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

Product: OnSite COVID-19 Ag Self Test
Manufacturer: CTK Biotech, Inc.
EUL Number: EUL 0689-143-00
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.

OnSite COVID-19 Ag Self Test with product codes R0182CST-1T, R0182CST-2T, R0182CST-5T, and R0182CST-20T, TGA regulatory version manufactured by CTK Biotech, Inc., 13855 Stowe Dr. Poway, CA 92064, United States of America, was listed as eligible for WHO procurement on 18 July 2022.

Intended use

According to the claim of intended use from CTK Biotech, Inc., “the OnSite COVID-19 Ag Self Test is a single-use lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens from individuals suspected of COVID-19, within the first seven days of the onset of symptoms. The test is intended for use by individuals 18 years or older, or children ages 12 and up with adult supervision, as an aid in identifying SARS-CoV-2 infection. The OnSite COVID-19 Ag Self Test does not differentiate between SARS-CoV and SARS-CoV-2.”
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 other bacterial or viral infections. Individuals who test positive should self-quarantine following the recommended guidelines from their health authorities, and seek proper care from their healthcare provider.

Negative results from patients with symptom onset beyond seven days should be confirmed with a molecular assay. 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. 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. Those who test negative and continue to exhibit symptoms associated with COVID-19 such as fever, difficulty breathing or cough may still have SARS-CoV-2 infection and should contact their healthcare provider.

*This product is intended to be used for self-use and/or for adults over the age of 18 in a non-laboratory setting, or by children ages 12 and up with adult supervision. For in vitro diagnostic use only.*

**Specimen type that was validated:** Nasal swab specimens.

**Test kit contents**

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity (product code R0182CST-1T)</th>
<th>Quantity (product code R0182CST-2T)</th>
<th>Quantity (product code R0182CST-5T)</th>
<th>Quantity (product code R0182CST-20T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer and nozzle pouch</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Cassette pouch</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Swab</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>Waste bag</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>/</td>
</tr>
<tr>
<td>Tube rack</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>1</td>
</tr>
</tbody>
</table>

**Items required but not provided**

A mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.

**Storage**

The test kit should be stored at 2-30 °C.
**Shelf-life upon manufacture**
12 months (real-time stability studies are ongoing)

**Warnings/limitations**
Please refer to the attached instructions of use (IFU).

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**Product dossier assessment**

CTK Biotech, Inc. submitted a product dossier for the OnSite COVID-19 Ag Self Test as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (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 for listing, the manufacturer is required to:

1. Assess the traceability of the materials used in the validation of the product (including estimation of LoD) with the WHO International Standard when available.
2. Partake in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be performed using the protocol and technical criteria established by WHO.
3. Submit the FIND usability study upon completion.

Risk-benefit assessment conclusion is acceptable.

**Quality Management Systems Review**

To establish the eligibility for WHO procurement, CTK Biotech, Inc. 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 CTK Biotech, Inc. to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_347)”.

The quality management documentation assessment conclusion is acceptable.
Plan for Post-Market Surveillance

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

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with “WHO procedure for changes to a WHO prequalified in vitro diagnostic” (document number PQDx_121); and

CTK Biotech, Inc. is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

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

Scope and duration of procurement eligibility

The OnSite COVID-19 Ag Self Test with product codes R0182CST-1T, R0182CST-2T, R0182CST-5T, and R0182CST-20T, manufactured by CTK Biotech, Inc., is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome 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, CTK Biotech, Inc. must engage in post-market surveillance activities to ensure that the product meets safety, quality, and performance requirements, CTK Biotech, Inc. must 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.

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1 https://www.who.int/publications/i/item/9789240015319
WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, 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**
1.0 Labels
OnSite®
COVID-19 Ag Self Test

Nasal swab
Result in 15 minutes

1 Test cassette
1 Swab
1 Buffer tube
1 Nozzle
1 Waste bag
1 Instructions for Use

Read instructions for use carefully before testing.

