NIDS® COVID-19 Antigen Rapid Test Kit Instructions for Use Package Insert

For Directly Collected Mid-Turbinate Nasal Swab Specimens

For use under Emergency Use Authorization (EUA) only.

For in vitro diagnostic use only.

For prescription use only.

INTENDED USE

The NIDS COVID-19 Antigen Rapid Test Kit is a lateral flow immunoassay (LFI) intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct mid-turbinate (MT) nasal swabs from individuals who are suspected of having COVID-19 by their healthcare provider within the first seven (7) days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

The NIDS COVID-19 Antigen Rapid Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein. Antigen is generally detectable in MT nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigen, 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. Additional confirmatory testing with a molecular test for positive results may be necessary for results with and without serial testing, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. 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.

The NIDS COVID-19 Antigen Rapid Test is intended for use by medical professionals or operators who are performing tests in point of care settings. The NIDS COVID-19 Antigen Rapid Test Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

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

PRINCIPLE OF THE PROCEDURE

The NIDS COVID-19 Antigen Rapid Test Kit is an immunochromatographic lateral flow membrane assay that uses antibodies to detect SARS-CoV-2 nucleocapsid protein in MT nasal swabs. The MT nasal 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 the test 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 should not be read after 30 minutes.

REAGENTS AND MATERIALS

Materials Provided in Each Test Kit

- **Forty (40) NIDS COVID-19 Antigen Test Devices** – Test devices containing LFI test strip in a plastic housing, (Part No.: PN-0002)
- **Forty (40) NIDS Antigen Buffer Tubes** – Nasal swab specimen collection & dispensing tube containing ANP Swab Buffer (Part No.: PN-0001)
- **Forty (40) Sterile, Nasal Swabs** (Part No.: 25-1506 1PF)
- **One (1) Instructions For Use (IFU)** (Part No.: IFU-02)
- **One (1) Quick Reference Guide for Direct Nasal Swab Samples** (Part No.: QRG-016F).

- **Four (4) Visual Guide Cards** (Part No.: VGC-01)

Materials Required But Not Provided

- Clock, timer, or stopwatch
- Gloves
- Disinfection agent
- **NIDS COVID-19 Antigen Test External Control Kit (Part No. PN-0005KT) contains the following components:**
  - Antigen Positive Control Swab (REF: PN-0004) QTY 1
  - Antigen Negative Control Swab (REF: 25-1506 1PF) QTY 1
  - Antigen Rapid Test Devices (REF: PN-0002) QTY 2
  - Antigen Swab Buffer Tubes (REF: PN-0001) QTY 2
  - Instructions For Use (REF: IFU-03) QTY 1
  - Visual Guide Card (REF: VGC-01) QTY 1

CHEMICAL AND SAFETY INFORMATION

NIDS Antigen Buffer		
Material Components	**Hazards**	**MSDS/SDS Reference**
Triton X-100	• Oral acute toxicity • Skin irritation • Serious eye damage • Short-term (acute) aquatic hazard • Long-term (chronic) aquatic hazard	SDS
Lauryldimethylamine oxide (LDAO)	• Skin irritation • Serious eye damage • Short-term (acute) aquatic hazard • Long-term (chronic) aquatic hazard	SDS

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For prescription use only.
3. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
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 diagnostic tests 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 the authorization is revoked

sooner.

5. Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. only).
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
8. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, the test kit and its contents.
9. Leave test device sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not use the test kit past its expiration date.
11. Do not mix components from different test kit lots.
12. Test devices are single use only and should be discarded after use. Do not reuse test device.
13. Do not store specimens in viral transport media for specimen storage or transport.
14. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
15. To obtain accurate results, the test must be performed as indicated in this Instructions for Use.
16. All components of this test kit should be discarded as biohazard waste according to federal, state and local regulatory requirements.
17. Solutions used to prepare the positive control swab are non-infectious. However, patient samples, controls and test devices should be handled as though they contain infectious agents. Observe established precautions against microbial hazards during use and disposal.
18. Wear appropriate personal protection equipment when handling patient specimens and running each test. Change gloves between processing of specimens from persons suspected or confirmed to be infected with COVID-19.
19. **INVALID RESULTS**, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test device. To ensure delivery of an adequate volume, hold the sample tube vertically, ~¼ inch above the sample well of the test device and dispense five (5) free drops quickly by squeezing the sides of the dropper tube into the sample well of the test device.
20. False negative results can occur if the sample swab is not extracted properly in the buffer solution.
21. Swabs in the kit are approved for use with NIDS COVID-19 Antigen Rapid Test Kit. **Do not use other swabs.**
22. The swab buffer solution packaged in the collection tube of this test kit contains buffer validated for use with this test. **Do not use other buffer solutions.**
23. Do not use the original packaging to store the swabs after specimen collection. Dispose of the swab as biohazard waste in accordance with state and federal laws.

