

Rapigen

One Step SARS-CoV-2 Antigen Rapid Test

BIOCREDIT COVID-19 Ag Home Test Nasal

One step, rapid, immuno-chromatographic assay for the qualitative detection of SARS-CoV-2 antigen from Nasal swab

Intended Use

BIOCREDIT 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) samples using the sterilized nasal swab provided in the kit.

Principle of Test

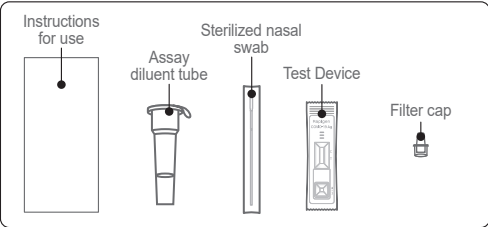
BIOCREDIT COVID-19 Ag Home Test Nasal is a lateral flow immunochromatographic assay that adopted dual color system. The test contains colloid gold conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test line (T). If SARS-CoV-2 antigen is present in the 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 more than one test will be used, you will need to clean the table and wash your hands before and 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]

Test Device, Assay diluent tube, Filter cap, Sterilized nasal swab, Instruction for use



[Components required but not provided]

Clock or timer, Tissues, Mirror, soap or hand sanitizer, disposable gloves

Specimen collection using Nasal swab

- 1. Wash your hands with soap or hand sanitizer, wear gloves (not included) and prepare timer (not included).
- 2. Remove the aluminum seal from the assay diluent tube. (The tube contains a colorless liquid)
- 3. Open the wrapper and remove the swab by holding the handle. Do not touch the soft, fabric tip of the swab with your hands.

- 4. Gently insert the swab into the nostril (about 2cm). Collect sample from nasal wall by rotating the swab in a circular path for 10 times against the nasal wall. Slowly remove the swab.
- 5. Repeat the procedures above to the opposite nostril.
- 6. Take the assay diluent tube and immerse the entire tip of the swab into the assay diluent. Rotate the swab for about 10 times with the head in contact with the bottom and the wall of the tube.
- 7. Leave the swab in the tube and break the swab stick at the break point. Make sure that the tip of the swab is inserted into the tube. Throw the broken plastic handle away in the product packaging (using waste disposal bag)
- 8. Press the cap tightly onto the tube to avoid any leaks (Do not separate the combined filter cap from the assay diluent tube).

Test Procedure

- 1. Remove the test device from the aluminum pouch and place it on a flat surface.
- 2. Invert the assay diluent tube gently 10 times for mix.
- 3. Hold the tube vertically and apply 3 drops of assay diluent into the sample well (▲×3).
- 4. Check the results after 15 to 30 minutes.

Interpretation

Result	Representation	Interpretation
Negative		One red control line "C" in result window
Positive		Two bands; black test line "T" and a red control line "C" in the result window
Invalid		There is no control line in the result window "C". It is recommended to retest the samples.

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

- 1. Check the result window of the test device and see 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 a negative result.
[A negative test result means that it is unlikely that you have COVID-19 at the time of testing. The SARS-CoV-2 antigen that causes COVID-19 was not found in your specimen, but it is possible that the concentration of the SARS-CoV-2 antigen in the sample is less than the detection limit of the test, or the sample is collected or transported improperly. This may 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 a positive result.
[An antigen of the COVID-19 virus has been found in your specimen, which means that you are very likely to be infected with COVID-19. It is very unlikely that this test can give a false positive result. You should self-isolate to avoid spreading the virus to the 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 appears, 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.
- 2. Dispose of all samples and materials used in performing the test in accordance with all local, state, and national regulations.

Clinical Performance

'BIOCREDIT COVID-19 Ag Home Test Nasal' is developed as a personal COVID-19 test kit and was undergone a clinical trial conducted prospectively for men and women between the ages of 19 to 74 in South Korea. The individuals used the test 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 'BIOCREDIT COVID-19 Ag Home Test Nasal' were analyzed as 93.15% (95% CI: 84.76% ~ 97.74%) and 100% (95% CI: 98.30% ~ 100%). There were no cases of Invalid in the entire test.

[Clinical sensitivity and specificity]

		Reference Test		
		Positive	Negative	Total
BIOCREDIT COVID-19 Ag Home Test Nasal	Positive(+)	68	0	68
	Negative(-)	5	215	220
	Total	73	215	288
Sensitivity		93.15% (68/73) [95% CI: 84.76% ~ 97.74%]		
Specificity		100% (215/215) [95% CI: 98.30% ~ 100%]		
Positive predictive value		100% (68/68) [95% CI: 97.81% ~ 100%]		
Negative predictive value		97.73% (215/220) [95% CI: 94.86% ~ 99.01%]		
Invalid rate		(Invalid result number/Total test number *100) = 0%		

[Sensitivity for symptom]

Symptom	Positive	Negative	Sensitivity [95% CI, %]
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]

Post onset symptoms	Positive	Negative	Sensitivity [95% CI, %]
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%]

General precautions

- 1. For *in vitro* diagnostic use only.
- 2. This test kit serves as a screening test, therefore it is recommended to conduct the test periodically.
- 3. The user should not draw any conclusions on health based on the results obtained, without first consulting those results with your doctor.
- 4. Do not re-use the test kit and other components.
- 5. Only perform the test with the components provided in this test kit.
- 6. Wear protective gloves (not provided), and wash your hands before and after testing.
- 7. Do not use the kit beyond the expiration date.
- 8. 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.
- 9. 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.
- 10. Do not store the test kit in direct sunlight and freezer.
- 11. One kit should be used by one person and it must not be reused. Also, do not use on animals.
- 12. Keep out of reach from children.

