

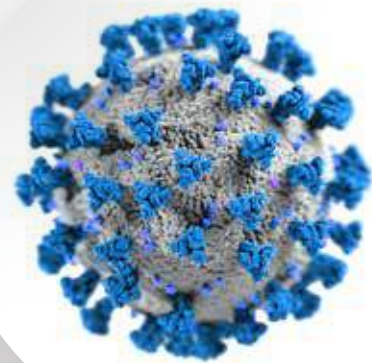


Coronavirus Ag Rapid Test

► COVID-19 Overview

The novel coronaviruses belong to the 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, mostly 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.

Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.



Product Information

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens directly or after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

Benefits

- Rapid testing for SARS-CoV-2 antigen within 15 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Specification

Information	InDetail
Time to result	15 minutes
Storage	2-30°C
Shelf life	24 months
Specimen type	Nasopharyngeal swab

Contents

- 20 Test cassettes • 20 Sterile swabs
- 20 Extraction tubes and dropper tips
- 1 Workstation • 2 Buffers • 1 Package insert

Performance Characteristics

The Coronavirus Ag Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the Coronavirus Ag Rapid Test Cassette (Swab) has a high overall relative accuracy.

Method		PCR		Total Results
Results	Positive	Negative		
Coronavirus Ag Rapid Test Cassette	Positive	39	0	39
	Negative	6	116	122
Total Results		45	116	161

Relative Sensitivity: 86.7%
 Relative Specificity: 100%
 Accuracy: 96.3%

▶ Test Procedure & Interpretation

Specimen collection

Use the nasopharyngeal swab supplied in the kit.

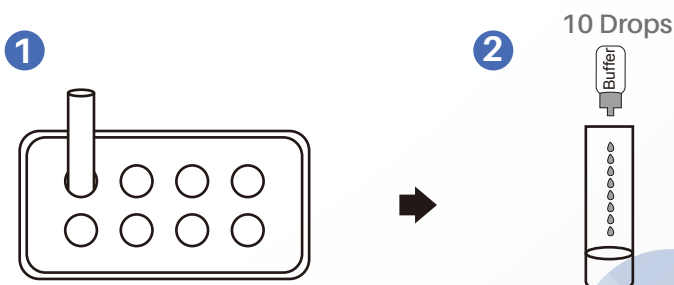
1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.



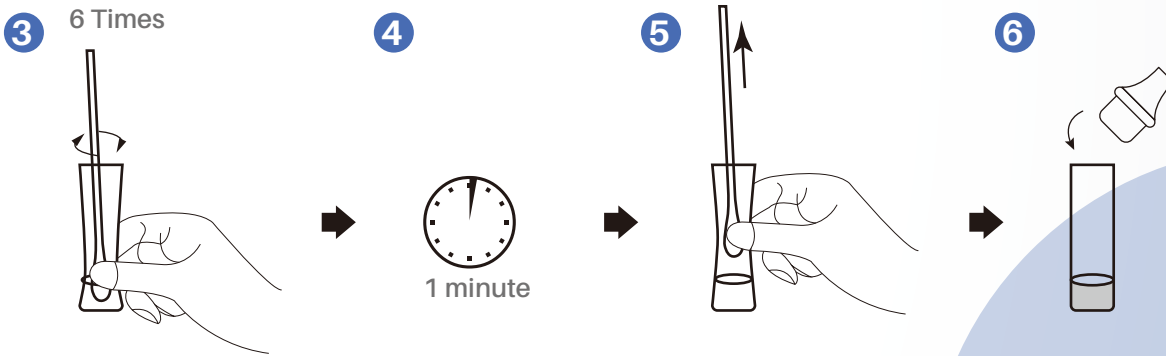
Sample preparation

1. Insert the test extraction tube into the workstation in this product. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.

Performance Characteristics



3. Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
4. Leave the swab in the extraction tube for 1 minute.
5. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
6. Fit the dropper tip with filter on top of the extraction tube tightly.



Test procedure & interpretation of results



Ordering Information

Product Description	Specimen	Catalog No.	Format	Kit Size
Coronavirus Antigen Rapid Test	Nasopharyngeal Swab	GCCOV-502a ✓	Cassette	20 Tests/Kit

✓ CE Marked

Healgen Scientific LLC
 001-713-733-8088
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CE-DOC-H070
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Healgen Scientific Limited Liability Company*

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

Coronavirus Ag Rapid Test Cassette (Swab)	GCCOV-502a
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Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: July 20, 2020

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President



**Coronavirus Ag Rapid Test
Cassette (Swab)**



Healgen Scientific Limited Liability Company
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Website: www.healgen.com

Revision Date: 2020-07-21
B21934-01

For Rapid Detection of SARS-CoV-2

INTENDED USE

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens directly or after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the 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, mostly 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.

