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

Product: SARS-CoV-2 Antigen Rapid Test (Flowflex)
Manufacturer: Acon Biotech (Hangzhou) Co. Ltd
EUL Number: EUL 0597-021-00
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 (Flowflex) with product codes L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5 and L031-129Y5, CE mark regulatory version, manufactured by Acon Biotech (Hangzhou) Co. Ltd, 398 TianMushan Road, Gundang Industrial Park Hangzhou 310023, China was listed as eligible for WHO procurement on 4 April 2022.

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 chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection.
Positive results indicate the presence of viral antigens, but clinical correlation with patient 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 definite cause of disease.

Negative results, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.”

**Specimen type(s) that were validated:** Nasal and nasopharyngeal 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 qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal and nasopharyngeal swab specimens. When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been precoated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.”
### Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>25 Tests (T)/Kit (product code L031-129R5)</th>
<th>25 T/Kit (product code L031-129V5)</th>
<th>25 T/Kit (product code L031-129T5)</th>
<th>25 T/Kit (product code L031-129W5)</th>
<th>5 T/kit (product code L031-129U5)</th>
<th>5 T/kit (product code L031-129Y5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test cassettes</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Positive control swab</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Not provided</td>
<td>Not provided</td>
</tr>
<tr>
<td>Negative control swab</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Not provided</td>
<td>Not provided</td>
</tr>
<tr>
<td>Extraction buffer tubes</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Extraction buffer</td>
<td>Not provided</td>
<td>Not provided</td>
<td>2 x 6mL vials</td>
<td>2 x 6mL vials</td>
<td>Not provided</td>
<td>Not provided</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>
</tr>
<tr>
<td>Specimen collection guide</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Items required but not provided:
- Personal Protective Equipment
- Permanent marker pen and Timer

### Storage:
The test kit should be stored at 2 - 30 °C.
Shelf-life upon manufacture:
24 months (stability studies are 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 (Flowflex) 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 external assessor appointed by WHO.

Post listing Commitments for EUL:

As a requirement to listing, the manufacturer is required to:

1. Estimate the limit of detection with the WHO international standard for SARS-CoV-2 Antigens when available.
2. Submit interim and final stability study reports by 31 December 2022.

Risk benefit assessment conclusion: Acceptable.

Quality Management Systems Review

To establish the 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 ”.

Quality management documentation assessment conclusion: 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 ensure 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 ARS-CoV-2 Antigen Rapid Test (Flowflex) with product codes L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5 and L031-129Y5 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 on-going 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.

---

1 [https://www.who.int/publications/i/item/9789240015319](https://www.who.int/publications/i/item/9789240015319)
WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.
Labelling

1. Labels

2. Instructions for use
1.1.1 Kit box

25 Tests (T)/Kit (product code L031-129R5) labels

1.1.2 Kit box label

---

**SARS-CoV-2 Antigen Rapid Test**

**REF** L031-129R5

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

For professional *in vitro* diagnostic use only.

**Contents:**

- 25 Test Cassettes
- 25 Extraction Buffer Tubes
- 1 Positive Control Swab
- 1 Negative Control Swab
- 25 Disposable Swabs (Nasal Swabs)
- Package Insert
- Specimen Collection Guide

**LOT** X XXXX

**YY-MM-DD**

25
1.1.3 Cassette pouch for all product codes L031-129R5, L031-129V5, L031-129T5, L031-129T5, L031-129W5, L031-129U5, L031-129Y5
1.1.4 Pouch label for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129U5, L031-129Y5

![SARS-COV-2 ANTIGEN RAPID TEST](image)

1.1.5 Extraction buffer tube bag label L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129U5, L031-129Y5

![Extraction Buffer Tubes](image)

1.1.6 Positive control swab label for product codes L031-129R5, L031-129V5, L031-129T5 and L031-129W5

![SARS-CoV-2 Antigen Positive Control Swab](image)
1.1.7  Negative control swab label for product codes L031-129R5, L031-129V5, L031-129T5 and L031-129W5

