Rapigen

REF G61RHA20/G61RHA20C

BIOCREDIT
COVID-19 Ag
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 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.

■ Contents
Contents provided

Cat. No. G61RHA20	Cat. No. G61RHA20C
- Test device (individually in a foil pouch with desiccant)×20 - Assay diluent tube (in a foil pouch) (0.4 ml/tube)×20 - Filter cap×20 - Plastic tube rack×2 - Sterilized nasopharyngeal swab×20 - Instructions for use×1	- Test device (individually in a foil pouch with desiccant)×20 - Assay diluent tube (in a foil pouch) (0.4 ml/tube)×20 - Filter cap×20 - Plastic tube rack×2 - Sterilized nasopharyngeal swab×20 - Positive control swab×1 - Negative control swab×1 - Instructions for use×1

Contents required but not provided
- Personal protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
- Timer
- Biohazard container (for potentially infectious waste)

■ Nasopharyngeal swab Specimen Collection
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. Specimen should be tested immediately after collection. If the sample has to be stored, store the swab sample in the assay diluent at room temperature (15-25°C) up to 2 hours, at 2–8°C up to 8 hours prior to testing.
4. To collect nasopharyngeal swab specimen, tilt the patient's head back 70 degrees. Insert a nasopharyngeal swab horizontally into the nasal cavity until resistance is met at the level of the turbinate, reaching the surface of the posterior nasopharynx. The distance is equivalent to that from the nostril to the ear of the patient, indicating contact with the nasopharynx. Gently rub and rotate the swab gently against the nasopharyngeal mucosa for 10–15 seconds to absorb secretion. Remove the swab while making sure that the tip of the swab is wet.
   * When collect the specimens, follow the Instructions for use thoroughly.

【Transport medium specimen】
If the nasopharyngeal swab is immersed into UTM/VTM, the media should be diluted with assay diluent (400㎕) with 1:1 ratio.

* Due to dilution process, tests using swab specimens stored in transport media can lead to a lower sensitivity than processing directly without transport media.

Universal Transport Medium (UTM)	Recommended storage Condition		
	-20±3°C	5±3°C	20±5°C
Clinical Virus Transport Medium (CTM) (Noble Bio)	140 days	12 hours	4 hours
ASAN PHARM UTM	140 days	12 hours	4 hours

■ 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. Do not eat or smoke while handling specimens.
6. Wear protective clothing, gloves and eye protection while handling specimens. Wash hands afterwards.
7. Repeated freeze-thawing specimen can cause false positive or false negative results.
8. Discard the solid waste by autoclaving at 121°C for 1 hour.
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 use the kit beyond the expiration date.
11. Do not reuse the test device and kit components.
12. Do not interchange or mix reagents of different lots.
13. A clinical decision should be made by physician after all clinical and laboratory findings have been evaluated.
14. When using transport media, sensitivity can be reduced due to dilution.

■ Assay Procedure
【PREPARATION】
1. Equilibrate kit components and specimen to room temperature (15–25°C) 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. Place the assay diluent tube in the plastic tube rack.
5. Remove the device from the foil pouch and place it on a flat and dry surface.
6. Invert the assay diluent tube and gently squeeze it to dispense 3-4 drops (90-150 ㎕) into a sample well (S) of the device.

Note: 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.

Note: The reagent should be dropped on the site marked with sample well (S). The test can lead to erroneous or invalid results, if the reagent is dropped in the results window.

7. Read the result within 10~15 minutes.
   ▶Do not interpret the result after 30 minutes.
8. Dispose of the used device according to your local, state and national regulations and biohazard waste disposal protocol.

■ 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 using a new test device.

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

■ Performance Characteristics
1. Limit of Detection (LoD)
BIOCREDIT COVID-19 Ag was confirmed to detect 5.62×10^2 PFU/ml of SARS- CoV-2 which was cell culture derived live virus (SARS-CoV-2 (2019-nCOV) NCCP 43326 from KCDC pathogen bank).

2. Hook Effect
There was no hook effect up to 9×10^5 PFU/ml of cell culture virus (SARS-CoV-2 (2019-nCOV) NCCP 43326 from KCDC pathogen bank).

3. Clinical Sensitivity and Specificity:
1) BIOCREDIT COVID-19 Ag has been evaluated with clinical specimens in transport media which were identified with the RT-PCR test in KOREA.

