COVID-19 At-Home Test

Healthcare Provider Instructions for Use

For In Vitro Diagnostic Use.

For use under an FDA Emergency Use Authorization (EUA) only.

For use with anterior nasal swab specimens.

For FDA Emergency Use Authorization (EUA) only.

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Intended Use

The COVID-19 At-Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The COVID-19 At-Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. 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 bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the COVID-19 At-Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

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

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal

requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The COVID-19 At-Home Test is authorized for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting.

The COVID-19 At-Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Principle of the test

The COVID-19 At-Home Test has two pre-coated lines: A "C" Control line and a "T" Test line on the surface of the nitrocellulose membrane. Neither the control line nor the test line is visible in the test window before applying the sample. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with color particles is used as a detector for the SARS-CoV-2 antigen. During the test, the SARS-CoV-2 antigen in the sample interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making an antigen-antibody color particle complex. This complex migrates on the membrane via capillary action to the test line, where it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line becomes visible in the result window if SARS-CoV-2 antigens are present in the sample.

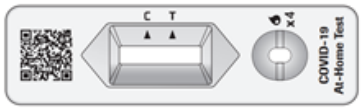
Reagents

- mAb anti-COVID-19 antibody
- mAb anti-chicken-IgY
- mAb anti-COVID-19 antibody-gold conjugate
- purified chicken-IgY-gold conjugate

Materials provided

- Test device
- Tube with liquid
- Nozzle cap
- Sterile swab
- Tube holder
- Quick Reference Instructions

Note: This test comes in a 1 test (order no.: 09620702160), 4 test (order no.: 09666672160) or 25 test (order no.: 09620729160) quantity. The number of items supplied in the kit will vary depending on which kit is purchased.

Test device 	Tube with liquid 	Nozzle cap 
Sterile swab 	Tube Holder 	Quick Reference Instructions 

Materials required (but not provided)

- Timer

Warnings and Precautions

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

- Follow directions for use.
- Use the test kit once only. Do not use with multiple specimens.
- The test is intended to aid in the diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use. If ingested, seek medical advice.
- Children below the age of 14 should not swab themselves and should instead be swabbed by an adult.
- You should wear a face mask if swabbing others.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use.
- Do not use the test after the expiry date shown on the test device pouch.
- Do not use the test if the pouch is damaged or open.
- Make sure there is sufficient light when testing.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.

- In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- Use only the components of this test kit.
- If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat the test with a fresh one.
- Remove any piercings from the nose before starting the test.
- The control line may show up within a few minutes of starting the test. It may take up to 20 minutes for a test line to show up.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the soft pad at the top of the swab when handling the swab.
- The test is intended to be read at 20 minutes. If the test is read before 20 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test device.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The chemicals in the reagent solution may be hazardous to the skin and eye. Please see the table below for safety recommendations for skin and eye irritation. No personal protective equipment is currently recommended for use with this test.

Chemical Name/ CAS	**Hazard Category (mixture)**	**Hazard Statement for Mixture**	**Labeling of Harm(s)**
Sodium chloride / 7647-14-5 L-Arginine / 74-79-3	Category 2	Eye irritation	May cause eye irritation
Polidocanol / 3055-99-0 ProClin® 300	Category 3	Skin irritation	Causes mild skin irritation

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Limitations

- Do not use on anyone under 2 years of age.
- Children aged 2 to 13 years of age should be tested by an adult. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.

- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after six days are more likely to be negative compared to RT-PCR.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
- The performance of the COVID-19 At-Home Test was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of viral antigen in the sample and may or may not correlate with viral culture results performed on the same sample.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Positive test results do not rule out co-infections with other pathogens.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results should be treated as presumptive and confirmed with a molecular assay for clinical management, if necessary.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in December 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Storage and Stability

Store the kit at 36-86 °F / 2-30 °C and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging. Do not freeze the kit.

Test Procedure and Results Interpretation

Read instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.