![Negative Control Swab Label](image)

1.1.8  Nasal swab pouch label L031-129R5, L031-129T5 and L031-129U5
1.2 25 T/Kit (product code L031-129V5) labels

1.2.1 Kit box label

![Kit box label](image)

1.2.2 Nasopharyngeal swab label for product codes L031-129V5, L031-129W5 and L031-129Y5

![Nasopharyngeal swab label](image)
1.2.3 Extraction buffer label for product codes L031-129T5 and L031-129W5

1.3 5 T-kit (product code L031-129U5) kit box label
1.4 5 T/kit (product code L031-129Y5) kit box label
2.0 Instructions for use

2 English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
2.1 Nasal swab collection guide
How to collect an anterior nasal swab sample:

1. Carefully insert one of the Disposable Nasal Swabs, provided with your kit, into one nostril. Using gentle rotation, push the swab less than 2.5 cm (1 inch) from the edge of the nostril.

2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.

3. Using the same swab, repeat the process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.

4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.
2.2 Nasopharyngeal swab specimen collection guide
Specimen Collection Guide  
- Nasopharyngeal Swabs

How to collect a nasopharyngeal swab sample:

1. Tilt patient’s head back 70 degrees. Gently and slowly insert a nasopharyngeal swab, provided with your kit, through the nostril parallel to the palate until resistance is encountered.
2. Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
3. Slowly remove swab while rotating it. The specimen is now ready for preparation using the extraction buffer tubes.
2.3 Instructions for use
The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their symptoms.

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

**Materials Provided**
- Positive control swabs
- Negative control swabs
- Extraction buffer tubes
- Test cassettes
- Specimen Collection Guide
- Nasal swabs
- Nasopharyngeal swabs

**Precautions**
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not open the foil pouch or specimen collection tube before specimen collection.
- Do not combine specimens from different individuals.
- Do not mix and match components from other test kits.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use after the expiration date.
- **Materials**
  - Product code L031-129S Nasal
  - Product code L031-129S Nasopharyngeal
- **Test Cassette**
  - L031-129S Nasal
  - L031-129S Nasopharyngeal

**Preparation of Specimen**
1. **Sampling**
   - Nasal swabs: Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times and allow to air-dry for 2 minutes.
   - Nasopharyngeal swabs: Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

2. **Extraction**
   - a. Unscrew the small cap from the dropper tip.
   - b. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   - c. Gently squeeze the tube, dispensing 4 drops of the extracted specimen into the sample well.

3. **Interpretation of Results**
   - **Negative**: The test result is negative. The specimen is not SARS-CoV-2 positive.
   - **Positive**: The test result is positive. The specimen is SARS-CoV-2 positive.
   - **Invalid**: The test result is invalid. The procedure was not performed correctly or the test was used after the expiration date.

**Storage and Stability**
The kit is stable until the expiration date printed on the sealed pouch.

The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample is processed.

The test line for a low viral load sample may become visible within 30 minutes.

**Special Conditions for Use**
- The test cassette should be kept at room temperature (15-30°C) and protected from light.
- Do not store the test kit at temperatures below 2°C or above 30°C.
- The expiration date must be observed.

**Interpretation of Results**
- Negative: The test result is negative. The specimen is not SARS-CoV-2 positive.
- Positive: The test result is positive. The specimen is SARS-CoV-2 positive.
- Invalid: The test result is invalid. The procedure was not performed correctly or the test was used after the expiration date.

**Limitations**
- The SARS-CoV-2 Antigen Rapid Test is not in vitro diagnostic use only.
- The test should not be used for the detection of antibodies to SARS-CoV-2 in patient specimens.
- The test does not rule out other viral or bacterial infections.
- The test is not designed to be used as a screening test for the asymptomatic carrier state or as a method to guide the patient's public health and decisions, including infection control decisions.

