drink for 30 minutes before you use the kit. If you have a nosebleed, you should use the product after 24 hours.
6. If you have any piercings on your nose, remove them all before testing.
7. Keep a sufficient distance from other people and conduct the test in a well-ventilated area and in a bright place.

### Precautions during test

1. Do not dip the swab into the assay diluent or other liquid before inserting the swab into the nose.
2. When opening the enclosed swab, do not touch the head.
3. After collecting specimens using the nasal swab, put it into the assay diluent tube immediately.
4. Open the aluminum pouch containing the test kit before use and use immediately.
5. Dropping less than 3 drops or more of the sample may affect the results, please hold the sample extract containing the sample extract vertically and drip it slowly.

### General precautions

1. For in vitro diagnostic use only.
2. The test kit is a screening test. It is recommended to conduct the test periodically.
3. Do not re-use the test kit and other components.
4. The test device is sensitive to humidity as well as heat. The test device must remain sealed in the foil pouch until use. Do not use the test kit if the foil pouch is damaged or the seal is broken.
5. Dispose of the used sample and all components in a plastic bag for disposal.
6. Wear protective gloves (not provided), and wash your hands before and after testing.
7. The assay buffer 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.
8. Do not use the kit beyond the expiration date.
9. Be sure to test with the components in the product packaged together.
10. Keep out of reach from children.
11. Do not use a sterilized nasal swab to collect specimens from any part other than the nostril.
12. Do not use any other swabs other than the provided sterilized nasal swab.
13. Do not mix with any liquid other than the provided assay diluent.
14. Be careful not to let children swallow the desiccant added to the device packaging. If swallowed, let it spit out and see if necessary for treatment.
15. Be careful not to swallow the filter cap by children. If swallowed, let it spit out and see if necessary for treatment.
16. The user should not draw any conclusions on the health impact of the results obtained, without first consulting those results with your doctor.
17. People who have difficulty distinguishing colors or have low vision may find it difficult to see results.
18. For older users, read the results with the help of a guardian.

### Precautions for results

1. The test result for this product is not possible to diagnose for COVID-19 infection, and cannot be used for the purpose of confirming negative for COVID-19. It must be confirmed by an approved molecular diagnostic method and followed by a doctor's decision.
2. This product has not been evaluated for those under the age of 19. If you are under the age of 19, please use it under the guidance of a guardian.
3. The clinical performance test of this product was evaluated in patients within 7 days of onset of COVID-19 symptoms and in asymptomatic patients.
4. Very rarely, false positives or false negatives results can occur.
5. This product cannot distinguish between SARS-CoV and SARS-CoV-2 antigens.

### Storage condition


1. Store kit between 2-30 °C and keep away from direct sunlight.
2. Do not freeze the product.

# COVID-19 Ag Home Test Nasal

## BIOCREDIT RapiGen


**EN** Quick guide **FR** Guide rapide **DE** Kurzanleitung  
**ES** Guía rápida **IT** Guida veloce **PT** Guia rápida

**1** **EN** Preparation before test  
**FR** Préparation avant le test  
**DE** Vorbereitung vor dem Test  
**ES** Preparación antes de la prueba  
**IT** Preparazione prima del test  
**PT** Preparação antes do teste




**1** **EN** Bow nose  
**FR** Se mouchoir  
**DE** Schlags Nase  
**ES** Sonarse la nariz  
**IT** Sfricare il naso  
**PT** Assar o nariz

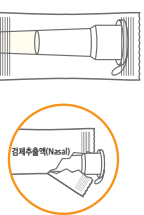
**2** **EN** Wash hands  
**FR** Lavez vos mains  
**DE** Hände waschen  
**ES** Lávate las manos  
**IT** Lavarsi le mani  
**PT** Lavar as mãos



**3** **EN** Wear gloves  
**FR** Porter des gants  
**DE** Trag Handschuhe  
**ES** Usar guantes  
**IT** indossare guanti  
**PT** Usar luvas




