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.


Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the product under EUL, for which WHO has been notified and has undertaken a review. Amendments to the report are summarized 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>
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<tbody>
<tr>
<td>2.0</td>
<td>1. Added new supplier of a swab from Jiangsu HanHeng Medical Technology Co., Ltd. and Goodwood Medical Care Ltd.</td>
<td>17 November 2022</td>
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<td></td>
<td>2. Added a new format of extraction buffer tube with aluminium foil sealed, resulting in 4 new product codes for new kit configuration with the prefilled buffer tube.</td>
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<td>3. Changed the intended population to include asymptomatic individuals.</td>
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<td>4. Labelling update for the above changes.</td>
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**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 can also test specimens from asymptomatic individuals. 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 types 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:

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<tr>
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<tr>
<td>Extraction buffer tubes</td>
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<td>Prefilled extraction buffer with aluminium foil</td>
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<td>Specimen collection guide</td>
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</table>
Items required but not provided:

- Personal Protective Equipment
- Permanent marker pen and Timer

Storage:
The test kit must 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 the 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 an 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.
3. Submit the final validation study report for the real-time stability of the proposed extraction buffer with an aluminium foil seal. Please submit this information as part of the EUL renewal application.

The risk-benefit assessment 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 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 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

1 https://www.who.int/publications/i/item/9789240015319
The ARS-CoV-2 Antigen Rapid Test (Flowflex) with product codes L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5, L031-129Y5, L031-129K5, L031-129M5, L031-129L5, and L031-129N5 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.
Labelling

1. Labels

2. Instructions for use
1.1.1 Kit box for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5 and L031-129M5
25 Tests (T)/Kit (product code L031-129R5) labels

1.1.2 Kit box label

![Kit box label]


SARS-COV-2 ANTIGEN RAPID TEST

| LOT | XXXXXXXX | YYYY-MM-DD | YYYY-MM-DD |
1.1.5 Extraction buffer tube bag label L031-129R5, L031-129V5, L031-129U5, L031-
129Y5, L031-129K5, L031-129M5, L031-129L5, L031-129N5

1.1.6 Positive control swab label for product codes L031-129R5, L031-129V5, L031-129T5,
L031-129W5, L031-129K5, L031-129M5

1.1.7 Negative control swab label for product codes L031-129R5, L031-129V5, L031-
129T5, L031-129W5, L031-129K5, L031-129M5

1.1.8 Nasal swab pouch label L031-129R5, L031-129T5, L031-129U5, L031-129K5 and
L031-129L5
1.2 Kit box label (product code L031-129K5)

SARS-CoV-2 Antigen Rapid Test
REF L031-129K5
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
- Specimen Collection Guide
- 1 Negative Control Swab
- Package Insert
- 25 Disposable Swabs (Nasal swabs)

LOT XXXXXX YYYYY-MM-DD LCA10566-01

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road
West Lake District
Hangzhou, P.R.China, 310030
Made in China
Executive Directive: IVDD 98/79/EC

Barcode area (EAN-13)
6921756494445

1.3 25 T/Kit(product code L031-129V5) labels

1.3.1 Kit box label
1.3.2 Nasopharyngeal swab label for product codes L031-129V5, L031-129W5, L031-129Y5, L031-129M5 and L031-129N5
1.4 Kit box label (product code L031-129M5)

SARS-CoV-2 Antigen Rapid Test

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
1 Positive Control Swab
1 Negative Control Swab
25 Disposable Swabs (Nasopharyngeal swabs)

LOT XXXXXXX YYY-MM-DD

1.5 Kit box label (product code L031-129T5)

SARS-CoV-2 Antigen Rapid Test

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
1 Positive Control Swab
Package Insert
2 Extraction Buffer
25 Disposable Swabs (Nasal swabs)

LOT XXXXXXX YYY-MM-DD
1.5.1 Extraction buffer label for product codes L031-129T5 and L031-129W5

1.6 Kit box label (product code L031-129W5)
1.7 5 T/kit (product code L031-129U5, L031-129L5) kit box
1.8 5 T/kit (product code L031-129Y5, L031-129N5) kit box
3.0 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.
3.1 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.
3.2 Nasopharyngeal swab specimen collection guide
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.
3.3 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 specimen swabs from asymptomatic individuals.