Positive Negative

Invalid

15min

C=0  M=51  Y=100  K=0

C=76  M=0  Y=52  K=0

PM-R0182CST-EUL-1T-BH Rev A
Perforated kit box design for COVID-19 Ag Self Test, 1 test/kit, Revision A.

size 135 x 80 x 22.5mm
PM-R0182CST-EUL-2T-BH Rev. A
Perforated kit box design for COVID-19 Ag Self Test, 2 test/kit, Revision A.
size 135 x 80 x 30mm

Read instructions for use carefully before testing
Scan to find the Instructions for Use & procedural video

Early Detection within 7 days of symptom onset
Positive
Negative
Invalid

OnSite®
R0182CST-2T
Nasal swab
Result in 15 minutes
COVID-19 Ag
Self Test

CTK Biotech, Inc.
13855 Stowe Drive
Poway, CA 92064, USA
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

For Export Only, Not for Re-sale in the USA
PM-R0182CST-EUL-5T-BH Rev. A
Perforated kit box design for COVID-19 Ag Self Test, 5 test/kit, Revision A.
size 135 x 110 x 40 mm

- C=0  M = 51  Y= 100  K=0
- C=76  M = 0  Y=52  K=0

CTK Biotech, Inc.
13855 Stowe Drive
Poway, CA 92064, USA
+1-833-919-0617

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

For Export Only, Not for Re-sale in the USA
2.0 Instructions for use (IFU)²

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

1. Prepare the test
   - Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.
   - Blow your nose with a tissue and throw it away.
   - Wash your hands thoroughly and DRY them.

2. Collect and prepare sample
   - Remove all the contents from the kit box. For multiple tests/kit formats, use only one kit (buffer, nozzle, cassette, swab, and waste bag) at a time. Verify that the contents are all included and undamaged.
   - Open the pouch labeled “Buffer and Nozzle”.
   - Puncture through the perforated circle on the kit box to form a tube rack. Carefully peel off the seal of the buffer tube. Place the open tube in the tube rack.

3. Test the sample
   - Insert the fabric tip of the swab into one nostril, about 2 cm into the nose. DO NOT insert the swab any deeper if you feel strong resistance or pain. Rotate the swab inside the nostril at least 5 times, pressing against the nasal wall.
   - Using the same swab, repeat the process in the other nostril.
   - Remove the buffer tube from the rack, and insert the fabric tip of the swab into the tube. Swirl the swab in the liquid at least 5 times. Squeeze the tube against the submerged swab at least 5 times.
   - Lift the swab out of the liquid while squeezing the tube against the fabric tip to remove excess fluid from the swab. Remove the swab from the buffer tube.
   - Insert the nozzle firmly into the tube while holding the tube with your other hand.
   - Open the pouch labeled “COVID-19 Ag Self Test” and remove the cassette. Lay it on the clean, flat surface.
   - Hold the tube over the cassette and slowly add 3 drops of the liquid into the sample well (S) to avoid forming bubbles. Discard the buffer tube into the waste bag.

4. Read test results
   - Add the liquid drop by drop, and in a vertical manner.
   - If you are testing more than one sample, always clean the surface and wash your hands between each test.
   - DO NOT touch the fabric tip of the swab with your hands.

5. Dispose the test kit
   - If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.
   - Use the test kit at room temperature (15°C-30°C).
   - Keep the test kit away from children.
   - Do not touch your cheeks, teeth, gums or any other surfaces with the fabric tip of the swab, or it might contaminate your sample.
   - DO NOT turn or invert the tube during this step. Do not use the kit if it’s expired or the sealed packaging is damaged.
   - For 2 and 5 test kits, do not throw the kit box and Instructions for Use into the waste bag, then discard the waste bag in the trash can (not recycling), or according to your local guidelines.

Materials needed but not provided:
- a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.
- a testing area, such as a well-lit surface, such as a table or countertop.

Negative Result
- Only the Control (C) line develops. You are likely not infectious at the time the test was taken. It does not guarantee that you do not have coronavirus.

