

INSTRUCTIONS FOR USE

REF R0182CST

- 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.

Before opening the test

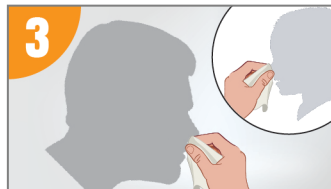
If you are testing more than one sample, always clean the surface and wash your hands between each test.



You will need: a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.



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



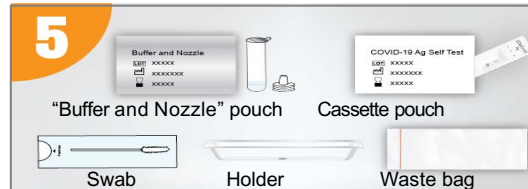
Blow your nose with a tissue and throw it away.
If helping a child, help the child blow their nose.



Wash your hands thoroughly and **DRY** them.

Prepare for testing

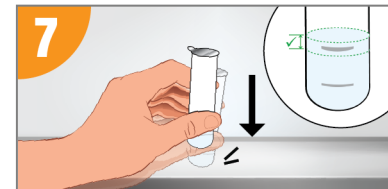
Do not use the kit if the sealed packaging is damaged.



Open one test and remove all the contents from the holder. Verify that the contents are all included and undamaged.



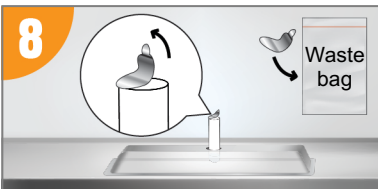
Open the pouch labeled "Buffer and Nozzle".



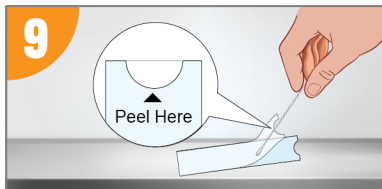
Hold the buffer tube upright. Tap the bottom of the tube on the flat surface so most of the liquid is moved down to the bottom of the tube. Check that the liquid is close to the upper line.

Collect the nasal swab sample

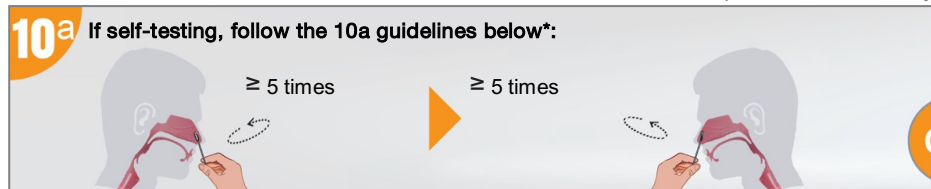
Do not touch your cheeks, teeth, gums or any other surfaces with the fabric tip of the swab, or it might contaminate your sample. **DO NOT** touch the fabric tip of the swab with your hands.



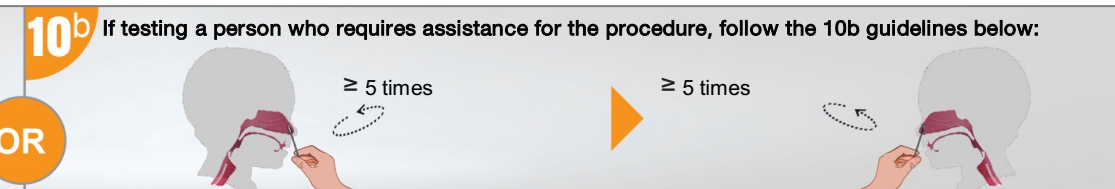
Flip the empty holder over to use as a tube rack. Carefully peel off the seal of the buffer tube. Place the open tube in the tube rack. Discard the seal in the waste bag provided with the test.



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 with your hands or anything else.

