SARS-CoV-2 Antigen Rapid Test Cassette

Package Insert

Cat: COVG-602 **Specimens:**Oropharyngeal/Nasopharyngeal/Nasal Swab

Version: B **Effective Date:** 2022.10.24

FM For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in human Oropharyngeal swabs,Nasopharyngea1 swabs or Nasal swabs.The identification is based on the monoclonal antibodies specific for the Nucleocapsid (N) Protein of SARS-CoV-2.It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

PACKAGE SPECIFICATIONS

I test/pack, 5tests/pack, 25 tests/pack, 50 tests/pack, 100 tests/pack

INTRODUCTION

The novel coronaviruses belong to β genus.COVID-19 is an acute respiratory infectious disease.People are generally susceptible.Currently, the patients infected by the novel coronavirus are the main source of infection;asymptomatic infected people can also be an infectious source.Based on the current epidemiological investigation,the incubation period is 1 to 14 days,most1y 3 to 7 days.The main manifestations include fever,fatigue and dry cough.Nasal congestion,runny nose,sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human Oropharyngeal swabs,Nasopharyngeal swabs or Nasal swabs. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette.During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein particles and anti-SARS-CoV-2 Nucleocapsid protein coated on the membrane,

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1.For professional in vitro diagnostic use only.Do not use after the expiration date,

2.The test should remain in the sealed pouch until ready to use .

3. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.

4. The used test should be discarded according to local regulations,

5.Avoid using bloody samples,

6.Wear gloves wen handing the samp1es,avoid touching the reagent membrane and sample well.

STORAGE AND STABILITY

The validity period is 36 months if this product is stored in an environment of 2-30 ℃.The test is stable through the expiration date printed on the sealed pouch.The test must remain in the sealed pouch until use.

DO NOT FREEZE.

Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARTION

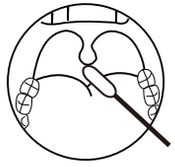
For **Oropharyngeal swabs:**

1. Throat secretion collection:

Insert a sterile swab into the throat completely from the mouth, centering on the throat wall and the reddened area of the palate tonsils,wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall with moderate force, avoid touching the tongue and take out the swab.

2.Process the sample immediately with sample extraction solution provided in the kit alter the sample is collected. If it cannot be processed immediately,the sample should be stored in a dry,sterilized and strictly sealed plastic tube. It can be stored at 2-8 ℃ for 8 hours,and can be stored for a long time at -70 ℃.

3. Samples that are heavily contaminated by oral food residues cannot be used for testing of this product.Samples collected from swabs that are too viscous or agglomerated are not recommended for testing of this product.If the swabs are contaminated with a large amount of blood, they are not recommended for testing. It is not recommended to use the samples that are processed with sample extraction solution not provided in this kit for testing of this product.



For **Nasopharyngeal swabs:**

1. Nasal secretion collection: Let the patient's head relax naturally,and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.Using the same swab,wipe the other nostril in the same way; place the swab specimen in the extraction tube with the extraction solution added in advance,rotate the swab for about 10 seconds,and press the swab head against the tube wall to release the swab antigen.

2. Process the sample immediately with sample extraction solution provided in the kit alter the sample is collected.If it cannot be processed immediately,the sample should be stored in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2-8 ℃ for 8 hours,and can be stored for a long time at -70 ℃.

3. Samples collected from swabs that are too viscous or agglomerated are not recommended for testing of this product.If the swabs are contaminated with a large amount of blood,they are not recommended for testing.It is not recommended to use the samples that are processed with sample extraction solution not provided in this kit for testing of this product.

Nasopharyngeal swab collection

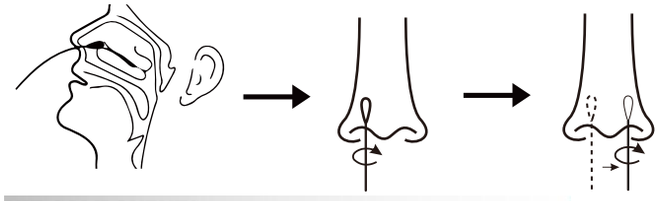
For **Nasal swabs:**

1. Sampling:

Nasal swab: the nasal cavity must be moist. Remove the swab from the test kit. Do not touch the swab at the end of the cotton wool! Gently insert the swab into one nostril. Insert the swab tip 2-4 cm (1-2 cm in children) until resistance is felt.Rotate the swab along the nasal mucosa 5 times within 7-10 seconds to ensure that both mucus and cells are picked up.Repeat the process with the same swab in the other nostril to ensure that a sufficient sample is drawn from both nasal cavities, pull swabs out of the nasal cavity.

4. Process the sample immediately with sample extraction solution provided in the kit after the sample is collected. If it cannot be processed immediately, the sample should be stored in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2-8 ℃ for 8 hours,and can be stored for a long time at -70 ℃.