**Clinical Sensitivity, Specificity and Accuracy**
- The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from patients who were suspected of COVID-19 and whose samples were confirmed to be positive for SARS-CoV-2 by real-time reverse transcription polymerase chain reaction (RT-qPCR).
- The results of the SARS-CoV-2 Antigen Rapid Test were compared to the results of the RT-qPCR test for the presence of SARS-CoV-2 RNA in each sample.
- The test was found to be 98.5% sensitive and 100% specific for the detection of SARS-CoV-2 in patient specimens.
- The test was found to be 99.5% sensitive and 100% specific for the detection of SARS-CoV-2 in patient specimens.
- The test was found to be 99.5% sensitive and 100% specific for the detection of SARS-CoV-2 in patient specimens.

**Performance Characteristics**
- **Sensitivity**: The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The test showed a sensitivity of 97.9%.
- **Specificity**: The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The test showed a specificity of 100%.
- **Positive Predictive Value**: The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The test showed a positive predictive value of 99.5%.
- **Negative Predictive Value**: The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who were suspected of COVID-19. The test showed a negative predictive value of 99.5%.
Clinical Performance for SARS-CoV-2 Antigen Rapid Test

<table>
<thead>
<tr>
<th>Method</th>
<th>SARS-CoV-2 Antigen Rapid Test</th>
<th>RT-PCR</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>RT-PCR</td>
<td>434</td>
<td>5</td>
<td>439</td>
</tr>
<tr>
<td>Total Results</td>
<td>434</td>
<td>5</td>
<td>439</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 97.1% (93.1%-98.9%)*
Relative Specificity: 99.5% (98.3%-99.9%)*
Accuracy: 98.6% (97.9%-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 has a higher positive percent agreement of PPA of 98% (n=161). The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100%, which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100%, which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

### 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 ornasopharynx, were evaluated. Each organism and virus were tested in the absence or presence of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Active Ingredient</th>
<th>Concentration</th>
<th>Results (in the presence of SARS-CoV-2 virus)</th>
<th>Results (in the presence of SARS-CoV-2 virus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endogenous</td>
<td>Moine</td>
<td>2.4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Ahn Original Nasal Spray</td>
<td>Oxydrolazine</td>
<td>1%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>ALKALOS Allergy Relief Nasal Spray</td>
<td>Homeopathic</td>
<td>1:10 Dilution</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Chloroquine Sulfate Nasal Spray</td>
<td>Menthol, Benzocaine</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>OVS Health Fractose Prophylate Nasal Spray</td>
<td>Fludronicotine</td>
<td>5%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Equate Fast Acting Nasal Spray</td>
<td>Phospholipids</td>
<td>15%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Squo Super Threat Phosph Oral Anesthetic Spray</td>
<td>Phospholipids</td>
<td>15%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Original Extra Strong Methyl Cough Lozenges</td>
<td>Menthol</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>NasalCrom Nasal Spray</td>
<td>Cymolyn</td>
<td>15%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>NezMed NasoCet for Dry Noises</td>
<td>Sodium Hyalurionate</td>
<td>5%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Throat Lozenge</td>
<td>Dystromine Hydro/Noridate</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Zicam Cold Remedy</td>
<td>Galbrian Glaucor Hydrorat</td>
<td>5%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>Mupirocin</td>
<td>10 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Tamiiflu</td>
<td>Oseltamivir Phosphate</td>
<td>5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>Tobramycin</td>
<td>4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Neosporin Nasal Spray</td>
<td>Mimosalone Furoxone</td>
<td>5%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Physiological Saline Water Nasal Cleaner</td>
<td>NaCl</td>
<td>15%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
</tbody>
</table>
The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleoprotein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by the healthcare provider within the first seven days of the onset of symptoms.

