WHO Emergency Use Assessment SARS-CoV-2 IVDs

PUBLIC REPORT

Product: OnSite COVID-19 Ag Rapid Test
Manufacturer: CTK Biotech, Inc.
EUL Number: EUL 0653-143-00
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:


OnSite COVID-19 Ag Rapid Test, product code RO182C, CE mark regulatory version, manufactured by CTK Biotech, Inc., 13855 Stowe Dr. Poway, CA 92064, United States of America was listed on 1 February 2022.

Intended use

According to the claim of intended use from CTK Biotech, Inc., “OnSite COVID-19 Ag Rapid Test is a 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 healthcare providers or personnel trained in rapid test procedure, as an aid in identifying SARS-CoV-2 infection.

The OnSite COVID-19 Ag Rapid 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. Positive results do not require another confirmatory testing method, but local regulatory requirement may request additional PCR testing.
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.

The product is intended to be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulations. For in vitro diagnostic use only.

Specimen type that was validated:
Nasal swab specimens.

Test kit contents

<table>
<thead>
<tr>
<th>Component</th>
<th>20 tests (product code R0182C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individually sealed foil pouches containing:</td>
<td></td>
</tr>
<tr>
<td>a. One cassette device</td>
<td>20</td>
</tr>
<tr>
<td>b. One desiccant</td>
<td></td>
</tr>
<tr>
<td>Sealed pouch containing pre-filled extraction tubes</td>
<td>20</td>
</tr>
<tr>
<td>Extraction tube nozzles</td>
<td>20</td>
</tr>
<tr>
<td>Extraction tube rack</td>
<td>1</td>
</tr>
<tr>
<td>Individually sealed pouches containing sterile swab</td>
<td>20</td>
</tr>
<tr>
<td>Instructions for Use</td>
<td>1</td>
</tr>
</tbody>
</table>

Items required but not provided

- Clock, watch or other timing device.
- Disposable gloves.
- Biohazard disposal container.
- A pencil or pen to label each test device.
- Positivia COVID-19 Ag Rapid Test External Control Kit (not required, sold separately).

Storage

2-30°C.

Shelf-life upon manufacture

12 months (real time stability studies are ongoing).
**Warnings/limitations:**

Refer to the instructions for use (IFU).

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**Product dossier assessment**

CTK Biotech, Inc. submitted a product dossier for the OnSite COVID-19 Ag Rapid Test for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_0347)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

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**Post listing Commitments for EUL**

As commitments to listing, CTK Biotech, Inc. committed to:

1. To provide a new specimen stability study report to WHO by 28 February 2022.
2. To submit a study report on traceability of all relevant materials to the WHO International Standard for SARS-CoV-2 antigen when it becomes available.
3. Estimate the LoD of the product with the WHO International Standard for SARS-CoV-2 antigen when available and to provide the report to WHO within one month of completion of the study.
4. Provide the following stability reports to WHO:
   - In-use stability by 30 June 2022.
   - Stability of unopened controls by 31 August 2022.

Risk benefit assessment conclusion: acceptable.

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**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, 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 and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_347)”.

Quality management documentation assessment conclusion: acceptable.
Plan for Post-Market Surveillance

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

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL 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 submit all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensure that post-emergency use listing safety, quality and performance monitoring activities are in place which are in accordance with WHO guidance “Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics” (ISBN 978-92-4-001531-9).¹

Scope and duration of procurement eligibility

OnSite COVID-19 Ag Rapid Test, product code R0182C, manufactured by CTK Biotech, Inc. 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 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 on-going requirements for listing as eligible for WHO procurement, CTK Biotech, Inc. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. CTK Biotech, Inc. is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.

¹ Available on the web page
Labelling

1.0 Labels

2.0 Instructions for Use (IFU)
1.0 Product labels
1.1 Kit box design label
Lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal (NP) or nasal swab specimens from individuals suspected of COVID-19, within the first seven days of the onset of symptoms. It is intended to be used by healthcare providers as an aid in identifying SARS-CoV-2 infection.

