WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: SARS-CoV-2 Antigen Rapid Test (Self-Testing)
Manufacturer: Acon Biotech (Hangzhou) Co. Ltd
EUL Number: EUL 0707-021-00
Outcome: Accepted.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

SARS-CoV-2 Antigen Rapid Test (Self-Testing) with product codes L031-13025, L031-13035, L031-13045, L031-13055, L031-13065, L031-13075, L031-013085, L031-13095, RoW regulatory version, manufactured by Acon Biotech (Hangzhou) Co. Ltd, 210 Zhenzhong Road, West Lake District Hangzhou, 310030, China was listed as eligible for WHO procurement on 18 May 2023.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarised in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Corrected the manufacturer's physical address to reflect the new address.	22 August 2023

Intended use:

According to the claim of intended use from Acon Biotech (Hangzhou) Co. Ltd, *"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 for self-testing by untrained lay users in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult."

Specimen type that was validated: Nasal swab specimens.

Assay Description:

According to the claim of assay description from Acon Biotech (Hangzhou) Co. Ltd, *"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."

Test kit contents:

Component	1 Test (T)/Kit (product code L031-13025)	2 T/Kit (product code L031-13035)	3 T/Kit (product code L031-13045)	5 T/Kit (product code L031-13055)	7 T/kit (product code L031-13065)	10 T/kit (product code L031-13075)	20 T/kit (product code L031-13085)	25 T/kit (product code L031-13095)
Test cassettes	1	2	3	5	7	10	20	25
Extraction buffer	1	2	3	5	7	10	20	25
Disposable swab (sterile)	1	2	3	5	7	10	20	25
Waste bag	1	2	3	5	7	10	20	25
Tube holder	On the kit box						1	1
Package insert	1	1	1	1	1	1	1	1

Materials required but not provided: Timer

Storage:
The test kit should be stored at 2 - 30 °C.

Shelf-life upon manufacture:
24 months (real-time stability ongoing).

Warnings/limitations:
Please refer to the attached instructions for use (IFU).

Product dossier assessment

Acon Biotech (Hangzhou) Co. Ltd submitted a product dossier for SARS-CoV-2 Antigen Rapid Test (Self-Testing) as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL:

As a requirement to listing, the manufacturer is required to estimate the limit of detection with the WHO international standard for SARS-CoV-2 Antigens when available.

The risk-benefit assessment conclusion is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, Acon Biotech (Hangzhou) Co. Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that sufficient information was provided by Acon Biotech (Hangzhou) Co. Ltd to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347 "*.

The quality management documentation assessment conclusion is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

Acon Biotech (Hangzhou) Co. Ltd is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in place, which are in accordance with WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics."*[1]

Scope and duration of procurement eligibility

The SARS-CoV-2 Antigen Rapid Test *(Self-Test)* with product codes L031-13025, L031-13035, L031-13045, L031-13055, L031-13065, L031-13075, L031-013085, L031-13095, manufactured by Acon Biotech (Hangzhou) Co. Ltd is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may be used for the detection of the Severe Acute Respiratory Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Acon Biotech (Hangzhou) Co. Ltd must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. Acon Biotech (Hangzhou) Co. Ltd is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes made to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

[1] https://www.who.int/publications/i/item/9789240015319

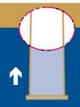
Labelling

1. **Labels**
2. **Instructions for use**

1.1 Packaging Artwork labels

COVID-19 Test

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.



FlowFlex™

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

1 Test

ACON®

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

1130592801

Results Interpretation:

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

Contents:
- 1 Test Cassette
- 1 Extraction Buffer Tube
- 1 Disposable Swab
- 1 Waste Bag
- Package Insert

LOT XXXXXXXXXX REF L031-13025
YYYY-MM-DD

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXX

6 921756 494773

1130592901

COVID-19 Test

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.

2 Tests

FlowFlex™

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

ACON®

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:

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

Contents:
- 2 Test Cassettes
- 2 Extraction Buffer Tubes
- 2 Disposable Swabs
- 2 Waste Bags
- Package Insert

IVD

LOT XXXXXXXXXX REF L031-13035
YYYY-MM-DD

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXX

6 921756 494780

COVID-19 Test

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.

