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:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- 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.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the 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.

Version	Summary of amendment	Date of report amendment
1.0 to 4.0	Added a footnote to the shelf-life to reflect that the validated shelf-life is 12 months; a shelf-life of 18 months or 24 months has not been validated.	26 January 2023

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

Component	Quantity (product code R0182CST-1T)	Quantity (product code R0182CST-2T)	Quantity (product code R0182CST-5T)	Quantity (product code R0182CST-20T)
Buffer and nozzle pouch	1	2	5	20
Cassette pouch	1	2	5	20
Swab	1	2	5	20
Waste bag	1	2	5	/
Tube rack	/	/	/	1

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)[1]

Warnings/limitations
Please refer to the Instructions for Use (IFU) attached to this public report.

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.

[1] The validated shelf-life is 12 months; a shelf-life of 18 months or 24 months has not been validated.

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 eligibility for WHO procurement, CTK Biotech, Inc. was asked to provide up-to-date information about the status of its 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
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics*" (ISBN 978-92-4-001531-9).

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."*[2]

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.

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.

[2] https://www.who.int/publications/i/item/9789240015319

Labelling

1. **Labels**
2. **Instructions for use**

1.0 Labels

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

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

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

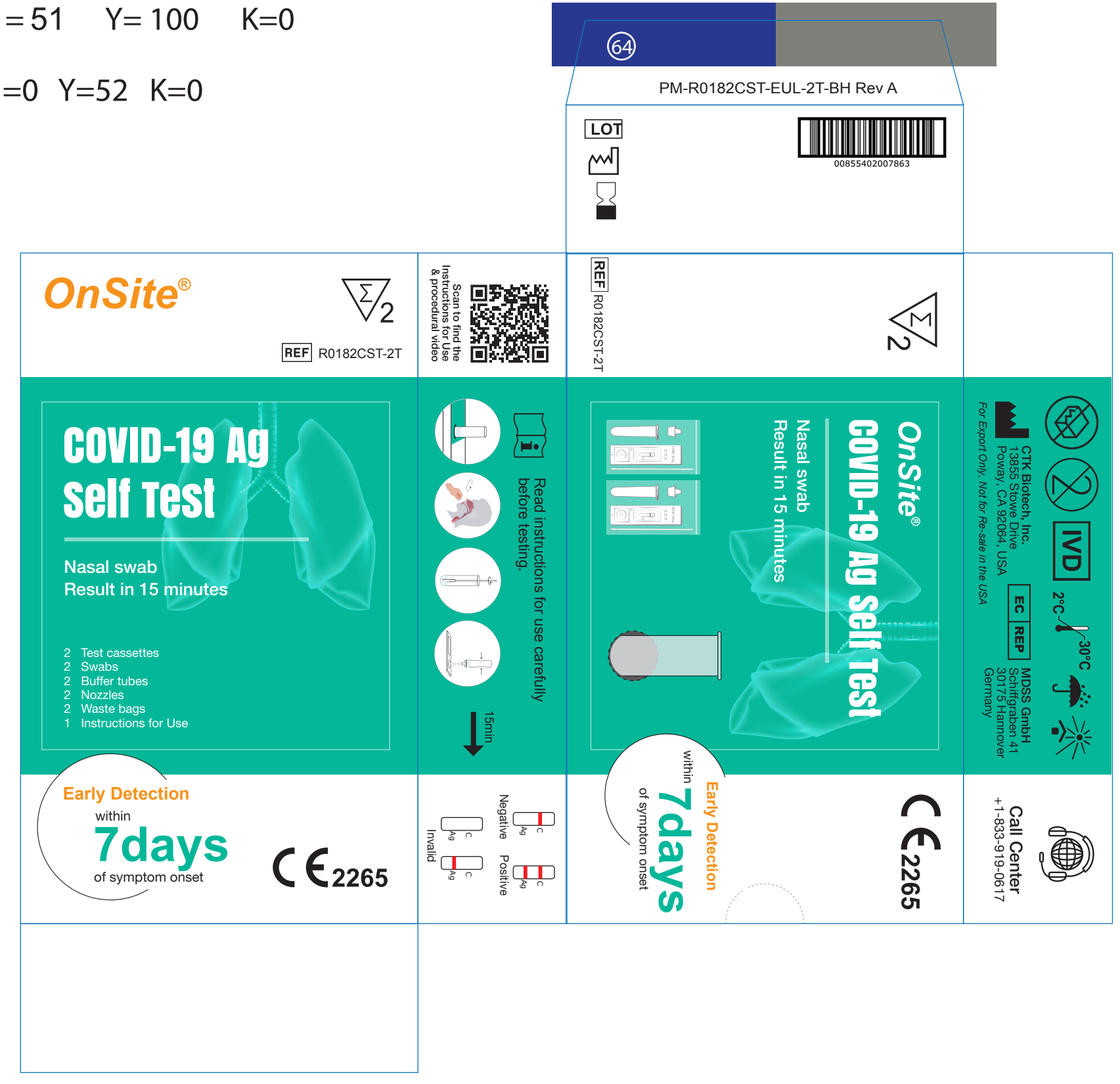
PM-R0182CST-EUL-2T-BH Rev. A

Perforated kit box design for COVID-19 Ag Self Test, 2 test/kit, Revision A.

size 135 x 80 x 30mm

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

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

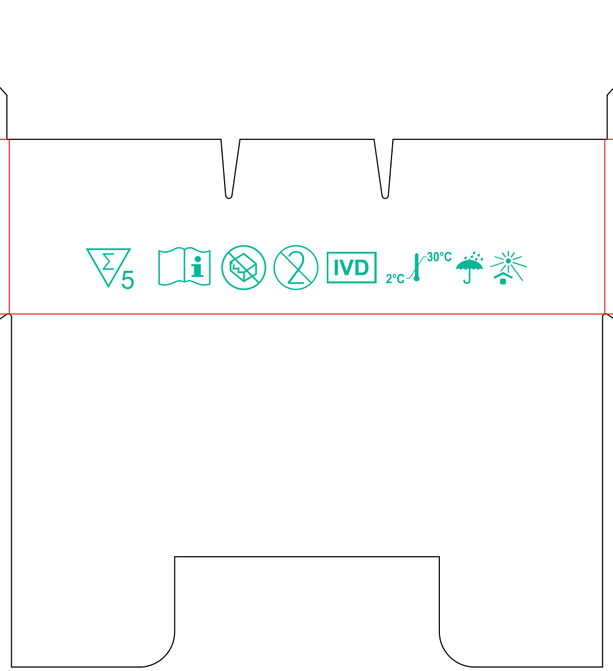


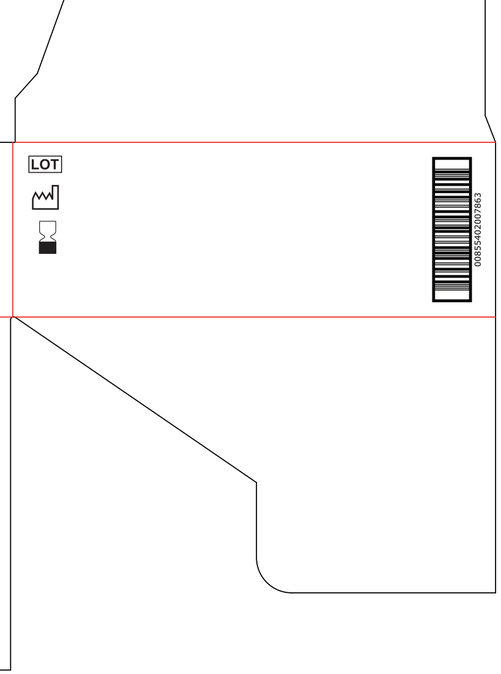
135mm 110mm 135mm 110mm

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





40mm

PM-R0182CST-20T Rev. B

Kit box design for COVID-19 Ag Self Test, 20 test/kit, Revision B.

