NIDS® COVID-19
Antigen Rapid Test
Quick Reference Guide

For use under Emergency Use Authorization (EUA) only.

For in vitro diagnostic use only

For prescription use only

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.

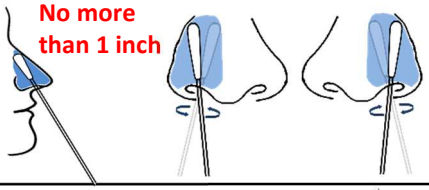
For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high 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.

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.

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

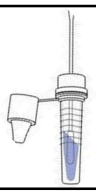


Prior to collecting the nasal swab, the patient should be instructed to BLOW THEIR NOSE.
Remove the test device from the foil pouch and lay it on a flat, level surface.

Carefully insert swab into the nostril, parallel with the bridge of the nose, **no more than 1" deep**. Rotate the swab in a circular path 4 times around the entire inside nostril wall. Repeat with the ***same swab*** in the other nostril.

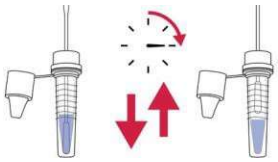
AVOID COLLECTING EXCESS MUCUS ON THE SWAB TIP.

2 Remove white cap and immerse swab in buffer



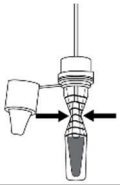
Hold the tube vertically upright and tap the bottom of the tube on the table to insure all of the buffer liquid is down in the bottom of the tube. Remove the white cap of the collection tube and insert the entire tip of the test swab into buffer liquid completely.

3 Plunge swab up and down for 15 seconds



Carefully plunge the swab up and down for 15 seconds.
DO NOT SPILL THE CONTENTS OR CONTAMINATE THE SWAB.

4 Remove swab and cap tube with affixed clear dropper



Remove the test swab while squeezing the tube, and rotating the swab tip to extract all the liquid from the swab tip.
Discard the swab and cap the tube with affixed clear dropper tip.

5 Invert tube and dispense 5 drops into sample well

Invert the capped collection tube and tap the side to remove air bubbles. Hold the tube vertically, 1/4 inch above the device. Squeezing gently, and slowly, **dispense all of the extracted sample solution** into the sample well (5 drops or more, use both of your hands if needed to dispense).

Test Device should be on a flat, level surface to avoid spillage. 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 30MINUTES 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.

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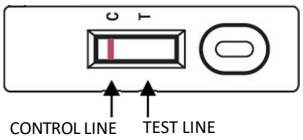
RESULTS INTERPRETATION

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 in an individual with as a close contract 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

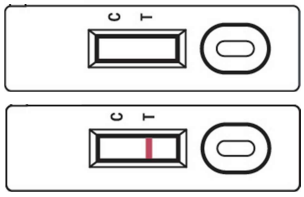
A **positive specimen** will give two red/pink colored lines. This means that SARS-CoV-2 nucleocapsid protein antigen was detected. Specimens with low levels of antigen may give a faint test line. Any visible pink/purple colored line is positive.

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**.

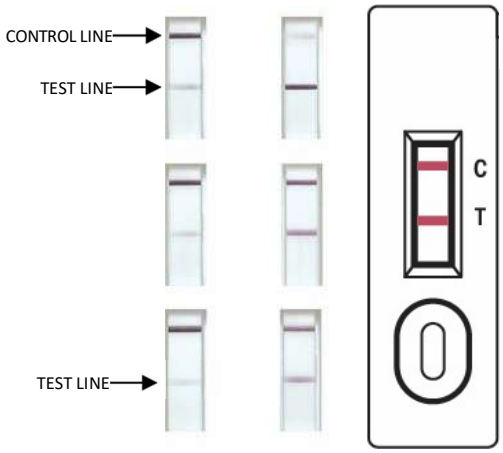
Invalid tests should be repeated. If the problem persists, contact ANP Technical Support.



TEST DEVICE

Positive Specimen Indication

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



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.

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