NIDS® COVID-19 Antigen Home Test
Healthcare Provider Instructions for Use (IFU)

For use with anterior nasal swab specimens.
For Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use only.

INTENDED USE

The NIDS COVID-19 Antigen Home Test is a rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

The test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years and older with symptoms of COVID-19 within the first 7 days of symptom onset.

Theis test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years and older with symptoms of COVID-19 within the first 7 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 (nares) swabs samples from individuals 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 NIDS COVID-19 Antigen Home Test does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definite cause of disease. Individuals who test positive with the NIDS COVID-19 Antigen 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 a patient'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 SARS-CoV-2 infection, 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-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 NIDS COVID-19 Antigen Home Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another aged 2 years or older.

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

SUMMARY AND EXPLANATION OF THE TEST

COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 infection and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus, which causes COVID-19, can trigger mild to severe respiratory illness and has spread rapidly worldwide.

The NIDS COVID-19 Antigen Home Test Kit is a lateral flow immunochromatographic assay for the detection of nucleocapsid protein antigen specific to SARS-CoV-2 in anterior nasal (nares) swab specimens directly collected and extracted using NIDS buffer. The NIDS COVID-19 Antigen Home Test Kit contains all components required to carry out a test for SARS-CoV-2.

PRINCIPLE OF THE PROCEDURE

The NIDS COVID-19 Antigen Home Test Kit is an immunochromatographic lateral flow membrane assay that uses antibodies to detect SARS-CoV-2 nucleocapsid protein in anterior nasal (nares) swabs. The anterior nasal (nares) swab specimen requires a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is then added to the sample well of the test device to initiate the test. When the swab sample migrates on the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein monoclonal

antibody conjugated to an indicator and detector particles on the test strip forming an immune complex. The immune complex is then migrated to and captured at thetest line, which contains another monoclonal antibody against SARS-CoV-2, anchored to the nitrocellulose membrane which captures any formed immune complex with the SARS- CoV-2 antigen. Test results are interpreted at 15 minutes. The presence of a colored line in the control line region "C" and the test line region "T" indicates COVID-19 positive. The presence of one colored line in the control line region "C" indicates COVID-19 negative. No appearance of a colored line in the control region "C" indicates an invalid test regardless if a colored test line is present or not at the test line region "T". Results shouldnot be read after 30 minutes.

REAGENTS AND MATERIALS PROVIDED IN EACH TEST KIT

The NIDS COVID-19 Antigen Home Test is offered in a 1, 2, 4, 20, and 40 test/kit size. The kit configuration are presented below:

Number of Tests/Kit		1 Test/Kit	2 Tests/Kit	4 Tests/Kit	20 Tests/Kit	40 Tests/Kit
Reagent/Material	NIDS COVID-19 Antigen Rapid Test Devices	1	2	4	20	40
	NIDS Antigen Swab Buffer Tubes	1	2	4	20	40
	Sterile Nasal Swabs	1	2	4	20	40
	Antigen Buffer Insert/Stand	1	1	1	20	40
	User Instructions	1	1	1	1	1

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer.

QUALITY CONTROL

Each NIDS COVID-19 Antigen Home Test has a built-in internal procedural control. The pink/purple line appearing at the "C" position is an internal procedural control. This procedural Control Line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. A distinct pink/purple Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed.

TEST PROCEDURES

Read all of the instructions entirely before testing. Check the tests expiration date. Do not use an expired test. Make sure you have all of the test kit components. Wash your hands with soap and water for 30 seconds or use hand sanitizer.

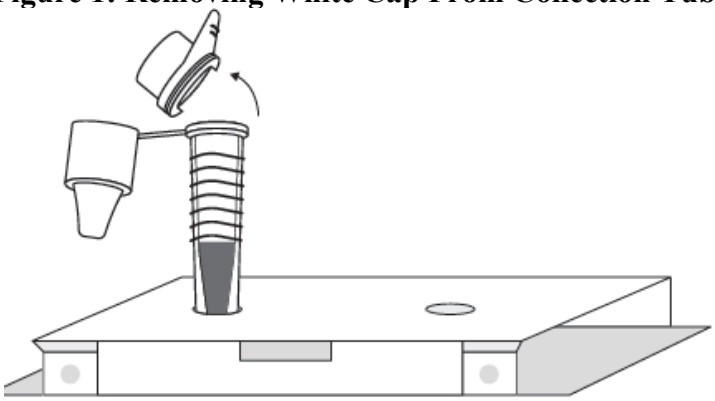
WARNING – HANDS MUST BE RINSED THOROUGHLY BEFORE TESTING

Make sure hands are dry before starting. Remove the test device from the foil pouch by tearing along the indexed tear-line. Lay the test device on a flat, level surface (table or countertop). Instruct

the individual to blow his/her nose to remove excess mucus. Open the nasal swab package. Do not touch the swab tip or lay it down on any surface.