• The day of collection relative to the onset of illness is recorded. The results are summarized as below table.:

Specimen collection time	TP/Test specimen number	BIOCREDIT COVID-19 Ag
		Sensitivity(95% CI)
0-3 days	28/29	96.5% (82.2-99.9)
4-7 days	26/28	92.8% (76.4-99.1)
After 8 days	11/15	73.3% (44.9-92.2)

• The total results are summarized in the following table.:

BIOCREDIT COVID-19 Ag	RT-PCR	
	Positive	Negative
Positive (+)	65	0
Negative (-)	7	100
Total	72	100
Sensitivity	90.2% (95% CI: 80.9~96.0%)	
Specificity	100% (95% CI: 96.3~100%)	

2) BIOCREDIT COVID-19 Ag has been evaluated with prospective clinical specimens in ITALY.

BIOCREDIT COVID-19 Ag	RT-PCR	
	Positive	Negative
Positive (+)	67	2
Negative (-)	5	209
Total	72	211
Sensitivity	93.05% (95% CI: 83.86~97.41%)	
Specificity	99.05% (95% CI: 96.25~99.83%)	

4. Precision
Within-run, between-run, between day, between lot and between site precision has been determined in quintuplicate using the following specimen: negative, low positive, medium positive and strong positive. All specimens are correctly identified 100% of the time.

5. Cross reactivity & Microbial interference
BIOCREDIT COVID-19 Ag has been tested with 39 potentially cross reacting microorganisms and viruses. The results showed that BIOCREDIT COVID-19 Ag has no cross-reaction with microorganisms and viruses except cross reacting with SARS-coronavirus in the following substances.:

No.	Type	Potential Cross-Reactant	Concentration
1	Other high priority pathogens from the same virus family	Human coronavirus(229E)	2.2×10^5 PFU/ml
2		Human coronavirus(OC43)	6.1×10^5 PFU/ml
3		Human coronavirus(HKU1)	1 μg/ml*
4		Human coronavirus(NL63)	1.7×10^5 $TCID_{50}$/ml
5		SARS-coronavirus(Tor2)	1 μg/ml**
6		MERS-CoV	0.1μg/ml***
7	Other high priority organisms	Adenovirus type 1	1×10^6 $TCID_{50}$/ml
8		Adenovirus type 2	5×10^5 $TCID_{50}$/ml
9		Adenovirus type 3	5×10^5 $TCID_{50}$/ml
10		Adenovirus type 5	5×10^6 $TCID_{50}$/ml
11		Adenovirus type 6	5×10^6 $TCID_{50}$/ml
12		Adenovirus type 8	5×10^5 $TCID_{50}$/ml
13		*Chlamydia pneumoniae*	1.34×10^6 CFU/ml
14		*Haemophilus influenzae*	1.0×10^6 CFU/ml
15		*Human metapneumovirus*	1.51×10^6 $TCID_{50}$/ml
16		Parainfluenza 1	1.6×10^5 PFU/ml
17		Parainfluenza 2	1.0×10^6 PFU/ml
18		Parainfluenza 3	5.0×10^6 PFU/ml
19		Parainfluenza 4a	2.82×10^7 $TCID_{50}$/ml
20		Influenza A-H1N1	3.1×10^5 PFU/ml
21		Influenza A-H3N2	5×10^6 PFU/ml
22		Influenza B	8.5×10^6 PFU/ml
23		Human enterovirus D Enterovirus 70	8.6×10^5 PFU/ml
24		Respiratory syncytial virus-virus A	2.4×10^6 PFU/ml
25		Respiratory syncytial virus-virus B	4.6×10^5 PFU/ml
26		Human Rhinovirus 14(B)	1.2×10^5 PFU/ml
27		Human Rhinovirus 21(A)	2.4×10^5 PFU/ml
28	Another	Pooled human nasal wash-to *represent diverse microbial flora in the human respiratory tract*	N/A
29	Microbial organisms related to upper respiratory infection similar to COVID-19	*Legionella pneumophila*	1×10^6 CFU/ml
30		*Streptococcus pneumoniae*	1×10^6 CFU/ml
31		*Streptococcus pyogenes*	1×10^6 CFU/ml
32		*Bordetella pertussis*	1×10^6 CFU/ml
33		*Mycoplasma pneumonia*	4.5×10^6 CFU/ml
34		*Klebsiella pneumonia*	1×10^6 CFU/ml
35		*Candida albicans*	1×10^6 CFU/ml
36		*Staphylococcus aureus*	1×10^6 CFU/ml
37		*Staphylococcus epidermidis*	1.0×10^6 CFU/ml
38		*Mycobacterium tuberculosis (In- silico (protein blast))*	-
39		*Pneumocystis jirovecii (PJP) (In- silico (protein blast))*	-

* Human coronavirus (HKU1) has been tested with recombinant nucleocapsid protein in the absence of SARS-CoV-2 and cross-reaction was not happened. The % identity of the protein sequence of recombinant nucleocapsid protein for HKU1 with the NP protein sequence of SARS-CoV-2 is 37.6% which is considered as low homology.