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

For professional in vitro diagnostic use only.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use 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 pouch is damaged.
- Do not mix batch 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 specimens and waste materials.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- Do not use after the expiration date.

MATERIALS

- Test Cassette
- Extraction Buffer Tube
- Control Swabs
- Negative Control Swab
- Specimen Collection Guide
- Specimen Collection Cassette
- Disposable Swab
- Permanent marker pen and Timer

DIRECTIONS FOR USE

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 intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer 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 or if the sample was collected incorrectly.
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. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2. A negative test result is not other viral pathogens.
8. A negative result, from a patient with symptom onset beyond seven days, should be treated as provisional and additional testing with molecular diagnostic tests may be necessary, for clinical management.
9. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), 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. Performance characteristics are as follows:

**Clinical Sensitivity, Specificity and Accuracy**

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:

**PERFORMANCE CHARACTERISTICS**

- **Relative Sensitivity**: 69.1%
- **Relative Specificity**: 99.2%

**INTERPRETATION OF RESULTS**

NEGATIVE: Only one colored control line appears in the control line region (C). No apparent colored line appears in the test line region (T).

POSITIVE: Two distinct colored lines appear in the test line region (T) and the other in the control line region (C). This means that the presence of SARS-CoV-2 antigen was detected.

* * *

NOTE: The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most common reasons for this outcome. Review the procedure, and correct the test kit as described in the Specimen Collection Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 swabs can be tested under any of the following circumstances:

1. When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. At periodic intervals as dictated by local requirements, and/or by the user’s Quality Control procedures.

EVICTION CRITERIA

The SARS-CoV-2 Antigen Rapid Test is 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 intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer 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 or if the sample was collected incorrectly.
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. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not other viral pathogens.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as provisional and additional testing with molecular diagnostic tests may be necessary, for clinical management.
10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), 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. Performance characteristics are as follows:

**PERFORMANCE CHARACTERISTICS**

- **Clinical Sensitivity, Specificity and Accuracy**

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:
Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method RT-PCR Total Results

SARS-CoV-2 Antigen Test Negative Positive Total

Results 433 5 438

Negative 433 170 603

Positive 165 5 170

Total Results

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

Accuracy: 98.8% (97.1%-99.9%)∗

∗95% Confidence intervals

Stratification of the positive samples at onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.9% (n=81) and 4-7 days has a PPA of 96.8% (n=62).

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

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was determined using limiting dilutions of a inactivated viral sample. The viral sample was spiked with negative human nasal and nasopharyngeal sample pool into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.6*10 1 TCID50/mL.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level.

No cross-reactivity or interference was observed with the following microorganisms 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.

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).

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 were found not to affect test performance.

Interfering Substances

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).

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 were found not to affect test performance.
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 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 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 for the SARS-CoV-2 nucleoprotein antigen test will not be 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 bacteriologic infection or coinfection 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 correlation with the patient history and clinical management decisions, including infection control decisions. Negative results should be considered in the context of patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The novel coronavirus belongs to the β genus SARS-CoV-2 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection to others. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days.

The main manifestations are 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 qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleoprotein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. 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 swab. Then the antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of anti-SARS-CoV-2 antibody-coated particles. If the specimen contains SARS-CoV-2 antigens, the test line will appear. A negative test result should be considered in the context of patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

**REAGENTS**

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. Do not use 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 pouch 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 specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be discarded potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

**MATERIALS Required But Not Provided**

- Personal Protective Equipment
- Permanent marker pen and Timer

**MATERIALS Provided**

- Extraction Buffer
- Specimen Collection Guide
- Control Swab 1
- Positive Control Swab 1
- Disposable Swab

**INTERPRETATION OF RESULTS**

(Please refer to the Illustration above)

NEGATIVE: Only one colored 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 antigens were detected. **POSITIVE:** Two distinct colored lines appear in both the control region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected.

