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

<table>
<thead>
<tr>
<th>Material Components</th>
<th>Hazards</th>
<th>MSDS/SDS Reference</th>
</tr>
</thead>
</table>
| 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 – 30°C). 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)

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**

<table>
<thead>
<tr>
<th>Result</th>
<th>Device Image</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td></td>
</tr>
<tr>
<td>A <strong>negative specimen</strong> 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.</td>
<td><img src="image" alt="" /></td>
</tr>
<tr>
<td><strong>Positive</strong></td>
<td></td>
</tr>
<tr>
<td>A <strong>positive specimen</strong> 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.</td>
<td><img src="image" alt="" /></td>
</tr>
<tr>
<td><strong>Invalid</strong></td>
<td></td>
</tr>
<tr>
<td>If no control or only test line is seen, the test is invalid. It is recommended to collect the specimen and test again.</td>
<td><img src="image" alt="" /></td>
</tr>
</tbody>
</table>

**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


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 \(2.8 \times 10^5\) 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>
<thead>
<tr>
<th>Concentration (TCID(_{50})/mL)</th>
<th>Negative Results</th>
<th>Positive Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>311</td>
<td>0/20</td>
<td>20/20</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Virus/Bacteria/Fungi</th>
<th>Cross-Reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>PNM collected in VTM</td>
<td>No Cross-Reactivity</td>
<td>No Interference</td>
</tr>
<tr>
<td>SARS virus</td>
<td>Cross-Reactive</td>
<td>Interference</td>
</tr>
<tr>
<td>MERS Coronavirus</td>
<td>No Cross-Reactivity</td>
<td>No Interference</td>
</tr>
<tr>
<td>Coronavirus 229E</td>
<td>No Cross-Reactivity</td>
<td>No Interference</td>
</tr>
<tr>
<td>Pathogen</td>
<td>Cross-Reactivity</td>
<td>Interference</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Coronavirus OC43</td>
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<td>No</td>
</tr>
<tr>
<td>Coronavirus NL63</td>
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<td>No</td>
</tr>
<tr>
<td>Coronavirus HKU1</td>
<td>In-Silico Analysis</td>
<td>In-Silico Analysis</td>
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<td>Adenovirus</td>
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<tr>
<td>Parainfluenza virus 1</td>
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<td><em>Mycoplasma pneumoniae</em></td>
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<tr>
<td><em>Legionella pneumophila</em></td>
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</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em></td>
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<tr>
<td><em>P. jiroveci-S. cerevisae</em></td>
<td>In-Silico Analysis</td>
<td>In-Silico Analysis</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. Aureus</em></td>
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</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

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 jiroveci* was carried out using 11,975 *Pneumocystis jiroveci* 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 jiroveci*. 

---

Page 13 of 17
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

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

4) **High-dose Hook Effect:**
High-dose hook effect was evaluated by testing the gamma-irradiated, inactivated stock virus at 2.8E+05 TCID₅₀/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>
<thead>
<tr>
<th>Test Concentration (TCID₅₀/mL)</th>
<th>Replicates</th>
<th>Positive Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.80E+05</td>
<td>3</td>
<td>3/3</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Method</th>
<th>RT-PCR Test</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIDS COVID-19 Antigen Rapid Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pos</td>
<td>39</td>
<td>47</td>
</tr>
<tr>
<td>Neg</td>
<td>2</td>
<td>257</td>
</tr>
<tr>
<td>Total</td>
<td>41</td>
<td>304</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Age Group (years)</th>
<th>NIDS Positive</th>
<th>Sum</th>
<th>% Positivity Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 21</td>
<td>9</td>
<td>54</td>
<td>16.7%</td>
</tr>
<tr>
<td>22 to 59</td>
<td>32</td>
<td>205</td>
<td>15.6%</td>
</tr>
<tr>
<td>≥ 60</td>
<td>6</td>
<td>45</td>
<td>13.3%</td>
</tr>
<tr>
<td>Sum</td>
<td>47</td>
<td>304</td>
<td>15.5%</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Days Post-Symptom Onset</th>
<th>Number of the specimens tested</th>
<th>NIDS Antigen Positive</th>
<th>RT-PCR Positives</th>
<th>PPA (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 2 days</td>
<td>75</td>
<td>5</td>
<td>3</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>Cases</td>
<td>True</td>
<td>False</td>
<td>Sensitivity (%)</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>------</td>
<td>-------</td>
<td>-----------------</td>
</tr>
<tr>
<td>2-3 days</td>
<td>130</td>
<td>19</td>
<td>19</td>
<td>94.7%</td>
</tr>
<tr>
<td>4-5 days</td>
<td>65</td>
<td>19</td>
<td>15</td>
<td>100.0%</td>
</tr>
<tr>
<td>6-7 days</td>
<td>34</td>
<td>4</td>
<td>4</td>
<td>75.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>304</td>
<td>47</td>
<td>41</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📖</td>
<td>Consult Instructions for use</td>
<td>📖</td>
<td>For Investigational Use Only</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog #</td>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>∑</td>
<td>Number of Tests per kit</td>
<td>℃</td>
<td>Temperature storage</td>
</tr>
<tr>
<td>🏭</td>
<td>Manufactured by</td>
<td>📜</td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td>⌚</td>
<td>Use by</td>
<td>☢️</td>
<td>Single Use only</td>
</tr>
<tr>
<td>☀️</td>
<td>Humidity limitation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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IFU-02 v.03
Effective Date: 24 September 2021
**Directly Collected Mid-Turbinate Nasal Swab**