Positive Result
- Both Control (C) & Test (Ag) line develop. A positive result means that you are very likely infected with coronavirus and could infect others. Consult your healthcare provider for additional confirmatory laboratory PCR test and follow-up clinical care.

Invalid Result
- No Control (C) line develops. There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

Each test will take 10-15 minutes to set up and another 15-20 minutes to get the test results.
- Store the test kit at room temperature or in a cool, dry place (2°C-30°C). Keep the kit away from direct sunlight and do not store it in a freezer.
- Keep the test kit away from children.
- Use the test kit at room temperature (15°C-30°C).
- If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.

Scan the QR code to access IFU and procedural video.
The OnSite COVID-19 Ag Self Test is a single-use lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens collected from individuals suspected of COVID-19, within the first seven days of the onset of symptoms. The test is intended for use by healthcare providers,laymen, and/or for adults over 12 years of age for self-use and/or for adults over 12 years of age and up with adult supervision, as an aid in identifying SARS-CoV-2 infection.

The OnSite COVID-19 Ag Self Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

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 other bacterial or viral infections. Individuals who test positive should self-quarantine following the recommended guidelines from their health authority, and seek healthcare provider consultation with a new test.

Negative results from patients with symptom onset beyond seven days should be confirmed with a molecular assay. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for self-quarantine following the recommended guidelines from their health authority, and seek healthcare provider consultation with a new test.

Correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial or viral infections. Individuals who test positive should self-quarantine following the recommended guidelines from their health authority, and seek healthcare provider consultation with a new test.

Negative results should be considered in the context of a patient’s recent exposure, history and the presence of clinical signs and symptoms consistent with COVID-19.

For in vitro diagnostic use only.

1. Clinical Performance

The clinical performance of the OnSite COVID-19 Ag Self Test was evaluated at five clinical sites (Colombia, Brazil, India, Bangladesh and Slovakia), in nasal swab specimens collected from subjects suspected of COVID-19. Two swabs were collected from each subject, one nasal swab for testing by the OnSite COVID-19 Ag Self Test and one NP swab for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2, and used as the reference method for this study. The performance of the OnSite COVID-19 Ag Self Test in a self-testing environment is shown in the table below:

<table>
<thead>
<tr>
<th>Days Since Symptom Onset</th>
<th>RT-PCR Results</th>
<th>OnSite COVID-19 Ag Self Test Results</th>
<th>PCM Positive Agreement</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>437</td>
<td>400</td>
<td>92.0% (95% CI: 89.6-94.3)</td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>171</td>
<td>159</td>
<td>96.7% (95% CI: 95.0-98.4)</td>
<td></td>
</tr>
<tr>
<td>6-8</td>
<td>139</td>
<td>129</td>
<td>96.3% (95% CI: 94.7-97.7)</td>
<td></td>
</tr>
<tr>
<td>9-10</td>
<td>100</td>
<td>85</td>
<td>95.0% (95% CI: 92.5-97.0)</td>
<td></td>
</tr>
<tr>
<td>11-13</td>
<td>79</td>
<td>64</td>
<td>84.9% (95% CI: 81.0-88.3)</td>
<td></td>
</tr>
<tr>
<td>14-16</td>
<td>54</td>
<td>38</td>
<td>70.4% (95% CI: 64.0-76.3)</td>
<td></td>
</tr>
</tbody>
</table>

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 other bacterial or viral infections. Individuals who test positive should self-quarantine following the recommended guidelines from their health authority, and seek healthcare provider consultation with a new test.

2. Clinical Performance in a Self-Testing Environment

In the self-testing study, the OnSite COVID-19 Ag Self Test correctly identified 100% (95% CI: 99.5-100%) of infected study participants, and 98% of non-infected participants. Two swabs were collected from each subject, one nasal swab for testing by the OnSite COVID-19 Ag Self Test and one NP swab for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2, and used as the reference method for this study. The performance of the OnSite COVID-19 Ag Self Test in a self-testing environment is shown in the table below:

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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 other bacterial or viral infections. Individuals who test positive should self-quarantine following the recommended guidelines from their health authority, and seek healthcare provider consultation with a new test.

