Flowflex™

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

REF L031-118M5 REF L031-118L5 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	5 T	20 T	25 T
Test Cassette	1	2	5	20	25
Extraction Buffer Tube	1	2	5	20	25
Disposable Swab	1	2	5	20	25
Waste Bag	1	2	5	20	25
Tube Holder	/	/	/	1	1
Package Insert	1	1	1	1	1

Materials Required But Not Provided
Timer

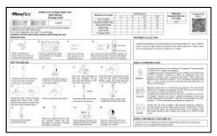
INSTRUCTION VIDEO:

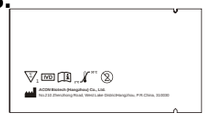
PREPARATION

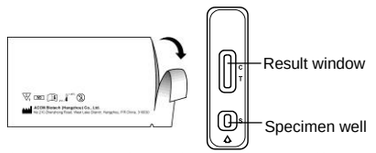
(Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.)

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. Place the test cassette on a flat and clean surface. Check for the Result window and Specimen well on the cassette.

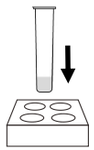
SPECIMEN COLLECTION

Anterior nasal swab specimens can be self-collected by an individual aged 14 years or older. For children aged 2 to 13 years of age, anterior nasal swab specimens should be collected and tested by an adult. Do not use on anyone under two years of age.

TEST PROCEDURE

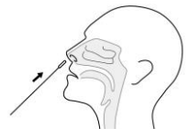
1.

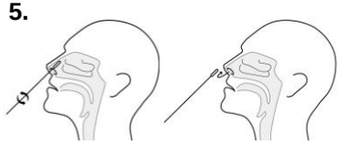
Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.

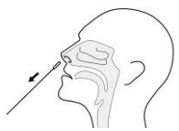
2.

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

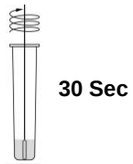
3.

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

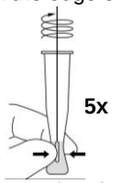
4.

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.

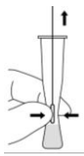
6.

Remove swab from the nostril.

7.


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

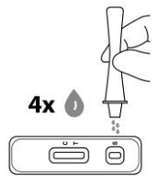
8.


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.

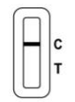
11.


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

12.

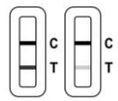
15-30 min.
Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.

RESULT INTERPRETATION



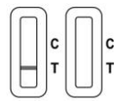
Negative

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 Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing) is a single use, visually read, lateral flow test intended to detect the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with symptoms of COVID-19 within the first seven days of symptom onset, or in individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. It does not differentiate between SARSCoV and SARS-CoV-2.

Persons who test positive with the Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing) should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.

Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

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. See below table for summary of the extraction buffer components, concentrations, along with their potential associated hazard.

Chemical Name	Harms (GHS) code for each ingredient	Concentration
Triton X-100	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	1%
Sodium Azide	Acute Tox. 2 * (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0.02%

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.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. The reagent solution in the tube contains hazardous ingredients (see table in REAGENTS). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice.
- Keep the test kit away from children and animals.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal swab specimen.
- Children aged 2 to 13 years of age should be tested by an adult. Do not use on anyone under two years of age.

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.
8. The performance of the SARS-CoV-2 Antigen Rapid Test has not been assessed in a population vaccinated against COVID-19.
9. You may be required to report all positive results in accordance with any country-specific or public health authority requirements.
10. Use in conjunction with the testing strategy outlined by public health authorities in your area.
11. The performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
12. There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
13. For asymptomatic patients:
    a) Clinical studies in asymptomatic patients using serial testing are ongoing to establish clinical performance.
    b) The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications.
    c) Note that performance may differ in these populations.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Performance of the SARS-CoV-2 Antigen Rapid Test was established with 419 nasal swabs self-tested or tested by another study participant from 167 individual symptomatic patients (within 7 days of onset) and 252 asymptomatic patients. The study was conducted in a simulated home setting environment. The SARS-CoV-2 Antigen Rapid Test results were compared to RT-PCR to determine test performance in the tables below:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test in ALL subjects

Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing)	**Reference Method** (RT-PCR)		
	Positive	Negative	Total
Positive	160	1	161
Negative	10	248	258
Total	170	249	419
Positive Percent Agreement(PPA)	94.12%（95% CI: 89.39%-96.90%）		
Negative Percent Agreement(NPA)	99.60%（95% CI: 97.53%-99.99%）		

Age distribution of patients and specimen positivity

Age group	Total Sample (n)	Positive Sample (n)	Negative Sample (n)
< 14 years	24	8	16
14-24 years	29	6	23
25-64 years	305	142	163
≥65 years	61	14	47

Cumulative PPA results by days since symptom onset

Days Since Symptom Onset	RT-PCR Postive Results	Flow*flex* SARS-CoV-2 Antigen Rapid Test (Self-Testing) Positive Results	PPA
0-3 days	66	65	98.5%
4-7 days	89	83	93.3

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
Haemophilus influenza	Bordetella pertussis	Chlamydia trachomatis
Mycoplasma pneumoniae	Legionella pneumophila	Mycobacterium tuberculosis
Streptococcus pneumoniae	Staphylococcus aureus	Staphylococcus epidermidis
Pseudomonas aeruginosa	Streptococcus pyogenes	Pneumocystis jirovecii-S. cerevisiae
Pooled human nasal wash	Chlamydia pneumoniae	Candida albicans

Cross-reactivity with human coronavirus HKU1 cannot be completely ruled out. 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 444 samples. Positive percent agreement is 92.1% and negative percent agreement is 98.9%. Overall agreement is 96.4%.

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 in 96.6% cases.

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		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
	Date of manufacture		Biological risks		

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