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. 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 a recent history of 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 recent exposure to SARS-CoV-2 or residing in communities with low prevalence of infection.

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

**See Instructions for Use for complete use instructions, warnings, precautions, and limitations.**

In the USA, 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 CLIA, 42 U.S.C. §263a, that meet requirements 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. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

**1. Collect specimen**

Prior to collecting the nasal swab, the patient should be instructed to blow their nose.

Tilt head back 70 degrees. Carefully insert swab into the nostril, parallel with the bridge of the nose, no more than 1” deep, or until you feel resistance at the turbinates.

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.

**2. Remove white cap and immerse swab in buffer**

Remove white cap of collection tube and insert test swab into buffer.

**3. Plunge swab up and down for 15 seconds**

Carefully plunge swab up and down for 15 seconds.

DO NOT SPILL CONTENTS OR CONTAMINATE THE SWAB.

**4. Remove swab and cap tube with affixed clear dropper**

Remove the test swab while pressing and rotating the tip against the inside wall of the tube to extract the liquid. Discard the swab and cap tube with affixed clear dropper tip.

**5. Invert tube and dispense 5 drops into sample well**

Remove test device from foil pouch and lay it flat. Invert the capped collection tube and tap the side to remove 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 to the sample well.

Test Device should be on a flat surface to avoid spillage and inaccurate results. Adding fewer drops may produce invalid or inaccurate results.

**6. Read results at 15 minutes**

Read results in test window at 15 minutes.

RESULTS READ BEYOND 30 MINUTES MAY BE INACCURATE.

Notes:

- Testing must be performed within 30 minutes of specimen collection.
- Do not use visually bloody or overly viscous specimen.
- Inadequate specimen collection or improper sample handling/storage may yield erroneous results.
- Use only the swab provided in the test kit.
RESULTS INTERPRETATION

Negative

A negative specimen will give a single red/pink colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test 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. 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 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 with and without serial testing 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.

Positive

A positive specimen will give two red/pink 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 pink/purple colored line is positive.

Invalid

If no control line or test line are seen, the test is invalid. If the test line is seen, but the control line is not, the test is invalid. Invalid tests should be repeated. If the problem persists, contact ANP Technical Support.

IMPORTANT

Negative Procedural Control

The clearing of the test strip’s background color in the results viewing window is a built-in negative control, indicating that the test has been performed correctly. The test area’s color in the window should turn from dark red to light pink or white within 15 minutes and allow for clear interpretation of the test result. If the background color remains dark red and interferes with the reading of the test result, then the test is invalid. Should this occur, review the procedure, and repeat the test with a new patient sample using a new test device. Do not reuse patient samples and swabs.

TEST DEVICE

Positive Specimen Indication

Any visible pink/purple colored test line is positive. All six examples below are positive.

At 15 minutes read the result by either:
1. Holding the Visual Guide Card next to the test device.
   OR
2. Laying the test device directly onto the outline image here and use as the guide incorporated herein.

Do not read the test beyond 30 minutes, as results interpreted after 30 minutes may result in false positive, false negative or invalid results.

