Flowflex™

SARS-CoV-2 Antigen Rapid Test (Self-Testing) Package Insert

REF L031-118M5 REF L031-118N5 REF L031-118W5 REF L031-118P5 REF L031-118Z5 REF L031-118R5	English

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.
For in vitro diagnostic use only. For self-testing.
Carefully read the instructions before performing the test.

Materials Provided	Quantity (pcs)					
	1 T	2 T	3 T	5 T	20 T	25 T
Test Cassette	1	2	3	5	20	25
Extraction Buffer Tube	1	2	3	5	20	25
Disposable Swab	1	2	3	5	20	25
Waste Bag	1	2	3	5	20	25
Tube Holder	/	/	/	/	1	1
Package Insert	1	1	1	1	1	1

Materials Required But Not Provided
Timer

INSTRUCTION VIDEO:

PREPARATION

1.

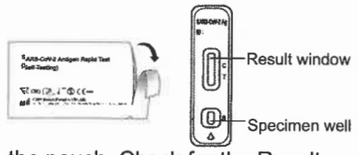
Wash or sanitize your hands. Make sure they are dry before starting the test.

2.

Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.

3.

Check the expiration date printed on the cassette foil pouch.

4.


Open the pouch. Check for the Result window and Specimen well on the cassette.

SPECIMEN COLLECTION

SELF COLLECTION

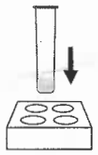
COLLECTION BY AN ADULT CAREGIVER

A nasal swab sample can be self-collected by an individual aged 18+ years. Children under 18 years of age should be performed by a parent or legal guardian. Please follow your local guidelines for specimen collection by children.

TEST PROCEDURE

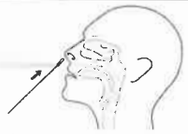
1.

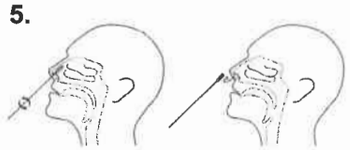
Remove the aluminum foil from the top of extraction buffer tube.

2.

Insert the tube into the hole on the kit box. (Or place the tube in the tube holder.)

3.

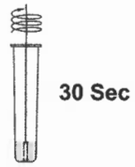
Open the swab packaging at stick end. ***Caution***: Do not touch the absorbent tip of the swab with your hands.

4.

Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab less than 2.5 cm from the edge of the nostril.

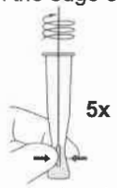
5.

Rotate the swab 5 times brushing against the inside of the nostril. Remove the swab and insert it into the other nostril. Repeat step 4.

6.

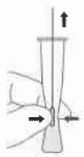
Remove swab from the nostril.

7.


Insert the swab into the tube and swirl for 30 seconds.

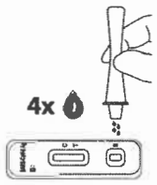
8.


Rotate the swab 5 times while squeezing the side of the tube.

9.

Remove the swab while squeezing the tube.

10.

Attach the dropper tip firmly onto the extraction buffer tube. Mix thoroughly by swirling or flicking the bottom of the tube.

11.


Gently squeeze the tube and dispense **4 drops** of solution into the Specimen well.

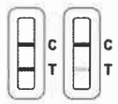
12.


Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.

RESULT INTERPRETATION

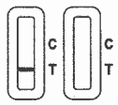
Negative

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.
A negative test result indicates that you are unlikely to currently have COVID-19 disease. Continue to follow all applicable rules and protective measures when contacting with others. There may be an infection even if the test is negative. If it is suspected, repeat the test after 1 - 2 days, as the coronavirus cannot be precisely detected in all phases of an infection.



Positive

Both the control line (C) and test line (T) appears. This means that SARS-CoV-2 antigen was detected. ***NOTE:*** *Any faint line in the test line region (T) should be considered positive.*
A positive test result means it is very likely you currently have COVID-19 disease. Contact your doctor / general practitioner or the local health department immediately. Follow the local guidelines for self-isolation. A PCR confirmation test should be carried out.



Invalid

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the test results remain invalid, contact your doctor or a COVID-19 test center.

SAFELY DISPOSE OF YOUR TEST KIT

Once your test is complete, put all of the used test kit contents in the waste bag provided. Put in your general household waste.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. It does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 antigen. This antigen is generally found in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but individual 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 agent detected may not be the exact cause of disease.