**NOTE:** The intensity of the control line may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discuss it immediately and contact your local distributor.

**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 swabs can be tested under any of the following circumstances:

1. When a new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. 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 a qualitative diagnostic test. The test should be used for the detection of SARS-CoV-2 antigens in nasal and nasopharyngeal swab specimens only. The intensity 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 result may be obtained in a sample below the detection limit of the test or if the sample was collected incorrectly.
5. 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. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not proof that the level of antigen in a sample is below the detection limit of the test.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and correlation with the patient history and other clinical data is necessary.
10. The performance has been evaluated under rigorous conditions, i.e., optimal temperature, relative humidity, and other conditions that are necessary for clinical management.

**PERFORMANCE CHARACTERISTICS**

**Clinical Sensitivity, Specificity and Accuracy**

The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swab samples collected from individual patients who were suspected of COVID-19. The results show that the sensitivity and the relative specificity are as follows:
<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></td>
<td></td>
<td>(in the absence of SARS-CoV-2 virus)</td>
<td>(in the presence of SARS-CoV-2 virus)</td>
</tr>
<tr>
<td>Biotin</td>
<td>2.4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Mucin</td>
<td>0.5% w/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Whole Blood</td>
<td>4% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Nasal Cremor nasal spray</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Nasal Cremor nasal spray</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Zicam cold remedy</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Antibiotic</td>
<td>10 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Antibiotic</td>
<td>5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Antibiotic</td>
<td>4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Mometasone Furoate nasal spray</td>
<td>5 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td></td>
</tr>
<tr>
<td>Physical nasal saline nasal cleaner</td>
<td>NaCl</td>
<td>15% v/v</td>
<td>3/3 positive</td>
<td></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 were found not to affect test performance.

**Interfering Substances**

- **Endogenous**
  - Biotin: 2.4 mg/mL, 3/3 negative, 3/3 positive
  - Mucin: 0.5% w/v, 3/3 negative, 3/3 positive
  - Whole Blood: 4% v/v, 3/3 negative, 3/3 positive
- **Nasal Cremor nasal spray**
  - 1.5 mg/mL, 3/3 negative, 3/3 positive
- **Zicam cold remedy**
  - 1.5 mg/mL, 3/3 negative, 3/3 positive
- **Antibiotic**
  - 10 mg/mL, 3/3 negative, 3/3 positive
  - 5 mg/mL, 3/3 negative, 3/3 positive
  - 4 mg/mL, 3/3 negative, 3/3 positive
- **Mometasone Furoate nasal spray**
  - 5 mg/mL, 3/3 negative, 3/3 positive
- **Physical nasal saline nasal cleaner**
  - NaCl: 15% v/v, 3/3 positive

**Bacteria**

- **Staphylococcus aureus**: 1.38 x 10^8 CFU/mL, No (3/3 negative), No (3/3 positive)
- **Staphylococcus epidermidis**: 2.32 x 10^9 CFU/mL, No (3/3 negative), No (3/3 positive)
- **Streptococcus pneumoniae**: 1.04 x 10^9 CFU/mL, No (3/3 negative), No (3/3 positive)

**Clinical Performance for SARS-CoV-2 Antigen Rapid Test**

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value (PPV)</th>
<th>Negative Predictive Value (NPV)</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RT-PCR</td>
<td>98.8%</td>
<td>99.5%</td>
<td>99.5%</td>
<td>96.8%</td>
<td>99%</td>
</tr>
<tr>
<td>Rapid Test</td>
<td>98.8%</td>
<td>97.6%</td>
<td>97.6%</td>
<td>99.5%</td>
<td>96.8%</td>
</tr>
</tbody>
</table>

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 liquid into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.6 x 10^2 TCID50/mL.

**Cross-Reactivity (Analytical Specificity) and Microbial Interference**

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level. No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV-2 and SARS-CoV-1.
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 from individuals who are suspected to be infected with SARS-CoV-2 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individuals.

STORAGE AND STABILITY

STORAGE

-30°C to 4°C

STABILITY

The test is stable until the expiration date printed on the sealed pouch.