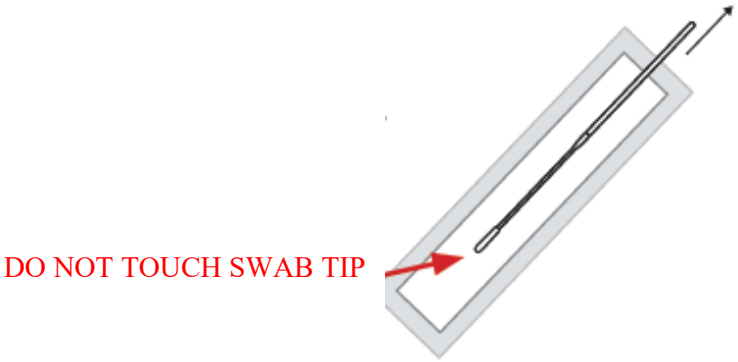
1. Remove the white cap from the collection tube and place the tube into the hole within the box insert. (Figure 1).

Figure 1: Removing White Cap From Collection Tube



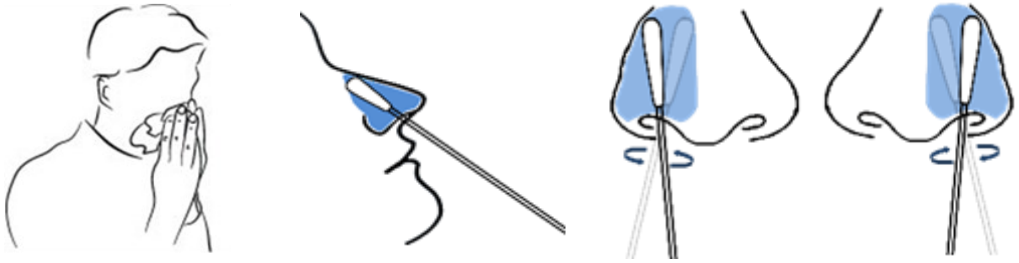
2. Remove the swab from the packaging and be careful not to touch the swab tip or lay the swab down on the table (Figure 2).

Figure 2: Removing swab from packaging



3. Swab both nostrils of the individual carefully as shown. Insert the entire soft tip of the swab into the individual's first nostril about ½ to ¾ of an inch. Firmly brush against the entire inner walls of the nostril in a complete circle at least 4 times. Do not just spin the swab. Remove the swab. Using the same swab, repeat the step above in the other nostril. Repeat with the same swab in the other nostril (Figure 3).

Figure 3: Anterior Nares Nasal Swab Collection



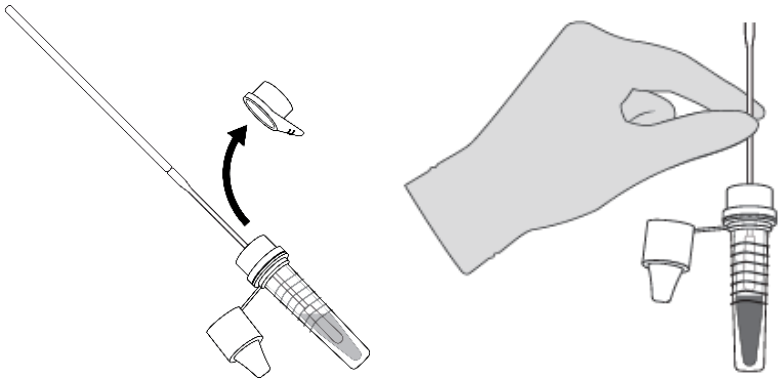
Note: With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing

Sample Preparation and Testing

The NIDS COVID-19 Antigen Home Test Kit and components can be used immediately upon opening and should be stored at room temperature (15 – 30ºC). Opened or in-use test kits should be used promptly (within 30 minutes) if possible. It is not recommended to store opened or in-use test kits after opening.