3. Additional supporting evidence for self-testing performance

Comparison of the test results conducted by comparing 85 adult participants interpreted test results with healthcare professionals interpreted test results. The positive agreement between the reading performance of participants and the healthcare professional in this study was 92.6% and the negative agreement was 100%. An important advantage is that real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2 was used as the reference test in both studies.

In another self-testing study, the performance of OnSite COVID-19 Ag Self Test in 57 adults who learned to use self-testing (aged 18 and above) showed a sensitivity of 98.0%. The positive agreement between the reading performance of participants and the healthcare professional in this study was 95.6% and negative agreement was 100%. An important advantage is that real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2 was used as the reference test in both studies.

OnSite © 2023 CTK Biotech, Inc.

Cassette, tube and membrane used for testing:

- CTK Biotech, Inc.
- 13855 Stowe Drive
-cura, Bethesda, Maryland
- 20814, USA
- E-mail: info@ctkbiotech.com

For Export Only. Not for Sale in the USA.

English version
Read these instructions before testing and follow the steps in order. Keep this guide as a reference until the entire kit is used.

- Each test will take 10-15 minutes to set up and another 15-20 minutes to get the test results.
- Store the test kit at room temperature or in a cool, dry place (2°C-30°C). Keep the kit away from direct sunlight and do not store it in a freezer.
- Keep the test kit away from children.
- Use the test kit at room temperature (15°C-30°C).

If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.

INSTRUCTIONS FOR USE

Materials Provided

x20 Buffer  x20 Nozzle  x20 Cassette  x1 Tube rack  x20 Swab

Materials needed but not provided: a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.

1. Prepare the test

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

Blow your nose with a tissue and throw it away.

Wash your hands thoroughly and DRY them.

Choose a well-lit surface, such as a table or countertop.

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

2. Collect and prepare sample

Collect the materials needed for 1 test:
1 buffer tube, 1 nozzle, 1 cassette pouch, 1 tube rack, and 1 swab. Verify that the contents are all included and undamaged.

3. Test the sample

Open the pouch labeled “COVID-19 Ag Self Test” and remove the cassette. Lay it on the clean, flat surface.

Hold the buffer tube over the cassette and slowly add 3 drops of the liquid into the sample well (S) to avoid forming bubbles. Discard the buffer tube.

Add the liquid drop by drop, and in a vertical manner.

If you are testing more than one sample, always clean the surface and wash your hands between each test.

DO NOT touch the fabric tip of the swab with your hands.

If you are testing more than one sample, always clean the surface and wash your hands between each test.

DO NOT turn or invert the tube during this step. Do not use the kit if it’s expired or the sealed packaging is damaged.

DO NOT turn or invert the tube during this step. Do not use the kit if it’s expired or the sealed packaging is damaged.

There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

4. Read test results

Negative Result

Only the Control (C) line develops. You are likely not infectious at the time the test was taken. It does not guarantee that you do not have coronavirus.

Positive Result

Both Control (C) & Test (Ag) line develop. A positive result means that you are very likely infected with coronavirus and could infect others. Consult with your healthcare provider for additional confirmatory laboratory PCR test and follow-up clinical care.

Invalid Result

No Control (C) line develops. There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

5. Dispose the test kit

Dispose all contents of the used test kit except instructions for Use and paper tube rack in the trash can (not recycling), or according to your local guidelines.

A positive result means that you are very likely infected with coronavirus and could infect others. Consult with your healthcare provider for additional confirmatory laboratory PCR test and follow-up clinical care.

If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.

Materials Provided

x20 Buffer  x20 Nozzle  x20 Cassette  x1 Tube rack  x20 Swab

Materials needed but not provided: a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.

1. Prepare the test

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

Blow your nose with a tissue and throw it away.

Wash your hands thoroughly and DRY them.