DO NOT FREEZE.

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 indicates that no SARS-CoV-2 antigen was detected.

POSITIVE: Two distinct colored lines appear. One line in the control line region (C) and the other in the test line region (T). This indicates that SARS-CoV-2 antigen was detected.

*NOTE: The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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. Test 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.

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 intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer 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 result 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.

5. Test results should be interpreted in the context of other clinical data available to the physician.

6. A positive test result does not rule out co-infections with other pathogens.

7. A positive test result does not differentiate between SARS-CoV-2 and SARS-CoV-1.

8. A negative test result is not intended to rule out other viral or bacterial infections.

9. A negative result, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for diagnostic purposes.

10. The performance has been evaluated in a limited number of cases and may vary according to different viral load levels, specimen types and storage conditions. The results show that the relative sensitivity and the relative specificity are as follows:

**Clinical Performance for SARS-CoV-2 Antigen Rapid Test**

<table>
<thead>
<tr>
<th>Method</th>
<th>Positive</th>
<th>Negative</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Antigen Rapid Test</td>
<td>2</td>
<td>165</td>
<td>167</td>
</tr>
<tr>
<td></td>
<td>435</td>
<td>70</td>
<td>505</td>
</tr>
<tr>
<td><strong>Total Results</strong></td>
<td>437</td>
<td>175</td>
<td>612</td>
</tr>
</tbody>
</table>

The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individuals who had no evidence of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:
Interfering Substances

<table>
<thead>
<tr>
<th>Potential Cross-Reagent</th>
<th>Test Concentration</th>
<th>Cross-Reactivity (in the absence of SARS-CoV-2 virus)</th>
<th>Interference (in the presence of heat-inactivated SARS-CoV-2 virus)</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>Adenovirus</td>
<td>1.14 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Bodin</td>
<td>2.4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Enterovirus</td>
<td>9.50 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Whole Blood</td>
<td>4% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Human coronavirus 229E</td>
<td>1.04 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>ALKALOL Allergy Relief</td>
<td>0.15%</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>2.85 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Propionate Nasal Spray</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>1.0 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Biotin</td>
<td>2.4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Human Metapneumovirus</td>
<td>1.25 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Mucin</td>
<td>0.5% w/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>MERS-coronavirus</td>
<td>7.50 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>0.5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Influenza A</td>
<td>1.04 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Influenza B</td>
<td>1.04 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Parainfluenza virus 1</td>
<td>1.25 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Parainfluenza virus 2</td>
<td>3.78 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Parainfluenza virus 3</td>
<td>1.0 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Parainfluenza virus 4</td>
<td>2.88 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>3.15 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Rhinovirus</td>
<td>3.15 x 10^5 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Human coronavirus- HKU1</td>
<td>1.10 x 10^5 copies/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>2.83 x 10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>3.13 x 10^6 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Haemophilus influenza</td>
<td>1.36 x 10^6 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>4.06 x 10^8 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>1.72 x 10^8 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Mycoplasma pneumoniaiae</td>
<td>7.90 x 10^8 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1.38 x 10^9 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>2.32 x 10^9 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>1.04 x 10^9 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Nasopharyngeal Swabs</td>
<td>5% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
</tbody>
</table>

**Interference**

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

Between-run precision was determined using 60 independent assays on the same specimen: negative and SARS-CoV-2 antigen positive samples. 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**


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

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

**Disposables**

Jiangsu Changfeng Medical Industry Co., Ltd. No.210 Zhenzhong Road, West Lake District Hangzhou, P.R. China, 310030

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**CMC Medical Devices & Drugs S.L.**

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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test Name</th>
<th>Code</th>
<th>Batch code</th>
<th>Use-by date</th>
<th>Index of Symbols</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SARS-CoV-2 Antigen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extraction Buffer Tubes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disposable Swabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nasal Swabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Nasopharyngeal Swabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SARS-CoV-2 Antigen Rapid Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Effective Date:** 2022-08-17

**Number:** 1151368082
The 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 of this test may only be used for the qualitative detection of SARS-CoV-nucleocapsid protein antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of SARS-CoV nucleocapsid protein antigen in 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 definitive cause of disease.