Contains

20 Individually packed cassette devices
20 Sealed pre-filled extraction tubes
20 Extraction tube nozzles
20 Sealed pouches containing a sterile swab
1 Sample extraction tube rack
1 Instructions for Use

REF R0182C yyyy-mm-dd
LOT xxxxxxxx yyyy-mm-dd

CTK Biotech, Inc.
13855 Stowe Drive
Poway, CA 92064, USA

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
PM-R0182C Rev.A
OnSite COVID-19 Ag RDT kit box design file Revision A
Effective date: 09/29/2020
Dimension: 205 X 122 X 70 mm
1.2 Component labels
<table>
<thead>
<tr>
<th>Item</th>
<th>Component</th>
<th>Label Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Pouch</td>
<td><img src="image1" alt="Label Template" /></td>
</tr>
<tr>
<td></td>
<td>Material code</td>
<td>RM0257</td>
</tr>
<tr>
<td></td>
<td>Document code:</td>
<td>PC-R0180C Rev. A</td>
</tr>
<tr>
<td></td>
<td>Size:</td>
<td>120 x 65mm</td>
</tr>
<tr>
<td>2.</td>
<td>Cassette</td>
<td><img src="image2" alt="Label Template" /></td>
</tr>
<tr>
<td></td>
<td>Material code</td>
<td>RM-0182C</td>
</tr>
<tr>
<td></td>
<td>Doc code</td>
<td>RM-R0182C Rev. B</td>
</tr>
<tr>
<td></td>
<td>Size</td>
<td>20 x 72 mm</td>
</tr>
<tr>
<td>3.</td>
<td>Pre-filled, foil sealed extraction tube (Controlled by BGB)</td>
<td><img src="image3" alt="Label Template" /></td>
</tr>
<tr>
<td></td>
<td>Material code</td>
<td>RM3387</td>
</tr>
<tr>
<td>4.</td>
<td>Nozzle</td>
<td><img src="image4" alt="Label Template" /></td>
</tr>
</tbody>
</table>
COVID-19 Ag Rapid Test
Labeling - R0182C, 20T/kit

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 5. | **Swab**  
(From swab supplier)  
Size 150mm (length) |
|   | See swab label below on separate page |
| 6. | **Kit box**  
Material code  
PM-R0182C  
Doc code  
PM-R0182C Rev. A  
Size 205 x 122 x 70 mm |
| 7. | **Sample extraction buffer**  
PL-SB-R0182-FS  
Rev D  
Size: 55 x 20 mm |
8. Kit box label

Doc code
PL-R0182C-2-FS Rev D

Size 146 x 95 mm

Lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal (NP) or nasal swab specimens from individuals suspected of COVID-19, within the first seven days of the onset of symptoms. It is intended to be used by healthcare providers as an aid in identifying SARS-CoV-2 infection.

Contains
20 Individually packed cassette devices
20 Sealed pre-filled extraction tubes
20 Extraction tube nozzles
20 Sealed pouches containing a sterile swab
1 Sample extraction tube rack
1 Instructions for Use

REF R0182C yyyy-mm-dd
LOT xxxxxxxx yyyy-mm-dd

CTK Biotech, Inc.
13855 Stowe Drive
Poway, CA 92064, USA

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

9. Paper tube rack
2.0 Instructions for use

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2 English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
The OnSite COVID-19 Ag Rapid Test is a lateral flow immunassay for the qualitative detection of SARS-CoV-2 nucleoprotein 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 healthcare providers or personnel trained in rapid test procedure, as an aid in identifying SARS-CoV-2 infection.

**INTENDED USE**

The OnSite COVID-19 Ag Rapid Test does not differentiate between SARS-CoV-2 and SARS-CoV-1. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine their significance. Positive results do not rule out other bacterial or viral infections. Negative results do not require another confirmatory testing method, but local regulatory requirement may request additional PCR testing.

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 the patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The product is intended to be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulations. For in vitro diagnostic use only.

**INTENDED USE**

**SUMMARY AND EXPLANATION OF THE TEST**

SARS-CoV-2 belongs to the broad family of coronaviruses which are capable of causing illnesses ranging from the common cold to more severe diseases. SARS-CoV-2 infections cause COVID-19 disease resulting in a wide range of clinical symptoms, ranging from asymptomatic to fever, tiredness and dry cough, and possibly leading to severe sickness and even death. Most patients recover without special treatment. According to recent data, approximately 15-20% of infected individuals become seriously ill and develop difficulty breathing. The elderly and those with underlying medical problems, such as high blood pressure, heart problems or diabetes may be more likely to develop serious illness.

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about six feet (1.8 m). Viral RNA may also be found in stool samples from patients. It is possible that the virus can be infectious even during the incubation period, but this has not been proven.