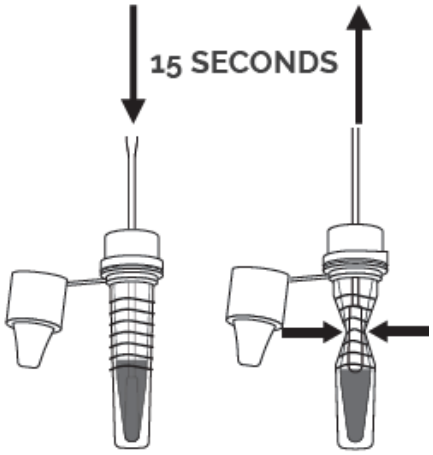
4. Remove the collection tube from the box insert and insert the swab into the collection tube containing buffer liquid. See Figure 4 below.

Figure 4: Transfer Sample Swab into Buffer Tube



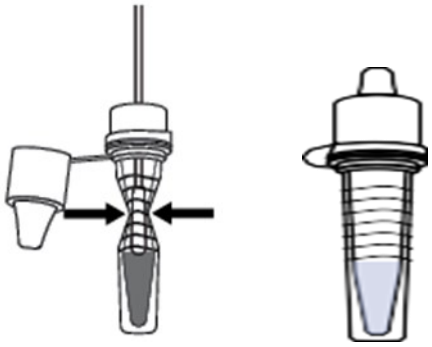
5. Plunge the test swab up and down while squeezing the swab tip repeatedly from the outside of the tube for 15 seconds, see Figure 5. Be careful not to contaminate the swab. Avoid spilling or splashing of the collection tube contents.

Figure 5: Illustration of Sample Extraction



6. Remove the swab while squeezing the sides of the tube to extract the liquid. Dispose the swab and firmly cap the collection tube with the attached dropper tip, see Figure 6.

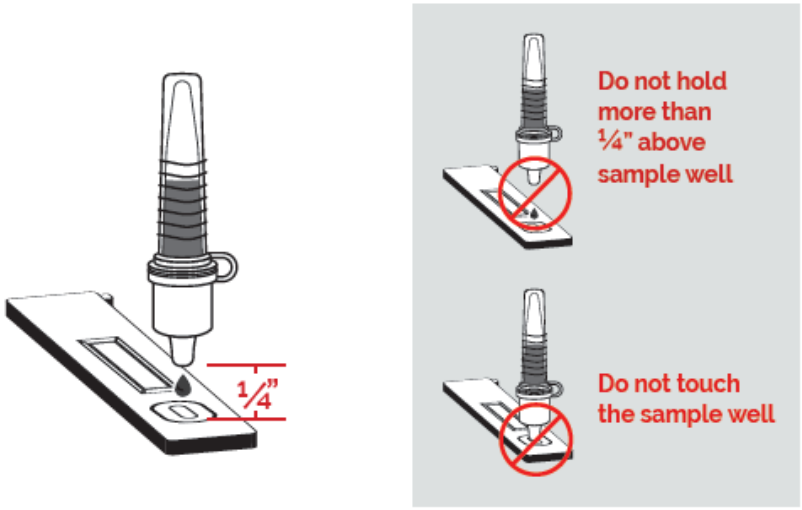
Figure 6: Remove Swab and Close the Buffer Tube



7. Invert the collection tube and tap the side of the tube to remove any air bubbles from the dropper tip. Hold the dropper tip about 1/4 of an inch vertically above the test device sample well (use both of your hands if needed) and slowly squeeze the tube until all of the liquid (at least 5 drops) is dispensed into the sample well.

Do **NOT** touch the sample pad with the dropper tip, Do **NOT** dispense the liquid into the rectangular result viewing window, see **Figure 7**.

Figure 7: Dispensing Sample Solution into the Sample Well



8. Wait 15 minutes, then read your test results. Do not read test results after 30 minutes. **Results read before 15 minutes or beyond 30 minutes may be inaccurate.** Dispose of the used test in the household trash.

RESULTS INTERPRETATION

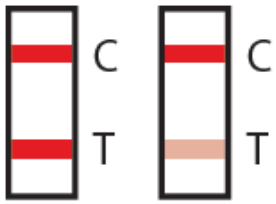
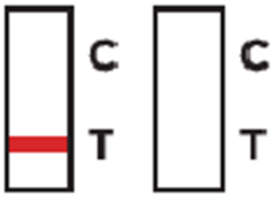
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Test results are read and interpreted visually. Wait 15 minutes, then read the test results. Do not read test results after 30 minutes.