The SARS-CoV-2 Antigen Rapid Test is visually read, visually intended for use by trained clinical laboratory personnel and individuals in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.
The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleoprotein antigen. This antigen is generally detected in up to 90% of exam samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to confirm a positive status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results, from patients with symptoms beyond seven days, should be treated as presumptive information is necessary to determine infection status. Positive results do not rule out bacterial infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

**SUMMARY**
The novel coronaviruses belong to the β genus. SARS-CoV-1 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 of COVID-19 is about 2–7 days. Main symptoms include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few patients.

**PRINCIPLE**
The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleoprotein antigen from SARS-CoV-2 in human nasal and nasopharyngeal swab specimens. When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antibodies bound to the test strip will form a colored line antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines.

To serve as a procedure control, a colored line will always appear in the control line region indicating on the presence or absence of visually colored line. This means that the presence of SARS-CoV-2 antigen was detected.

**RAGARAGE**
The test cassette contains anti-SARS-CoV-2 antibodies. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

**PRECAUTIONS**
- For professional in vitro diagnostic use only. The test should not be used after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the package is damaged.
- Do not mix and match components from other test kits.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of positive specimens. Carefully dispose of all used test kits.

Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.

- Do not open the product to clinical laboratories, and then use the product as per the instructions provided.
- Precautions include:
  - Do not use excessive force to open the tube.
  - Do not use excessive force to open the test cassette.
- Expiration of the kit: The test cassette has an expiration date of 24 months after manufacture. The test cassette must be used before the expiration date.

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

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Hold the extraction buffer bottle upside down vertically, then add approximately 300 μL (10-12 drops) of extraction buffer to the extraction tube.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Attach the dropper tip firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Label the test cassette with the patient identification number. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
   a. Invert the extraction buffer tube with the dropper tip downwards and hold it vertically.
   b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
   c. Set the timer for 15 minutes and rotate at least 5 times while squeezing the tube.
9. 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 result should be read at 15-30 minutes.
10. Do not read the result after 30 minutes.

**INTERPRETATION OF RESULTS**

- Negative: Only one colored control line appears in the control region (C). No apparent colored line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected.
- Positive: Two distinct colored lines appear. One line in the control region (C) and the other in the test region (T). SARS-CoV-2 positive result can be considered positive.

**SPECIMEN COLLECTION AND PROCESSING**
The SARS-CoV-2 Antigen Rapid Test can be performed using nasopharyngeal and nasopharyngeal swab specimens.

- **Negative Control Swab**: Use the Negative Control Swab to confirm that the extraction buffer and test cassette are functioning appropriately.

**SPECIMEN MATERIALS**
- **Materials Provided**: L031-129T5, L031-129WS
- **Materials Required But Not Provided**: Nasal swabs, dropper, timer, and test kit instruction sheet.

**MATERIALS**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>L031-129T5</th>
<th>L031-129WS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Cassette</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive control strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative control strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraction Tubes</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Extraction Buffer</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Package Contents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Swab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Control Swab</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PERFORMANCE CHARACTERISTICS**
The performance of SARS-CoV-2 Antigen Rapid Test was evaluated with 605 nasal swab collected from individual patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

- **Sensitivity**: 98.7%
- **Specificity**: 99.2%

**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 sufficient specimen volume and correct procedural technique.

Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "DIRECTIONS FOR USE" section to perform the control test.

The control swab(s) can be used under any of the following circumstances:
- When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
- At periodic intervals as dictated by local requirements, and/or by the user’s Quality Control procedures.

**LIMITATIONS**
1. The SARS-CoV-2 Antigen Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal and nasopharyngeal swab specimens only. The test result of the test line does not necessarily correlate to SARS-CoV-2 viral load in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test.
5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. The test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A positive result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
10. The performance has been evaluated on diminished sensitivity with SARS-CoV-2 Variants of Concern, such as Alpha, Beta, Gamma, Delta, Omicron. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and the subsequent change over time.

The performance of SARS-CoV-2 Antigen Rapid Test was extracted with 605 nasal swabs collected from individual patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:
Differentiate between SARS-CoV-2 and other respiratory pathogens.