size 205 x 122 x 70mm

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

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

IVD

2°C 30°C

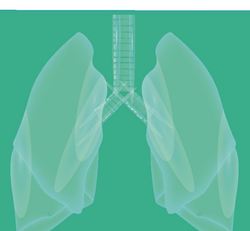
00855402007863

OnSite®

COVID-19 Ag Self Test

Nasal swab

Result in 15 minutes



Call Center
+1-833-919-0617

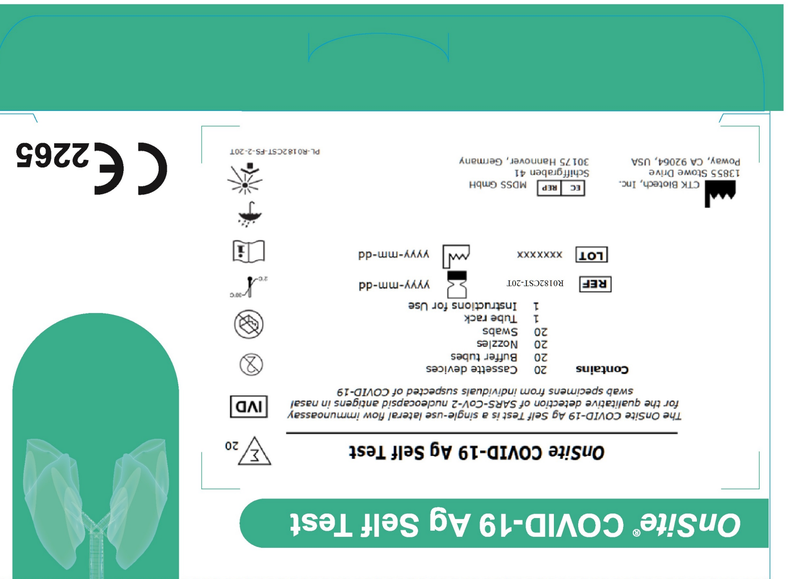
CTK Biotech, Inc.
13855 Stowe Drive, Poway, CA 92064, USA

EC REP MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany

Scan to find the Instructions for Use & procedural video

Read instructions for use carefully before testing

Negative Positive Invalid



2.0 Instructions for use (IFU)[3]

[3] 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

REF R0182CST

R0182CST-1T
R0182CST-2T
R0182CST-5T

Scan the QR code to access IFU and procedural video

Materials Provided

Test Kit Configuration	"Buffer and Nozzle" Pouch	Cassette Pouch	Swab	Waste bag
R0182CST-1T	x1	x1	x1	x1
R0182CST-2T	x2	x2	x2	x2
R0182CST-5T	x5	x5	x5	x5

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

- 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.

1. Prepare the test

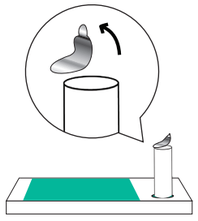
1A Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.

Blow your nose with a tissue and throw it away.

Wash your hands thoroughly and DRY them.

1B 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".



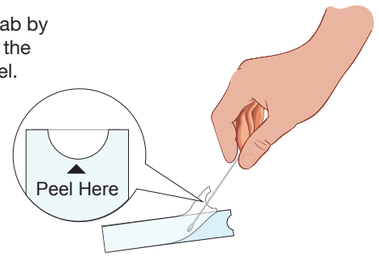
1C Puncture through the perforated circle on the kit box to form a **tube rack**.

Carefully peel off the seal of the buffer tube.

Place the open tube in the tube rack.

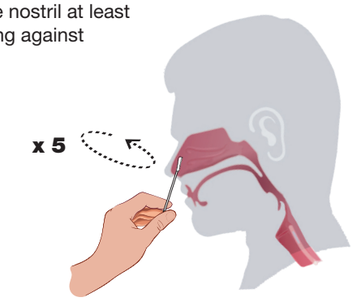
1D Remove the swab by peeling back at the "Peel Here" label. Only touch the handle of the swab.

DO NOT touch the fabric tip of the swab.

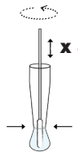


2. Collect and prepare sample

2A 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.

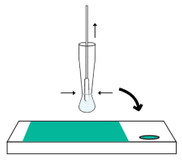


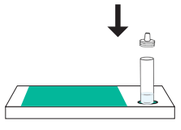
2B **Using the same swab, repeat** the process in the other nostril.



2C 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.



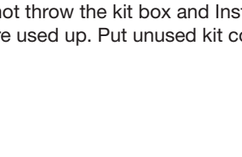


2D **Insert** the nozzle firmly into the tube while holding the tube with your other hand.