STORAGE AND STABILITY

The NIDS COVID-19 Antigen Rapid Test Kit and components should be used immediately upon opening and unopened kits should be stored at room temperature (15 – 30ºC). Opened or in-use test kits should be used promptly (within 30 minutes). Test devices should not be used 30 minutes after opening.

CONTROLS

NIDS COVID-19 Antigen Rapid Test Kit contains built-in procedural as well as external controls.

Procedural Control Description

The built-in "Control" region serves as an internal procedural control when a colored line appears in the control line region ("C line"). It confirms sufficient specimen volume and correct procedural technique.

External Control Description

EXTERNAL CONTROL SWAB KIT (Part No.: PN-0005KT, IFU-03)

ANP Technologies provides an external positive and negative assayed quality control kit, the NIDS COVID-19 Antigen Test External Control Kit to monitor the performance of the NIDS COVID-19 Antigen Rapid Test. Good laboratory practice recommends running positive and negative external controls regularly. Evaluation of external controls is recommended prior to using a new shipment or new lot of NIDS COVID-19 Antigen Rapid Test Kits. Evaluation of external controls is also recommended when there is a new operator. External controls may also be used in initial laboratory validations of the NIDS COVID-19 Antigen Rapid Test Kit in accordance with appropriate federal, state, and local guidelines or accreditation requirements, as applicable. The NIDS COVID-19 Antigen Test External Control Kit is to be used with the NIDS COVID-19 Antigen Rapid Test Kit. The procedure for running the external controls is provided separately by IFU-03 incorporated herein as reference. The Positive and Negative Controls can be used in the same fashion as patient samples for the purpose of verification of the test performance or to evaluate new operators or new lots of test kits. The user may also utilize additional control kits as required by laboratory specific requirements.

- Positive Control Swab: The external positive control swab (Part No. PN-0004) consists of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen spiked onto a sterile nasal swab. It is labeled specifically as the Positive Control swab.
- Negative Control Swab: The negative control swab (Part No. 25-1506 1PF) consists of a sterile swab without non-infectious SARS-CoV-2 nucleocapsid recombinant antigen.

If the correct control results are not obtained, do not report patient results or perform further patient testing. Contact ANP Technical Support at +1 (302) 283-1730 or +1-888-280-0685 during normal business hours (Mon. to Fri. – 8:00 AM to 5:00 PM EST) or Techhelp@anptinc.com (24/7).

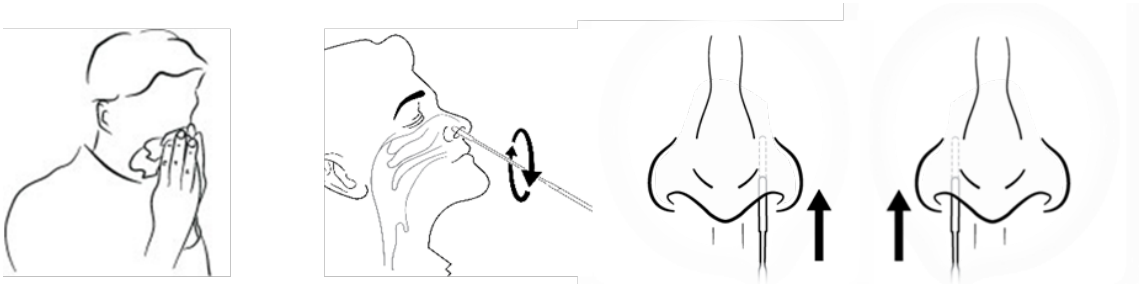
SPECIMEN COLLECTION AND HANDLING

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019- nCoV/lab/guidelines-clinical-specimens.html

1. Prior to collecting the mid-turbinate nasal swab, the patient should be instructed to blow their nose. Open the sterile packaging and remove the swab. Do NOT touch any part of the swab other than the shaft. Tilt head back 70 degrees. Carefully insert swab

into the nostril, parallel with the bridge of the nose, no more than 1 inch deep, or until you feel resistance at the turbinate. Rotate the swab in a circular path at least 4 times around the entire inside nostril's wall for approximately 15 seconds. Repeat with the same swab in the other nostril (**Figure 1**).

