

Nano-Check™ COVID-19 Antigen Test

For use under emergency use authorization (EUA) only

For *in vitro* diagnostic use

For prescription use only

For use with kit provided nasopharyngeal swab

1. INTENDED USE

The Nano-Check™ COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptoms 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 48 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, 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.

The Nano-Check™ COVID-19 Antigen Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to fully 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 and/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 Nano-Check™ COVID-19 Antigen Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The Nano-Check™ COVID-19 Antigen

Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. SUMMARY AND EXPLANATION OF THE TEST

The first case of the coronavirus disease 19 (COVID-19) was reported when an outbreak of unknown respiratory illnesses occurred in Wuhan, China on December 31, 2019. The COVID-19 Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a respiratory illness, like influenza, with symptoms such as a cough, fever, fatigue, and in more severe cases, difficulty breathing or shortness of breath. The WHO officially declared COVID-19 a pandemic on March 11, 2020.

Nano-Check™ COVID-19 Antigen Test is a rapid chromatographic immunoassay intended for the direct detection of presence or absence SARS-CoV-2 antigen in 15 min using respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset.

3. PRINCIPLE

The Nano-Check™ COVID-19 Antigen Test is designed to detect the extracted nucleocapsid protein antigen specific to SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

When specimens are extracted and added to the sample well of test device, SARS-CoV-2 viral antigens present in the specimen bind to antibodies against SARS-CoV-2 nucleocapsid conjugated to gold colloidal particles and biotin in the test strip. The antigen-conjugate immunocomplexes migrate across the test strip and are captured at the test line of nitrocellulose membrane.

Test results are interpreted at 15-20 minutes visually. The presence of two pinkish red colored lines in the control line "C" and test line "Ag" indicates COVID-19 positive. The presence of one colored lines in the control line "C" indicates COVID-19 negative. The control line (C) must be present in the test window for self-procedure validation control. This colored control band always appears at the control line position (C) in valid test result. Any test result is not valid without appearance of the control line in the test window.

4. REAGENTS and MATERIALS

Provided

- 20 Test devices in sealed aluminum foil pouch with desiccant
- 20 Reagent tubes with extraction buffer (0.3 mL)
- 20 Sample collection swabs
- 1 Positive control swab
- 1 Negative control swab
- 1 Instructions for Use/ Quick Reference Instruction

Required but not provided

- Timer
- Tube rack for specimens
- Any necessary personal protective equipment

5. STORAGE AND STABILITY

- The test kit should be stored at 2°C - 30°C in the original sealed pouch. Do not freeze and bring to room temperature at least 30 minutes prior to use.
- The freshly collected nasopharyngeal swab specimen are recommended to be processed no later than one hour after specimen collection at room temperature (15°C - 30°C) or before 48 hours when stored at 2°C to 8°C.

6. WARNINGS AND PRECAUTIONS

- For *in-vitro* diagnostic use only.
- For prescription use only.
- For use with kit provided nasopharyngeal swab. Use only swabs provided with the kit.
- 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, that meet the 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.
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Federal Law restricts this test to sale by or on the order of a licensed practitioner (U.S. only).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Do not use test kit if the pouch is damaged or improperly sealed.
- Do not use test kit beyond expiration date.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Immediately use after opening the test device in the pouch. Tests should be used no more than one hour after opening the pouch.
- In order to obtain accurate results, the test must follow the instructions on this package insert.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as though they contain infectious agents.

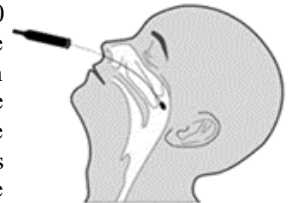
- Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- For additional information on hazard symbols, safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at Nano-Ditech Corp.

7. SPECIMEN COLLECTION AND PREPARATION

Acceptable specimen type for testing with the Nano-Check™ COVID-19 Antigen Test is a direct nasopharyngeal swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

Freshly collected specimens should be processed as soon as possible, but no later than one-hour at room temperature or up to 48 hrs at 2-8°C after specimen collection. Specimens in extraction buffer can be processed up to thirty minutes after collection when kept at room temperature.