1) **POSITIVE:** The presence of two lines, i.e., a control line (C) and a test line (T) within the result window indicates a positive result.
2) **NEGATIVE:** The presence of only the control line (C) within the result window indicates a negative result.
3) **INVALID:** If the control line (C) is not visible within 15 minutes after adding the sample to the sample well, the result is considered invalid. If the control line does not appear, the specimen should be collected and tested again.

The Positive, Negative, and Invalid test results are explained in Table 1 below:

Table 1: Results Interpretation

Result	Device Image
Negative A **negative** test result will show a single pink/purple colored line for the control (C). • A Negative test means that antigen from the virus that causes COVID-19 is not detected in the sample. • Negative results do not rule out SARS-CoV-2 infection. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.	
Positive A positive test result will show two pink/purple colored lines. • A Positive test result is interpreted as protein antigen from the virus that causes COVID-19 was detected in the specimen. The individual is positive for COVID-19. Test results should be considered in association with the patient's history and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations). Note: The Test line ([color] line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Any faint visible [color] Test line should be interpreted as positive, when the control line (C) line is also present.	
Invalid If there are no lines showing, the test is invalid. • If the test (T) line is seen, but the control (C) line is not, the test is invalid. • If the blue line is present on the top of the viewing window after 15 minutes, the test is invalid. • If the background color in the test device result viewing window fails to turn from dark red to light pink or white AND interferes with the clear, visual interpretation of the test results after the 15 minute read time, the test is invalid. • An invalid test can occur when you do not have enough sample liquid dispensed to the test device sample well, failure to remove excess mucus during sampling, or if the test is performed incorrectly. • Invalid test may be repeated using a new test kit and new nasal sample. • If a repeat test is invalid, contact ANP Technical Support at +1.302.283.1730.	

STORAGE AND STABILITY

Store the NIDS® COVID-19 Antigen Home Test and components between 15-30°C (59-86°F). Ensure all kit components are at room temperature before use. Kit components are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. The Test Device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 30 minutes. Test samples immediately after collection, but no more than **30 minutes after collection** after placement into extraction buffer and 30 minutes after placement in extraction buffer, if kept at room temperature.

WARNINGS AND PRECAUTIONS

1. For in-vitro diagnostic use only.
2. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
3. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
4. 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.
5. Read the NIDS® COVID-19 Antigen Home Test Package Insert carefully before performing a test.
6. Failure to follow directions may produce inaccurate test results.
7. The Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
8. Keep test kit and materials out of the reach of children and pets before and after use.
9. You should wear a face mask if swabbing others.
10. This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
11. Children aged 2 to 13 years of age should be tested by an adult.
12. The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for a test line to show up.
13. Do not use on anyone under two years of age.
14. Do not open the kit contents until ready for use. If the test cassette is open for an hour or
15. longer, invalid test results may occur.
16. Do not use the test after the expiration date shown on the test cassette pouch.
17. Do not use if any of the test kit contents or packaging is damaged or open.
18. Do not touch swab tip when handling the swab sample.
19. Test components are single-use. Do not re-use.
20. Keep the test device on flat surface during testing.
21. Make sure there is sufficient light when testing. For best results, read test in a well-lit area.
22. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
23. Remove any piercings from the nose before starting the test.
24. Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/ surgery in the past six months.
25. Inadequate or improper nasal swab sample collection may yield false negative test results.

26. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
27. Do not touch the swab tip (specimen collection area) when handling the swab.
28. The test is intended to be read at 15 minutes. Do not read the test after 30 minutes.
29. Do not ingest any kit components.
30. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
31. A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample was collected improperly.
32. Do not mix components from different kit lots.
33. Test devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE) and gloves when running the test and handling a patient's test device. Change gloves between tests.
34. In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
35. Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
36. 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. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name/CAS/ Concentration (%)	**Hazard category**	**Hazards (GHS Code) for each ingredient**
Triton X-100/9002-93-1 /0.1%	4 (acute toxicity, oral) 2 (skin corrosion/irritation) 1 (serious eye damage/eye irritation)	Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H318)
Lauryldimethylamine oxide (LDAO)/1643-20-5/0.05%	4 (acute toxicity, oral) 2 (skin corrosion/irritation) 1 (serious eye damage/eye irritation)	Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H318) Causes serious eye irritation (H319)

LIMITATIONS

- Do not use on anyone under 2 years old
- Children aged 2-13 years should be tested by an adult.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 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 as compared to a molecular test.
- The performance of the NIDS COVID-19 Antigen Home Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- 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.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

- The test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Failure to follow instructions for use may adversely affect test performance and/or invalidate the test result.
- False negative results may occur if a specimen is improperly collected or handled.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Negative results do not rule out COVID-19, should be treated as presumptive, and confirmed with an FDA-authorized molecular assay, if necessary for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- 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 performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February and XX 2022. 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.