3. Test the sample

3A Open the pouch labeled "COVID-19 Ag Self Test" and remove the cassette. Lay it on the clean, flat surface.

3B **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 into the waste bag.



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

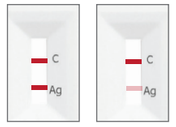
3C **Immediately** start timing 15 minutes and wait.

⚠ **Stop** the timer at 15 minutes and read the test results immediately.

4. Read test results

Negative Result
Only the Control (C) line develops.

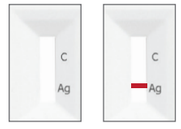
You are likely not infectious at the time the test was taken. It does not guarantee that you do not have coronavirus.



Positive Result
Both Control (C) & Test (Ag) line develop.

Look closely, the Ag line can be **very faint**.

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 into the waste bag, then discard the waste bag in the trash can (not recycling), or according to your local guidelines.

- 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.
- DO NOT turn or invert the tube during this step.
- 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 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 away until all tests are used up. Put unused kit components back into the kit box.

OnSite® COVID-19 Ag Self Test

REF R0182CST CE 2265

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 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.

WARNINGS AND PRECAUTIONS

1. Read these instructions and follow the steps in order to ensure accurate results.
2. 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 with specimen.
5. When opening the test kit, verify that all contents are included and undamaged. Do not use the test if any contents are damaged.
6. Be sure to blow your nose before opening and starting the test. 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 progress or treatment.
8. The *OnSite* COVID-19 Ag Self Test kit showed 98.6% accuracy when tested by laymen. A positive result 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 when in use. If you feel pain, stop the test and seek advice from your healthcare provider.
10. If your results are negative and you continue to have symptoms associated with COVID-19 such as fever, difficulty breathing and/or cough, you should take another test. You may have a different virus or infection causing your symptoms.
11. A negative test result does not guarantee that you don't have coronavirus. You may have COVID-19 and still get a negative result (known as a false negative) if:
    a. You did not perform the test accurately, such as not collecting the sample correctly or not waiting 15 minutes for your result.
    b. The amount of virus antigen present in the sample was below the test limits.
    c. You have had signs and symptoms of COVID-19 for longer than seven (7) days. This means you can still have COVID-19 even though the test is negative. Please see your healthcare provider for the next steps you should take.
12. A positive result means you are very likely infected with coronavirus and risk of infecting others. Follow the recommended guidelines from your health authorities such as self-quarantining 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.
13. No visible C line means that your result is invalid and there was a testing error. This could be caused by overflowing the test cassette with too much sample, or by extra mucus on the sample. You need to read the procedure instructions and repeat the entire procedure with a new kit.
14. You must read the results within the 15-20 minute window. Any result read later than 20 minutes must be repeated with a new test.
15. As long as the C line appears, any visible Ag line is a positive result. If you are not confident in the result interpretation, repeat the test.
16. This test is specific for testing nasal swab samples ONLY. Using a throat or saliva sample will give inaccurate results.
17. If you had symptoms for more than seven days you can still have COVID-19 even though the test is negative. Please see your healthcare provider for next steps.
18. Opening the pouch too early and exposing the cassette prematurely may lead to inaccurate results. If the steps are not followed as instructed, the performance of the test may be affected.
19. If contents of the buffer tube are spilled while performing the test, clean the spill with dish soap and water. Dispose all contents of the open test kit into the waste bag, then discard the waste bag in the trash can. Repeat the entire procedure with a new test.
20. The performance of this test has only been validated for self-testing and for adults or children 12 and above.

LIMITATIONS

1. Test results should be considered in addition to clinical correlation with patient history, other diagnostic information, and guidance from your healthcare provider.
2. The test detects both viable and non-viable SARS-CoV and SARS-CoV-2 antigens. Test performance depends on antigen loaded in the sample. A positive test does not rule out the possibility that other viruses or pathogens may be present.
3. A negative result may occur if the amount of virus antigen present in the sample is below the test limits.
4. Inaccurate results may occur if the swab sample has not been properly collected and processed.
5. Inaccurate results may occur if not enough sample was added in the sample well, the sample well was overloaded with sample, or sample was added too fast into the sample well forming air bubbles.
6. Inaccurate results may occur if the swab specimen has not been swirled and squeezed into the extraction tube at least 5 times.
7. Inaccurate results may occur if the results are read before the 15-20 minute window or after 20 minutes.
8. False negative results are likely if you have had signs and symptoms of COVID-19 for longer than seven (7) days. You may still have COVID-19 even though the test is negative.
9. *OnSite* COVID-19 Ag Self Test has been tested by laymen using the procedure in this Instructions for Use. Follow the steps in the Instructions for Use correctly to ensure accurate results.