Visual Guide Card
Part No. VGC-01

ANP Technologies, Inc.
824 Interchange Blvd. Newark, DE 19711
Tel:+1 302-283-1730 / +1 888-283-0685 (8:00 AM – 5:00 PM EST)
Technical Help: Techhelp@anptinc.com (24/7)
ANP Technologies, Inc.

NIDS® COVID-19 Antigen Test
External Control Kit

REF PN-0005KT
For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use only.
For prescription use only.

Package contents:
- Part No.: PN-0004 – External Positive Control Swab (QTY 1)
- Part No.: 25-1506 1PF – External Negative Control Swab (QTY 1)
- Part No.: PN-0002 – Antigen Rapid Test Devices (QTY 2)
- Part No.: PN-0001 – Antigen Swab Buffer Tubes (QTY 2)
- Part No.: IFU-03 – Instructions For Use (QTY 1)
- Part No.: VGC-01 – Visual Guide Card (QTY 1)

Summary and Explanation of the Test
ANP Technologies provides an external positive and negative assayed quality control kit, the NIDS COVID-19 Antigen 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.

- **Positive Control Swab:** The External Positive Control swab 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 External Negative Control swab consists of a sterile swab without non-infectious SARS-CoV-2 nucleocapsid recombinant antigen.

Storage Instructions
Store at 15 - 30°C. Controls should not be used past the expiration date on the package.

Procedure / Interpretation / Limitations
Users should refer to the NIDS COVID-19 Antigen Rapid Test Kit Instructions for Use (Part No.: IFU-02) available on the website: www.anptinc.com

External Control Testing Procedures

1. Remove the Positive/Negative control swab from external packaging.
2. Remove the white cap from the collection tube and insert the first (positive or negative) control swab into the buffer.
3. Carefully plunge the control swab up and down for 15 seconds. Make sure to hold the tube in an upright position to prevent spillage or splashing of the contents.
4. Remove the control 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.
5. Remove the test device from the sealed foil pouch and lay flat on a clean surface.
6. 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.
7. 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.
8. Repeat steps 2 – 7 for the second control swab.

Results Interpretation
For the negative control swab, the presence of only the control line (C) within the result window indicates the negative control has passed. For the positive control swab, the presence of two lines, i.e., a control line (C) and a test line (T) within the result window indicates the positive control has passed.

In the USA, 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 CLIA, 42 U.S.C. §263a, that meet requirements 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. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="i" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Catalog number</td>
</tr>
<tr>
<td><img src="image" alt="" /></td>
<td>Contains sufficient for &lt;n&gt; tests per kit</td>
</tr>
<tr>
<td><img src="image" alt="" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image" alt="IVD" /></td>
<td>In vitro Diagnostic medical device</td>
</tr>
</tbody>
</table>

If you have any questions regarding the use of this product or if you want to report any testing issues, please contact ANP’s Technical Support at +1 (302) 283-1730 or 1 (888) 280-0685 (toll free in US) during normal business hours (Mon. to Fri. – 8:00 AM to 5:00 PM EST) or Techhelp@anptinc.com (24/7)

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824 Interchange Blvd  
Newark, DE 19711 USA  
www.anptinc.com

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Visual Guide Card
Part No.: VGC-01

Control Line
SARS-CoV-2

Version: 00
Effective: SEP21
authorization is revoked sooner.

Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1),
declaration that circumstances exist justifying
detection of proteins from SARS-CoV-2, not for
Compliance, or Certificate of Accreditation.

CLIA Certificate of Waiver, Certificate of
i.e., in patient care settings operating under a
authorized for use at the Point of Care (POC),
waived complexity tests. This product is
requirements to perform moderate, high or
laboratories; use by laboratories certified
In the USA, this product has not been FDA
cleared or approved, but has been authorized
under an EUA for use by authorized laboratories;
use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet
requirements 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
Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the
detection of proteins from SARS-CoV-2, not for
any other viruses or pathogens; and in the
USA, - 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
the virus that causes COVID-19 under Section
564(b)(1) of the Federal Food, Drug and
Compliance, or Certificate of Accreditation.

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detection of proteins from SARS-CoV-2, not for
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declaration that circumstances exist justifying
the authorization of emergency use of in vitro
diagnostics for detection and/or diagnosis of
the virus that causes COVID-19 under Section
564(b)(1) of the Federal Food, Drug and
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This product has been authorized only for the
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