PERFORMANCE CHARACTERISTICSANALYTICAL PERFORMANCE

The following studies have been performed to validate the performance of the NIDS COVID-19 Antigen Home Test:

1) ***Limit of Detection (LoD) - Analytical Sensitivity***:

The Limit of Detection (LoD) of the NIDS COVID-19 Antigen Home Test was determined using serial dilutions of gamma-irradiated, inactivated virus from the USA-WA1/2020 SARS-CoV-2 strain. Contrived samples were prepared by spiking the strain into pooled human [mid-turbinate/nasal] swab matrix obtained from healthy volunteers confirmed negative by RT-PCR. 50 µL of the spiked sample preparation was pipetted onto a swab and subsequently transferred to a pre-filled NIDS COVID-19 Antigen Buffer Tube and tested as per the IFU. The preliminary LoD initially determined by testing two-fold dilution series of 3 replicates per concentration was confirmed by testing in 20 replicates. The confirmed LoD was 311 $TCID_{50}$/mL.

Omicron data is pending

2) ***Cross-reactivity (Analytical Specificity) & Interference***:

Cross-reactivity and interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen from the nasal cavity. Each organism and virus (15 bacteria and 29 viruses) were tested in both the absence and presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate USA-WA1/2020) at 2x LoD. All testing samples were prepared in the negative clinical mid-turbinate matrix. No cross reactivity or interference was observed at the concentrations tested as shown in the table below.

Table 3: Cross-Reactivity & Microbial Interference Testing of the NIDS COVID-19 Antigen Home Test

Virus/Bacteria/Fungi	Cross-Reactivity Results	Interference Results
PNM collected in VTM	No Cross-Reactivity	No Interference
SARS virus	Cross-Reactive	Interference
MERS Coronavirus	No Cross-Reactivity	No Interference
Coronavirus 229E	No Cross-Reactivity	No Interference
Coronavirus OC43	No Cross-Reactivity	No Interference
Coronavirus NL63	No Cross-Reactivity	No Interference
Coronavirus HKU1[1]	In-Silico Analysis	In-Silico Analysis
Adenovirus	No Cross-Reactivity	No Interference
Human metapneumovirus	No Cross-Reactivity	No Interference
Parainfluenza virus 1	No Cross-Reactivity	No Interference
Parainfluenza virus 2	No Cross-Reactivity	No Interference
Parainfluenza virus 3	No Cross-Reactivity	No Interference
Parainfluenza virus 4b	No Cross-Reactivity	No Interference

[1] *In-Silico analysis of HKU1 revealed two experimentally-derived linear B-cell epitopes specific for SARS-CoV-2. However, upon review of the overlap in both SARS-CoV-1, SARS-CoV-2 and HKU1, it was observed that regions of high homology are not associated with B-cell epitopes. While we cannot rule out cross-reactivity, we conclude there is low probability of cross reactivity with HKU1 nucleocapsid.*

Influenza A	No Cross-Reactivity	No Interference
Influenza B	No Cross-Reactivity	No Interference
Enterovirus 68	No Cross-Reactivity	No Interference
Respiratory syncytial virus	No Cross-Reactivity	No Interference
Human Rhinovirus 75	No Cross-Reactivity	No Interference
Haemophilus influenzae	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	No Cross-Reactivity	No Interference
Streptococcus pyogenes	No Cross-Reactivity	No Interference
Candida albicans	No Cross-Reactivity	No Interference
Bordetella pertussis	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	No Cross-Reactivity	No Interference
Chlamydia pneumoniae	No Cross-Reactivity	No Interference
Legionella pneumophila	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	No Cross-Reactivity	No Interference
P. jiroveci-S. cerevisiae[2]	In-Silico Analysis	In-Silico Analysis
Staphylococcus aureus subsp. *Aureus*	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	No Cross-Reactivity	No Interference

[2] *In-Silico* analysis of *Pneumocystis jirovecii was carried out using 11,975 Pneumocystis jirovecii protein sequences available from GenBank and aligned with the SARS-CoV-2 nucleocapsid protein sequences using BLASTP with parameters set to find significant homologous sequences. No significant homology was observed with regard to the SARS-CoV-2 nucleocapsid protein. Therefore, we conclude that there is very low chance of cross-reactivity with Pneumocystis jirovecii.*

3) ***Endogenous and Exogenous Interference Substances Studies***:
The interference study was performed for the [14] potentially interfering substances that may be present in an upper respiratory tract specimen. The positive (2x LoD SARS-CoV-2 isolate USA-WA1/2020) and negative samples were tested with the addition of potentially interfering substances. The performance of the NIDS COVID-19 Antigen Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested (Table 4).