Figure 1: Mid-turbinate Nasal Swab Collection



- Do not use visually bloody or overly viscous specimens.
- Do not return the nasal swab to the original paper packaging.
- The swabs provided are authorized for use with the NIDS COVID-19 Antigen Rapid Test Kit — **do not use other swabs**.

Directly collected nasal swabs should be tested immediately after collection.

SPECIMEN TRANSPORT AND STORAGE

For best performance, specimens should be tested as soon as possible following collection, but no more than **30 minutes after collection**.

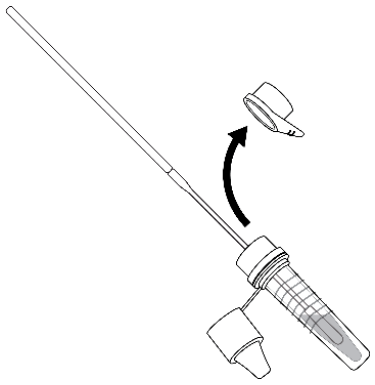
TEST PROCEDURE

Sample Preparation and Testing

The NIDS COVID-19 Antigen Rapid Test Kit and components can be used immediately upon opening and should be stored at room temperature (15 – 30°C). Opened or in-use test kits should be used promptly (within 30 minutes). Do not use the test device if the package has been open longer than 30 minutes.

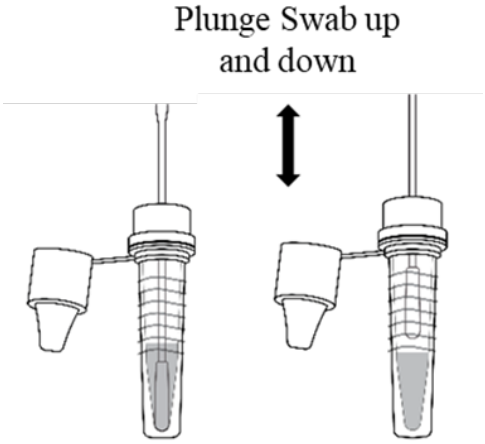
2. After specimen collection (see instructions above), remove the white cap from the collection tube and insert the test swab into the buffer, see **Figure 2** below

Figure 2: Transfer Sample Swab into Buffer Tube



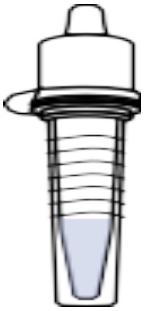
Carefully plunge the test swab up and down for 15 seconds, see **Figure 3** below. Make sure to hold the tube in an upright position to prevent spillage or splashing of the contents.

Figure 3: Illustration of Sample Extraction



3. Remove the test swab while pressing and rotating the tip against the inside wall of the tube to extract the liquid. Discard the swab safely. Firmly cap the collection tube with the affixed clear dropper tip, see **Figure 4** below.

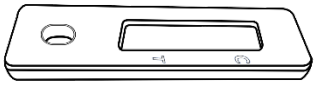
Figure 4: Close the Buffer Tube



4. Remove the test device from the sealed foil pouch and lay flat on a clean surface, see **Figure 5** below.

Test Device should be on a flat surface to avoid spillage and inaccurate results.

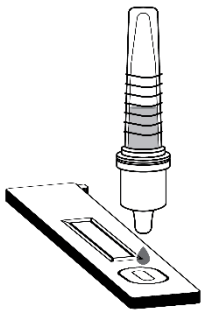
Figure 5: Test Position During Testing



5. Invert the capped sample extraction tube and tap the side to remove any air bubbles from the dropper tip. Hold the tube vertically, 1/4 inch above the device. Squeezing gently, dispense five (5) drops of sample solution into the sample well. Do **NOT** touch the sample pad with the dropper tip, see **Figure 6** below.

Adding fewer drops may produce invalid or inaccurate results.

Figure 6: Dispensing Sample Solution into the Sample Well



6. Wait for the colored line(s) to appear. Read results in test window 15 minutes after dispensing. **Results read beyond 30 minutes may be inaccurate.**

RESULTS INTERPRETATION

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, patient results cannot be interpreted. The patient should be tested again with a new device.

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.
   Note: 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 SARS-CoV-2 or residing in communities with low prevalence of infection.