3 Tests

Flowflex™

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

1130593001

ACON®
ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:

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

Contents:
- 3 Test Cassettes
- 3 Extraction Buffer Tubes
- 3 Disposable Swabs
- 3 Waste Bags
- Package Insert

IVD 2°C 30°C Σ 3

LOT XXXXXXXXXX REF L031-13045
YYYY-MM-DD

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXXX

6 921756 494797

5 Tests

Flowflex™

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

COVID-19 Test

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.

1130593101

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

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

LOT XXXXXXXXXX
YYYY-MM-DD

REF L031-13055

ACON®

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:

Contents:
- 5 Test Cassettes
- 5 Extraction Buffer Tubes
- 5 Disposable Swabs
- 5 Waste Bags
- Package Insert

IVD

2°C 30°C

5

MADE IN CHINA
EXECUTIVE DIRECT VE: XXXXXXXXX

6 921756 494803

COVID-19 Test

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.

7 Tests

Flowflex™

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

1130593201

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

LOT XXXXXXXXXX
YYYY-MM-DD

REF L031-13065

ACON®

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXXX

6 921756 494810

Results Interpretation:

Contents:
- 7 Test Cassettes
- 7 Extraction Buffer Tubes
- 7 Disposable Swabs
- 7 Waste Bags
- Package Insert

IVD

2°C 30°C

Σ 7

COVID-19 Test

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in saliva swab specimens.
For *in vitro* diagnostic use only. For self-testing.

10 Tests

Flowflex™

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

1130593301

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

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

LOT XXXXXXXXXX
YYYY-MM-DD

REF L031-13075

ACON®
ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:

Contents:

- 10 Test Cassettes
- 10 Extraction Buffer Tubes
- 10 Disposable Swabs
- 10 Waste Bags
- Package Insert

IVD 2°C-30°C Σ10

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXXX

6 921756 494827

COVID-19 Test

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specmens.
For in vitro diagnostic use only. For self-testing.

Contents:
- 20 Test Cassettes
- 20 Extraction Buffer Tubes
- 20 Disposable Swabs
- 20 Waste Bags
- 1 Tube Holder
- Package Insert

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

20 Tests

1130593401

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

ACON®
ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:

Contents:
- 20 Test Cassettes
- 20 Extraction Buffer Tubes
- 20 Disposable Swabs
- 20 Waste Bags
- 1 Tube Holder
- Package Insert

IVD
2°C
30°C
20

LOT XXXXXXXXX
YYYY-MM-DD

REF L031-13085

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXX

6 921756 494834

COVID-19 Test

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.

25 Tests

Flowflex™

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

Contents:
- 25 Test Cassettes
- 25 Extraction Buffer Tubes
- 25 Disposable Swabs
- 25 Waste Bags
- 1 Tube Holder
- Package Insert

1130593501

Flowflex™

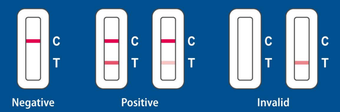
SARS-CoV-2 Antigen Rapid Test (Self-Testing)

ACON®

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R. China, 310030
Tel: +86-571-87775689
Email: information@aconlab.com.cn
Website: www.aconbio.com

INSTRUCTION VIDEO

Results Interpretation:



Contents:
- 25 Test Cassettes
- 25 Extraction Buffer Tubes
- 25 Disposable Swabs
- 25 Waste Bags
- 1 Tube Holder
- Package Insert

IVD 2°C 30°C 25

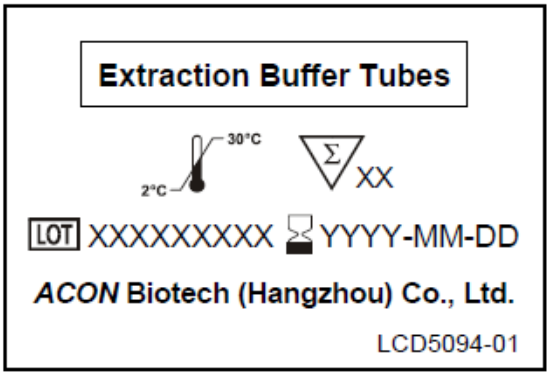
LOT XXXXXXXXXX
YYYY-MM-DD

REF L031-13095

MADE IN CHINA
EXECUTIVE DIRECTIVE: XXXXXXXXX

6 921756 494841

1.2 Extraction Buffer label



1.3 Nasal Swab labels

PEEL HERE

Disposable swabs

STERILE | EO

Nasal Swab

1、Single use only.
2、There is a risk of cross- infection if re-use
3、Do not use if package is damaged