Table 4. Potential Interfering Substances Testing of the NIDS COVID-19 Antigen Home Test

Substance	Concentration	Cross-Reactivity Results*	Interference Results*
Human Blood	4% v/v	No Cross-Reactivity	No Interference
Mucin	0.5%	No Cross-Reactivity	No Interference
Chloraseptic® CH23902	1.5 mg/mL	No Cross-Reactivity	No Interference
NeilMed Naso GEL	5% v/v	No Cross-Reactivity	No Interference
Nasal Drops	15% v/v	No Cross-Reactivity	No Interference
Nasal Spray	15% v/v	No Cross-Reactivity	No Interference
Nasal Spray	15% v/v	No Cross-Reactivity	No Interference
Zicam®	5% v/v	No Cross-Reactivity	No Interference
Homeopathic	10% v/v	No Cross-Reactivity	No Interference
Sore Throat Chloraseptic® spray	15% v/v	No Cross-Reactivity	No Interference
Tobramycin	4 µg/mL	No Cross-Reactivity	No Interference
Mupirocin	10 mg/mL	No Cross-Reactivity	No Interference
Tamiflu®	5 mg/mL	No Cross-Reactivity	No Interference
Walgreens Fluticasone Propionate	5% v/v	No Cross-Reactivity	No Interference

Interfering substances testing was carried out using a panel of seven (7) common household items including cleaners, lotions and soap in **Table 5** below. Each substance was spiked into a positive sample tested in triplicate. No interference was observed, except for hand soap liquid gel, which caused a false negative result at a concentration of 5% w/v.

Table 5 Potential Interfering Household Substance Information

Potentially Interfering Substances Testing of the NIDS COVID-19 Antigen Home Test			
Substance	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Body & Hand Lotion	1% v/v	No Cross-Reactivity	No Interference
Body Lotion, with 1.2% dimethicone	1%	No Cross-Reactivity	No Interference
Hand Lotion	10% w/v	No Cross Reactive	No Interference
Hand Sanitizer with	10% v/v	No Cross-Reactivity	No Interference

Aloe, 62% ethyl alcohol			
Hand Sanitizer cream lotion	30% v/v	No Cross-Reactivity	No Interference
Hand sanitizer, 80% ethanol, fast drying	30% v/v	No Cross-Reactivity	No Interference
Hand soap liquid gel	5% v/v	No Cross-Reactivity	Interference

4) ***High-dose Hook Effect***:
The NIDS COVID-19 Antigen Home Test was tested up to at $2.8x10^5$ $TCID_{50}$/mL of gamma-irradiated, inactivated SARS-CoV-2 isolate USA-WA1/2020 stock virus and no high-dose hook effect was observed.

5) ***Flex Study***
The robustness of the NIDS® COVID-19 Antigen Home Test was demonstrated by ten (10) Flex studies: Reading Time Analysis, Mix Duration and Method Analysis, Specimen Volume Analysis, Sample Buffer Volume Analysis, Temperature and Humidity System Analysis, Lighting Conditions Analysis, Operator Error/Human Factors Analysis, Specimen Stability (Specimen in Sample Buffer), Specimen Stability (Dry Swab), and Sample Buffer Evaporation.

CLINICAL PERFORMANCE

Clinical data is pending

Symbols

	Consult Instructions For Use		For *in vitro* Diagnostic Use Only
	Catalog/Part #		Lot Number (Batch Code)
	Number of Tests Per Kit		Temperature Limitation (Storage Temperature)
	Manufacturer		Date of Manufacture
	Use by (Expiration Date)		One Time Use (Single Use only)
	Humidity limitation		

ORDERING AND CONTACT INFORMATION
Reorder Numbers:
PN-0003KT: NIDS® COVID-19 Antigen Home Test Pack (Includes testing components for conducting 1, 2, 4, 20, and 40 Tests).

US +1 (302) 283-1730

Technical Support Hot Line
Further information can be obtained from your distributor, or by contacting Technical Support at +1 (302) 283-1730 or +1 (888) 280-0685 (24/7) during normal business hours (Mon. to Fri. – 8:00 AM to 5:00 PM EST) / Techhelp@anptinc.com (24/7)

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