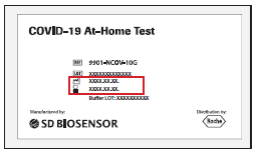
Prepare to perform the test

1. Bring test kit to room temperature (59-86 °F / 15-30 °C).

2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.

3. Check test expiry date on the back of the foil pouches. Do not use if the expiry date has passed.

   NOTE: Testing should commence immediately after opening the sealed pouches.

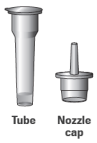


4. Open foil pouch 1 by tearing along the tear-line. Remove the test device and desiccant package from the foil pouch. Place the test device on a flat surface.

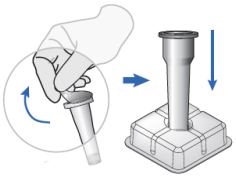
5. Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected). Do not open the desiccant package.

Test procedure

1. Open foil pouch 2 and place one tube and one nozzle cap on the table.

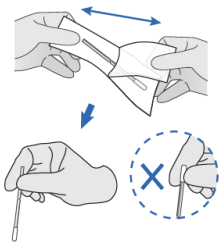


   Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder.



   If any liquid spills, do not use the tube.

2. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.



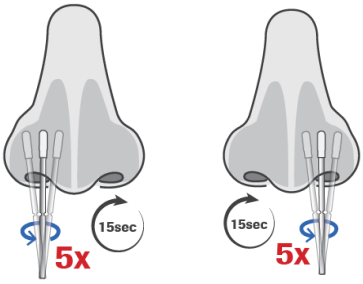
3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¾ of an inch.

4. ****Swab Both Nostrils****
Firmly and slowly rotate the swab **at least 5 times**, brushing against the inside walls of the nostril, for a total of 15 seconds.

****Do not just spin the swab.****
Gently remove the swab and, using the **same** swab, repeat in the second nostril with the same end of the swab.

WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

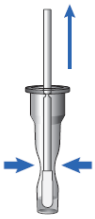
NOTE: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.



5. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Then stir the swab **more than 10 times**.
This is to transfer the biological material from the swab to the liquid

6. Remove the swab **while** squeezing the sides of the tube to extract the liquid from the swab.

WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

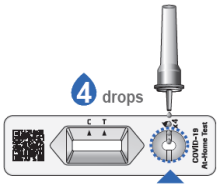


7. Dispose of the swab and seal the tube securely with the nozzle cap.

   ****Ensure that the nozzle cap is securely fitted before proceeding to the next step****

8. Hold the tube upright above the sample well. **Drop 4 drops** onto the sample well.

   ****Do not apply the liquid in the rectangular result window****



9. Set the timer and read the test result at 20 minutes. Do not read the result before 20 minutes **or** after 30 minutes.

   WARNING! Do not move or lift the test device during this time.

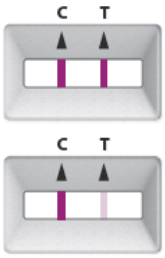
   NOTE: Dispose of the used test in the household trash. Do not flush or pour test liquids down a drain.

Read and interpret the results

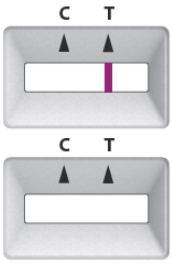
WARNING! Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

Look at the result window and locate the letters C and T on the top side of the window. A colored line should always appear at the C position; this is the control line and signals that the test is working properly.

Negative result
If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms worsen), contact your doctor/ primary care physician. You may have another infection, or your test result may be false. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you do not have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.



Positive result
If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a molecular PCR test to confirm the result. There is a very small chance that this test can give a positive result that is incorrect (a false positive).



Invalid result
If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Quick Reference Instructions and repeat the test. If your test result is still invalid, please contact Roche HCP Support 1-866-987-6243.