Negative results, from patients with symptom beyond seven days, should be treated as presumptive and not be interpreted as a molecular assay, if necessary, for 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 coronavirus belongs to the β genus. 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, and can contaminate 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 of clinical symptoms are fever and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

MATERIALS

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.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the strip. The test cassette is stable at temperatures between 2 - 30 °C. The test is stable until the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do NOT FREEZE. Do not use after the expiration date.

The kit can be stored at temperatures between 2 - 30 °C. The test is stable until the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do NOT FREEZE. Do not use after the expiration date.

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

4 drops of the processed specimen

15-30 min. Negative Positive Invalid

INTERPRETATION OF RESULTS

(See the Illustration above)

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 line region (C) and the other line in the test line region (T). This means that SARS-CoV-2 Antigen was detected. ** Note: The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for this result. Check that all the reagents are present in the kit and that the correct sample has been tested with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 swabs can be tested under any of the following circumstances:

1. When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. At periodic intervals as dictated by local requirements, and/or by the user’s Quality Control procedures.

LIMITATIONS

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 positive test result may not necessarily correlate to SARS-CoV-2 viral load in the specimen.

Specimen should be tested as quickly as possible after specimen collection and at most within the hour following collection.

Use of viral transport media may result in decreased test sensitivity.

A false-negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.

Test results should be correlated with other clinical data available to the physician.

A positive test result does not correlate co-infections with other pathogens.

A negative test result is not intended to rule out other viral or bacterial infections.

A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and not be interpreted as a molecular assay, if necessary, for clinical management.

The performance of SARS-CoV-2 Antigen Rapid Test was validated 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:

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of SARS-CoV-2 Antigen Rapid Test was validated 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:

1. Clinical Sensitivity: 96.0%
2. Specificity: 99.5%
Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method  | RT-PCR  | Total Results
--- | --- | ---
SARS-CoV-2 Antigen Rapid Test  | 435  | 170  | 605

Relative Sensitivity: 97.1% (93.1%-98.9%)*
Relative Specificity: 99.5% (98.2%-99.9%)*
Accuracy: 98.8% (97.6%-99.9%)*
*95% Confidence Intervals

Staphylococcus epidermidis 2.32 x 10^9 CFU/mL No (3/3 negative) No (3/3 positive)
Streptococcus pneumoniae 1.04 x 10^6 CFU/mL No (3/3 negative) No (3/3 positive)
Pneumocystis jirovecii, carinii 8.63 x 10^5 CFU/mL No (3/3 negative) No (3/3 positive)
Pneumocystis aerogenes 1.87 x 10^9 CFU/mL No (3/3 negative) No (3/3 positive)
Chlamydia pneumoniae 1 x 10^10 CFU/mL No (3/3 negative) No (3/3 positive)
Yeast Candida albicans 1.57 x 10^9 CFU/mL No (3/3 negative) No (3/3 positive)
Posot human nasal wash No (3/3 negative) No (3/3 positive)

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 absence or presence of SARS-CoV-2 virus at low positive levels.

<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>Biolin 2.4 mg/mL</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Mucin 0.5% w/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Whole Blood 4% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Afin Original Nasal Spray</td>
<td>15% v/v</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>AINACLIN Allergy Relief Nasal Spray</td>
<td>1.10% Dilution</td>
<td>3/3 negative</td>
<td>3/3 positive</td>
</tr>
<tr>
<td></td>
<td>Chloraseptic Max Sore Throat Lozenges</td>
<td>Menthol, Benzocaine, Propriionate</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Equate Fast Acting Nasal Spray</td>
<td>Phenylephrine</td>
<td>15% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Equate Sore Throat Phenol Oral Anesthetic Spray</td>
<td>Phenol</td>
<td>15% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Original Extra Strong Menthol Cough Lozenges</td>
<td>Menthol</td>
<td>1.5 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>NasalCrom Nasal Spray</td>
<td>Cremophor</td>
<td>15% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>NasalCrom Nasal Spray</td>
<td>Sodium Hyaluronate</td>
<td>5% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>NasalCrom Nasal Spray</td>
<td>Dyclonine Hydrochlordroprazine</td>
<td>1.5mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Zicam Cold Remedy</td>
<td>Dapoxetine, Luffa operculum, Sabadilla</td>
<td>5% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Mupirocin</td>
<td>10 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Tarmifl</td>
<td>Gatifloxacin</td>
<td>5 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Tobramycin</td>
<td>4 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Mentocortifume Nasal Spray</td>
<td>Mometasone Furoate</td>
<td>5% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td></td>
<td>Physiological Saline Nasal Cleaner</td>
<td>NaCl</td>
<td>15% v/v</td>
<td>3/3 negative</td>
</tr>
</tbody>
</table>