** Cross-reactivity test of SARS-CoV (Tor2) has been performed with recombinant SARS-CoV (Tor2) nucleoprotein in the absence of SARS-CoV-2 and cross-reaction was happened. The % identity of the protein sequence of recombinant SARS-CoV (Tor2) nucleoprotein in the absence of SARS-CoV-2 was 90.3% which is considered as high homology.

***Cross-reactivity test of MERS-CoV has been performed with recombinant nucleocapsid protein of MERS-CoV in the absence of SARS-CoV-2 and cross-reaction was not happened. The % identity of the protein sequence of recombinant nucleocapsid protein for MERS-CoV with the NP protein sequence of SARS-CoV-2 is 48.2% which is considered as low homology.

6. Interference
BIOCREDIT COVID-19 Ag has been tested with 36 potentially interfering endogenous or exogenous substances. None of 36 substances tested showed an interference effect:

1) Endogenous factors

No.	Type	Virus	Concentration
1	Serum protein	HAMA Serum, Type I (Occurring in healthy donors)	63 ng/ml
2		HAMA Serum, Type II (Occurring after treatment with monoclonal antibodies)	63 ng/ml
3		Rheumatoid factor	20 U/ml
4		Bilirubin	200 ㎍/ml
5		Bilirubin Conjugate	290 ㎍/ml
6		Hemoglobin	200 ㎍/ml
7		Cholesterol	2.2 mg/ml
8		Whole blood (human)	5% (w/w)

2) Exogenous factors

No.	Type	Virus	Concentration
1	Anticoagulants	EDTA-2Na	5 mg/ml
2		Heparin	20 mg/L
3		Sodium citrate	10 mg/ml
4	Hypoglycemia medication	Glucose	10 mg/ml
5	Anti-inflammatory medication	Acetaminophen	200 μm
6		Acetylsalicylic acid	3.7 mM
7	Antihistamine	Diphenhydramine hydrochloride	456 mg/ml
8	Nasal sprays, gels or drops	Nasal spray	15% (v/v)
9		Saline nasal gel	5% (v/v)
10		Rhinocort (Nasal corticosteroids Budesonide)	256μg
11		Fluticasone Propionate	5% v/v
12		Afrin (Oxymetazoline)	15% v/v
13		Naso Gel (GelMed)	5% v/v
14		Homeopathic (Alkalol)	10% v/v
15		CVS Nasal Drops (Phenyleprine)	15% v/v
16		CVS Nasal Spray (Cromolyn)	15% v/v
17	Sore throat sprays, betadine, or medicine	Sore Throat Phenol Spray	15% v/v
18		Betadine sore throat	5% (w/v)
19		Chloraseptic (Menthol/Benzocaine)	1.5 mg/ml
20	Anti-viral drugs	Zanamivir	5% (w/v, 1 mg/ml)
21		Favipiravir	5% (w/v, 1 mg/ml)
22		Tamiflu (Oseltamivir Phosphate)	5 mg/ml
23	Antibiotic	Mupirocin	10 mg/ml
24		Ciprofloxacin (antibiotic)	5% (w/v, 250 mg/ml)
25		Tobramycin	4 μg/ml
26	Cold remedy	Zicam	5% (v/v)
27	Others	Biotin	1.2 μg/ml
28	Others	Mucin:bovine submaxillary gland, type I-S	100 μg/ml

■ 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.
3. The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens.
4. A negative result may occur if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA.

■ External Quality Control
As optional contents, external control swabs can be provided as a means on additional quality control to demonstrate a positive or negative reaction. Recommend tests these swabs once with each new lot (or new shipment) received and each untrained operator. Quality control should be treated and tested the same as patient specimens. As required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements. If the correct control results are not obtained, do not perform patient tests or report patient results.

* G61RHA20C package kit contains only.
* Do not insert the external control swabs into your nose.

■ Package 20 tests/kit

■ Storage Condition
Store at 2-30°C. Kit materials are stable until the expiration date marked on the kit box and/or the packaging of individual contents when stored as specified. Do not store the kit in the freezer.