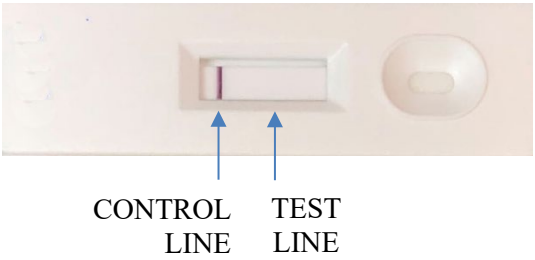
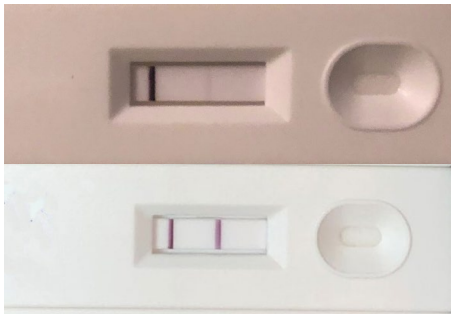
2) **NEGATIVE:** The presence of only the control line (C) within the result window indicates a negative result.
   Note: **If the first test result is negative for individuals without symptoms, individuals should be retested with a second test after 24 hours but no more than 36 hours**. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

   Note: For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as 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 SARS-CoV-2 or residing in communities with low prevalence of infection.

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 re-collected and tested again.

The Positive, Negative, and Invalid test results are explained in **Table 1**.

Table 1: Results Interpretation

Result	Device Image
Negative A **negative specimen** will give a single-colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means sufficient specimen volume and procedural technique was done correctly, but no SARS-CoV-2 nucleocapsid protein antigen was detected. if the first test result is negative for individuals without symptoms, individuals should be retested with a second test after 24 hours but no more than 36 hours.	
Positive A **positive specimen** will give two colored lines. This means that SARS-CoV-2 nucleocapsid protein antigen was detected. Specimens with low levels of antigen may give a faint test line. Any visible colored test line is positive.	
Invalid If no control or only test line is seen, the test is invalid. It is recommended to collect the specimen and test again.	

LIMITATIONS

- This test detects both viable (live) and non-viable SARS-CoV-1, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- This test is only used for testing direct human mid-turbinate nasal swab specimens.
- Viral transport media (VTM) should not be used with this test.
- This test is not for use in at-home testing settings.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

- The performance of the NIDS COVID-19 Antigen Rapid Test Kit was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Performance has not been established for use with specimens other than mid-turbinate nasal swabs. Other specimen types have not been evaluated and should not be used with this assay.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if a specimen is tested more than 30 minutes after collection. Specimen should be tested as quickly as possible after specimen collection.
- False negative results may occur if an inadequate volume of extraction buffer is used (e.g., less than 5 drops).
- False negative results may occur if the test kit is not used within 60 minutes after opening in environmental conditions of 40ºC/95%RH.
- False negative results may occur if testing is performed at unleveled surfaces of 45° angle up or 45° angle down.
- False negative results may occur if testing is performed under disturbances equal to or greater than shaking at 500 rpm.
- False negative results may occur if swabs are stored in their original paper packaging following specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- All negative results from patients should be treated as presumptive, and, if necessary, for patient management purposes, confirmation with a molecular assay may be performed. 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 results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID -19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g., PCR testing) should be considered.
- All operators using the product must be appropriately trained in performing and interpreting the results of the product, use appropriate personal protective equipment when handling this test kit, and use the product in accordance with the authorized labeling.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 04/09/2021 and 05/25/2021. 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.
- The performance of this device has not been assessed in a population vaccinated

against COVID-19.

- The clinical performance of this test has not been evaluated in patients without signs and symptoms of respiratory infection or other reasons to suspect COVID-19 infection, or for serial testing when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. A clinical study to support use in these individuals will be completed.
- False positive results may occur, particularly in areas with low numbers of COVID-19 infections and individuals without known exposure to COVID-19, and confirmation with a molecular assay may be considered.
- Positive and negative predictive values are highly dependent on COVID-19 prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.

CONDITIONS OF AUTHORIZATION FOR LABORATORY

The NIDS COVID-19 Antigen Rapid Test Kit Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for patients, and authorized labeling are available on the FDA website: (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

However, to assist clinical laboratories using the NIDS COVID-19 Antigen Rapid Test Kit ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
B. Authorized laboratories using your product must use your product as outlined in the "authorized labeling". Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.
D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and ANP Technologies Inc. (via email: Techhelp@anptinc.com for any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling.

G. ANP Technologies Inc. authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC) i.e., in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

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

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

To first establish the LoD range, a panel of serially diluted contrived samples were made using gamma-irradiated, inactivated virus supplied at a concentration of 2.8×10^5 $TCID_{50}$/mL and tested in triplicate according to the IFU instructions. The preliminary LoD was 311 $TCID_{50}$/mL, which was further confirmed by an additional 20 replicates. **Table 2** below summarizes LoD testing results.

