Coronavirus Ag Rapid Test Cassette (Swab)

CE

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 direct nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of symptom onset, and asymptomatic individuals. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

Coronavirus Ag Rapid Test Cassette (Swab) is intended for use by healthcare professionals or trained operators who are proficient in performing rapid tests and trained clinical laboratory personnel specifically instructed on in vitro diagnostic procedures and proper infection control procedures or individuals similarly trained in point of care settings.

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.

To effectively monitor the SARS-CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical. Particularly, the identification of subclinical or asymptomatic cases is important to reduce or stop the infection because these individuals may transmit the virus. Coronavirus Ag Rapid Test Cassette (Swab) allows effective screening of COVID-19 infection .

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 direct nasal 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 nucleocapsid antigen is present in the sample, a complex forms 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 test line (T) 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

1. 1/2/3/5 Test Cassette(s)
2. 1/2/3/5 Extraction Tube(s) with Buffer and Tip(s)
3. 1/2/3/5 Sterile Swab(s)
4. 1 Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

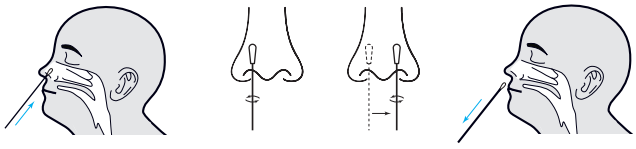
1. For *in vitro* diagnostic use only.
2. The test device should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes, and test devices are for single use only.
5. Do not interchange or mix components from different kit lots.
6. Testing should only be performed using the swabs provided within the kit.
7. To obtain accurate results, do not use visually bloody or overly viscous samples.
8. If the test is carried out by or being supervised by a healthcare professional or trained individual, it is recommended they wear appropriate PPE, whist changing gloves between patients. The patient themselves does not need to wear PPE.
9. Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE PREPARATION PROCEDURE sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
10. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
11. Inadequate or inappropriate specimen collection and storage can adversely affect results.
12. Humidity and temperature can adversely affect results.
13. Dispose of test device and materials as biohazardous waste in accordance with federal, state, and local requirements.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C).
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after expiration date.
4. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit box and secure its contents when not in use.

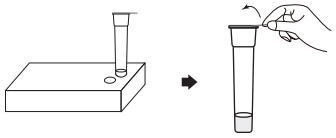
SPECIMEN COLLECTION

1. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the Coronavirus Ag Rapid Test Cassette (Swab)

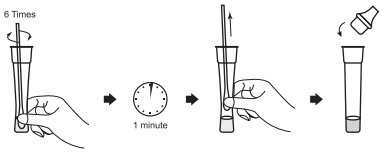


SAMPLE PREPARATION PROCEDURE

1. Insert the test extraction tube into the hole on the kit box as marked. Make sure that the tube is standing upright and reaches the bottom of the box.
2. Tear off the sealing film on the extraction tube gently to avoid spilling out the liquid.
3. Insert the swab into the extraction tube which contains the extraction buffer (approximately 0.3 mL).



4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times from the outside to immerse the swab. Remove the swab.
7. Insert the tip into the extraction tube tightly.



SPECIMEN TRANSPORT AND STORAGE

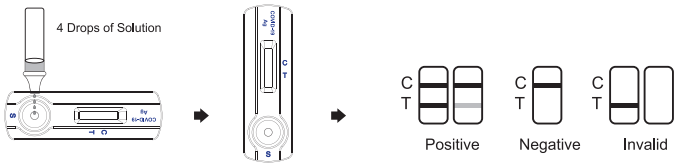
Do not return the nasal swab to the original paper packaging.

Specimen should be tested immediately after collection. If immediate testing of specimen is not possible, insert the swab into an unused general-purpose plastic tube. Ensure the breakpoint swab 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. Ensure the swab fits within the plastic tube and secure a tight seal. The specimen should be disposed and recollected for retesting if untested for longer than 1 hour.

TEST PROCEDURE

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

1. Just prior to testing remove the test device from the sealed pouch and lit it on a flat surface.
2. Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
3. Start the timer.
4. Read the results at 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. 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) can detect 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. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 10 of illness are more likely to be negative compared to a RT-PCR assay.
8. Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
9. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

A total of 237 fresh nasal swab samples was collected and tested, which includes 109 positive samples and 128 negative samples. The Coronavirus Ag Rapid Test results were compared to results of USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2. Overall study results are shown in Table 1.

Table 1: The Coronavirus Ag Rapid Test vs PCR

Method		PCR		Total Results
Coronavirus Ag Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	106	0	106
	Negative	3	128	131
Total		109	128	237

Relative Sensitivity: 97.25% (95% CI*: 92.17% to 99.43%) *Confidence Intervals
Relative Specificity: 100% (95% CI*: 97.69% to 100%)
Accuracy: 98.73% (95%CI*: 96.35% to 99.74%)

2.Limit of Detection (LOD)

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Heat inactivated SARS-CoV-2 virus, with a stock concentration of 4.6×10^5 $TCID_{50}$ / mL, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the Coronavirus Ag test. The Limit of Detection of the Coronavirus Ag Rapid Test Cassette (Swab) is 1.15×10^2 $TCID_{50}$ / mL (Table 2).

Table 2: Limit of Detection (LOD) Study Results

Concentration	No. Positive/Total	Positive Agreement
1.15 x 10^2 $TCID_{50}$ / mL	180/180	100%

3. High Dose Hook Effect

No high dose hook effect was observed when testing up to a concentration of 4.6 x 10^5 $TCID_{50}$ / mL of heat inactivated SARS-CoV-2 virus.

4. Cross Reactivity

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the Coronavirus Ag Rapid Test Cassette (Swab).