To collect the nasopharyngeal swab sample, tilt the patient's head back 70 degrees. Carefully insert the swab into the nostril that presents the most secretion under visual inspection. Slowly insert the swab parallel to the palate until resistance is encountered, or the distance is equivalent to that from the ear to the nostril of the patient. Rotate the swab several times, leave the swab in place for several seconds to absorb secretions and then remove it from the nasopharynx.




Refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

8. TEST PROCEDURE AND PROTOCOL

Collect specimen according to instructions in "Specimen Collection and Preparation". Test device and sample should be brought to room temperature (20°C- 30°C) prior to testing. Remove the test device from the sealed pouch immediately before use. Label the device with patient or control identification. Conduct all testing on a level surface.

1.  Remove the cap from the Reagent tube.
2.  Insert the collected swab into the Reagent tube.
3.  Swirl and plunge the swab up and down in the extraction buffer while squeezing the sides of the tube for 15 seconds.
4.  Remove the swab while squeezing the sides of the tube to the swab head for extracting the maximum amount of liquid from the swab. Properly discard the swab.
5.  Firmly close the dropper tip onto the Reagent tube containing the sample.
6.  With the processed Reagent Tube hold vertically, squeeze gently to dispense 2 drops of the sample into the sample well of the test device.

Note: Too few drops can result in invalid results, and too many drops could produce incorrect results.

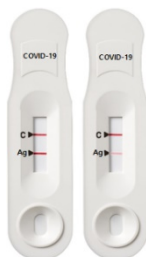
7.  Read the results at 15 minutes visually. Do not read result more than 20 minutes after the sample application.

Note: False negative or false positive results can occur if read before or after 15-20 minutes.

9. INTERPRETATION OF RESULTS

Positive

Appearance of pinkish red colored bands at both the control line and the test line indicates positive result. The colored test line depending on the concentration of SARS-CoV-2 virus in the test specimen will appear. The line in the control region (C) is the control line, which is used to indicate proper performance of the device. The color



intensity of the test lines may be weaker or stronger than that of the control line.

Negative

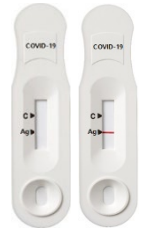
A single pinkish red colored band at the control line without visual test line is a negative result. Negative result does not indicate the absolute absence of SARS-CoV-2 virus in specimen or rule out COVID-19; it only indicates that the specimen does not contain the virus concentration at above the detection limit of the level.

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



Invalid

If no lines are seen or no colored line appears in the control region (C), the test result is invalid. If the invalid result is obtained during initial testing, the assay should be repeated with a new test device.



10. QUALITY CONTROL

Internal Quality Control: The presence of a pinkish red colored band in the Control area of the window acts as an internal control to ensure adequate migration has occurred, but does not determine if an adequate sample has been added. In the absence of this Control line, the test is invalid and must be repeated. If the control line does not develop in 15 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the Technical Support at +1- 855-297-7877 or info@nanoditech.com.

External Control: Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as clinical sample swab, and conduct the assay as described in Test Procedure section. Controls should minimally be run before using each new lot or shipment of Nano-Check™ COVID-19 Antigen Test, at regular intervals afterwards or any time when the validity of the test results are questioned. All users should follow local, state and federal regulations regarding quality control procedures. If the controls do not perform as expected, do not report patient results. Contact please the Technical Support at +1- 855-297-7877 or info@nanoditech.com.

Limitations:

- This test is not for use in at-home testing settings.
- Viral transport media (VTM) should not be used with this test.
- Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
- Positive test results do not rule out co-infections with other bacterial or viral pathogens.

- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- Read the test results at 15 minutes. Do not interpret the test past after 20 minutes.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result. Make sure to swirl and plunge the swab up and down in extraction buffer while squeezing the sides of the tube for 15 seconds; squeezing the swab head at least once or more in the reagent tube during the swab removal procedure. Insufficient swirling or squeezing of the swab head may produce false negative results.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
- This test detects both viable and non-viable SARS-CoV-2 virus. 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.
- The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- False negative results can occur if the cassette is not placed on a flat surface.
- False negative results may occur if testing is performed in conditions of low humidity and low temperatures (e.g., <5°C, <20% RH).
- This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 19, 2021 and March 23, 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

CONDITIONS OF AUTNORIZATION FOR LABORATORIES

The Nano-Check™ COVID-19 Antigen Test Letter of Authorization¹, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling will be available on the FDA website post authorization: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

However, to assist clinical laboratories in using the Nano-Check™ COVID-19 Antigen Test, the relevant Conditions of Intended Authorization are listed below:

- A. Authorized laboratories using your product must include with the 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 the 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 the product are not permitted.
- C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the product prior to initiating testing.
- 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 Nano-Ditech Corporation Product Support website: (www.nanoditech.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the 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 authorized labeling.
- G. Nano-Check™ COVID-19 Antigen Test, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

11. PERFORMANCE CHARACTERISTICS

1) Clinical Performance

The clinical performance of the Nano-Check™ COVID-19 Antigen Test was evaluated in a prospective study in the U.S. in which patients were sequentially enrolled and tested in March 2021.

The performance of the Nano-Check™ COVID-19 Antigen Test was established with a total of 76 direct nasopharyngeal swabs collected from symptomatic patients within 5 days from onset. The samples were

tested at a Point of Care (POC) CLIA waived clinical site. Test results were compared to the results of nasal swabs collected from the same patients and tested with a highly sensitive EUA Covid-19 RT-PCR test. Nano-Check™ COVID-19 Antigen Test was performed by operators with no laboratory experience and who were representative of the intended users. Operators were only using the QRI for the test without any training provided.

31 prospective samples were tested positive with the comparator RT-PCR tests while 28 samples were positive and the other 3 samples were negative using Nano-Check™ COVID-19 Antigen Test. All 45 samples tested negative with the comparator RT-PCR tests were negative on Nano-Check™ COVID-19 Antigen Test. The agreement between the Nano-Check™ COVID-19 Antigen Test and RT-PCR are presented below.

Table 1. Comparison Result with Comparator RT-PCR method

Nano-Check COVID-19 Antigen Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	28	0	28
Negative	3	45	48
Total	31	45	76
Positive Agreement: 28/31		90.32% (95% CI: 75.10% - 96.66%)	
Negative Agreement: 45/45		100.0% (95% CI: 92.14% - 100.0%)	

Table 2. Positive Results by Age Group

Age Group	Nano-Check™ COVID-19 Antigen Test		
	# of Specimen Tested	# of Positive Specimen	Prevalence (%)
≤ 5 years	0	0	N/A
6 to 21 years	4	0	0.00
22 to 60 years	63	23	36.51
≥ 61 years	9	5	55.56

Table 3. Positive Results Stratified by Days Post-Symptom Onset

Days Post Onset	RT-PCR Positive ¹	Nano-Check™ COVID-19 Antigen Test Positive	Positive Rate (%)
0	5	5	100.00
1	9	9	100.00
2	20	18	90.00
3	24	21	87.50
4	28	25	89.29
5	31	28	90.32

2) Assay Sensitivity: Limit of Detection (LoD)

(POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.” as “authorized laboratories.”

¹ The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets the requirements to perform high, moderate, or waived complexity tests. This product is authorized for use at the Point of Care

To verify analytical sensitivity of Nano-Check™ COVID-19 Antigen Test, Limit of Detection (LoD, the lowest concentration at which 19 out of 20 replicates are confirmed positive) was established using limiting dilutions of a SARS-CoV-2 inactivated by gamma irradiation. The study was designed to estimate the LoD of Nano-Check™ COVID-19 Antigen Test when using a direct nasal swab, with a starting material spiking into a volume of real clinical matrix of nasal wash solution. A tentative LoD was determined in preliminary test. At each dilution, 50 µL samples were spiked on swab head for Swab method; samples were tested in the Nano-Check™ COVID-19 Antigen Test. With tentative concentrations selected from each method, the LOD was verified in an additional 20 replicates tested in the same way. It was verified that LoD of Nano-Check™ COVID-19 Antigen Test was 7.0×10^2 TCID₅₀/mL for Swab method.