Choose a well-lit surface, such as a table or countertop.

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

2. Collect and prepare sample

Collect the materials needed for 1 test:
1 buffer tube, 1 nozzle, 1 cassette pouch, 1 tube rack, and 1 swab. Verify that the contents are all included and undamaged.

3. Test the sample

Open the pouch labeled “COVID-19 Ag Self Test” and remove the cassette. Lay it on the clean, flat surface.

Hold the buffer tube over the cassette and slowly add 3 drops of the liquid into the sample well (S) to avoid forming bubbles. Discard the buffer tube.

Add the liquid drop by drop, and in a vertical manner.

If you are testing more than one sample, always clean the surface and wash your hands between each test.

DO NOT touch the fabric tip of the swab with your hands.

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Negative Result

Only the Control (C) line develops. You are likely not infectious at the time the test was taken. It does not guarantee that you do not have coronavirus.

Positive Result

Both Control (C) & Test (Ag) line develop. A positive result means that you are very likely infected with coronavirus and could infect others. Consult with your healthcare provider for additional confirmatory laboratory PCR test and follow-up clinical care.

Invalid Result

No Control (C) line develops. There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

5. Dispose the test kit

Dispose all contents of the used test kit except instructions for Use and paper tube rack in the trash can (not recycling), or according to your local guidelines.

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If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.

Materials Provided

x20 Buffer  x20 Nozzle  x20 Cassette  x1 Tube rack  x20 Swab

Materials needed but not provided: a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.

1. Prepare the test

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

Blow your nose with a tissue and throw it away.

Wash your hands thoroughly and DRY them.

Choose a well-lit surface, such as a table or countertop.

Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

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Collect the materials needed for 1 test:
1 buffer tube, 1 nozzle, 1 cassette pouch, 1 tube rack, and 1 swab. Verify that the contents are all included and undamaged.

3. Test the sample

Open the pouch labeled “COVID-19 Ag Self Test” and remove the cassette. Lay it on the clean, flat surface.

Hold the buffer tube over the cassette and slowly add 3 drops of the liquid into the sample well (S) to avoid forming bubbles. Discard the buffer tube.

Add the liquid drop by drop, and in a vertical manner.

If you are testing more than one sample, always clean the surface and wash your hands between each test.

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No Control (C) line develops. There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

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Dispose all contents of the used test kit except instructions for Use and paper tube rack in the trash can (not recycling), or according to your local guidelines.
**OnSite COVID-19 Ag Self Test**

**Instructions for Use**

**INTENDED USE**

The OnSite COVID-19 Ag Self Test is a single-use lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens from individuals suspected of COVID-19, within the first seven days of the onset of symptoms. The test is intended for use by individuals, under the age of 18 in a non-laboratory setting, or by children ages 12 and up with adult supervision, as an aid in identifying SARS-CoV-2 infection.

The OnSite COVID-19 Ag Self Test does not differentiate between SARS-CoV-2 and SARS-CoV-2 antigens. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. False positive results may occur if the test is not used as directed. Inaccurate results may occur if not enough sample was added in the sample well; if the steps are not followed as instructed, if the performance of the test may be affected.

