



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




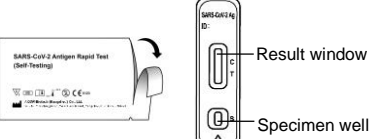
REF L031-118M5	REF L031-118P5	English
REF L031-118Z5	REF L031-118R5	

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.


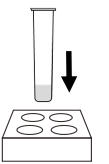


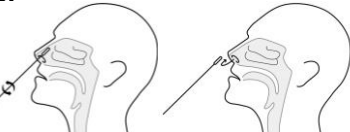
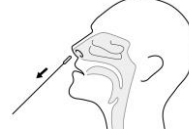
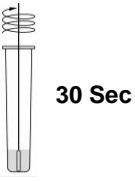
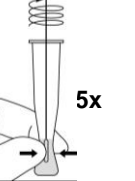
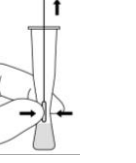



For in vitro diagnostic use only. For self-testing.

Carefully read the instructions before performing the test.

PREPARATION

<p>1.</p>  <p>Wash or sanitize your hands. Make sure they are dry before starting the test.</p>	<p>2.</p>  <p>Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.</p>	<p>3.</p>  <p>Check the expiration date printed on the cassette foil pouch.</p>	<p>4.</p>  <p>Open the pouch. Check for the Result window and Specimen well on the cassette.</p>
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TEST PROCEDURE

<p>1.</p>  <p>Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.</p>	<p>2.</p>  <p>Insert the tube into the hole on the kit box. (Or place the tube in the tube holder.)</p>	<p>3.</p>  <p>Open the swab packaging at stick end. Caution: Do not touch the absorbent tip of the swab with your hands.</p>	<p>4.</p>  <p>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.</p>
<p>5.</p>  <p>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.</p>	<p>6.</p>  <p>Remove swab from the nostril.</p>	<p>7.</p>  <p>30 Sec</p> <p>Insert the swab into the tube and swirl for 30 seconds.</p>	<p>8.</p>  <p>5x</p> <p>Rotate the swab 5 times while squeezing the side of the tube.</p>
<p>9.</p>  <p>Remove the swab while squeezing the tube.</p>	<p>10.</p>  <p>Attach the dropper tip firmly onto the extraction buffer tube. Mix thoroughly by swirling or flicking the bottom of the tube.</p>	<p>11.</p>  <p>4x</p> <p>Gently squeeze the tube and dispense 4 drops of solution into the Specimen well.</p>	<p>12.</p>  <p>15-30 min.</p> <p>Read the result when the timer reaches 15-30 minutes. Do not read after 30 minutes.</p>



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

Materials Required But Not Provided
Timer

INSTRUCTION VIDEO:


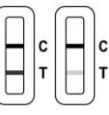
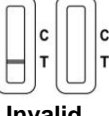


SPECIMEN COLLECTION

<p>SELF COLLECTION</p> 	<p>COLLECTION BY AN ADULT CAREGIVER</p> 
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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.

RESULT INTERPRETATION

 <p>Negative</p>	<p>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.</p>
 <p>Positive</p>	<p>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.</p>
 <p>Invalid</p>	<p>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.</p>

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.

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.

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.
- Keep the test kit away from children and animals.

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.

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.

Index of Symbols

	Manufacturer		Contains sufficient for <n> tests
	Temperature limit		Do not reuse
	Catalogue number		In vitro diagnostic medical device
	Biological risks		Use-by date
	Consult instructions for use		Batch code
	Date of manufacture		



Distributor
Alcotech Pte. Ltd.
25 Bukit Batok Crescent, #09 - 13
The Elitist, Singapore 658066
www.flowflex.sg
contact@flowflex.sg

For Singapore Market Only