Clinical Evaluation

The clinical performance of the COVID-19 At-Home Test was evaluated in a prospective, all-comer's study at 5 clinical sites in the United States. Patients or legal guardians of patients above 2 years of age visiting the study sites seeking testing and presenting symptoms suspicious of COVID-19 were approached to participate in the study. Those beyond 7 days since the onset of symptoms were excluded. Participants aged 14 years or older followed the Quick Reference Instructions provided in the test kit to self-collect an anterior nasal (nares) swab sample and performed the test using the COVID-19 At-Home Test. Participants younger than 14 years of age were sampled and tested by an adult participant (e.g., parent or legal guardian). A bilateral mid-turbinate nasal swab sample was also taken from each study participant by a healthcare professional for testing on a high-sensitivity, FDA EUA-authorized RT-PCR method as the comparator.

In total, 138 participants were enrolled in this study, and valid rapid antigen and RT-PCR results were obtained for 128 participants. The COVID-19 At-Home Test correctly identified 41 out of 43 SARS-CoV-2-positive individuals, and 85 out of 85 SARS-CoV-2-negative individuals. The relative diagnostic sensitivity and specificity of COVID-19 At-Home Test were calculated in comparison to the comparator method and summarized in the tables below.

Performance summary against an authorized RT-PCR comparator method.

		RT-PCR Results		
		Positive	**Negative**	**Total**
SARS-CoV-2 Antigen Test Results	**Positive**	41	0	41
	Negative	2**	85	87

	Total	43	85	128
Relative sensitivity		95.3 % (95 % CI*: 84.5 - 98.7 %)		
Relative specificity		100 % (95 % CI*: 95.7 - 100 %)		

* The two-sided 95% confidence interval was calculated using the Wilson Method.
** The two discordant (false-negative) samples were re-tested on a different high-sensitivity, FDA EUA-authorized RT-PCR method, and both samples tested negative on this.

Relative sensitivity stratified by days post symptoms onset.

DPSO	RT-PCR Positives	Rapid Antigen Positives
0-1	3	2
2	16	15
3	10	10
4	12	12
5	1	1
6	1	1
All	43	41

Performance stratified by age groups

Age group	RT-PCR Positives	Rapid Antigen Positives
< 14	5	5
14 - 24	8	8
>24 - 64	29	27
≥ 65	1	1
All	43	41

ANALYTICAL PERFORMANCE

Limit of Detection (LoD)

The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (isolate USA-WA1/2020) into pooled negative nasal matrix (PNM) that was confirmed to be negative with PCR. LoD was determined to be $1.4x10^3$ $TCID_{50}$/mL for serially diluted positive specimens.

Cross-reactivity

No cross-reactivity was observed for the following organisms at the indicated concentrations, except for SARS-coronavirus, which exhibited cross-reactivity when tested at 1.58×10^4 $TCID_{50}$/mL. A titration of SARS-CoV was performed to determine the concentration at which cross reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 1.58×10^1 $TCID_{50}$/mL. These results are not unexpected as the COVID-19 At-Home Test targets the nucleocapsid protein, which is present in both the SARS-CoV and SARS-CoV-2 viruses and is highly homologous.

Microorganism / Specimen	Concentration Tested for Cross Reactivity	Result
Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	NEG
Human coronavirus OC43	8.50×10^4 $TCID_{50}$/mL	NEG
Human coronavirus NL63	1.17×10^5 $TCID_{50}$/mL	NEG
SARS-coronavirus	1.58×10^4 $TCID_{50}$/mL	POS
SARS-coronavirus (1:1000)	1.58×10^1 $TCID_{50}$/mL	NEG
MERS-coronavirus	1.43×10^5 $TCID_{50}$/mL	NEG
Adenovirus	1.43×10^5 $TCID_{50}$/mL	NEG
Human metapneumovirus 4 Type B2	1.43×10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 1	5.50×10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	NEG