5. Samples collected from swabs that are too viscous or agglomerated are not recommended for testing of this product. If the swabs are contaminated with a large amount of blood,they are not recommended for testing.It is not recommended to use the samples that are processed with sample extraction solution not provided in this kit for testing of this product.



KIT COMPONENTS

Materials provide

Test cassettes

Extraction Reagent with Integrated Extraction Tube Extraction tube cover

Sterile Swabs Package Insert Work Station

Materials required but not provide

Timer For timing use.

DIRECTIONS FOR USE

Allow the test specimen,extraction reagent to equilibrate to room temperature(15-30 °C) prior to testing.

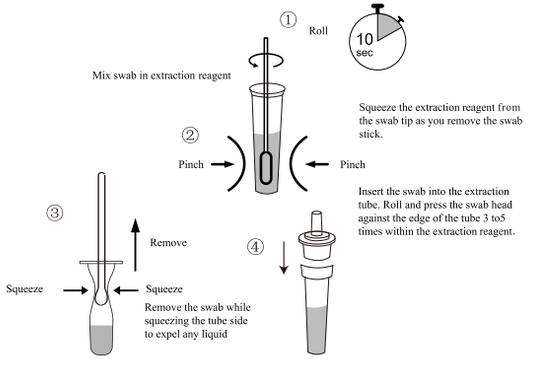
1.Take out the extraction tube and the extraction tube cover, peel off the aluminum foil on the extraction tube carefully and place the tube in the Work Station. Insert the swab into the Extraction tube and immerse the entire tip of swab into the extraction reagent.

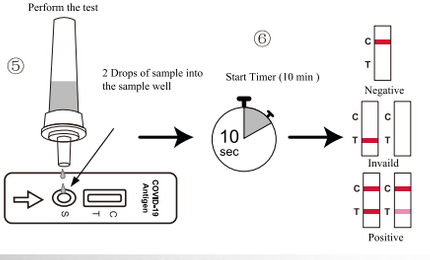
2. Soak the sampling swab below the liquid level of the extraction reagent. Rotate the swab and press for about 10 seconds. (Insert the swab into the extraction tube.Roll and press the swab head against the edge of the tube3 to 5 times within the extraction reagent)

3. Squeeze the swab head against the inside of the extraction tube, then take out the swab and Place the extraction tube cover firmly on the extraction tube.(Squeeze the extraction reagent from the swab tip as you remove the swab stick)

4.Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.

5. Lay the cassette flat and add 2 drops of the treated sample into the sample well of the test cassette. Read the test result after adding the sample for 10 minutes. The result obtained after 30 minutes is invalid.





INTERPRETATION OF RESULTS

NEGATIVE RESULT:

One colored line appears in the control line region (C).No line appears in the test region(T).A negative result indicates that SARS-CoV-2 antigen is not present in the specimen,or is present below the detectable level of the test.

POSITIVE RESULT:

Two lines appear.one colored line should be in the control region (C) and another apparent colored line should be in the test region (T).A positive result indicates that SARS-CoV-2 was detected in the specimen.

INVALID RESULT:

Control line fails to appear.Insufficient specimen volume or incorrect procedural techniques are most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

The intensity of the color in test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen.Therefore,any shade of color in the test line region(T) should be considered positive.

QUALITY CONTROL

- A procedural control is included in the test.A colored line appearing in the control region(C) is considered an internal procedural control.It confirms adequate membrane winking.
- Control standards are not supplied with this kit; however,it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The SARS-CoV-2 Antigen Rapid Test Cassette is for professional in vitro diagnostic use only.The test should be used for the detection of SARS-CoV-2 Antigen in Oropharyngeal Swab, Nasopharyngeal swabs or Nasal swabs. Neither the quantitative value nor the rate of increase in SARS-CoV-2 concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample.False negatives may result form improper sample collection storage.
3. The SARS-CoV-2 Antigen Rapid Test Cassette will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests,all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR.A negative result may be obtained if the concentration of the SARS-CoV-2 present in the swab is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the swab specimen may interfere with performance and may yield a false positive result.
7. A positive result for SARS-CoV-2 does not preclude an underlying co-infection with anther pathogen. Therefore the possibility of an underlying bacterial infection should be considered.
8. Negative results do not rule out SARS-CoV-2 infection,particularly in those who have been in contact with the virus,Fo1low-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains,such as coronavirus HKU1,NL63,OC43,or 229E.
10. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. Extraction reagent has the ability to kill the virus , but it cannot inactivate 100% of the virus.The method of inactivating the virus can be referred to: what method is recommended by WHO/CDC,or it can be handled according to local regulations.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The SARS-CoV-2 Antigen Rapid Test Cassette has been evaluated with Oropharyngeal swabs,Nasopharyngea1 swabs or Nasal swabs specimens obtained from the patients.PCR is used as the reference method for the SARS-CoV-2 Antigen Rapid Test Cassette.Specimens were considered positive if PCR indicated a positive result.The comparative PCR tests were performed with nasopharyngeal samples.