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 Slovakia), in nasal swabs 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, used as the reference method for this study. The combined performance of the *OnSite* COVID-19 Ag Self Test in these studies is shown on the table below:

RT-PCR Test (Reference)	*OnSite* COVID-19 Ag Self Test Result		
	Positive	Negative	Total
Positive	155	15	170
Negative	2	523	525
Total	157	538	695

Relative Sensitivity: 91.2% (95% CI: 85.9-95.0%); Relative Specificity: 99.6% (95% CI: 98.6-100%); Overall Agreement: 97.6% (95% CI: 96.1-98.6%)

1.1 Stratification of the positive specimens post onset of symptoms in the professional study

Days Since Symptom Onset	*OnSite* COVID-19 Ag Self Test Positive	PCR Positive	Agreement	95% CI
≤1	5	5	100%	47.8%-100%
≤2	31	33	93.9%	80.0%-99.3%
≤3	75	84	89.3%	80.6%-95.0%
≤4	108	121	89.3%	82.3%-94.2%
≤5	133	148	89.9%	83.8%-94.2%
≤6	144	159	90.6%	84.9%-94.6%
≤7	151	166	91.0%	85.5%-94.9%
Total	155*	170	91.2%	85.9%-95.0%

***There were 4 positive specimens collected at 8-9 days post onset of symptoms**

1.1.1 The positive agreement of the *OnSite* COVID-19 Ag Self Test with the reference RT-PCR tests in these studies is presented in the table below relative to the average RT-PCR target Ct values, representative of the SARS-CoV-2 viral load in the samples:

RT-PCR Results		*OnSite* COVID-19 Ag Self Test Results		
Average target Ct value	N positives	N positives	Positive agreement	95% CI
<24	108	105	97.2%	92.0% - 99.4%
<27	119	116	97.5%	92.8% - 99.5%
<30	125	121	96.8%	92.0% - 99.1%
<33	132	125	94.7%	89.4% - 97.8%
All	170	155	91.2%	85.9% - 95.0%

2. Clinical Performance in a Self-Testing Environment

In the self-testing study, the *OnSite* COVID-19 Ag Self Test correctly identified 100% % (CI: 93.0 % - 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, 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:

RT-PCR Test (Reference)	*OnSite* COVID-19 Ag Self Test Result		
	Positive	Negative	Total
Positive	51	0	51
Negative	2	98	100
Total	53	98	151

Relative Sensitivity: 100%% (95% CI: 93.0%-100%); Relative Specificity: 98.0% (95% CI: 93.0%-99.8%); Overall Agreement: 98.7% (95% CI: 95.3-99.8%)

2.1 Stratification of the positive specimens post onset of symptoms in the self test study

Days Since Symptom Onset	*OnSite* COVID-19 Ag Self Test Positive	PCR Positive	Agreement	95% CI
≤1	11	11	100%	71.5%-100%
≤2	20	20	100%	83.2%-100%
≤3	21	21	100%	83.9%-100%
≤4	24	24	100%	85.8%-100%
≤5	28	28	100%	87.7%-100%
Not Disclosed	23	23	100%	85.2%-100%

2.2 Additional supporting evidence for self-testing performance

A comparison of the test results study was conducted by comparing 85 adult participants interpreted test results with healthcare professionals interpreted test results. The positive agreement between the reading performed by participants and the professional healthcare personnel in this study was 89.2% and the 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.

In another self-testing study, the performance of OnSite-19 Ag Self Test in 107 asymptomatic and mild symptomatic participants (aged above 18) showed a sensitivity of 86.0%. The positive agreement between the reading performed by the participants and professional health care personnel was 95.6% 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.

3. Analytical Performance

3.1 Analytical Sensitivity (Limit of Detection, LoD)

The LoD of the *OnSite* COVID-19 Ag Self Test in nasal swab matrices was determined to be 466.7 $TCID_{50}$/mL.

