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Coronavirus - Antigen Rapid Test Cassette (Swab)

Self-Test

For the rapid detection of SARS-CoV-2
(the virus responsible for COVID-19)

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INTENDED USE

For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days after onset of symptoms.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M), and nucleocapsid (N).

The antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, which 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. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

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. Coronavirus Ag Rapid Test Cassette (Swab) allows effective screening of COVID-19 infection.

PRINCIPLE OF THE TEST

Corona Antigen Rapid Test Kit uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19.
Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody, and goat anti-chicken IgY antibody.
When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A color band will show up when antigen-conjugate is deposited at the Test “T” position and the Control “C” position on the device.

MATERIALS PROVIDED

5 Test Cassettes
5 Extraction Buffer Vials
5 Sterile Swabs
5 Extraction Tubes and Tips
1 Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Clock, timer, or stopwatch

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.
6. Keep away from sunlight, moisture, and heat.

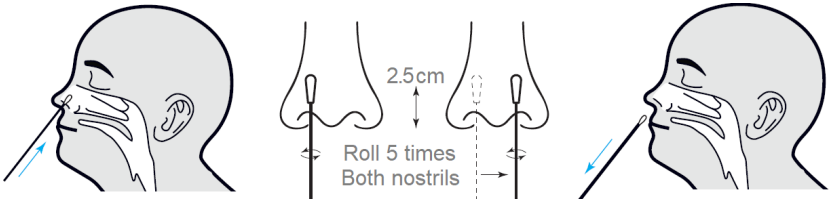
WARNINGS AND PRECAUTIONS

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. The kit components 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. Not for the screening of donated blood.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning
10. To obtain accurate results, do not use visually bloody or overly viscous samples.
11. 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.
12. Inadequate or inappropriate specimen collection and storage can adversely affect results.
13. Humidity and temperature can adversely affect results.
14. Dispose of test device and materials as biohazardous waste in accordance with federal, state, and local requirements.

SPECIMEN COLLECTION

Acceptable specimens for testing with this kit include nasal swab specimens obtained by the dual nares collection method. Correct specimen collection and preparation methods must be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

1. Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities
3. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the kit.

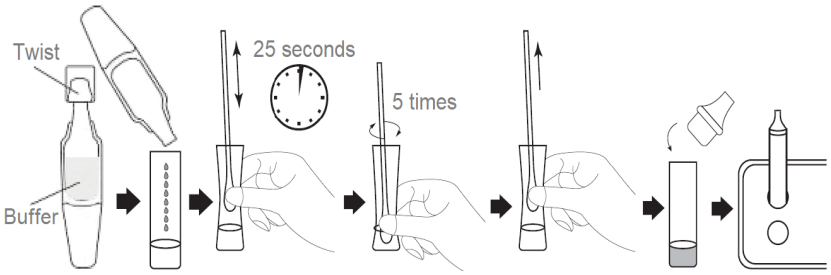


SPECIMEN TRANSPORT AND STORAGE

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Correct specimen collection and preparation methods must be followed.

SAMPLE PREPARATION PROCEDURE

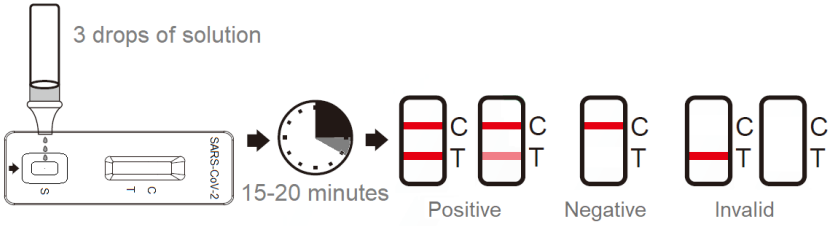
1. Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction tube.
2.After collection of nasal swab specimen, insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 25 seconds, then hold the swab against the bottom of the tube and roll 5 turns, taking care not to splash contents out of the tube.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Press the nozzle cap firmly onto the extraction tube containing the processed sample (threading or twisting is not required). Mix thoroughly by swirling or flicking the bottom of the tube. Place the extraction tube(s) in a rack in the designated area of the workspace.



TEST PROCEDURE

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

1. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface. Label the test device and one extraction tube for each specimen or control to be tested.
2. Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.
3. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.



INTERPRETATION OF RESULTS

1. POSITIVE:

Two lines appear. A coloured line should be in the control line region (C), a coloured line appears in the test line (T) region. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

2. NEGATIVE:

Only one coloured control line appears. Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

3. INVALID:

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

4. Result determination time:

The result should be judged within 15~20 minutes after the sample is added into the sample well, and the result displayed after 20 minutes is invalid**.**

If the test result is positive, please contact your local municipal health organisation!

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

The performance of the kit is determined by the nasal swab samples of 492 patients suspected of COVID-19 collected from the daily clinical practice at the Centro Diagnostico Delta S.r.l. located in Piazza San Giuseppe Moscati, 8 - 82030 Apollosa (Benevento) ITALY. between October 2020 and January 2021. The rhinoceros / oropharyngeal swabs and nasal swabs of 492 patients were collected. rhinoceros / oropharyngeal swabs are determined by RTPCR, and nasal swabs are determined by antigen rapid test kit. The samples are collected by qualified personnel according to the method described in the instructions.