Parainfluenza virus 3	1.43 × 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 4b	1.43 × 10^5 $TCID_{50}$/mL	NEG
Influenza A	1.43 × 10^5 $CEID_{50}$/mL	NEG
Influenza B	1.43 × 10^5 $TCID_{50}$/mL	NEG
Enterovirus 68	1.43 × 10^5 $TCID_{50}$/mL	NEG
Respiratory syncytial virus	1.43 × 10^5 PFU/mL	NEG
Rhinovirus	1.43 × 10^5 $TCID_{50}$/mL	NEG
Haemophilus influenzae	1.00 ×10^6 CFU/mL	NEG
Streptococcus pneumonia	1.00 × 10^6 CFU/mL	NEG
Streptococcus pyogenes	2.59 × 10^6 CFU/mL	NEG
Candida albicans	1.00 × 10^6 CFU/mL	NEG
Bordetella pertussis	1.00 × 10^6 CFU/mL	NEG
Mycoplasma pneumonia	2.57 × 10^8 CFU/mL	NEG
Chlamydia pneumoniae	1.00 × 10^6 IFU/mL	NEG
Legionella pneumophila	1.00 × 10^6 CFU/mL	NEG

Mycobacterium tuberculosis	1.00 × 10^8 CFU/mL	NEG
Pneumocystis carinii	1.00 × 10^6 nuclei/mL	NEG
P. jiroveci-S. cerevisiae	8.10 × 10^5 CFU/mL	NEG
Staphylococcus aureus subsp. aureus	1.00 × 10^6 CFU/mL	NEG
Staphylococcus epidermidis	1.00 × 10^6 CFU/mL	NEG
Pooled Negative Matrix	N/A	NEG

Microbial interference

For the microorganisms which did not demonstrate cross-reactivity, additional microbial interference testing with SARS-CoV-2 positive samples spiked into pooled negative nasal matrix were performed and no microbial interference was observed.

Endogenous / exogenous cross-reactivity study

No cross-reactivity was observed for the following substances at the indicated concentrations. Each substance was spiked into pooled negative nasal matrix for testing.

Potentially Interfering Substance	Concentration	Result
Human Whole Blood (EDTA tube)	4% v/v	NEG
Mucin (Porcine Stomach, type II)	0.5%	NEG
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	NEG
Naso GEL (NeilMed)	5% v/v	NEG

Nasal Drops (Phenylephrine)	15% v/v	NEG
Nasal Spray (Oxymetazoline)	15% v/v	NEG
Nasal Spray (Cromolyn)	15% v/v	NEG
Zicam	5% v/v	NEG
Homeopathic (Alkalol)	10% v/v	NEG
Sore Throat Phenol Spray	15% v/v	NEG
Tobramycin	4 µg/mL	NEG
Mupirocin	10 mg/mL	NEG
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	NEG
Fluticasone Propionate	5% v/v	NEG
Body & Hand Lotion (Cerave)	0.5% w/v	NEG
Body Lotion with 1.2% Dimethicone	0.5% w/v	NEG
Hand Lotion (Eucerin)	5% w/v	NEG
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	NEG
Hand Sanitizer Cream Lotion (Vaseline)	15% v/v	NEG

Hand Sanitizer, 80% Ethanol, Fast Drying	15% v/v	NEG
Hand Soap Liquid Gel (Soft Soap)	10% w/v	NEG

Endogenous / exogenous interference substances study

For the substances listed above, additional endogenous / exogenous interference studies were performed with samples containing SARS-CoV-2 in pooled negative nasal matrix. Each substance was spiked into a positive sample and no endogenous / exogenous interference was found, except for hand soap liquid gel, which caused a false negative result at a concentration of 10% w/v and 5% w/v. A positive result (no interference) was observed at a concentration of 1% w/v.

High-Dose Hook Effect

SARS-CoV-2 cultured virus was spiked into pooled negative nasal matrix. SARS-CoV-2 cultured virus did not show hook effect at the virus stock concentration of 2.80 x 10^6 $TCID_{50}$/mL.

Manufacturer

SD Biosensor, Inc.
Head office: C- 4th & 5th, 16, Deogyeong-daero 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC of KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Distribution in USA by:

Roche Diagnostics, Indianapolis, IN
US COVID-19 General Support 1.866.987.6243
www.diagnostics.roche.com