Table 2: Results of LoD Confirmation

Concentration ($TCID_{50}$/mL)	Negative Results	Positive Results
311	0/20	20/20

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

To establish that the NIDS COVID-19 Antigen Rapid Test does not cross-react with or suffer from interference with other human coronaviruses, microbes, or other high prevalence disease agents/normal or pathogenic flora likely to be encountered in the clinical specimen, cross-reactivity studies were conducted. The results are presented in **Table 3** below. Other than the SARS-CoV-1 Urbani strain, no other cross-reactivity was observed with any of the tested organisms. Moreover, no interference was found with any of the tested organisms spiked with low positive SARS-CoV-2.

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

3) *Endogenous and Exogenous Interference Substances Studies*:
Interfering substances testing was carried out using a panel of fourteen (14) endogenous and exogenous substances tested at concentrations recommended by FDA in the EUA

[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.*

template guidance for Antigen Tests. No interference (false negative or false positive) was observed for any of the tested substances (Table 4).

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

4) *High-dose Hook Effect*:

High-dose hook effect was evaluated by testing the gamma-irradiated, inactivated stock virus at 2.8E+05 $TCID_{50}$/mL in triplicate to verify that false negative results do not occur when tested with extremely high concentrations of SARS-CoV-2 virus. None of the assays tested produced a false negative at the concentration tested (**Table 5**).

Table 5: Hook Effect Study Results

Test Concentration ($TCID_{50}$/mL)	Replicates	Positive Results
2.80E+05	3	3/3

CLINICAL PERFORMANCE

To evaluate the clinical performance of the NIDS COVID-19 Antigen Rapid Test, individuals aged ≥ 5 years who were identified by their clinicians as being symptomatic for COVID-19 (e.g., any symptom such as fever, dry cough, tiredness, aches and pains, sore throat, diarrhea, conjunctivitis, headache, loss of taste or smell, a rash on skin, or discoloration of fingers or toes) within the previous 7 days, were enrolled prospectively into an IRB-approved study. The study was conducted between April and May 2021 at four (4) point-of-care (POC) sites in the U.S. by 9 test operators who were blinded to the patient

diagnosis. Mid-turbinate specimens were tested immediately after collection, and no transport media was used for shipping the samples to a different location for testing. All clinical specimens were tested and evaluated in accordance with the proposed diagnostic algorithm, including retesting when appropriate. Test results were compared to the results from a highly sensitive EUA approved COVID-19 RT-PCR test.

Results

A total of 304 evaluable specimens were tested at three POC sites (one of the original 4 sites was removed due to all subjects being unevaluable). The agreement between the RT-PCR comparator and the NIDS COVID-19 Antigen Rapid Test was calculated as indicated below by **Table 6**.

Table 6: Clinical Study Performance Analysis

Method		**RT-PCR Test**		**Total**
NIDS COVID-19 Antigen Rapid Test		Pos	Neg	
	Pos	39	8	47
	Neg	2	255	257
Total		41	263	304

Positive Percent Agreement = (39/41) x 100% = **95.1% (95% CI = 83.5 to 99.4%)**

Negative Percent Agreement = (255/263) x 100% = **97.0% (95% CI = 94.1 to 98.7%)**

Patient Demographics: Demographics data is provided by Table 7 below

Table 7: NIDS Positive Results by Age Group

Age Group (years)	NIDS Positive	Sum	% Positivity Rate
5 to 21	9	54	16.7%
22 to 59	32	205	15.6%
≥ 60	6	45	13.3%
Sum	47	304	15.5%

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

Table 8: Clinical Performance Breakdown by Days Post-Symptom Onset

Days Post-Symptom Onset	Number of the specimens tested	NIDS Antigen Positive	RT-PCR Positives	PPA (95% CI)
Less than 2 days	75	5	3	100.0%

2-3 days	130	19	19	94.7%
4-5 days	65	19	15	100.0%
6-7 days	34	4	4	75.0%
Total	304	47	41	

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications and performance may differ in these populations.

Symbols

	Consult Instructions for use		For Investigational Use Only
	Catalog #		Lot Number
	Number of Tests per kit		Temperature storage
	Manufactured by		Date of Manufacture
	Use by		Single Use only
	Humidity limitation		

ORDERING AND CONTACT INFORMATION
Reorder Numbers:
PN-0003KT40: NIDS® COVID-19 Antigen Rapid Test Pack (Includes testing components for conducting up to 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)

ANP Technologies®, Inc.
824 Interchange Blvd
Newark, DE 19711 USA
www.anptinc.com

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