EC REP

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany
Email: info@llins-service.com

CE 0197

LOT

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

OPEN

Disposable sampling swab

Nasal Swab

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

EC REP CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006 Málaga-Spain

STERILE EO

2 STERILIZE

CE 0197

REF

LOT

1. The product is sterile
2. There is a risk of cross-infection if re-use
3. Do not use if package is damaged

OPEN

Disposable sampling swab (Nasal Swab)

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

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

1. The product is sterile
2. There is a risk of cross-infection if re-use
3. Do not use if package is damaged

STERILE EO

CE 0197

Type:

LOT

2.0 Instructions for Use[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

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

REF L031-13025	REF L031-13035	REF L031-13045	REF L031-13055	English
REF L031-13065	REF L031-13075	REF L031-13085	REF L031-13095	

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	Test Kit Configuration							
	L031-13025	L031-13035	L031-13045	L031-13055	L031-13065	L031-13075	L031-13085	L031-13095
Test Cassette	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Extraction Buffer Tube	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Disposable Swab (sterile)	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Waste Bag	x 1	x 2	x 3	x 5	x 7	x 10	x 20	x 25
Tube Holder	on the kit box						x 1	x 1
Package Insert	x 1	x 1	x 1	x 1	x 1	x 1	x 1	x 1

Materials Required But Not Provided: Timer

INSTRUCTION VEDIO

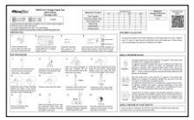
W4011

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.

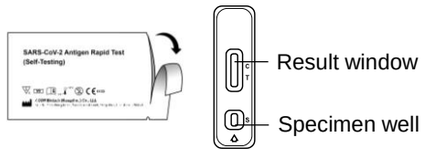


Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.

3.

Check the expiration date printed on the cassette foil pouch, extraction buffer tube and disposable swab bags.

4.



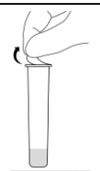
Open the pouch. Place the test cassette on a flat and clean surface. Identify the Result window and Specimen well on the cassette.

SPECIMEN COLLECTION

A nasal swab sample can be self-collected by an individual aged 14+ years. Specimen collection from children under 14 years of age should be performed by an adult or with adult supervision. Please follow your local guidelines for specimen collection by children.

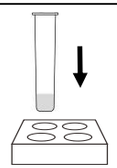
TEST PROCEDURE

1.



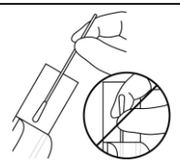
Carefully remove the aluminum foil from the top of extraction buffer tube, avoid spilling.

2.



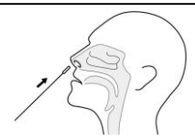
Read the instructions before using SARS-CoV-2 Antigen Rapid Test kit.

3.



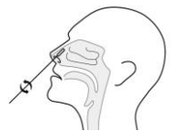
Open the swab packaging at stick end. ***Caution*****:** Do not touch the absorbent tip of the swab with your hands.

4.



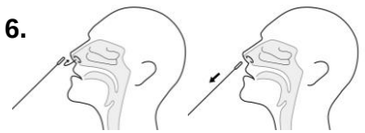
Insert the entire absorbent tip of the swab into one nostril. Using gentle rotation, push the swab from the edge of the nostril until resistance is felt (about 2.5 cm). With children, the depth of insertion may be less than 2.5cm.

5.



Rotate the swab 5 times brushing against the inside of the nostril.

6.



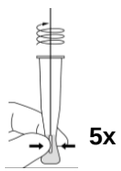
Remove the swab and insert it into the other nostril. Repeat step 4-5. Remove swab from the nostril.