Negative results from individuals with symptoms beyond seven days should be treated as likely negative. Confirm with a molecular assay, if necessary. Negative results do not rule out SARS-CoV-2 infection. SARS-CoV-2 Antigen Rapid Test is intended to be used to help the diagnosis of SARS-CoV-2 infection.

The usability of self-testing by an individual aged under 18 years has not been determined. It is suggested that individual under 18 years of age should be tested by an adult.

SUMMARY

The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms 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 is a test for the detection of the nucleocapsid antigen from SARS-CoV-2 in human anterior nasal swab specimens. Test results are read visually at 15-30 minutes based on the presence or absence of colored lines.

To serve as a procedural control, a colored line will always appear in the control line region indicating that sufficient specimen volume was added and membrane absorption has occurred.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies and goat anti mouse IgG. The extraction buffer tube contains detergent and tris buffer.

PRECAUTIONS

- Read the SARS-CoV-2 Antigen Rapid Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- Do not use the test after the expiration date shown on the pouch.
- Do not eat, drink, or smoke before and during the test.
- Do not use the test if the pouch is damaged.
- All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.
- Do not collect the nasal swab specimen when nosebleed happens.
- Wash hands thoroughly after use.
- If the extraction buffer contacts the skin or eyes accidentally, flush with large amounts of water and seek medical attention if necessary.

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch. Do not use after the expiration date.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms that enough specimen volume was added, and the correct procedure was carried out.

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for self-testing use only. The test should only be used for the detection of SARS-CoV-2 antigens in nasal swab specimens. The intensity of the test line does not necessarily relate to the SARS-CoV-2 viral load in the specimen.
2. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
3. Test results should be looked at with other clinical data available to the doctor.
4. A positive test result does not rule out co-infections with other pathogens.
5. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
6. A negative test result does not rule out other viral or bacterial infections.
7. A negative result, from an individual having symptoms beyond seven days, should be treated as likely negative and confirmed with a molecular assay, if necessary.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Performance of the SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from symptomatic individuals who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	
	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605

Relative Sensitivity: 97.1% (93.1%-98.9%)* Relative Specificity: 99.5% (98.2%-99.9%)*

Accuracy: 98.8% (97.6%-99.5%)* *95% Confidence Intervals

Stratification of the positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.8% (n=81) and 4-7 days has a PPA of 96.8% (n=62).

Positive samples with Ct value ⩽33 have a higher positive percent agreement (PPA) of 98.7% (n=153).

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of an inactivated viral sample. The viral sample was spiked with negative human nasal sample pool into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is $1.6*10^2$ $TCID_{50}$/mL.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level.

No cross-reactivity or interference was observed with the following microorganisms:

Adenovirus	Enterovirus	Human coronavirus 229E
Human coronavirus OC43	Human coronavirus NL63	Human Metapneumovirus
MERS-coronavirus	Influenza A	Influenza B
Parainfluenza virus 1	Parainfluenza virus 2	Parainfluenza virus 3
Parainfluenza virus 4	Respiratory syncytial virus	Rhinovirus
Human coronavirus- HKU1	Bordetella pertussis	Chlamydia trachomatis
Haemophilus influenza	Legionella pneumophila	Mycobacterium tuberculosis
Mycoplasma pneumoniae	Staphylococcus aureus	Staphylococcus epidermidis
Streptococcus pneumoniae	Streptococcus pyogenes	Pneumocystis jirovecii-S. cerevisiae
Pseudomonas aeruginosa	Chlamydia pneumoniae	Candida albicans
Pooled human nasal wash		

The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

USABILITY STUDY

A Usability Study indicated similar device performances comparing lay people to healthcare professionals (HCPs) from a pool of 425 samples. Positive percent agreement is 92.1% and negative percent agreement is 98.9%. Overall agreement is 96.2%.

The lay person questionnaire together with the observation recorded by a HCP showed that the package insert can be easily followed by a lay person, and that the test can be easily operated by a lay person.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer	Σ	Contains sufficient for <*n*> tests		Temperature limit
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Date of manufacture		Biological risks

Index of Contents

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

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CE 0123
EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109, Jiangsu, P.R China

CE 0197
EC REP
Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District, Changzhou, 213017 Jiangsu P.R. China

CE 0197
EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

Number: 1151327403
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