3.2 Variant Detection

The *OnSite* COVID-19 Ag Rapid Test can detect the U.K. South Africa, Brazil, and Omicron variants at similar levels as the original SARS-CoV-2 strain.

3.3 Analytical Specificity (Cross-Reactivity and Microbial Interference)

The *OnSite* COVID-19 Ag Self Test was tested with the following microbes. There was no crossreactivity and interference with: MERS-coronavirus NP antigen, Human coronavirus, HKU1 NP antigen,Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Human Metapneumovirus (hMPV), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A NP antigen, Influenza B NP antigen, Enterovirus, Respiratory syncytial virus, Rhinovirus, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Candida albicans*, Pooled human nasal wash *(representative of normal respiratory microbial flora)*, *Bordetella pertussis, Mycoplasma pneumoniae*, *Chlamydophila pneumoniae*, *Legionella pneumophila*, *Mycobacterium tuberculosis*, *Pneumocystis jirovecii* (PJP). Cross-reactivity was observed with SARS-coronavirus NP antigen.

4. Interfering Substances

No interference was observed with the following substances that were naturally present in respiratory specimens or may be artificially introduced into the nasal cavity or nasopharynx: Mucin, Whole Blood, Phenylephrine, Fluconazole, Budesonide, Nasal Gel, Menthol, Benzocaine, Lopinavir, Zanamivir, Oseltamivir, Ribavirin, Peramivir, Tobramycin, Diphenhydramine, Dextromethorphan, Acetaminophen, Acetylsalicylic Acid, Mupirocin, HAMA, Biotin.

5. Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 3×10^8 pg/mL of recombinant SARS-CoV-2 NP antigen with the *OnSite* COVID-19 Ag Self Test.

Description of Symbols Used

IVD	*In vitro* diagnostic medical device		Manufacturer
	Do not re-use		Date of manufacture
	Do not use if package is damaged	REF	Catalog number
	Keep dry	LOT	Batch code
	Keep away from sunlight		Used-by-date
	Store between 2-30°C	CE	CE marking
	Consult instructions for use	EC REP	Authorized representative in the European Community / European Union
Σ N	Contains sufficient for N tests		

CTK Biotech, Inc.
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Poway, CA 92064, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

PI-R0182CST-EUL2 Rev AH2.4
Date released: 2022-08-24
English version

INSTRUCTIONS FOR USE

REF R0182CST

R0182CST-20T
Scan the QR code to access IFU and procedural video

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.

- 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.

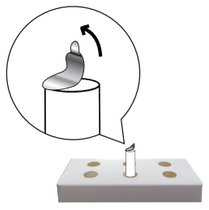
1. Prepare the test

1A 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.

1B 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.



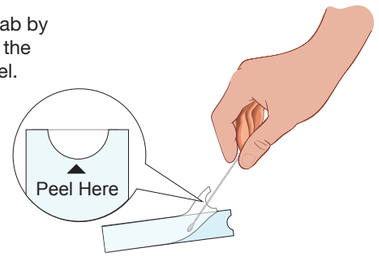
1C Fold and assemble the paper **tube rack**.

Carefully peel off the seal of the buffer tube.

Place the open tube in the tube rack.

1D Remove the swab by peeling back at the "Peel Here" label. Only touch the handle of the swab.

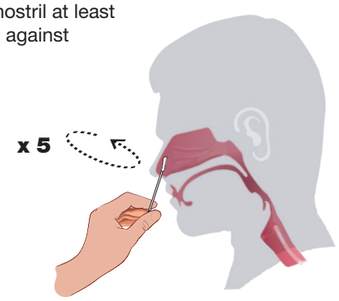
DO NOT touch the fabric tip of the swab.



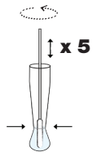
- If you are testing more than one sample, always clean the surface and wash your hands between each test.
- DO NOT touch the fabric tip of the swab with your hands.

2. Collect and prepare sample

2A 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.

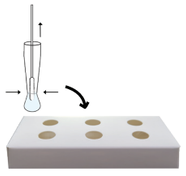


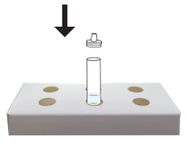
2B **Using the same swab, repeat** the process in the other nostril.