Oropharyngeal swabs: clinical study compare with RT-PCR

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	113	3	116
	Negative	5	480	485
Total Results		118	483	601

Relative Sensitivity :95.76%(95%CI*:90.39%-98.61%)
Relative Specificity:99.38%(95%CI*:98.20%-99.87%)
*Confidence Intervals

Nasopharyngeal swabs:clinical study compare with RT-PCR

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	113	2	115
	Negative	3	212	215
Total Results		116	214	330

Relative Sensitivity :97.4%(95%CI*:90.39%-98.61%)
Relative Specificity:99.1%(95%CI*:98.20%-99.87%)
*Confidence Intervals

Nasal swabs:clinical study compare with RT-PCR

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	113	2	115
	Negative	3	212	215
Total Results		116	214	330

Relative Sensitivity :97.4%(95%CI*:90.39%-98.61%)
Relative Specificity:99.1%(95%CI*:98.20%-99.87%)
*Confidence Intervals

Detection Limit

When the virus content is greater than 400$TCID_{50}$ /ml, the positive detection rate is greater than 95%. When the virus content is less than 200$TCID_{50}$ /ml, the positive detection rate is less than 95%, so the minimum detection limit of this product is 400$TCID_{50}$ /ml.

Precision

Three consecutive batches of reagents were tested for precision. Different batches of reagents were used to test the same negative sample 10 times in succession, and the results were all negative. Different batches of reagents were used to test the same positive sample 10 times in succession, and the results were all positive.

HOOK effect

When the virus content in the sample to be tested reaches 4.0*$10^5$$TCID_{50}$/ml, the test result still does not show the HOOK effect.

Cross-Reactivity

Cross-reactivity of the Kit was evaluated. The results showed no cross reactivity with the following specimen.

Name	Concentration
HCOV-HKU1	10^5TCID_{50}/ml
Staphylococcus aureus	10^6TCID_{50}/ml
Group A streptococci	10^6TCID_{50}/ml
Measles virus	10^5TCID_{50}/ml
Mumps virus	10^5TCID_{50}/ml
Adenovirus type 3	10^5TCID_{50}/ml
Mycoplasmal pneumonia	10^6TCID_{50}/ml
Paraimfluenzavirus,type2	10^5TCID_{50}/ml
Human metapneumovirus	10^5TCID_{50}/ml
Human coronavirus OC43	10^5TCID_{50}/ml
Human coronaviius 229E	10^5TCID_{50}/ml
Bordetella parapertusis	10^6TCID_{50}/ml
Influenza B Victoria STRAIN	10^5TCID_{50}/ml
Influenza B YSTRAIN	10^5TCID_{50}/ml
Influenza A H1N1 2009	10^5TCID_{50}/ml
Influenza A H3N2	10^5TCID_{50}/ml
H7N9	10^5TCID_{50}/ml
H5N1	10^5TCID_{50}/ml
Epstein-Barr virus	10^5TCID_{50}/ml
Enterovirus CA16	10^5TCID_{50}/ml
Rhinovirus	10^5TCID_{50}/ml
Respiratory syncytial virus	10^5TCID_{50}/ml
Streptococcus pneumoni-ae	10^6TCID_{50}/ml
Candida albicans	10^6TCID_{50}/ml
Chlamydia pneumoniae	10^6TCID_{50}/ml
Bordetella pertussis	10^6TCID_{50}/ml
Pneumocystis jiroveci	10^6TCID_{50}/ml
Mycobacterium tubercu- losis	10^6TCID_{50}/ml
Legionella pneumophila	10^6TCID_{50}/ml
Human coronavirus NL63	10^5TCID_{50}/ml
MERS coronavirus	10^5TCID_{50}/ml

Interfering Substances

The test results do not be interfered with the substance at the following concentration:

Interfering substance	Conc.	Interfering substance	Conc.
Whole Blood	4%	Compound Benzoin Gel	1.5mg/ml
Ibuprofen	1mg/ml	Cromolyn glycate	15%
tetracycline	3ug/ml	chloramphenicol	3ug/ml
Mucin	0.5%	Mupirocin	10mg/ml
Erythromycin	3ug/ml	Oseltamivir	5mg/ml
Tobramycin	5%	Naphazoline Hydrochlo-ride Nasal Drops	15%
menthol	15%	Fluticasone propionate spray	15%
Afrin	15%	Deoxyepinephrine hydro-chloride	15%

IBIBLIOGRAPHY

1. Weiss SR,Leibowitz IZ.Coronavirus pathogenesis.Adv Virus Res 2011;81:85-164
2. Cui J,Li F,Shi ZL.Origin and evolution of pathogenic coronaviruses.Nat Rev Mic robiol 2019;17:181-192.
3. Su S,Wong G,Shi W,et al.Epidemiology,genetic recombination,and pathogenesis of coronaviruses. TrendsMicrobiol2016;24:490-502.

Index of Symbols

	Consult instructions for use.	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

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EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

CE