- Presence of heat stability: likely to be present in the nasal cavity.
- Cross-reactivity: less likely to react with other respiratory pathogens.

The viral sample was inactivated by the addition of 10% DMSO and 1% sodium deoxycholate and stored at -70°C.

The LOD of SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

### 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 when tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level:

- 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 influenzae
- Legionella pneumophila
- Mycobacterium tuberculosis
- Neisseria gonorrhoeae
- Pneumococcus pyogenes
- Streptococcus pneumoniae
- Staphylococcus aureus
- Staphylococcus epidermidis

### Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the presence of SARS-CoV-2 virus at positive level. The final concentration of the substances tested are listed below and were found not to affect test performance.

- Endogenous:
  - Biotin: 2.4 µg/mL
  - Myoglobin: 0.5 µg/mL
  - Whole Blood: 4% v/v

- Anti-Original Nasal Spray:
  - Oermazoline: 15% w/v

- ALKALOIC Allergy Relief Nasal Spray:
  - Homeopathic: 1:10 Dilution

- Chlamydia pneumoniae
- Mycoplasma pneumoniae
- Pseudomonas aeruginosa
- Chlamydia pneumoniae
- Pseudomonas aeruginosa
- Chlamydia pneumoniae
- Pseudomonas aeruginosa
- Yeast: Candida albicans

- Yeast: 1.57 x 10^6 CFU/mL
- Poole Human nasal wash

### Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was found to be 1.6 x 10^1 TCID50/mL.

### Clinical Performance

- **Accuracy:**
  - Sensitivity: 98.9% (95% CI: 98.0-99.8)
  - Specificity: 98.5% (95% CI: 98.0-99.0)

- **Relative Sensitivity:** 97.1% (93.1%-98.9%)

- **Relative Specificity:** 99.9% (98.2%-99.9%)

- **Accuracy:** 98.9% (95.9%-95.0%)

- **95% Confidence Intervals**

The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimen from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100% which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

### Index of Contents

- **SARS-CoV-2 Antigen**:
  - Positive Control Swab
  - Negative Control Swab
  - Extraction Tubes
  - Extraction Buffer
  - Disposable Swabs
  - Nasal Swabs

- **Nasopharyngeal Swabs**
  - Nasopharyngeal Swabs

- **SARS-CoV-2 Antigen Rapid Test**:
  - Negative Control Swab
  - Positive Control Swab
  - Extraction Tubes
  - Extraction Buffer
  - Disposable Swabs

- **Interfering Substances**

- **Interfering Test**

- **Interfering Ingredient**

- **Interfering Concentration**

- **Interfering Results**

- **Interfering Conclusion**

- **Interfering Notes**

---

**BIBLIOGRAPHY**


The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane-based chromatographic immunosay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal and nasopharyngeal swab specimens. When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by the control line of antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of a visible line. Test results should be correlated with other clinical data available to the physician. A negative result does not preclude other viral or bacterial infections. A positive test result does not rule out co-infections with other pathogens.

**Sensitivity and Specificity**

A false-negative test result may result if the level of antigen in a sample is below the detection limit of the test and the specimen was processed and added to the test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**Limitations**

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control swabs are not supplied with this kit; however, it is recommended that positive and negative controls should be tested as a good laboratory practice to ensure that the test cassette and that the test procedure performed correctly.

**Performance Characteristics**

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

<table>
<thead>
<tr>
<th>Method</th>
<th>Results</th>
<th>RT-PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Antigen Rapid Test</td>
<td>Negative</td>
<td>433</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>435</td>
</tr>
<tr>
<td>Total Results</td>
<td></td>
<td>868</td>
</tr>
</tbody>
</table>

**Clinical Performance for SARS-CoV-2 Antigen Rapid Test**
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 and nasopharyngeal sample pools into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.0 x 10^2 TCID50.