The kit showed 98.13% of sensitivity and 99.22% of specificity

Coronavirus Ag Rapid Test Cassette (Swab) vs PCR

Method		PCR		Total Results
Coronavirus Ag Rapid Test Cassette	Results	Positive	Negative	
	Positive	105	3	108
	Negative	2	382	384
Total Results		107	385	492

Relative Sensitivity: 98.13% (95% CI*: 93.4%~99.8%)
Relative Specificity: 99.22% (95% CI*: 97.7%~99.8%)
Accuracy: 98.98%

*Confidence Intervals

2. Limit of Detection (LOD)

The LoD for the SARS-CoV-2 antigen rapid test kit was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 1.3 x 10^6 $TCID_{50}$/mL. In this study, designed to estimate the LoD of the assay when using a direct nasal swab, the starting material was spiked into a volume of virus dilution in saline. An initial range-finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

3. High Dose Hook Effect

No high dose hook effect was observed when testing up to a concentration of 1.3 x 10^6 $TCID_{50}$ / mL of heat inactivated SARS-CoV-2 virus.

4. Cross Reactivity

Cross-Reactivity: There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

Potential cross-reactive substances	Concentration Tested	Cross-Reactivity (Yes/No)
Influenza A	1.6 x 10^5 TCID50/mL	NO
Influenza B	1.6 x 10^5 TCID50/mL	NO
Human coronavirus HKU1	1.6 x10^5 TCID50/mL	NO
Human coronavirus OC43	1.6 x10^5 TCID50/mL	NO
Haemophilus influenzae	2.2x 10^5 TCID50/mL	NO
MERS-coronavirus	2.1 x 10^5 TCID50/mL	NO
SARS-coronavirus	3.2 x 10^5 PFU/mL	YES
Adenovirus C1	1.5 x 10^5 TCID50/mL	NO
Adenovirus 71	1.5 x 10^5 TCID50/mL	NO
Candida albicans	4.2 x 10^5 CFU/mL	NO
Respiratory syncytial virus	5.1 x 10^5 TCID50/mL	NO
Enterovirus	5.4 x 10^5 TCID50/mL	NO
Malaria	2.2 x 10^6 CFU/mL	NO
Dengue	1.2 x 10^5 TCID50/mL	NO
Human coronavirus NL63	1.7x 10^5 TCID50/mL	NO
Human coronavirus 229E	2.2 x 10^5 TCID50/mL	NO
Streptococcus pneumoniae	1.1 x 10^6 CFU/mL	NO
Pneumocystis jirovecii	1.0 x 10^5 TCID50/mL	NO
Legionella pneumophila	1.4 x 10^6 CFU/mL	NO
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	NO
Human Metapneumovirus(hMPV)	1.1 x 10^5 TCID50/mL	NO
Parainfluenza virus 1	1.0 x 10^5 TCID50/mL	NO
Parainfluenza virus 2	1.0 x 10^5 TCID50/mL	NO
Parainfluenza virus 3	3.5 x 10^5 TCID50/mL	NO
Parainfluenza virus 4	1.4 x 10^5 TCID50/mL	NO
Rhinovirus	1.3 x 10^5 PFU/mL	NO
Mycoplasma pneumoniae	1.8 x 10^6 CFU/mL	NO
Bordetella pertussis	1.5 x 10^6 CFU/mL	NO
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	NO
Pooled human nasal wash-representative ofnormal respiratory microbial flora	100%	NO
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	NO

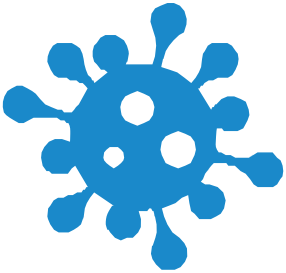
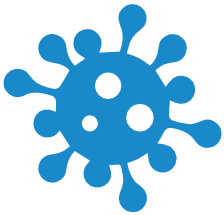
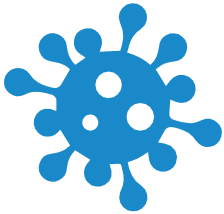
5. Interfering Substance

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, 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
Whole Blood	5%
Fluticasone Propionate	4%v/v
CVS Nasal Drops(Phenylephrine)	17%v/v
Tamiflu(Oseltamivir Phosphate)	6mg/ml
Sucrets(Dyclonin/Menthol)	1.4 mg/mL
Chloraseptic(Menthol/Benzocaine)	1.8 mg/mL
Homeopathic(Alkalol)	1:10dilution
Ore Throat PhenolSpray	16%v/v
Tobramycin	5ug/mL
Naso GEL(NeiMed)	6 %v/v
Mucin	0.54 %
Ricola(Menthol)	1.6 mg/mL
Afrin(Oxymetazo line)	14% v/v
CVC Nasal Spray(Cromolyn)	16% v/v
Nasal Gel(Oxymetazoline)	9% v/v
Mupirocin	12 mg/mL
Fisherman'sFriend	1.3 mg/ml
Zicam	4% v/v

INDEX OF SYMBOLS

	Consult instructions for use		Lot number		Catalogue #
	For in vitro diagnostic use only		Use by		Do not reuse
	CE Mark		Date of manufacture		Manufacturer
	Store between 2 and 30°C		Keep dry		Keep away from sunlight

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