COVID-19 Antigen Home Test

Package Insert for Healthcare Providers

If EYE Contact:
Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep and refer to a physician or call a physician or call a Poison Control Center immediately.

For further information, please visit:
https://www.fda.gov/medical-devices/emergency-authorization/covid-19-antigen-home-test-authorization

STORAGE AND STABILITY

The On/GoOne COVID-19 Antigen Home Test is performed using anterior nasal swab specimens.

Wisht or sanitize your hands. Make sure they are dry before starting the test.

If you have symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.

If you have 48 hours between any two tests.

This product has been designed only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

To obtain accurate results, the test must be performed as indicated in these Instructions for Use. False negative test results may occur if a specimen is incorrectly collected or handled.

Test samples immediately after collection, and no more than one hour after the swab is added to the test cassette.

Do not use the test after the expiration date shown on the test cassette pouch.

Test cassette seals in its pouch until just before use. Once opened, the test cassette must be used within 1 hour.

Do not touch the swab tip when handling the swab.

Do not use swabs.

Do not use on anyone under 2 years of age.

Keep test kit and kit components away from children and pets before and after use.

An anterior nasal swab sample can be self-collected by an individual an age 14 years and older.

Children age 2 to 13 years should be tested by an adult.

Wear a safety mask or other face covering when collecting a specimen from a child or another individual.

Leave the test cassette sealed in its pouch until just before use. Once opened, the test cassette should not be resealed.

Do not use test if any of the components are damaged or missing.

Test components are single-use. Do not use with multiple specimens.

Make sure there is sufficient light when reading and interpreting test results.

Do not follow up collection with any other virus or pathogen screening procedures.

Remove any piercing from the nose before starting the test. Do not use anyone who is known to have had nasal surgery or injury, or any allergy to the test reagents.

False negative test results may occur if a specimen is incorrectly collected or handled.

False positive test results may occur if saliva, body fluids, or soil is on the extraction tube.

Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.

Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.

Avoid direct exposure of your skin, eyes, nose, or mouth to the extraction in the extraction tube. Do not ingest any kit components.

The reagent solution in the tube contains a harmful chemical (see table below). If the solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice.

https://www.cdc.gov/mappingforSARS-CoV-2Tests.html

DIRECTIONS FOR USE

1. Gently insert the entire absorbent tip of the swab into 1 nostril (½ of 1 inch). With the swab, close one nostril and open the other nostril.

2. Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take care not to touch the side of the swab with the tip.

3. Remove the swab from the nostril and place into the extraction buffer tube.

4. Punch through the perforated circle on the kit box to form a tube holder.

5. Remove the foil from the top of the extraction buffer tube. Place the tube in the tube holder.

6. Roll the swab 5-6 times to expel all sample into the tube.

7. Remove the swab while squeezing the tube to extract as much liquid as possible. Dispose of the swab in the trash.

8. Place the tube in the test cassette.

9. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep and refer to a physician or call a Poison Control Center immediately.

For further information, please visit:
https://www.fda.gov/medical-devices/emergency-authorization/covid-19-antigen-home-test-authorization

For the most up to date information on COVID-19, please visit:
https://www.cdc.gov/covid19/index.html

If false negative result may occur if the nasal swab specimen is not properly collected and handled.

If false positive test results may occur if saliva, body fluids, or soil is on the extraction tube.

May still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for epidemiological reasons to suspect COVID-19 when tested at least three times over five days.

This product has been designed only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

No control lines (BLT/ILTS, indicated by no Control Line) should be present on the On/GoOne COVID-19 Antigen Home Test.

False negative test results may occur if the swab is not swirled at least 30 seconds after proper volume of specimen has been added, and membrane wicking has occurred.

False positive test results may occur if the test result is read before 15 minutes or after 30 minutes.

Note: A false negative result may occur if the nasal swab specimen is not properly collected and handled.

Note: A false positive result may occur if saliva, body fluids, or soil is on the extraction tube.

The On/GoOne COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

This test is designed for use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older and adult collected anterior nasal (nare) swab samples from individuals aged 14 years or older.