■ Symbol Key

Symbol	Explanation
	Contains sufficient for <n> tests
	Do not reuse
	Temperature limitation
	Do not use if packaging is damaged
	European Mark of conformity
IVD	*In vitro* diagnostic medical device
	Keep dry
	Consult instructions for use
LOT	Lot number
REF	Catalogue number
	Expiration date (YYYY.MM.DD)
	Manufacturer
EC REP	Authorized representative in the European Community
CONTROL -	Negative control
CONTROL +	Positive control

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Rapigen

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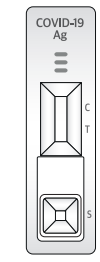
BIOCREDIT
COVID-19 Ag

One Step SARS-CoV-2 Antigen Rapid Test

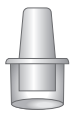
■ Description of materials provided

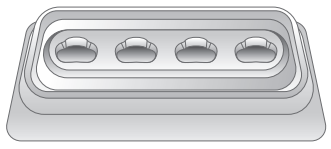


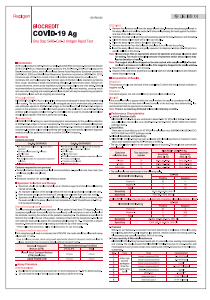
Test Device


Assay diluent tube

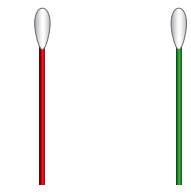
Sterilized swab


Filter cap

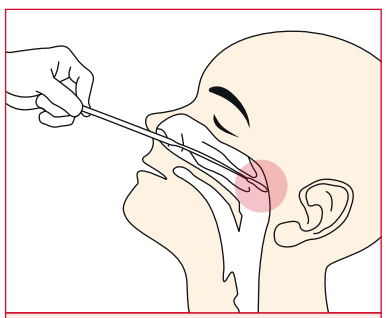

Plastic tube rack


Instructions for use

External control swab
(Only for G61RHA20C)

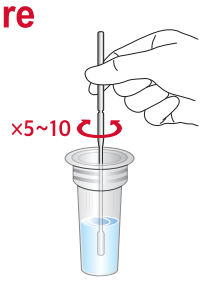


■ Specimen collection

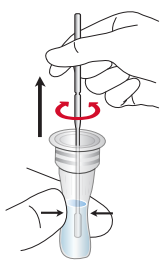

Nasopharyngeal Swab

- 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, reaching the surface of the posterior nasopharynx.
- The distance is equivalent to that from the nostril to the ear of the patient, indicating contact with the nasopharynx.
- Gently rub and rotate the swab gently against the nasopharyngeal mucosa for 10-15 seconds to absorb secretion.
- Remove the swab while making sure that the tip of the swab is wet.

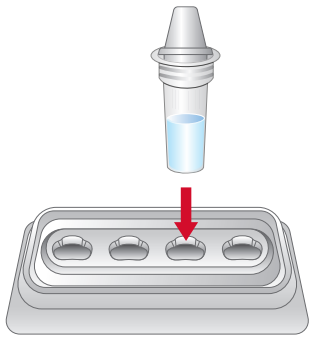
■ Assay Procedure

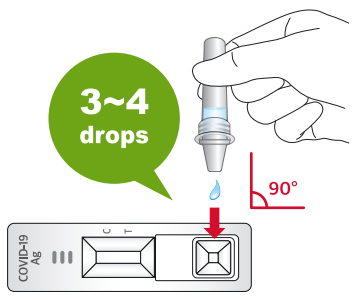


❶ Insert the swab specimen and swirl the swab 5-10 times.


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


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


❹ Place the assay diluent tube in the plastic tube rack. Remove the device from the foil pouch and place it on a flat and dry surface.

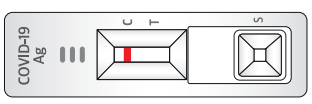


❺ Invert the assay diluent tube and gently squeeze it to dispense 3-4 drops (90-150㎕) into a sample well on the device vertically.

❻ Read the result within 10-15 minutes.
Do not interpret the result after 30 minutes.

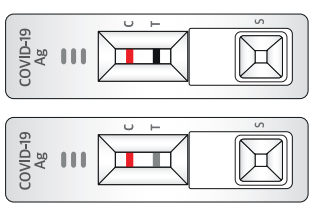
■ Interpretation of Results

Negative



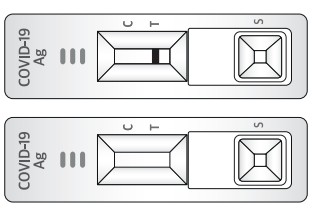
One red line "C" within the result window.

Positive



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

Invalid



No "C" line within the result window. It is recommended that the specimen be retested using a new test device.

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