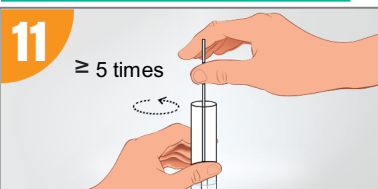


With the help of a mirror:
1a. Hold the handle of the swab between your fingers. Carefully insert the fabric tip of the swab into one nostril, about **2 cm** into the nose. **DO NOT** insert the swab any deeper if you feel strong resistance or pain. While pressing against the nasal wall, rotate the swab around the nostril at least **5 times**.
2a. Remove the swab from the nostril and, **using the same swab**, repeat "1a" in the other nostril.
*Children ages 12 and up may self-test with adult supervision

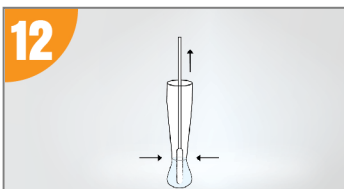


1b. Show the person the test kit and explain what you are going to do.
2b. Hold the handle of the swab between your fingers. Carefully insert the fabric tip of the swab in one of the person's nostrils, about **2 cm** into the nose. **DO NOT** insert the swab any deeper if you feel strong resistance or it causes pain. While pressing against the nasal wall, rotate the swab around the nostril at least **5 times**.
3b. Remove the swab from the nostril and, **using the same swab**, repeat "2b" in the person's other nostril.

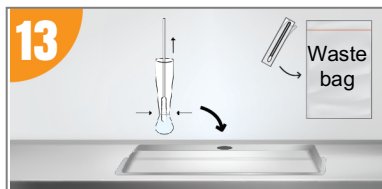
Process the swab sample



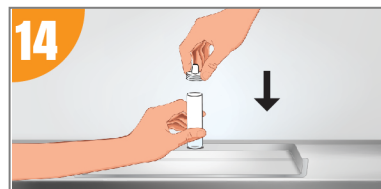
Remove the buffer tube from the rack, and insert the fabric tip of the swab into the tube as shown. **Swirl** the swab in the liquid at least **5 times**.



Squeeze the tube against the submerged swab at least **5 times**.

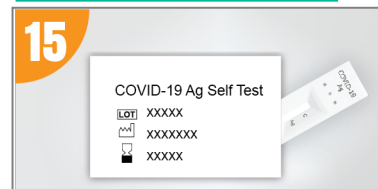


Lift the swab out of the liquid and **squeeze** the tube against the fabric tip to remove excess fluid from the swab. **Remove** the swab from the buffer tube. Place the tube back into the tube rack. Discard the swab into the waste bag.



Insert the nozzle into the tube while holding the tube with your other hand. It should fit snug like a cork.
DO NOT turn or invert the tube during this step.

Test the sample



Open the pouch labeled "COVID-19 Ag Self Test" and remove the cassette. Lay it on the clean, flat surface with sufficient lighting. Discard the pouch and desiccant into the waste bag.

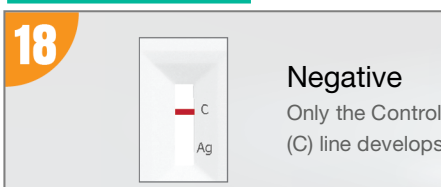


Invert the buffer tube over the cassette and gently squeeze to **slowly** add 3 drops of the liquid into the sample well (S), avoid forming bubbles. Discard the buffer tube into the waste bag. **Immediately start timing 15 minutes** and wait.
• **DO NOT** move the cassette during the test.

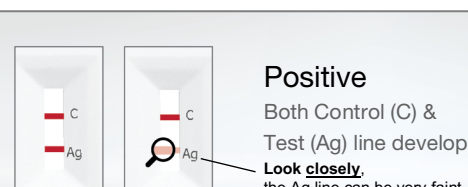
Read the result



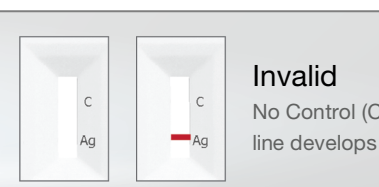
Read result after 15 minutes. You must read the result after 15 minutes, but not past 20 minutes.



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

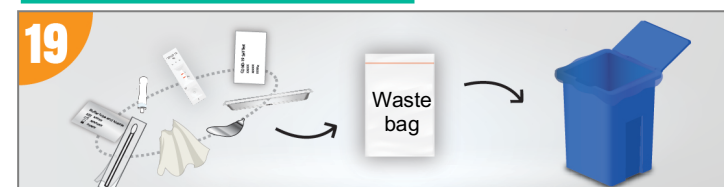


Positive result: You are currently infected with coronavirus and could infect others. Follow the recommended guidelines from your health authorities. You may need additional testing depending on your personal history.



Invalid result: There was a testing error. You need to read the procedure instructions and repeat the entire procedure with a new test.
DO NOT reuse any components from the first test.