7.

30 sec.

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

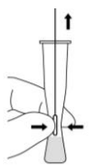
8.



5x

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.

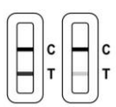
15-30 min.

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

RESULT INTERPRETATION

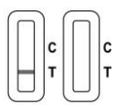
Negative

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.

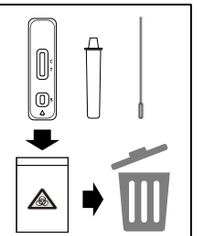


Invalid

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

Once your test is complete, put the used swab, extraction buffer tube and test cassette 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 for self-testing by untrained lay users in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.

SUMMARY

The novel coronaviruses belong to the β genus[1]. 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.

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.
- A desiccant is included in the test cassette pouch. Do not eat it.
- The test cassette, disposable swab and extraction buffer tube can only be used once. All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results. Remove the test cassette from the pouch and use it as soon as possible (in 1 hours with humidity ≤ 80% at 15-30 °C).
- 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.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal swab specimen.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored in the extraction buffer tube at room temperature (15-30°C).
- Dot not use swabs and extraction buffer other than the Disposable Swab and Extracton Buffer Tubes supplied in the kit.

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 cannot necessarily determine whether a person is infectious.
5. A positive test result does not rule out co-infections with other pathogens.
6. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
7. A negative test result does not rule out other viral or bacterial infections.
8. 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.
9. The test is less reliable in the later phase of infection and in asymptomatic individuals.
10. A higher chance of false-negative results with AgRDT self-tests than with laboratory-based molecular tests.
11. Recommend repeat testing (e.g. within 1-2 days) if ongoing suspicion of infection, high-risk setting or occupational or other requirement.
12. Test one individual at a time.
13. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Performance of the SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from 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 (Nasopharyngeal Swab Specimens)		Total Results
SARS-CoV-2 Antigen Rapid Test (Nasal Swab Specimens)	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). An additional clinical study was performed with total 412 nasal swab specimen from asymptomatic individuals. The results show that the relative sensitivity is 94.3% (n=70) and the relative specificity is 99.7% (n=342).

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[2]. 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.

INTERFERING SUBSTANCES

The substances listed in the talbe below were evaluated and were found not to affect test perfomance.

Biotin	Mucin	Whole Blood
Mupirocin	Tobramycin	Tamiflu
Afrin Original Nasal Spray	Equate Fast-Acting Nasal Spray	NasalCrom Nasal Spray
ALKALOL Allergy Relief Nasal Spray	CVS Health Fluticasone Propionate Nasal Spray	Mometasone Furoate Nasal Spray
NeilMed NasoGel for Dry Noses	Chloraseptic Max Sore Throat Lozenges	Dyclonine Hydrochloride Throat Lozenge
Equate Sore Throat Phenol Oral Anesthetic Spray	Original Extra Strong Menthol Cough Lozenges	Zicam Cold Remedy
Physiological Seawater Nasal Cleaner		

USABILITY STUDY

A usability study was conducted with a pool of 158 lay persons in the self-testing environment. The sensitivity is confirmed as 91.4% and specificity is confirmed as 100% in the hands of the lay person, comparing with professional RT-PCR testing.

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.

Information on what variants of COVID-19 the test can detect

SARS-CoV-2 variants was evaluated by testing different variants that are concerned in the world. Each variant was tested with recombination nucleocapsid antigen at low positive level. No interference was observed with the following variants:

Alpha (B.1.1.7)	Epsilon (B.1.427/B.1.429)
Beta (B.1.351) / Mu (B.1.621)	Zeta (P.2)
Gamma (P.1)	Eta (B.1.525)
B.1.617	Theta (P.3)
Kappa (B.1.617.1)	Iota (B.1.526)
Delta (B.1.617.2)	B.1.616
B.1.617.3	A.23.1
B.1.618	Lambda (C.37)
Delta Plus (AY.4.2)	Omicron (BA.1)
Omicron (BA.2/BA.3/XE)	N/A

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.

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		

Index of Contents

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Number: 1151445101
Revision Date: 2023-05-05