SARS-CoV-2 Ag Rapid Test

CE

Dutch Diagnostics
human and animal care

Rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens from nasopharyngeal swab specimen
For professional in vitro diagnostic use only.
Product-# 21.143-1

INTENDED USE

The SARS-CoV-2 Ag Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2 antigens. The antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decision. Negative results should be treated as presumptive, and be confirmed with a molecular assay if necessary for patient management. 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.

The SARS-CoV-2 Ag Rapid Test is intended for use by trained clinical laboratory personnel.

SUMMARY

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. 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 Ag Rapid Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region (T). If the specimen contains SARS-CoV-2 antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region (C), indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-SARS-CoV-2 antibody as the capture reagent and anti-SARS-CoV-2 antibody as the detection reagent.

PRECAUTIONS

Please read all the information in this package insert before performing the test. Failure to follow directions in package insert may yield inaccurate test results.

- For professional in vitro diagnostic use only!
- Do not use twice!
- Do not use the kit beyond expiration date.
- Store and transport the test components at 2-30℃ (36°-86℉).
- Do not freeze the test components.
- Do not open the foil pouch with the test cassette until you are ready to perform the test.
- Do not use if pouch was damaged, because the test is humidity-sensitive. Humidity and high temperature can adversely affect results.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit content. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Wash hands thoroughly after handling.
- **The used test components and specimen should be disposed according to local regulations for infectious waste**.
- Do not eat, drink or smoke in the area where the specimen or devices are handled.
- Please ensure to use an appropriate amount of specimen for testing. Too much or too little specimen may lead to deviation of results.
- Do not spill solution into the reaction zone.
- Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test
- Do not touch the reaction zone of the device to avoid contamination!

MATERIALS PROVIDED

- 20 Test cassettes (single sealed in foil pouch)
- 20 Extraction tubes prefilled with extraction buffer
- 1 Workstation
- 20 Sterile nasopharyngeal swabs (see description page 2)
- 1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

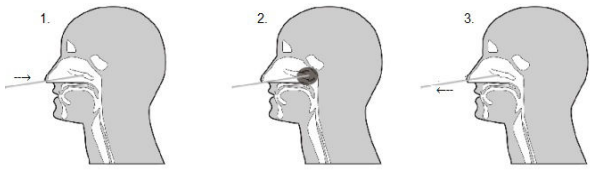
STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (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**.

SPECIMEN COLLECTION AND PREPARATION

Specimen collection

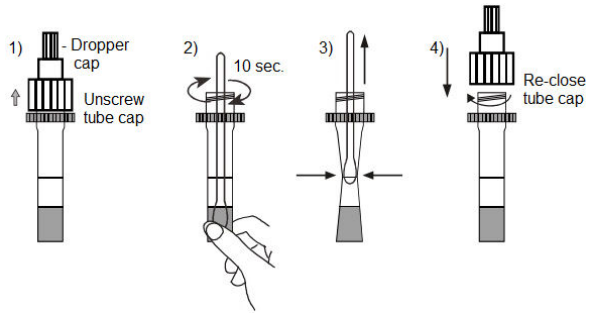
1. Insert a sterilized swab into a nostril from the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



Specimen preparation

Only the extraction buffer and tubes provided in the kit are to be used for swab specimen preparation.

1) Unscrew the cap of the specimen extraction tube with extraction buffer.
2) Insert the swab specimen into the specimen extraction tube. Press against the inner wall of the tube and stir the swab for approximately 10 seconds while pressing the swab head against the inner wall of the tube to release the antigens in the extraction buffer in the tube.
3) Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4) Re-close and tighten the cap onto the specimen extraction tube.



Note: the storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8℃.