2C 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 and squeeze the tube against the fabric tip to remove excess fluid from the swab. **Remove** the swab from the buffer tube. **Place** the tube back into the tube rack. **Discard** the swab.





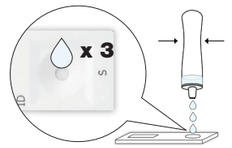
2D **Insert** the nozzle firmly into the tube while holding the tube with your other hand.

- DO NOT turn or invert the tube during this step.
- Do not touch your cheeks, teeth, gums or any other surfaces with the fabric tip of the swab, or it might contaminate your sample.

3. Test the sample

3A Open the pouch labeled "COVID-19 Ag Self Test" and remove the cassette. Lay it on the clean, flat surface.

3B **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.

3C **Immediately** start timing 15 minutes and wait.

⚠ **Stop** the timer at 15 minutes and read the test results immediately.

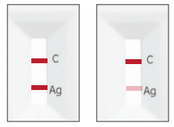
- Do not use the kit if it's expired or the sealed packaging is damaged.
- Do not throw the Instructions for Use and paper tube rack away until all tests are used up. Put unused kit components back into the kit box.

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.

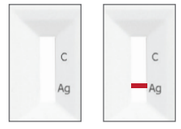


Positive Result

Both Control (C) & Test (Ag) line develop.

Look closely, the Ag line can be **very faint**.

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.

OnSite® COVID-19 Ag Self Test

REF R0182CST CE 2265

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 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.

WARNINGS AND PRECAUTIONS

1. Read these instructions and follow the steps in order to ensure accurate results.
2. 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 with specimen.
5. When opening the test kit, verify that all contents are included and undamaged. Do not use the test if any contents are damaged.
6. Be sure to blow your nose before opening and starting the test. 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 progress or treatment.
8. The *OnSite* COVID-19 Ag Self Test kit showed 98.6% accuracy when tested by laymen. A positive result 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 when in use. If you feel pain, stop the test and seek advice from your healthcare provider.
10. If your results are negative and you continue to have symptoms associated with COVID-19 such as fever, difficulty breathing and/or cough, you should take another test. You may have a different virus or infection causing your symptoms.
11. A negative test result does not guarantee that you don't have coronavirus. You may have COVID-19 and still get a negative result (known as a false negative) if:
    a. You did not perform the test accurately, such as not collecting the sample correctly or not waiting 15 minutes for your result.
    b. The amount of virus antigen present in the sample was below the test limits.
    c. You have had signs and symptoms of COVID-19 for longer than seven (7) days. This means you can still have COVID-19 even though the test is negative. Please see your healthcare provider for the next steps you should take.
12. A positive result means you are very likely infected with coronavirus and risk of infecting others. Follow the recommended guidelines from your health authorities such as self-quarantining 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.
13. No visible C line means that your result is invalid and there was a testing error. This could be caused by overflowing the test cassette with too much sample, or by extra mucus on the sample. You need to read the procedure instructions and repeat the entire procedure with a new kit.
14. You must read the results within the 15-20 minute window. Any result read later than 20 minutes must be repeated with a new test.
15. As long as the C line appears, any visible Ag line is a positive result. If you are not confident in the result interpretation, repeat the test.
16. This test is specific for testing nasal swab samples ONLY. Using a throat or saliva sample will give inaccurate results.
17. If you had symptoms for more than seven days you can still have COVID-19 even though the test is negative. Please see your healthcare provider for next steps.
18. Opening the pouch too early and exposing the cassette prematurely may lead to inaccurate results. If the steps are not followed as instructed, the performance of the test may be affected.
19. If contents of the buffer tube are spilled while performing the test, clean the spill with dish soap and water. Dispose all contents of the open test kit into the waste bag, then discard the waste bag in the trash can. Repeat the entire procedure with a new test.
20. The performance of this test has only been validated for self-testing and for adults or children 12 and above.