The current laboratory method for detecting COVID-19 is PCR. However, this method requires sophisticated equipment and highly trained laboratory technicians. The OnSite COVID-19 Ag Rapid Test is an easy-to-use and cost-efficient assay that can be performed at point-of-care settings.

The OnSite COVID-19 Ag Rapid Test detects the presence of antigens from the SARS-CoV-2 virus within the first seven days of the onset of symptoms. Test results should be interpreted at 15 minutes. Results should not be interpreted after 20 minutes. Minimally skilled personnel can perform the test, without the use of laboratory equipment.

**REAGENTS AND MATERIALS PROVIDED**

1. 20 Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. 20 Sealed pouch containing pre-filled extraction tubes
3. 20 Extraction tube nozzles
4. 1 Extraction tube rack
5. 20 Individually sealed pouches containing a sterile swab
6. 1 Instructions for Use

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock, watch or other timing device
2. Disposable gloves, biohazard disposal container
3. A pencil or pen to label each test device and the Positivity COVID-19 Ag Rapid Test External Control Kit (not required, sold separately)

**WARNINGS AND PRECAUTIONS**

**In Vitro Diagnostic Use**

1. Read these instructions for Use completely before performing the test. Failure to follow these instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wash hands thoroughly before and after testing. We recommend wearing disposable gloves while handling kit reagents and clinical specimens.
7. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. Re-test the results 15 minutes after specimen is applied to the test area of the device to confirm results read after 20 minutes invalid and repeat the test.
10. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS**

- Wash or sanitize hands thoroughly and put on gloves and additional personal protective equipment (PPE) following local healthcare and authority guidelines.
- Fold/disassemble the sample extraction tube rack.
- Remove one pre-filled extraction tube from the sealed pouch and close the pouch with the unused tubes.
- Hold the pre-filled extraction tube upright and, before opening it, tap the bottom of the tube on a clean, flat surface to ensure that liquid on the seal is moved down into the tube.
- Carefully remove the foil seal from the extraction tube and place the open tube in the sample extraction tube rack provided with the kit.
- Remove mucus from the patient's nose.
- Open the swab package.
- Read the specimen collection instructions and test procedure.
- Before running the assay, ensure the test area is sanitized. Open the kit and ensure all materials described in “Reagents and Materials Provided” are included and the kit is not expired.
- Obtain a timing device (clock, watch or timer) and read the Quick Reference Guide and these Instructions for Use. Consider any materials of human origin as potentially infectious, and handle them with standard biosafety procedures.

**NEGATIVE RESULT:** If only the C line develops, the test did not detect SARS-CoV-2 virus (antigen) in the specimen. The result is negative or non-reactive.

**POSITIVE RESULT:** If both the C line and Ag line develop, SARS-CoV or SARS-CoV-2 virus (antigen) is detected in the specimen. The result is positive or reactive. Some specimens might produce a faint band, but every visible test line band indicates a positive result independently of the band intensity.

**QUALITY CONTROL**

1. **Internal Control:** This test contains a built-in control feature, the C line. If the C line does not develop after sample application, the result is invalid. Review the entire procedure and repeat the test with a new device.
2. **External Control:** External controls for the OnSite COVID-19 Ag Rapid Test are available and sold separately (Positivia COVID-19 Ag Rapid Test External Control Kit catalog number C0182C). Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly the following circumstances:
   a. A new operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is use
c. A new shipment of test kits is used.

1. Clinical Performance

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

### RT-PCR Test (Reference) vs OnSite COVID-19 Ag Rapid Test Result

<table>
<thead>
<tr>
<th>Days since Symptom Onset</th>
<th>PCR Positive</th>
<th>OnSite COVID-19 Ag Rapid Test Positive</th>
<th>Agreement</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤7</td>
<td>Positive</td>
<td>Positive</td>
<td>71.4%</td>
<td>68.3%</td>
</tr>
<tr>
<td>≤15</td>
<td>Positive</td>
<td>Positive</td>
<td>71.4%</td>
<td>68.3%</td>
</tr>
<tr>
<td>≥16</td>
<td>Negative</td>
<td>Negative</td>
<td>71.4%</td>
<td>68.3%</td>
</tr>
</tbody>
</table>

**PERFORMANCE CHARACTERISTICS**

**OnSite COVID-19 Ag Rapid Test**

- **Specificity:** 99.9% (95% CI: 98.6-100%
- **Overall Agreement:** 97.6% (95% CI: 96.1-98.6%)

Stratification of the positive specimens post onset of symptoms.

