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

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

INTENDED USE

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

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 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, which 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 definitive 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.

All negative results are 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 measures such as isolating from others and wearing masks. 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.

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 with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The NIDS COVID-19 Antigen Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

EXPLANATION OF THE TEST

COVID-19 (short for "Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms

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.

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 configurations are presented below:

Number of Tests/Kit			1 Test/Kit	2 Tests/Kit	4 Tests/Kit	20 Tests/Kit	40 Tests/Kit
Reagent/Material	Description						
	NIDS COVID-19 Antigen Test Devices	Individually pouched Test Device	1	2	4	20	40
	NIDS Antigen Swab Buffer Tubes	Tube containing 300µl buffer liquid	1	2	4	20	40
	Sterile Nasal Swabs	Sterile Swab	1	2	4	20	40
	Antigen Buffer Insert/Stand	Tube holder	1	1	1	20	40
	User Instructions	Quick Reference 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. 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 using a new swab and new test kit.

External run controls are not required to use the NIDS COVID-19 Antigen Home Test in a home setting.

TEST PROCEDURES

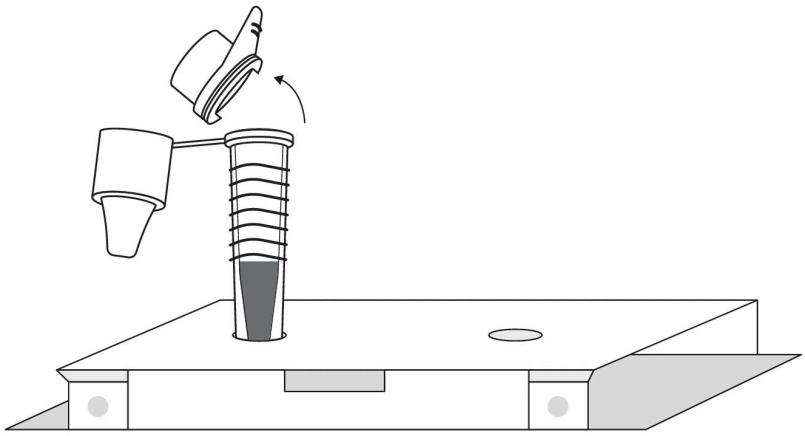
Read all of the instructions entirely before testing. Check the tests expiration date. Do not use an expired test. Make sure you have all of the test kit components. Wash your hands with soap and water for 30 seconds or use hand sanitizer.

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.

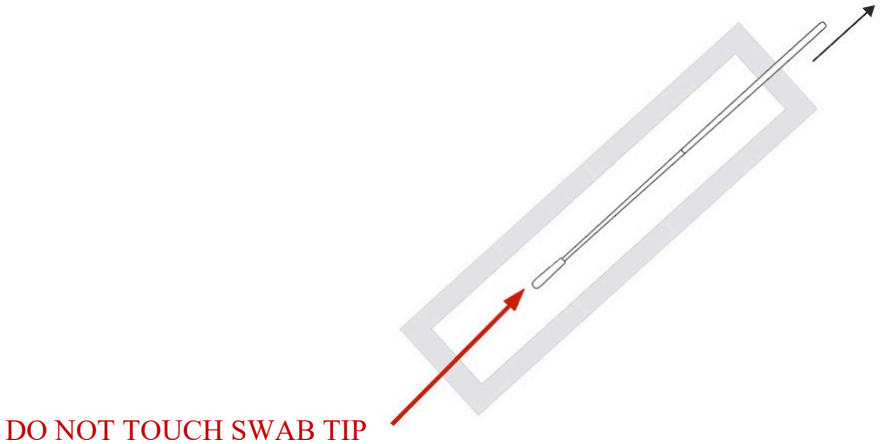
1. Remove the white cap from the collection tube and place the tube into the hole within the box insert. (**Figure 1**).

