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:

- 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.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Corrected the manufacturer’s physical address to reflect the new address.</td>
<td>22 August 2023</td>
</tr>
</tbody>
</table>
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:

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

**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

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.”

**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.

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

1. Labels

2. Instructions for use
1.1 Packaging Artwork labels
1.2 Extraction Buffer label

![Extraction Buffer Tubes]

LOT XXXXXXXXXX  YYYY-MM-DD

ACON Biotech (Hangzhou) Co., Ltd.

LCD5094-01

1.3 Nasal Swab labels
Disposable swabs

Single use only.

There is a risk of cross-infection if re-used.

Do not use if package is damaged.

Jiangsu Changfeng Medical Industry Co., Ltd
Touqiao Town, Guangling District, Yangzhou, Jiangsu 225109 China
Disposable sampling swab
Nasal Swab
Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006 Málaga-Spain

1. The product is sterile
2. There is a risk of cross-infection if re-use
3. Do not use if package is damaged
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
Lexus Lebenswell GmbH
Kochstr. 1, 47877, Willeich, Germany

STERILE EO
CE 0197

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

Type:
2.0 Instructions for Use

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

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

RESULT INTERPRETATION

- Only the control line (C) and no test line (T) appears. This means that SARS-CoV-2-CoV 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.

- 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.

- 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.

Materials Provided

- Test Cassette
- Extraction Buffer Tube
- Disposable Swab (sterile)
- Waste Bag
- Tube Holder

Test Kit Configuration

<table>
<thead>
<tr>
<th>Materials Provided</th>
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<tbody>
<tr>
<td>L031-13025</td>
<td>L031-13035</td>
</tr>
<tr>
<td>x 1</td>
<td>x 2</td>
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<tr>
<td>L031-13035</td>
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<tr>
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Negative results from individuals with symptoms beyond seven days should be treated as likely not to be infected as long as laboratory tests in SARS-CoV-2 infection. SARS-CoV-2 Antigen Rapid Test is intended to be used for self-testing by individuals in a private setting to aid in the diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.

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 visual within 15-30 minutes based on the presence or absence of colored lines. To serve as a procedural control, a control line will always appear in the control line region indicating that sufficient specimen volume was added and membrane absorption has occurred.

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

Read the SARS-CoV-2 Antigen Rapid Test Procedure Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results. Do not use after the expiration date shown on the pouch. Do not use, eat, or swallow before and during the test. Do not use the test if the pouch is damaged. Do not do anything to the test if the kit is damaged. 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 low viral load sample may become visible within 30 minutes. Do not collect nasal swabs from older children and adults.

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 store the test kit in the freezer.

Do not use nasal sprays for at least 30 minutes before collecting a nasal swab specimen.

Testing must be performed immediately after specimen collection, or at most within one (1) hour after collection, if stored in the extraction buffer tube at room temperature (15-30°C).

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.

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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.

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) indicates that sufficient specimen volume was added, and the correct procedure was carried out.

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