SPECIMEN STORAGE AND TRANSPORT

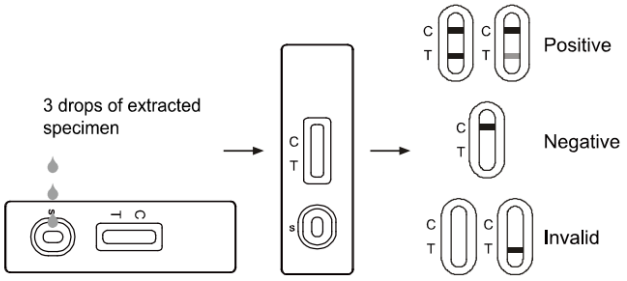
Specimens should be tested as soon as possible after collection.

If swabs are not been processed immediately, it is highly recommended that the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 8 hours at room temperature and 24 hours at 2-8℃

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Remove the dropper cap from the extraction tube cap and add **3 drops of the extracted specimen** (approx.100ul) to the sample well (S) and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). A positive result in the test region indicates detection of SARS-CoV-2 antigens in the sample.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

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

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QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

Positive/negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.[1]

LIMITATIONS

1. The test procedure and the interpretation of test result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The performance of the SARS-CoV-2 Ag Rapid Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
3. The SARS-CoV-2 Ag Rapid Test is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
4. The SARS-CoV-2 Ag Rapid Test will only indicate the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions: The concentration of the SARS-CoV-2 antigens in the sample is lower than the minimum detection limit of the test.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those individuals who have been in contact with the virus. Follow-up testing with a molecular diagnostic device should be considered to rule out infection in these individuals.
9. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
11. False positive results may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

EXPECTED VALUES

The SARS-CoV-2 Ag Rapid Test has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 97%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The SARS-CoV-2 Ag Rapid Test has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2 Ag Rapid Test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result:

SARS-CoV-2 Ag Rapid Test		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	80	1	81
	Negative	3	120	123
Total		83	121	204
Relative Sensitivity		96.4% (95%CI*: 89.8%~99.2%)		
Relative Specifity		99.2% (95%CI*: 95.5%~>99.9%)		
Accuracy		98.0% (95%CI*: 95.1%~99.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The SARS-CoV-2 Ag Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^5 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 104 TCID50/ml

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of Covid-19 standard control. Three different lots of the SARS-Cov-2 Ag Rapid Test have been tested using negative, SARS-COV-2 Antigen weak and SARS-COV-2 Antigen Strong. Ten replicates of each level were tested each day for three consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10^8org/ml and all found to be negative when tested with the SARS-Cov-2 Ag Rapid Test:

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Nesseria subllava	*Streptococcus sp group F*

LITERATURE

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501.

SYMBOLS

IVD	For *in-vitro* diagnostic use only	2	For single use only
Σ	Content		Expiry date
LOT	Lot number	-4°C +30°C	Storage temperature
	Manufacturer		Carefully read package insert

Vers. 146288104
Rev D1.1 – (EN) – 30-10-2020

Sterile nasopharyngeal swabs in the kit

(Additional material in accordance with 93/42/EEC)

• Sterile nasopharyngeal swabs (CE0197)

Jiangsu Hanheng Medical Technology Co. Ltd, 16-B4, #1 North Qingyang Road, Tianning District, 213017 Changzhou, Jiangsu, China (EC Repräsentant: Luxus Lebenswelt GmbH, Kochstr. 1, 47877 Willich)

or

• Sterile nasopharyngeal swabs (CE0197)

Miraclean Technology Co. Ltd, No. 18, Rongshuxia, Industrial Zone Tongle Longgang District, Shenzhen, 518116, China (EC Repräsentant: Share Info Consultant Service LLC., Repräsentanzbüro Heerdter, Lohweg 83, Düsseldorf)

or

• Sterile nasopharyngeal swabs (CE0197)

Jiangsu Changfeng Medical Industry Co. Ltd., Touqiao Town, Guangling District, Yangzhou, Jiangsu, 225109, China (EC Repräsentant: Landlink GmbH, Dorfstr. 2/4, 79312 Emmendingen)

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