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the

reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIALS PROVIDED

- 20 Test cassettes
- 20 Sterile swabs
- 20 Extraction tubes and dropper tips
- 1 Workstation
- 2 Buffers
- 1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, timer or stopwatch

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. The test device should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes and test devices are for single use only.
5. The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
6. Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
7. Do not interchange or mix components from different kit lots.
8. When collecting a nasopharyngeal swab sample, use the Nasopharyngeal Swab supplied in the kit.
9. To obtain accurate results, do not use visually bloody or overly viscous samples.
10. Wear suitable protective clothing, gloves, and eye/face protection when

handling the contents of this kit.

- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

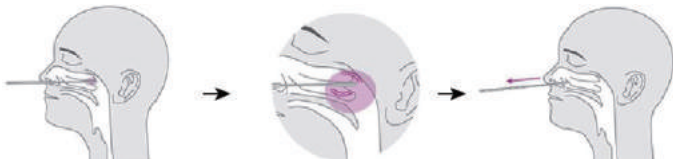
STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- Do not freeze any of the test kit components.
- Do not use test device and reagents after expiration date.
- Recap the desiccated container immediately after removing a test device.
- Test devices that have been outside of the desiccated container for more than 1 hour should be discarded.

SPECIMEN COLLECTION

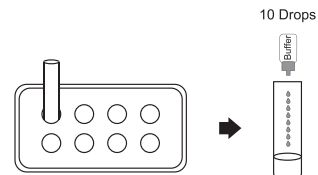
Use the nasopharyngeal swab supplied in the kit.

- Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
- Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
- Withdraw the swab from the nasal cavity.

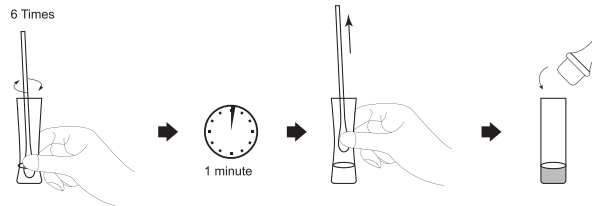


SAMPLE PREPARATION PROCEDURE

- Insert the test extraction tube into the workstation in this product. Make sure that the tube is standing firm and reaches the bottom of the workstation.
- Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.



- Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
- Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
- Leave the swab in the extraction tube for 1 minute.
- Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.



SPECIMEN TRANSPORT AND STORAGE

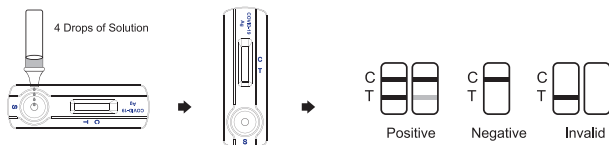
Specimens should be tested as soon as possible after collection. If transport of samples with viral transport medium (VTM) is required, minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less is best to avoid excessive dilution of the patient sample. While holding the swab, remove the cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage. Based on data generated with influenza virus, or nasopharyngeal swabs in VTM are stable for up to 72 hours at 2° to 8°C.

Note: When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Insert a nozzle with filter into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 4 drops (about 100 µL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

1. POSITIVE:

The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.

2. NEGATIVE:

The presence of only control line (C) within the result window indicates a negative result.

3. INVALID:

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. The intensity of color in the test line region (T) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The Coronavirus Ag Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the Coronavirus Ag Rapid Test Cassette (Swab) depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not rule out co-infections with other pathogens.

6. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
 7. Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Coronavirus Ag Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the Coronavirus Ag Rapid Test Cassette (Swab) has a high overall relative accuracy.

Table 1: The Coronavirus Ag Rapid Test vs PCR










Method		PCR		Total Results	
Coronavirus Ag Rapid Test Cassette	Results	Positive	Negative		
		Positive	39	0	39
		Negative	6	116	122
Total Results		45	116	161	

Relative Sensitivity: 86.7%

Relative Specificity: 100%

Accuracy: 96.3%

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#



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REF

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