LIMITATIONS

1. Test results should be considered in addition to clinical correlation with patient history, other diagnostic information, and guidance from your healthcare provider.
2. The test detects both viable and non-viable SARS-CoV and SARS-CoV-2 antigens. Test performance depends on antigen loaded in the sample. A positive test does not rule out the possibility that other viruses or pathogens may be present.
3. A negative result may occur if the amount of virus antigen present in the sample is below the test limits.
4. Inaccurate results may occur if the swab sample has not been properly collected and processed.
5. Inaccurate results may occur if not enough sample was added in the sample well, the sample well was overloaded with sample, or sample was added too fast into the sample well forming air bubbles.
6. Inaccurate results may occur if the swab specimen has not been swirled and squeezed into the extraction tube at least 5 times.
7. Inaccurate results may occur if the results are read before the 15-20 minute window or after 20 minutes.
8. False negative results are likely if you have had signs and symptoms of COVID-19 for longer than seven (7) days. You may still have COVID-19 even though the test is negative.
9. *OnSite* COVID-19 Ag Self Test has been tested by laymen using the procedure in this Instructions for Use. Follow the steps in the Instructions for Use correctly to ensure accurate results.

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 Slovakia), in nasal swabs 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, used as the reference method for this study. The combined performance of the *OnSite* COVID-19 Ag Self Test in these studies is shown on the table below:

RT-PCR Test (Reference)	*OnSite* COVID-19 Ag Self Test Result		
	Positive	Negative	Total
Positive	155	15	170
Negative	2	523	525
Total	157	538	695

Relative Sensitivity: 91.2% (95% CI: 85.9-95.0%); Relative Specificity: 99.6% (95% CI: 98.6-100%); Overall Agreement: 97.6% (95% CI: 96.1-98.6%)

1.1 Stratification of the positive specimens post onset of symptoms in the professional study

Days Since Symptom Onset	*OnSite* COVID-19 Ag Self Test Positive	PCR Positive	Agreement	95% CI
≤1	5	5	100%	47.8%-100%
≤2	31	33	93.9%	80.0%-99.3%
≤3	75	84	89.3%	80.6%-95.0%
≤4	108	121	89.3%	82.3%-94.2%
≤5	133	148	89.9%	83.8%-94.2%
≤6	144	159	90.6%	84.9%-94.6%
≤7	151	166	91.0%	85.5%-94.9%
Total	155*	170	91.2%	85.9%-95.0%

***There were 4 positive specimens collected at 8-9 days post onset of symptoms**

1.1.1 The positive agreement of the *OnSite* COVID-19 Ag Self Test with the reference RT-PCR tests in these studies is presented in the table below relative to the average RT-PCR target Ct values, representative of the SARS-CoV-2 viral load in the samples:

RT-PCR Results		*OnSite* COVID-19 Ag Self Test Results		
Average target Ct value	N positives	N positives	Positive agreement	95% CI
<24	108	105	97.2%	92.0% - 99.4%
<27	119	116	97.5%	92.8% - 99.5%
<30	125	121	96.8%	92.0% - 99.1%
<33	132	125	94.7%	89.4% - 97.8%
All	170	155	91.2%	85.9% - 95.0%

2. Clinical Performance in a Self-Testing Environment

In the self-testing study, the *OnSite* COVID-19 Ag Self Test correctly identified 100% % (CI: 93.0 % - 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, 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:

RT-PCR Test (Reference)	*OnSite* COVID-19 Ag Self Test Result		
	Positive	Negative	Total
Positive	51	0	51
Negative	2	98	100
Total	53	98	151

Relative Sensitivity: 100%% (95% CI: 93.0%-100%); Relative Specificity: 98.0% (95% CI: 93.0%-99.8%); Overall Agreement: 98.7% (95% CI: 95.3-99.8%)

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≤1	11	11	100%	71.5%-100%
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5. Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 3×10^8 pg/mL of recombinant SARS-CoV-2 NP antigen with the *OnSite* COVID-19 Ag Self Test.

Description of Symbols Used

IVD	*In vitro* diagnostic medical device		Manufacturer
	Do not re-use		Date of manufacture
	Do not use if package is damaged	REF	Catalog number
	Keep dry	LOT	Batch code
	Keep away from sunlight		Used-by-date
	Store between 2-30°C	CE	CE marking
	Consult instructions for use	EC REP	Authorized representative in the European Community / European Union
Σ_N	Contains sufficient for N tests		

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Date released: 2022-08-24
English version