Safely dispose of your test kit



Once your test is complete, ensure all used items (swab, swab wrapper, cassette, cassette pouch, desiccant, buffer tube, nozzle, tube pouch and holder) are placed into the waste bag. Close the bag and discard following local legislation governing disposal, regardless of the test result. Thoroughly wash or sanitize your hands and any surfaces and items used for the procedure.

OnSite® COVID-19 Ag Self Test

REF R0182CST C 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 and/or cough may still have SARS-CoV-2 infection and should check with 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

- Read these instructions and follow the steps in order to ensure accurate results.
- For *in vitro* diagnostic use.
- 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.
- Do not overload the sample well with specimen.
- When opening the test kit, verify that all contents are included and undamaged. Do not use the test if any contents are damaged.
- 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.
- Do not use this test to monitor disease progress or treatment.
- 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.
- 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.
- 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.
- 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:
 - You did not perform the test accurately, such as not collecting the sample correctly or not waiting 15 minutes for your result.
 - The amount of virus antigen present in the sample was below the test limits.
 - 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.
- A positive result means you are very likely infected with coronavirus and there is a risk of infecting others. Follow the recommended guidelines from your health authorities such as self-quarantining at home to avoid spreading COVID-19 to others. 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.

- 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.
- 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.
- 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.
- This test is specific for testing nasal swab samples ONLY. Using a throat or saliva sample will give inaccurate results.
- 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.
- 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.
- 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.
- The performance of this test has only been validated for self-testing and for adults or children 12 and above.

LIMITATIONS

- Test results should be considered in addition to clinical correlation with patient history, other diagnostic information, and guidance from your healthcare provider.
- This test is limited to the detection of proteins from SARS-CoV-2 only, not for any other viruses or pathogens.
- A negative result may occur if the amount of virus antigen present in the sample is below the test limits.
- Inaccurate results may occur if the swab sample has not been properly collected and processed.
- Inaccurate results may occur if: not enough buffer has been used into the sample well, the sample well is overloaded with buffer, or if buffer has been loaded too fast into the sample well and formed air bubbles.
- Inaccurate results may occur if the swab specimen has not been swirled and squeezed into the extraction tube at least 5 times.
- Inaccurate results may occur if the results are read before the 15-20 minute window or after 20 minutes.
- 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.
 - 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 pathogens may be present.
- 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 a clinical site in Germany in swab specimens collected from symptomatic subjects suspected of COVID-19. Samples were tested by the *OnSite* COVID-19 Ag Self Test and by a real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2, which was used as the reference method for this study. The 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	114	4	118
Negative	0	100	100
Total	114	104	218

Relative Sensitivity: 96.6% (95% CI: 91.6-98.7%); Relative Specificity: 100% (95% CI: 96.3-100%); Total Agreement: 98.2% (95% CI: 95.4-99.3%)

2. Analytical Performance

2.1 Analytical Sensitivity (Limit of Detection, LoD)

The LoD of the *OnSite* COVID-19 Ag Self Test was determined by evaluating a serial dilution of Gamma-Irradiated SARS-CoV-2 virus lysate (BEI Resources, NR-52287). Multiple negative nasopharyngeal or nasal swab specimens were eluted in PBS and were combined and mixed thoroughly to create clinical negative matrix pools for each matrix, to be used as the diluent. Inactivated SARS-CoV-2 virus lysate was diluted in each of these matrices to generate virus dilutions for testing. Each NP or nasal swab was spiked with 50 µL of each virus dilution, extracted with extraction buffer and tested

according to the product IFU. The assay LoD was determined for both NP and nasal swab specimens as the lowest concentration that was detected ≥ 95% of the time in the respective specimen matrix.

The LoD of the *OnSite* COVID-19 Ag Self Test in both nasopharyngeal and nasal swab matrices was determined to be 280 TCID₅₀/mL. The *OnSite* COVID-19 Ag Self Test detects the Alpha (U.K.), Beta (South Africa), Gamma (Brazil), Delta (India), Eta (Nigeria), Iota (USA), Kappa (India), Lambda (Peru), P.2 (Brazil), and B.1.620 variants at similar levels as the original SARS-CoV-2 strain.