### Table: Performance Characteristics

<table>
<thead>
<tr>
<th>Reactant</th>
<th>N positives</th>
<th>Concentration</th>
<th>Interference (Yes/No)</th>
<th>Interfering Substance</th>
<th>Concentration</th>
<th>Interference (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 NP antigen</td>
<td>25 µg/mL</td>
<td>No (6/6 correct)</td>
<td>No (3/3 positive)</td>
<td>Nasal swab</td>
<td>No (6/6 correct)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>MERS-CoV NP antigen</td>
<td>25 µg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Naturel saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Human H1N1 NP antigen</td>
<td>25 µg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Human coronavirus 229E</td>
<td>1.77×10^7 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Naturel saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>0.53×10^7 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Naturel saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Human coronavirus N460</td>
<td>0.51×10^7 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>7×10^9 NLM</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Naturel saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Human Metapneumovirus (HMPV)</td>
<td>0.76×10^7 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Parainfluenza virus 1</td>
<td>0.01×10^7 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Parainfluenza virus 2</td>
<td>1.8×10^6 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Parainfluenza virus 3</td>
<td>1.6×10^6 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Parainfluenza virus 4</td>
<td>1.15×10^6 TCID/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
<tr>
<td>Influenza A NP antigen</td>
<td>180 µg/mL</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
<td>Normal saliva</td>
<td>No (3/3 negative)</td>
<td>No (3/3 positive)</td>
</tr>
</tbody>
</table>

3. Limitations of Test

The following potentially interfering substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity, were evaluated with the OnSite COVID-19 Ag Rapid Test at the concentrations listed in the following table and were found not to affect test performance for detection of both positive and negative specimens:

### Table: Interfering Substance

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Concentration</th>
<th>Interference (Yes/No)</th>
<th>Interfering Substance</th>
<th>Concentration</th>
<th>Interference (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycoplasma pneumoniae</td>
<td>4.4×10^7 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>Chlamydia phlegmona</td>
<td>1.4×10^7 CFU/mL</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>7.8×10^5 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>Mycobacterium tuberculosis</td>
<td>5×10^1 CFU/mL</td>
<td>No (3/3 negative)</td>
</tr>
<tr>
<td>Mycobacterium avium (RD1)</td>
<td>2.4×10^7 CFU/mL</td>
<td>No (3/3 negative)</td>
<td>Mycoplasma pneumoniae</td>
<td>4.4×10^7 CFU/mL</td>
<td>No (3/3 negative)</td>
</tr>
</tbody>
</table>

4. Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 3×10^5 µg/mL of recombinant SARS-CoV-2 NP antigen with the OnSite COVID-19 Ag Rapid Test.

**LIMITATIONS OF TEST**

1. The assay procedure and the interpretation of assay result must be followed closely when testing for the presence of SARS-CoV-2 antigen in the nasal specimen from an individual subject. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may lead to inaccurate results.

2. It is intended for use only by healthcare professionals or personnel trained in rapid test procedure. For in vitro diagnostic use only.

3. The OnSite COVID-19 Ag Rapid Test is limited to the qualitative detection of SARS-CoV-2 antigen. The intensity of the test line does not have linear correlation with viral titer in the specimen.

4. Sensitivity can differ between strains of SARS-CoV-2 due to differences in antigen expression. Specimens might contain a new or non-identified strain of SARS-CoV-2 that expresses varying amounts of antigen.

5. A negative or non-reactive result for an individual subject indicates absence of detectable of SARS-CoV-2 antigen. However, a negative or non-reactive result does not rule out the possibility that SARS-CoV-2 infection may have occurred.

6. A negative or non-reactive result can occur if the quantity of the SARS-CoV-2 virus (antigen) present in the specimen is below the detection limit of the assay, or if the virus detected was not the predominant virus in the specimens, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.

7. The OnSite COVID-19 Ag Rapid Test detects both viable and non-viable SARS-CoV-2 and SARS-CoV-2 antigens. Test performance depends on antigen loaded in the test. A positive test does not rule out the possibility that SARS-CoV-2 infection may be present.

8. Performance of the test has not been established for monitoring antiviral treatment of SARS-CoV-2 infection.

**REFERENCES**