In vitro conditions

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 50 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 used testing these specimens. The specimens were correctly identified >99% of the time.
The SARS-CoV-2 Rapid Antigen Test is a lateral flow chromatographic immunosassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens. For professional in vitro diagnostic use only.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test uses a membrane based chromatographic immunosassay 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 conjugated to colloidal gold particles, which have been pre-coated on the test line strip. The reaction causes the gold particles to aggregate and form a visible line(s). A positive result is indicated by the appearance of a line(s) in the test line region (T). 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 visible 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.

The test cassette contains anti-SARS-CoV-2 antibodies.

PRECAUTIONS

• For professional in vitro diagnostic use only.
• Do not use 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 pouch 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 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 handle the test kit beyond the instructions on the label.
• Humidity and temperature can adversely affect results.

This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

The kit can be stored at temperatures between 2 - 30 °C.

STORAGE AND STABILITY

The test is stable until the expiration date printed on the sealed pouch.

Materials Provided

• Test Cassettes
• Disposable Swabs
• Extraction Buffer Tubes
• Specimen Collection Guide

The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit package you ordered.

MATERIALS Required But Not Provided

• Personal Protective Equipment
• Parmelan marker pen and Timer
• Positive Control Swab
• Negative Control Swab

SPECIMEN COLLECTION AND PREPARATION

• The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
• The test should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
• Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

DIRECTIONS FOR USE

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

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Remove the aluminum foil from the top of extraction buffer tube.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times to suspend the specimen. Then squeeze the sides of the tube. Take care to avoid splash outs coming 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 the mixture on the surface 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 pointing downwards and hold it vertically.

b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.

9. Set the timer for 15 minutes and wait for the colored line(s) to appear. The result should be read at 15-30 minutes. Do not read the result after 30 minutes.

10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), 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 their prevalence, which change over time.

PHARMACOLOGICAL ACTIONS

The performance of SARS-CoV-2 Rapid Antigen Test was established with 605 nasal swabs collected from different geographical areas. The test results show that the relative sensitivity and the relative specificity are as follows.

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. Do not use the test if the lubricant does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.

2. Remove the aluminum foil from the top of extraction buffer tube.

3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times to suspend the specimen. Then squeeze the sides of the tube. Take care to avoid splash outs coming 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 the mixture on the surface 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 pointing downwards and hold it vertically.

b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.

9. Set the timer for 15 minutes and wait for the colored line(s) to appear. The result should be read at 15-30 minutes. Do not read the result after 30 minutes.

10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), 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 their prevalence, which change over time.

Specificity

The performance of SARS-CoV-2 Rapid Antigen Test was established with 605 nasal swabs collected from different geographical areas. The test results show that the relative sensitivity and the relative specificity are as follows.

1. The SARS-CoV-2 Antigen Rapid Test is for in vitro diagnostic use only. Do not use the test if the lubricant does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.

2. Remove the aluminum foil from the top of extraction buffer tube.

3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times to suspend the specimen. Then squeeze the sides of the tube. Take care to avoid splash outs coming 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 the mixture on the surface 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 pointing downwards and hold it vertically.

b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.

9. Set the timer for 15 minutes and wait for the colored line(s) to appear. The result should be read at 15-30 minutes. Do not read the result after 30 minutes.

10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), 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 their prevalence, which change over time.