This test is authorized for the qualitative detection of SARS-CoV-2 viral antigens in anterior nasal swab samples from individuals aged 14 years or older and adult collected anterior nasal (nare) swab samples from individuals aged 14 years or older.

The On/GoOne COVID-19 Antigen Home Test is not for investigational use only authorized for the duration of the declaration that detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bb-3(b)(1), unless the declaration is terminated, or authorization is revoked.

The test is for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

The On/GoOne COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The On/GoOne COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep and refer to a physician or call a Poison Control Center immediately.

For the most up to date information on COVID-19, please visit:
https://www.cdc.gov/covid19/index.html

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For the most up to date information on COVID-19, please visit:
https://www.cdc.gov/covid19/index.html

If false negative result may occur if the nasal swab specimen is not properly collected and handled.

If false positive test results may occur if saliva, body fluids, or soil is on the extraction tube.

The On/GoOne COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

This test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab specimens.

The On/GoOne COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep and refer to a physician or call a Poison Control Center immediately.

For the most up to date information on COVID-19, please visit:
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For further information, please visit:
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For the most up to date information on COVID-19, please visit:
https://www.cdc.gov/covid19/index.html

If false negative result may occur if the nasal swab specimen is not properly collected and handled.

If false positive test results may occur if saliva, body fluids, or soil is on the extraction tube.
Internal procedural controls are included in the test. A red or pink line appearing in the control line (C) as an internal procedural control indicates that the volume of specimen has been added and capillary flow occurred. If the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new cassette is recommended.

LIMITATIONS

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in March 2021 and May 2021. The clinical specimen collection has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of the test may vary depending on the variety of circulating strains of SARS-CoV-2 and their prevalence, which change over time. 2. The test should be interpreted only by personnel trained in COVID-19 antigen testing. 3. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result. 4. A false negative result may occur if the level of antigen in a sample is below the detection limit of the test. 5. The test result may occur if the sample was collected incorrectly or handled. 6. A false negative result may occur if the test is not swabbed at least 30 seconds or rotated five times. 7. A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Reagent well. 8. The test result may be invalid if the test is not performed within 15 minutes from the time of swabbing.

INTERPRETATION OF RESULTS

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

<table>
<thead>
<tr>
<th>Status on first day of testing</th>
<th>With Symptoms</th>
<th>Without Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>N/A</td>
<td>Positive Positive Positive</td>
</tr>
<tr>
<td>Negative</td>
<td>N/A</td>
<td>Negative Negative Negative</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Positive for COVID-19</td>
<td>Negative for COVID-19</td>
</tr>
</tbody>
</table>

Results should be considered in the context of an individual’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

NEGEATIVE: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms persist, fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmed with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or in communities with high prevalence of infection. 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.

POSITIVE: If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint red or pink line appearing on the control line (C) should be read as positive. Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result indicates that SARS-CoV-2 was detected in the sample and it is very likely the individual has COVID-19 and is contagious. Please contact the patient’s primary care physician (if applicable) and the local health authority immediately and three (3) tests performed in an average of 48 hours apart should be performed to confirm the self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out other viral or bacterial infections. Indeterminate or invalid test results may not be the definitive cause of disease. Individuals who test positive with the OnGo One COVID-19 Antigen Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

QUALITY CONTROL

Internal procedural controls are included in the test. A red or pink line appearing in the control line (C) as an internal procedural control indicates that the appearance of the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new cassette is recommended.

INTERPRETATION OF RESULTS

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

<table>
<thead>
<tr>
<th>Status on first day of Testing</th>
<th>Interpretaion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative for COVID-19</td>
</tr>
</tbody>
</table>

Results should be considered in the context of an individual’s recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

NEGEATIVE: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance of false negative results with antigen tests as compared to a molecular test, especially in samples with low viral load.