### 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 levels. No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

### Potential Cross-Reactant

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Test Concentration</th>
<th>Cross-Reactivity (in the absence of SARS-CoV-2 virus)</th>
<th>Interference (in the presence of SARS-CoV-2 virus)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>1.14 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Enterovirus</td>
<td>3.50 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Human coronavirus 229E</td>
<td>1.94 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>2.63 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>1.0 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Human Metapneumovirus</td>
<td>1.25 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>MERs-coronavirus</td>
<td>7.90 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Influenza A</td>
<td>1.04 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Influenza B</td>
<td>1.04 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Parainfluenza virus 1</td>
<td>1.25 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Parainfluenza virus 2</td>
<td>3.78 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Parainfluenza virus 3</td>
<td>1.0 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Parainfluenza virus 4</td>
<td>2.88 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>3.15 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>3.15 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Human coronaviruses HKU1</td>
<td>1 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>2.83 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>3.13 x 10^5 TCID50/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>1.36 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>4.08 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>1.72 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Mycoplasma pneumoniae</td>
<td>7.90 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1.38 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>2.32 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>No (3/3 negative)</td>
</tr>
</tbody>
</table>

### Interfering Substances

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Active Ingredient</th>
<th>Concentration</th>
<th>Results (in the absence of SARS-CoV-2 virus)</th>
<th>Results (in the presence of SARS-CoV-2 virus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endogenous</td>
<td>Bovine</td>
<td>2.4 mg/mL</td>
<td>3/3 positive</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Mucin</td>
<td>0.5% w/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Whole Blood</td>
<td>4% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Afn Original Nasal Spray</td>
<td>Oxymetazoline</td>
<td>15% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>ALKALOS Allergy Relief Nasal Spray</td>
<td>Homeopathic</td>
<td>1/10 Dilution</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Chlorosalic Muc Soft Throat Lozenges</td>
<td>Menthol, Benzocaine</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>CVS Health Fluticasone Propionate Nasal Spray</td>
<td>Fluticasone propionate</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Equate Fluticasone Nasal Spray</td>
<td>Phenylephrine</td>
<td>15% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Equate Soft Thrush Oral Anesthetic Spray</td>
<td>Phenol</td>
<td>15% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Original Extra Strong Menthol Cough Lozenges</td>
<td>Menthol</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>NasalCrom Nasal Spray</td>
<td>Cresol</td>
<td>15% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>NexMed Nasal Gel for Dry Noses</td>
<td>Sodium Hyaluronate</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Throat Lozenges</td>
<td>Methyl Hydroxiborane</td>
<td>1.5mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Zicam Cold Remedy</td>
<td>Diflunisal, Luffa ochracea, Sabadilla</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>Mupirocin</td>
<td>10 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Tamsulosin</td>
<td>5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Pharmaceutical Saline Nasal Cleaner</td>
<td>Chlorhexidine</td>
<td>0.1% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
</tbody>
</table>

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The final concentration of the substances tested are listed below and not affect test performance.

### Precision

**Intra-Assay**

Within-run precision was determined using 60 replicates of specimens: negative specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision was determined using 60 independent assays on the same specimen: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.

### Bibliography


### Index of Contents

- SARS-CoV-2 Antigen
- Extraction Buffer Tubes
- Disposables Swabs
- Nasopharyngeal Swabs
- SARS-CoV-2 Antigen Rapid Test

ACON Biotech (Hangzhou) Co., Ltd., No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030

**ACON**

Medical EC REP GmbH
Borkhannstrasse 10
48163 Muenster, Germany

**BIBLIOGRAPHY**


**Index of Symbols**

- Manufacturer
- Ingredients
- Use-by date
- Batch code
- Authorized representative in the European community
- Date of manufacture

**Index of Contents**

- SARS-CoV-2 Antigen
- Extraction Buffer Tubes
- Disposable Swabs
- Nasopharyngeal Swabs
- SARS-CoV-2 Antigen Rapid Test