**1** **EN** Soak the assay diluent  
**FR** Soaker de diluent de essai  
**DE** Assay-Verdünnungsgefäß  
**ES** Soaker diluyente de ensayo  
**IT** Soaccatore diluente  
**PT** Soaque o diluente de ensaio




**1** **EN** Take out the assay diluent tube  
**FR** Sortir le tube de diluant de dosage  
**DE** Nehmen Sie das Messbehälterchen heraus  
**ES** Saque el tubo de diluyente del ensayo  
**IT** Estrarre il tubo del diluente del dosaggio  
**PT** Retire o tubo de diluente de ensaio

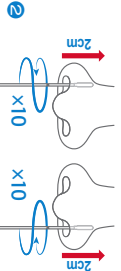
**2** **EN** Seal reservoir  
**FR** Raccorder du sceau  
**DE** Entfemen der Dichtung  
**ES** Remoción del sello  
**IT** Rimozione del sigillo  
**PT** Remoção do selo



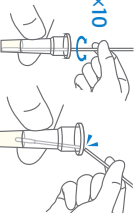
**1** **EN** Take out swab  
**FR** Sortir l'écouvillon  
**DE** Tügel herausnehmen  
**ES** Sacar hisopo  
**IT** Tra fuori l'impompe  
**PT** Trair o cotonete



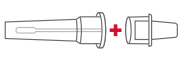
**2** **EN** Specimen collection from both nasal  
**FR** Prélèvement d'échantillon sur les deux narines  
**DE** Probenentnahme aus beiden Nasen  
**ES** Colección de muestras de ambos nasales  
**IT** Prelievo di campioni sia da nase  
**PT** Colecta de espécime de ambos nassos



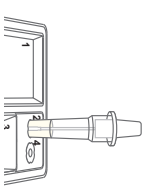
**3** **EN** Dilute and break  
**FR** Diluer et casser  
**DE** Verdünnen und brechen  
**ES** Diluir y romper  
**IT** Diluire e rompere  
**PT** Diluir e quebrar



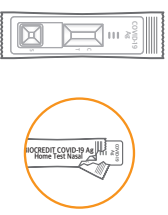
**1** **EN** Insert the filter cap  
**FR** Insérer le bouchon du filtre  
**DE** Setzen Sie das Filterkappe ein  
**ES** Inserta la tapa del filtro  
**IT** Inserire il tappo del filtro  
**PT** Inserir a tampa do filtro



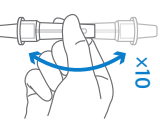
**2** **EN** Mounted on a fixed table  
**FR** Montage sur un fixe  
**DE** An einem festen Loch montiert  
**ES** Montado en un agujero fijo  
**IT** Montato su un foro fisso  
**PT** Montado em um orifício fixo



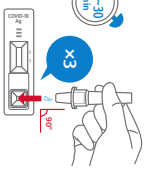
**1** **EN** Take out the device  
**FR** Sortir l'appareil  
**DE** Nimm das Gerät raus  
**ES** Sacar el dispositivo  
**IT** Estrarre il dispositivo  
**PT** Tirar o dispositivo



**2** **EN** Specimen mixing  
**FR** Mélange d'échantillons  
**DE** Probenmischung  
**ES** Mezcla de muestras  
**IT** Miscelazione del campione  
**PT** Mistura de espécimes

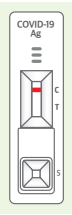


**3** **EN** Dispense  
**FR** Dispenser  
**DE** Dosieren  
**ES** Dispense  
**IT** Dispensare  
**PT** Dispensar

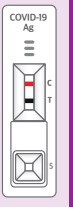


**EN** Interpretation **FR** Interprétation **DE** Interpretation  
**ES** Interpretación **IT** Interpretazione **PT** Interpretação

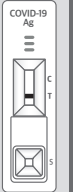
Negative



Positive



Invalid



**EN** Band intensity **FR** Intensité de la bande **DE** Bandintensität  
**ES** Intensidad de la banda **IT** Intensità della banda **PT** Intensidade da banda

Negative



Wick positive



Moderate positive



Strong positive