Figure 1: Removing White Cap From Collection Tube



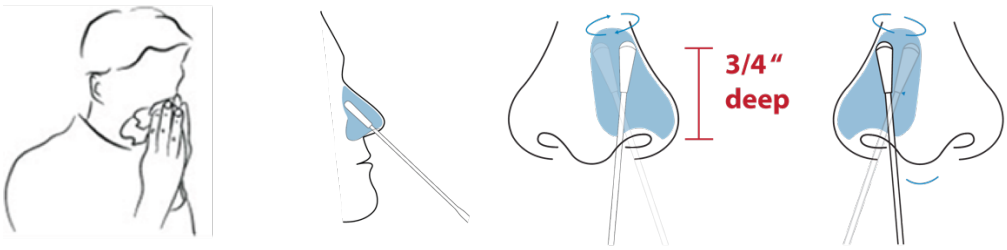
2. Remove the swab from the packaging and be careful not to touch the swab tip or lay the swab down on the table (**Figure 2**).

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



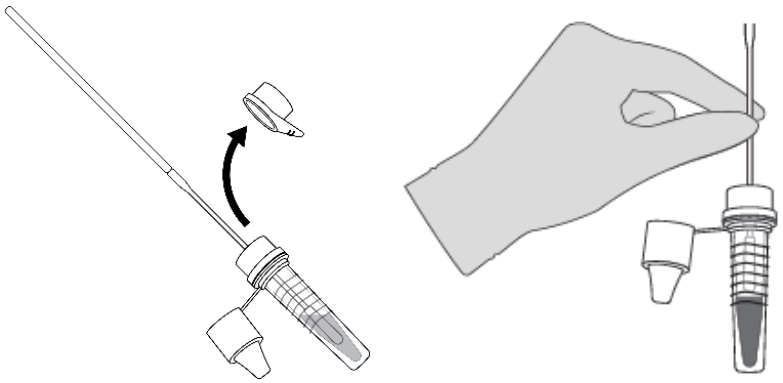
Note: With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing

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.

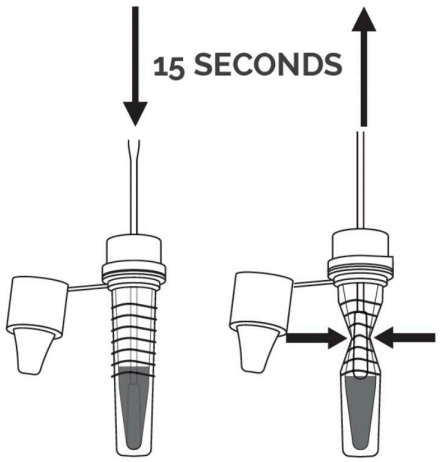
4. Remove the collection tube from the box insert and insert the swab into the collection tube containing buffer liquid. See **Figure 4** below.

Figure 4: Transfer Sample Swab into Buffer Tube



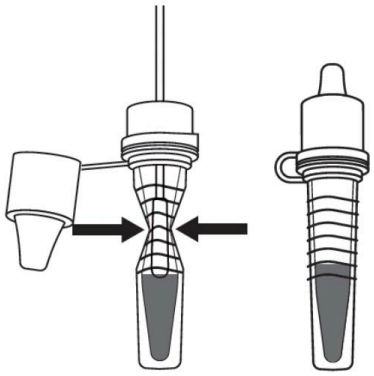
5. Plunge the test swab up and down while squeezing the swab tip repeatedly from the outside of the tube for 15 seconds, see **Figure 5**. Be careful not to contaminate the swab. Avoid spilling or splashing of the collection tube contents.

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**.

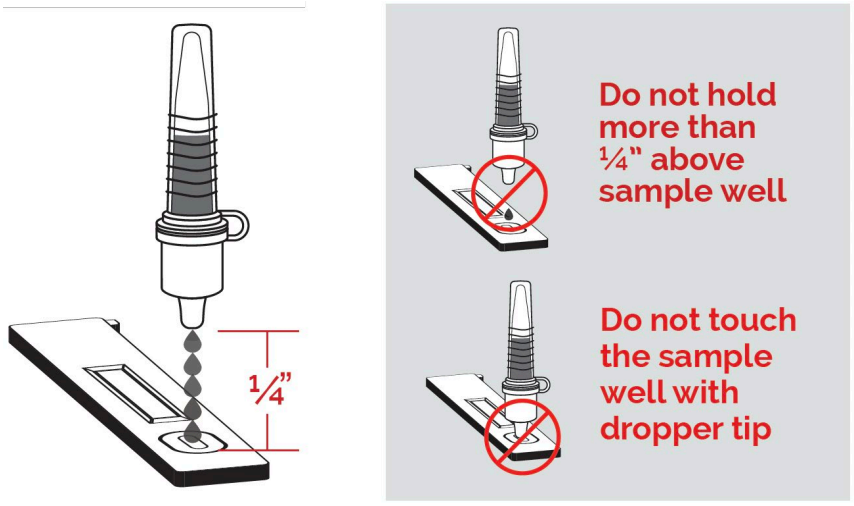
Figure 6: Remove Swab and Close the Buffer Tube