- 13. Be careful not to let children swallow the desiccant or the filter cap in the device packaging. If it is swallowed, make him/her spit it out or seek medical care when necessary.
- 14. People who have difficulty distinguishing colors or have low vision may find it difficult to see results.
- 15. For older users, read the results with the help of a guardian.
- 16. Dispose of the used test device and all components in the product packaging (using waste disposal bag).

Precautions for results

- 1. The test result of 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 (also known as RT-PCR tests) 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.

Precautions before test

- 1. Be sure to read and understand the instruction for use before using the test.
- 2. Do not eat or drink 30 minutes before you use the kit. If you have a nosebleed, you should use the product after 24 hours.
- 3. If you have any piercings on your nose, remove them all before testing.
- 4. Do not use a sterilized nasal swab to collect specimens from any part other than the nostril.
- 5. Do not use any other swabs other than the provided sterilized nasal swab.
- 6. Do not use with any liquid other than the provided assay diluent.
- 7. Do not dip the swab into the assay diluent or other liquid before inserting the swab into the nose.
- 8. When opening the enclosed swab, do not touch the head.

Precautions during test

- 1. After collecting specimens using the nasal swab, put it into the assay diluent tube immediately.
- 2. The aluminum pouch which contains the test kit should only be opened before performing the test.
- 3. Keep a sufficient distance from other people and conduct the test in a well-ventilated area and in a bright place.
- 4. All kit components should be brought to room temperature (15~25°C) for 30 minutes prior to performing the test.
- 5. Drop exactly 3 drops of sample extracts when performing the test. Failure to follow this instruction may adversely affect the results. Please hold the assay diluent tube containing the sample extract vertically and drip it slowly.

Storage condition

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

Package

Refer to outer packaging

Quick guide

One Step SARS-CoV-2 Antigen Rapid Test

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Scan the QR code for quick guide reference.

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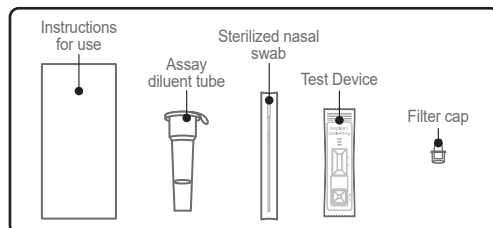
Refer to the back page for details.

1 Preparation before test



Wash your hands

2 Components provided



6 Test device



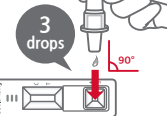
① Take out the device



② Specimen mixing



* Keep the device steady while testing.



③ Dispense



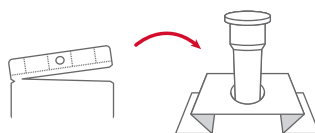
④ Wait 15-30 minutes and read result

3 Assay diluent solution



① Remove the seal

TIP !



Tear off the top of the pouch and fold it. Insert the assay diluent tube into the fixing hole for use.

7 Result interpretation

Negative



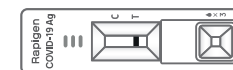
One red control line "C" in the result window

Positive



Two bands; a black line "T" and a red control line "C" in the result window

Invalid



If the result is invalid, you will need to obtain another test

4 Swab



① Take out the swab



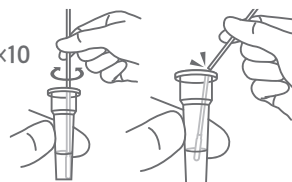
② Collect specimen from both nostrils

x10



③ Insert the swab into the tube and rotate it for 10 times

x10



④ Break the swab as marked

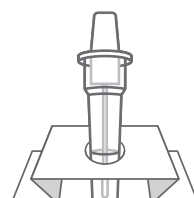
5 Filter cap



① Insert the filter cap and push it firmly



② Insert in the tube fixing hole

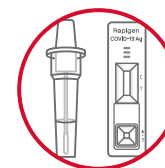


8 Waste disposal



Negative

If the result is negative, dispose of it in the trash can used at home



Dispose all materials according to local regulations.

Positive



If the result is positive, visit a screening clinic to request disposal.

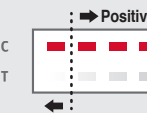
* Do not dispose of it in the trash can used at home.

Band intensity

* If the black band appears (including smear) on the test line, contact the nearest screening clinic.



Negative



Positive



Positive