10. All COVID-19 antigen test negative results are presumptive and confirmatory with a molecular test may be necessary.

11. If the patient continues to have symptoms of COVID-19, and both the patient’s first and second test results are negative, test the patient with another antigen test with COVID-19 as compared to a molecular test, especially in samples with low viral load.

12. If the test is positive, then proteins from the virus that causes COVID-19 has been found in the sample and the individual likely has COVID-19.

13. This test is read visually and has not been validated for use with those with impaired vision or color vision deficiencies.

14. Incorrect test results may occur if a specimen is incorrectly collected or handled.

15. This test detects both viable (live) and nonviable SARS-CoV-2. SARS-CoV-2 test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture and/or PCR results.

16. The OnGo One COVID-19 Antigen Home Test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

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

18. A positive or negative test result does not rule out co-infections with other pathogens such as other viral or bacterial infections.

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

20. Test results are not used to determine the presence of specific SARS viruses and strains in need of testing, required, in consultation with state or local public health departments, is required.

21. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially in individuals that do not have any symptoms.

22. If the test is positive, then proteins from the virus that causes COVID-19 has been found in the sample and the individual likely has COVID-19.

This test is read visually and has not been validated for use with those with impaired vision or color vision deficiencies.

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Serological tests are not used to determine the presence of specific SARS viruses and strains in need of testing, required, in consultation with state or local public health departments, is required.

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Serological tests are not used to determine the presence of specific SARS viruses and strains in need of testing, required, in consultation with state or local public health departments, is required.
Symptomatic Patient Age Distribution: A total of 108 symptomatic patients participated in the study. Ages of symptomatic patients ranged from 2 years to 93 years. The table below shows age distribution and the positive results broken down by age of symptomatic patient.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total</th>
<th>Positive</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-13 years</td>
<td>8</td>
<td>1</td>
<td>13%</td>
</tr>
<tr>
<td>14-24 years</td>
<td>12</td>
<td>4</td>
<td>33%</td>
</tr>
<tr>
<td>25-64 years</td>
<td>67</td>
<td>21</td>
<td>31%</td>
</tr>
<tr>
<td>65 years &amp; over</td>
<td>27</td>
<td>26</td>
<td>26%</td>
</tr>
<tr>
<td>Total</td>
<td>108</td>
<td>28</td>
<td>26%</td>
</tr>
</tbody>
</table>

**Analytical Sensitivity: Limit of Detection (LOD)**

The Limit of Detection (LOD) of the OnGo One COVID-19 Antigen Home Test was determined using dilutions of the heat-inactivated SARS-CoV-2 virus (USA-WA1/2020). Nasal swabs from healthy donors were collected and eluted with PBS. The swab dilutions were compared and mixed thoroughly to create a negative clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this negative clinical matrix pool to generate virus dilutions for testing. The contorted nasal swab samples were prepared by absorbing 50 µL of each virus dilution onto the band. The contorted swab samples were processed and tested according to the package insert. LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time. Based on this testing, the LOD in nasal matrix was confirmed to be 2.5 x 10^5 TCID50/mL. Based upon the testing procedure for this study, the LOD of 2.5 x 10^5 TCID50/mL equates to 1 x 10^4 TCID50/swab. The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were prepared for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx) initiative. The clinical specimens used to prepare this dilution series were identical to the previous specimen pools prepared and tested by RADx to evaluate performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have the same clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the OnGo One COVID-19 Antigen Home Test detected 100% of live virus Omicron samples at a Ct-value of 25.6 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ci-values greater than 25.6) were not detected by the OnGo One COVID-19 Antigen Home Test in this study.

**Cross-reactivity 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 tested in the absence or presence of heat-inactivated SARS-CoV-2 virus (USA-WA1/2020) at a low concentration. In addition to the nucleocapsid protein, each nucleic acid was found in the nasal cavity. Substances that are commonly found in the oral or nasal cavity were evaluated as interference. In addition to the nucleocapsid protein, each nucleic acid was found in the nasal cavity. Substances that are commonly found in the oral or nasal cavity were evaluated as interference. Interference results were generated in the presence of potential cross-reacting substances. The table below lists the results of these tests.