**WARNINGS AND PRECAUTIONS**

1. Read these instructions and follow the steps in order to ensure accurate results.
2. This test is for in vitro diagnostic use.
3. The chemicals in the buffer tube (a detergent, ProClin 300, and sodium azide) are known to be non-toxic, at the levels present in the liquid. The buffer should only be used as directed; do not ingest, keep out of the reach of children, avoid contact with skin and eyes.
4. Do not overload the sample well.
5. When opening the test kit, verify that all contents are intact and undamaged. Do not use test if any contents are damaged.
6. Do not allow the sample to freeze or thaw excessively. Too much viscous mucus on the swab, after transfer to the test cassette, might give incorrect results.
7. Do not use this test to monitor disease progression or treatment.
8. The OnSite COVID-19 Ag Self Test kit showed 98.6% accuracy when tested by laboratories, which means that you are very likely infected with coronavirus and could infect others.
9. The fabric tip of the nasal swab may tickle or cause mild discomfort.
10. Allergic reactions to benzocaine, lopinavir, zanamivir, oseltamivir, ribavirin, peramivir, phenylephrine, fluconazole, budesonide, nasal gel, menthol, cetyltrimethylammonium, parabens, sodium azide, breath, benzyl alcohol, benzoic acid, benzoate, cadaverine, cetyl alcohol, ethyl alcohol, formaldehyde, propyl alcohol, sodium azide, sodium bisulfite, sodium chloride, water, and other ingredients in the gel may occur.
11. False negative results may occur if you have cold symptoms and coronavirus of COVID-19 of longer than seven (7) days. You may still have COVID-19 even though the test is negative.
12. Positive results mean that you are very likely infected with coronavirus and risk of infecting others. Follow the recommended guidelines from your health authorities such as self-quarantine to avoid spreading COVID-19. Follow up with your healthcare provider to determine the best care for you based on your results. You may need additional testing depending on your personal history.

**PERFORMANCE CHARACTERISTICS**

1. **Clinical Performance**

   The clinical performance of the OnSite COVID-19 Ag Self Test was evaluated at five clinical sites (Colombia, Brazil, India, Bangladesh and Slovenia), in nasal swab specimens collected from subjects suspected of COVID-19. Two swabs were collected from each subject, one nasal swab for testing by the OnSite COVID-19 Ag Self Test and one NP swab for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2. The study included the performance of the OnSite COVID-19 Ag Self Test in a self-testing environment is shown in the self-testing environment.

   **1.1 Stratification of the positive results post onset of symptoms in the professional study**

   **Days Since Symptom Onset**

<table>
<thead>
<tr>
<th>Days</th>
<th>No Test</th>
<th>SARS-CoV-2 Test Positive</th>
<th>SARS-CoV-2 Test Positive Percent</th>
<th>P CR Positive</th>
<th>Agreement</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3</td>
<td>151</td>
<td>100%</td>
<td>98.2% (95% CI 93.0% - 99.8%)</td>
<td>100%</td>
<td>98.2%</td>
<td>95% CI</td>
</tr>
<tr>
<td>≤6</td>
<td>151</td>
<td>100%</td>
<td>98.2% (95% CI 93.0% - 99.8%)</td>
<td>100%</td>
<td>98.2%</td>
<td>95% CI</td>
</tr>
<tr>
<td>≤7</td>
<td>151</td>
<td>100%</td>
<td>98.2% (95% CI 93.0% - 99.8%)</td>
<td>100%</td>
<td>98.2%</td>
<td>95% CI</td>
</tr>
<tr>
<td>≤4</td>
<td>151</td>
<td>100%</td>
<td>98.2% (95% CI 93.0% - 99.8%)</td>
<td>100%</td>
<td>98.2%</td>
<td>95% CI</td>
</tr>
<tr>
<td>≤1</td>
<td>151</td>
<td>100%</td>
<td>98.2% (95% CI 93.0% - 99.8%)</td>
<td>100%</td>
<td>98.2%</td>
<td>95% CI</td>
</tr>
</tbody>
</table>

   **2.2 Additional supporting evidence for self-testing performance**

   A comparison of the test results conducted by comparing 85 adult participants interpreted test results with healthcare professionals interpreted test results. The positive agreement between the reading performance of the OnSite COVID-19 Ag Self Test and the healthcare professional in this study was 89.2% and the negative agreement was 100%. A common commercial available real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2 was used as the reference method.

   In another self-testing study, the performance of OnSite COVID-19 Ag Self Test in 151 participants (aged 18 years and older) showed a sensitivity of 80.0%. The positive agreement between the reading performance of the OnSite COVID-19 Ag Self Test and the healthcare professional health care personnel was 96.6% and negative agreement was 100%. A commercially available real-time Polymerase Chain Reaction (RT-PCR) for the detection of SARS-CoV-2 was used as the reference method.