Pathogens	Concentration	Pathogens	Concentration
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL	Human coronavirus NL63	1×10^6 PFU/mL
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL	Human coronavirus HKU1	1×10^6 PFU/mL
Novel influenza A H1N1 virus (2009)	1×10^6 PFU/mL	Parainfluenza virus 1	7.3×10^6 PFU/mL
Seasonal influenza A H1N1 virus	1×10^5 PFU/mL	Parainfluenza virus 2	1×10^6 PFU/mL
Influenza A H3N2 virus	1×10^6 PFU/mL	Parainfluenza virus 3	5.8×10^6 PFU/mL
Influenza A H5N1 virus	1×10^6 PFU/mL	Parainfluenza virus 4	2.6×10^6 PFU/mL
Influenza B Yamagata	1×10^5 PFU/mL	Haemophilus influenzae	5.2×10^6 CFU/mL
Influenza B Victoria	1×10^6 PFU/mL	Streptococcus pyogenes	3.6×10^6 CFU/mL
Rhinovirus	1×10^6 PFU/mL	Streptococcus pneumoniae	4.2×10^6 CFU/mL
Adenovirus 3	$5\times10^{7.5}$ $TCID_{50}$/mL	Candida albicans	1×10^7 CFU/mL
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL	Bordetella pertussis	1×10^4 bacteria/mL
EV-A71	1×10^5 PFU/mL	Mycoplasma pneumoniae	1.2×10^6 CFU/mL
Mycobacterium tuberculosis	1×10^3 bacteria/mL	Chlamydia pneumoniae	2.3×10^6 IFU/mL
Mumps virus	1×10^5 PFU/mL	Legionella pneumophila	1×10^4 bacteria/mL
Human coronavirus 229E	1×10^5 PFU/mL	Staphylococcus aureus	3.2×10^6 CFU/mL
Human coronavirus OC43	1×10^5 PFU/mL	Staphylococcus epidermidis	2.1×10^6 CFU/mL

5. Interfering Substance

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity , were evaluated with the Coronavirus Ag Rapid Test Cassette (Swab) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
Human blood (EDTA anticoagulated)	20% (v/v)	0.9% sodium chloride	20% (v/v)
Mucin	5 mg/mL	A natural soothing ALKALOL	20% (v/v)
Oseltamivir phosphate	5 mg/mL	Beclomethasone	20% (v/v)
Ribavirin	5 mg/mL	Hexadecadrol	20% (v/v)
Levofloxacin	5 mg/mL	Flunisolide	20% (v/v)
Azithromycin	5 mg/mL	Triamcinolone	20% (v/v)
Meropenem	5 mg/mL	Budesonide	20% (v/v)
Tobramycin	2 mg/mL	Mometasone	20% (v/v)
Phenylephrine	20% (v/v)	Fluticasone	20% (v/v)
Oxymetazoline	20% (v/v)	Fluticasone propionate	20% (v/v)

6. Microbial Interference

To evaluate whether potential microorganisms in clinical samples interfere with the detection of Coronavirus Ag Rapid Test so as to produce false negative results. Each pathogenic microorganism was tested in triplicate in the presence of heat inactivated SARS-Cov-2 virus (2.3×10^2 $TCID_{50}$ / mL). No cross reactivity or interference was seen with the microorganisms listed in the table below.

Microorganism	Concentration	Microorganism	Concentration
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL	Mumps virus	1×10^5 PFU/mL
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL	Varicella zoster virus	1×10^6 PFU/mL
Novel influenza A H1N1 virus (2009)	1×10^6 PFU/mL	Human coronavirus 229E	1×10^5 PFU/mL
Seasonal influenza A H1N1 virus	1×10^5 PFU/mL	Human coronavirus OC43	1×10^5 PFU/mL
Influenza A H3N2 virus	1×10^6 PFU/mL	Human coronavirus NL63	1×10^6 PFU/mL
Influenza A H5N1 virus	1×10^6 PFU/mL	Human coronavirus HKU1	1×10^6 PFU/mL
Influenza B Yamagata	1×10^5 PFU/mL	Human Metapneumovirus (hMPV)	1×10^6 PFU/mL
Influenza B Victoria	1×10^6 PFU/mL	Parainfluenza virus 1	7.3×10^6 PFU/mL
Rhinovirus	1×10^6 PFU/mL	Parainfluenza virus 2	1×10^6 PFU/mL
Adenovirus 1	1×10^6 PFU/mL	Parainfluenza virus 3	5.8×10^6 PFU/mL
Adenovirus 2	1×10^5 PFU/mL	Parainfluenza virus 4	2.6×10^6 PFU/mL
Adenovirus 3	$5\times10^{7.5}$ $TCID_{50}$/mL	Haemophilus influenzae	5.2×10^6 CFU/mL
Adenovirus 4	1×10^6 PFU/mL	Streptococcus pyogenes	3.6×10^6 CFU/mL
Adenovirus 5	1×10^5 PFU/mL	Streptococcus agalactiae	7.9×10^7 CFU/mL
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL	Streptococcus pneumoniae	4.2×10^6 CFU/mL
Adenovirus 55	1×10^5 PFU/mL	Candida albicans	1×10^7 CFU/mL
EV-A71	1×10^5 PFU/mL	Bordetella pertussis	1×10^4 bacterium/mL
EV-B69	1×10^5 PFU/mL	Mycoplasma pneumoniae	1.2×10^6 CFU/mL
EV-C95	1×10^5 PFU/mL	Chlamydia pneumoniae	2.3×10^6 IFU/mL
EV-D70	1×10^5 PFU/mL	Legionella pneumophila	1×10^4 bacterium/mL
Mycobacterium tuberculosis	1×10^3 bacterium/mL	Pooled human nasal wash	N/A

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
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

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

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