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

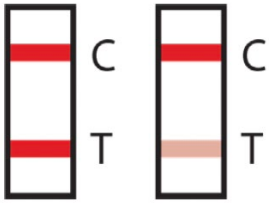
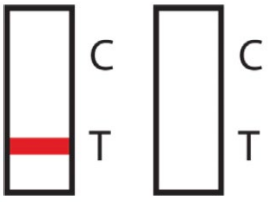


8. Wait 15 minutes, then read your test results. Do not read test results after 30 minutes. **Results read before 15 minutes or beyond 30 minutes may be inaccurate.** Dispose of the used test in the household trash. DO NOT disturb the test device during this time. Inaccurate results can occur if the card is disturbed/moved.

RESULTS INTERPRETATION

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 only a single pink/purple colored line on the control (C) line position with no line on the test line (T) position.	
Positive A positive test result will show two pink/purple colored lines, one on the test line (T) position and the other on the control line (C) position.	
Invalid If a line does not appear on the control line position (C) in 30 minutes, even if a Test line (T) is visible, the test is invalid. Re-test with a new NIDS COVID-19 Antigen Home Test. • If a repeat test is invalid, contact ANP Technical Support at +1.302.283.1730.	

REPEAT TESTING

Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow **Table 2** below when interpreting test results for COVID-19.

Table 2: Test Result Interpretation When Repeat Testing is Performed

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple test (T) line with the control (C) should be read as positive

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct the your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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 NIDS COVID-19 Antigen Home test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory based tests such as PCR tests. If the test is negative but COVID-19-like symptoms (e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay 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. 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.

Invalid
If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

STORAGE AND STABILITY
The NIDS COVID-19 Antigen Home Test and components should be stored between 15-30°C (59-86°F).
Ensure all kit components are at room temperature before use.
Kit components in the NIDS COVID-19 Antigen Home Test 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 60 minutes. Use beyond one hour may not produce accurate results.
Test samples immediately after collection. Swabs should be placed in extraction buffer within 60 minutes of collection. Inoculated buffer should be added to the device within120 minutes after placement in extraction buffer, if kept at ambient (room) temperature.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

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.

- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing**.
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [*e.g., skin, eyes, nose, or mouth]*. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., *skin, eyes, nose, or mouth]*, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222**.

Chemical Name	GHS Code for each Ingredient	Concentrations
Triton X-100/9002-93-1	H302, harmful if swallowed H315, skin irritation H318, serious eye damage	0.1%
Lauryldimethylamine oxide (LDAO)/1643-20-5	H302, harmful if swallowed H315, skin irritation H318, serious eye damage H319, serious eye irritation	0.05%

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2022 and July 2022. The clinical performance has not been established for 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This 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.
- Hand soap liquid gel may produce false positive results.

PERFORMANCE CHARACTERISTICS

ANALYTICAL 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 3.11×10^2 $TCID_{50}$/mL (9.44×10^4 virions/swab).

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant

(Table 3). This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the NIDS COVID-19 Antigen Home Test detected 100% of live virus Omicron samples at a Ct-value of 22.7. Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6) were not detected by the NIDS COVID-19 Antigen Home Test in this study.

Table 3: Performance Summary of Testing Dilutions of Clinical Specimens

Omicron Pool 2 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	NIDS COVID-19 Antigen Home Test Percent Positive (n=5)
Dilution 1	**19.8**	100	100	100
Dilution 2	**20.8**	100	100	100
Dilution 3	**21.5**	100	100	100
Dilution 4	**22.7**	100	100	100
Dilution 5	**23.6**	100	0	60
Dilution 6	**24.0**	60	0	0
Dilution 7	**24.8**	0	0	0
Dilution 8	**25.8**	0	0	0
Dilution 9	**27.4**	0	0	0
Dilution 10	**28.1**	0	0	0
Dilution 11	**29.1**	0	0	0

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 **Table 4** below.