If the differentiation of specific SARS-CoV-2 virus strains and variants is needed, additional testing is required.
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 nasopharyngeal sample in a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.0 x 10^4 TCID/mL.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence of heat-inactivated SARS-CoV-2 virus at low positive level.

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-2 and SARS-CoV-1.

**Potential Cross-Reactant** | **Test Concentration** | **Cross-Reactivity (in the absence of SARS-CoV-2 virus)** | **Interference (in the presence of SARS-CoV-2 virus)**
--- | --- | --- | ---
Adenovirus | 1.1 x 10^4 TCID/mL | No (3/3 negative) | No (3/3 positive)
Enterovirus | 9.5 x 10^3 TCID/mL | No (3/3 negative) | No (3/3 positive)
Human coronavirus 229E | 1.3 x 10^4 TCID/mL | No (3/3 negative) | No (3/3 positive)
Human coronavirus OC43 | 2.6 x 10^4 TCID/mL | No (3/3 negative) | No (3/3 positive)
Human coronavirus NL63 | 1.0 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Human Metapneumovirus | 1.2 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
MERS-coronavirus | 7.9 x 10^3 TCID/mL | No (3/3 negative) | No (3/3 positive)
Influenza A | 1.0 x 10^3 TCID/mL | No (3/3 negative) | No (3/3 positive)
Influenza B | 1.0 x 10^3 TCID/mL | No (3/3 negative) | No (3/3 positive)
Parainfluenza virus 1 | 1.25 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Parainfluenza virus 2 | 3.7 x 10^6 TCID/mL | No (3/3 negative) | No (3/3 positive)
Parainfluenza virus 3 | 1.0 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Parainfluenza virus 4 | 2.8 x 10^6 TCID/mL | No (3/3 negative) | No (3/3 positive)
Respiratory syncytial virus | 3.15 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Rhinovirus | 3.1 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Human coronavirus-HKU1 | 1.0 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Bordetella pertussis | 2.8 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Chlamydia trachomatis | 3.1 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Haemophilus influenza | 1.36 x 10^5 TCID/mL | No (3/3 negative) | No (3/3 positive)
Legionella pneumophila | 4.0 x 10^1 CFU/mL | No (3/3 negative) | No (3/3 positive)
Mycobacterium tuberculosis | 1.72 x 10^7 CFU/mL | No (3/3 negative) | No (3/3 positive)
Mycoplasma pneumoniae | 7.9 x 10^7 CFU/mL | No (3/3 negative) | No (3/3 positive)
Staphylococcus aureus | 1.38 x 10^4 CFU/mL | No (3/3 negative) | No (3/3 positive)
Staphylococcus epidermidis | 2.32 x 10^6 CFU/mL | No (3/3 negative) | No (3/3 positive)
Streptococcus pneumoniae | 1.04 x 10^6 CFU/mL | No (3/3 negative) | No (3/3 positive)

**Bacteria**

**Virus**

**Interfering Substances**

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Potential interfering 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 were found not to affect test performance.

<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>Brain</td>
<td>2.4 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Mucin</td>
<td>Mucin</td>
<td>0.5% w/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Whole Blood</td>
<td></td>
<td>4% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Afni Original Nasal Spray</td>
<td>Oxymetazoline</td>
<td>15% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Oral Anesthetic Spray</td>
<td>Phenylephrine</td>
<td>15% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>NasalCrom Nasal Spray</td>
<td>Furoate</td>
<td>5% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>NasoGel for Dry Noses</td>
<td>Sodium Hyaluronate</td>
<td>5% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Mucin</td>
<td>1.5 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Phenol</td>
<td>15% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Mupirocin</td>
<td>10 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Meprobamate</td>
<td>200 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Chloralon</td>
<td>200 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Hydromorphone</td>
<td>15% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Saline</td>
<td>0.9% w/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Phenol</td>
<td>15% v/v</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Methylcellulose</td>
<td>200 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>5 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>10 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>20 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>50 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>100 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Nasal Spray</td>
<td>Antibiotic</td>
<td>200 mg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
</tbody>
</table>

**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 >996% 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.