2.2 Analytical Specificity (Cross-Reactivity and Microbial Interference)

The analytical specificity of the *OnSite* COVID-19 Ag Self Test was evaluated by testing commensal and pathogenic microorganisms that may be present in the nasal cavity. Each of the organisms was tested at least in triplicate in the presence of 2-3X LoD recombinant SARS-CoV-2 NP antigen. No cross-reactivity (except for SARS-coronavirus) or microbial interference were observed with the following microorganisms when tested at the concentration presented in the table below:

Potential Cross-Reactant	Concentration	Cross-Reactivity (Yes/No)
SARS-coronavirus NP antigen	25 µg/mL	Yes
MERS-coronavirus NP antigen	25 µg/mL	No
Human coronavirus HKU1 NP antigen	66 µg/mL	No
Human coronavirus 229E	1.77×10 ⁵ TCID ₅₀ /mL	No
Human coronavirus OC43	0.53×10 ⁵ TCID ₅₀ /mL	No
Human coronavirus NL63	0.51×10 ⁵ TCID ₅₀ /mL	No
Adenovirus	7×10 ⁸ NIU/mL	No
Human Metapneumovirus (hMPV)	0.76×10 ⁴ TCID ₅₀ /mL	No
Parainfluenza virus 1	5.01×10 ⁴ TCID ₅₀ /mL	No
Parainfluenza virus 2	1.6 x 10 ⁵ TCID ₅₀ /mL	No
Parainfluenza virus 3	1.6 x 10 ⁵ TCID ₅₀ /mL	No
Parainfluenza virus 4	1.15×10 ⁵ TCID ₅₀ /mL	No
Influenza A NP antigen	180 µg/mL	No
Influenza B NP antigen	200 µg/mL	No
Enterovirus	2.8 x 10 ⁵ TCID ₅₀ /mL	No
Respiratory syncytial virus	2.8 x 10 ⁴ TCID ₅₀ /mL	No
Rhinovirus	2.2 x 10 ⁵ PFU/mL	No
<i>Haemophilus influenzae</i>	5.2 x 10 ⁵ CFU/mL	No
<i>Streptococcus pneumoniae</i>	>2×10 ³ CFU/mL	No
<i>Streptococcus pyogenes</i>	3.6 x 10 ⁵ CFU/mL	No
<i>Candida albicans</i>	4.5×10 ⁶ TCID ₅₀ /mL	No
Pooled human nasal wash, representative of normal respiratory microbial flora	N/A	No
<i>Bordetella pertussis</i>	3.9 x 10 ⁷ CFU/mL	No
<i>Mycoplasma pneumoniae</i>	4.4 x 10 ⁵ CFU/mL	No
<i>Chlamydomydia pneumoniae</i>	1.4 x 10 ⁷ IFU/mL	No
<i>Legionella pneumophila</i>	7.8 x 10 ⁵ CFU/mL	No
<i>Mycobacterium tuberculosis</i>	>2×10 ³ CFU/mL	No
<i>Pneumocystis jirovecii</i> (PJP)	3.45×10 ⁶ CFU/mL	No

3. Interfering Substances














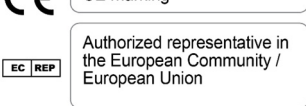

The following potentially interfering substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the *OnSite* COVID-19 Ag Self Test at the concentrations listed in the following table and were found not to affect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

Interfering Substance	Concentration	Interfering Substance	Concentration
Mucin	0.5%	Ribavirin	1 mg/mL
Whole Blood	4%	Peramivir	1 mg/ml
Phenylephrine	15% v/v	Tobramycin	4 µg/mL
Fluconazole	5% w/v	Diphenhydramine	0.08 mg/dL
Budesonide	5% w/v	Dextromethorphan	1.56 µg/dL
Nasal Gel	2% v/v	Acetaminophen	199 uM
Menthol	1.5 mg/mL	Acetylsalicylic Acid	3 mg/dL
Benzocaine	1.5 mg/mL	Mupirocin	10 mg/mL
Lopinavir	5 mg/mL	HAMA	4 ng/mL
Zanamivir	5 mg/mL	Biotin	100 µg/mL
Oseltamivir	5 mg/mL		


4. Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 3×10⁸ pg/mL of recombinant SARS-CoV-2 NP antigen with the *OnSite* COVID-19 Ag Self Test.

Description of Symbols Used

	In vitro diagnostic medical device		Manufacturer
	Do not re-use		Date of manufacture
	Do not use if package is damaged		Catalog number
	Keep dry		Batch code
	Keep away from sunlight		Used-by-date
	Store between 2-30°C		CE marking
	Consult instructions for use		
	Contains sufficient for 2 tests		


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English version

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