Table 4: Cross-Reactivity & Microbial Interference Testing of the NIDS COVID-19 Antigen Home Test

Virus/Bacteria/Fungi	Concentration	Cross-Reactivity Results	Interference Results
PNM collected in VTM	N/A	No Cross-Reactivity	No Interference
SARS virus	7.90E+03 $TCID_{50}$/mL	Cross-Reactive	Interference
MERS Coronavirus	2.50E+04 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus 229E	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus OC43	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus NL63	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus HKU1[1]	N/A	In-Silico Analysis	In-Silico Analysis
Adenovirus	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human metapneumovirus	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza virus 1	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza virus 2	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza virus 3	3.65E+06 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza virus 4b	1.70E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Influenza A	1.45E+05 $CEID_{50}$/mL	No Cross-Reactivity	No Interference
Influenza B	1.47E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Enterovirus 68	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Respiratory syncytial virus	1.00E+05 pfu/mL	No Cross-Reactivity	No Interference
Human Rhinovirus 75	1.45E+05 $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	1.01E+06 cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	1.00E+04 cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	9.90E+05 cfu/mL	No Cross-Reactivity	No Interference
Candida albicans	1.05E+06 cfu/mL	No Cross-Reactivity	No Interference
Bordetella pertussis	1.00E+06 cfu/mL	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	2.50E+07 cfu/mL	No Cross-Reactivity	No Interference
Chlamydia pneumoniae	1.00E+06 ifu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	1.05E+06 cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	1.00E+06 cfu/mL	No Cross-Reactivity	No Interference
P. jiroveci-S. cerevisiae[2]	1.00E+06 cfu/mL	In-Silico Analysis	In-Silico Analysis
Pneumocystis carinii	2.30E+06 cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus subsp. *Aureus*	1.00E+06 cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	1.02E+06 cfu/mL	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.*

[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 5**).

Table 5: 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 6** 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 6: 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 Aloe, 62% ethyl alcohol	10% v/v	No Cross-Reactivity	No Interference
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 Studies***:
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

The clinical performance of the NIDS COVID-19 Antigen 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. 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 NIDS COVID-19 Antigen Home Test. Participants younger than 14 years of age were sampled and tested by an adult participant (e.g., parent or legal guardian). A 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, 203 participants were enrolled in this study, and valid rapid antigen and RT-PCR results were obtained for 196 participants. The NIDS COVID-19 Antigen Home Test correctly identified 38 out of 45 SARS-CoV2-positive individuals, and 151 out of 151 SARS-CoV-2-negative individuals. The agreement between the RT-PCR comparator and the NIDS COVID-19 Antigen Home Test was calculated and summarized in the **Table 7** below.

Table 7: Performance summary against an authorized RT-PCR comparator method

		RT-PCR Test		
		Positive	**Negative**	**Total**
NIDS COVID-19 Antigen Home Test	**Positive**	38	0	38
	Negative	7	151	158
	Total	45	151	196
Positive Percent Agreement (PPA) = (38/45) x 100% = 84.4% (95% CI = 71.2 to 92.3%)				
Negative Percent Agreement (NPA) = (151/151) x 100% = 100.0% (95% CI = 97.5 to 100.0%)				

Performance Analysis – Per Days of Symptoms: Breakdown by days post-symptom onset is provided by **Table 8** below.

Table 8: Relative sensitivity stratified by days post symptoms onset

Days of COVID-19 Symptoms	RT-PCR Positives	Rapid Antigen Positives
0-1	7	6
2	12	11
3	9	6
4	9	8
5	8	7
6	0	0
All	45	38

Patient Demographics: Demographics data is provided by **Table 9** below.

Table 9: Performance stratified by age groups

Age group	RT-PCR Positives	Rapid Antigen Positives
< 14	9	8
14 – 24	9	7
>24 – 64	25	22
≥ 65	2	1
All	45	38

SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in **Table 10**.

Table 10: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100.0%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed on average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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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