<table>
<thead>
<tr>
<th>Potential Cross Reactant</th>
<th>Test Concentration</th>
<th>Cross-reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>1.14 x 10^5 TCID50/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Enterovirus</td>
<td>9.50 x 10^5 TCID50/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
</tbody>
</table>

**Potential Interfering Household Items**

<table>
<thead>
<tr>
<th>Source/Item</th>
<th>Test Concentration</th>
<th>Cross-reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naso GEL (NeilMed)</td>
<td>5 mg/vial</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Whole Blood</td>
<td>4% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Zicam</td>
<td>5% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
</tbody>
</table>

**Analytical Specificity: Cross-Reactivity 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 tested in the absence or presence of heat-inactivated SARS-CoV-2 virus (USA-WA1/2020) at a low concentration. No cross-reactivity or interference was observed with the following organisms when tested at the concentrations presented in the table below.

**Endogenous Interfering Substances**

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity during specimen collection, were evaluated as interference. In addition to the nucleocapsid protein, each nucleic acid was found in the nasal cavity. Substances that are commonly found in the oral or nasal cavity were evaluated as interference. Interference results were generated in the presence of potential cross-reacting substances. The table below lists the results of these tests.

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Source/Item</th>
<th>Test Concentration</th>
<th>Cross-reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulin</td>
<td>Sigma/B4501</td>
<td>3500 ng/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Chryseobacter luteo-loxigenes</td>
<td></td>
<td>1.5 mg/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Dicyclohexylhydroxilicinium</td>
<td>Sigma/PHR1849</td>
<td>1.5 mg/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Flucicanicin C</td>
<td>Sigma/3M895</td>
<td>5% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Lactobacillus</td>
<td></td>
<td>1% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>M. Bacteroides</td>
<td>Sigma/BI0461</td>
<td>0.5% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Nasal Drops (Phenylephrine)</td>
<td>Sigma/VA280</td>
<td>15% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Nasal Spray (Cromlyon)</td>
<td>Sigma/AL125</td>
<td>15% v/v</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Nasal Spray (Homeopathic)</td>
<td>ALKALOL</td>
<td>1.10 Dilution</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
</tbody>
</table>

**Potential Cross Reactant**

<table>
<thead>
<tr>
<th>Test Concentration</th>
<th>Cross-reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.14 x 10^5 TCID50/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>9.50 x 10^5 TCID50/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
</tbody>
</table>

**In Vitro Diagnostic Medical Device**

Use by-date: 2023-03-31

**Bibliography**


**Index of Symbols**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Catalogue number</th>
<th>Date of manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACON Laboratories, Inc.</td>
<td>San Diego, CA 92121, USA</td>
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No high dose hook effect was observed when tested up to a concentration of 1.0 x 10^6 TCID50/mL of heat-inactivated SARS-CoV-2 virus (USA-WA1/2020) with the OnGo One COVID-19 Antigen Home Test.

**Usability Study**

A total of 431 subjects were enrolled in the study and were instructed to self-collect or collect a sample from a child, complete the required procedural steps, and interpret the test results unassisted in a simulated home-setting. The overall success of each task completed by all users was determined by unassisted professional observation. Subjects performed 96.2% (409/425) of steps/tasks correctly compared to healthcare professional users. A total of 297/373 (79.6%) subjects were able to correctly interpret the test cassette and satisfaction questionnaire. Specifically, 98.8% of subjects indicated that it was easy to see and interpret the test results.

**Qualitative Testing**

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in-silico analysis was used to assess the degree of protein sequence homology. Compared to between the nucleocapsid proteins of HKU1 revealed a low homology of 36.7% across 82.8% of the SARS-CoV-2 nucleocapsid sequence. The result suggests that cross-reactivity with human coronavirus HKU1 cannot be completely ruled out. Compared is the sequence homology between the SARS-CoV-2 nucleocapsid protein and the structural proteins of SARS-CoV and SARS-CoV-2. The Omicron One COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

**Manufacturer and Technical Support**

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