Table 4. LoD of the Nano-Check™ COVID-19 Antigen Test

Testing method	Conc. of Stock (TCID ₅₀ /mL)	LoD (TCID ₅₀ /mL)	No. Positive /No. Total	Positive rate
Swab	2.8×10^6	7.0×10^2	20/20	100%

3) Assay Cross Reactivity and Microbial Interference

Cross-reactivity of the Nano-Check™ COVID-19 Antigen Test was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the Nano-Check™ COVID-19 Antigen Test. The final concentration of each organism is described in the table below.

The microbial interference was also performed with the same panel of microorganisms at the same concentrations in the samples that were spiked with SARS-CoV-2 at 3X LoD. The samples were tested in triplicates for both cross-reactivity and interference studies. No cross-reactivity and no microbial interference were observed. The results for cross-reactivity and microbial interference are presented in the table below.

Table 5. Cross-Reactivity/Microbial Interference of the Nano-Check™ COVID-19 Antigen Test

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
<i>Bordetella pertussis</i> , 5	1.0×10^6 cfu/ mL	No
<i>Candida albicans</i> , Z006	1.0×10^6 cfu/ mL	No
<i>Chlamydia pneumoniae</i>	1.0×10^6 IFU/ mL	No
<i>Haemophilus influenzae</i>	1.0×10^6 cfu/ mL	No
<i>Legionella pneumophila</i>	1.0×10^6 cfu/ mL	No
<i>Mycoplasma pneumoniae</i>	1.0×10^6 cfu/ mL	No
<i>Streptococcus pneumoniae</i> , Z022/Serotype 19F	1.0×10^6 cfu/ mL	No
<i>Streptococcus pyogenes</i> , Bruno	1.0×10^6 cfu/ mL	No
<i>Staphylococcus aureus</i> , MASA, COL	1.0×10^6 cfu/ mL	No
<i>Staphylococcus epidermidis</i> , MRSE, RP62A	1.0×10^6 cfu/ mL	No
<i>Pneumocystis jirovecii</i> , W303-Pji	1.0×10^6 cfu/ mL	No
Coronavirus, NL63	7.0×10^4 TCID ₅₀ / mL	No
Enterovirus 71, MP4	1.0×10^5 TCID ₅₀ / mL	No
Adenovirus type 2, C	1.0×10^5 TCID ₅₀ / mL	No
Coronavirus, 229E	1.0×10^5 TCID ₅₀ / mL	No
Coronavirus, OC43	4.5×10^4 TCID ₅₀ / mL	No
Metapneumovirus, TN/83-1211	1.0×10^5 TCID ₅₀ / mL	No
Parainfluenza Virus 1/FRA/ 29221106 / 2009	1.0×10^5 TCID ₅₀ / mL	No
Parainfluenza Virus 2, Greer	1.0×10^5 TCID ₅₀ / mL	No

Parainfluenza Virus 3, NIH 47885	1.0×10^5 TCID ₅₀ / mL	No
Parainfluenza Virus 4B, 19503	1.0×10^5 TCID ₅₀ / mL	No
RSV, A1998 / 12-21	1.0×10^5 TCID ₅₀ / mL	No
MERS-CoV, EMC/2012	1.0×10^5 TCID ₅₀ / mL	No
SARS-CoV, Urbani	1.0×10^5 pfu/ mL	No
Rhinovirus 20, 15-CV19	5.0×10^5 TCID ₅₀ / mL	No
Influenza A/New Caledonia/ 20/ 1999 (H1N1)	1.0×10^5 CEID ₅₀ / mL	No
Influenza A/San Diego/1/2009 (H1N1) pdm09	1.0×10^5 TCID ₅₀ / mL	No
Influenza A/Victoria/361/2011 (H3N2)	1.0×10^5 CEID ₅₀ / mL	No
Influenza A/Wisconsin/67/ 2005 (H3N2)	1.0×10^5 CEID ₅₀ / mL	No
Influenza B/Brisbane/60/2008	1.0×10^5 CEID ₅₀ / mL	No
Influenza B/Texas/06/2011	1.0×10^5 CEID ₅₀ / mL	No
Influenza B/GL/1739/54	1.0×10^5 CEID ₅₀ / mL	No

To estimate the likelihood of cross-reactivity with SARS-CoV-2 that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology was with the HKU1 nucleocapsid phosphoprotein. Although homology was relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.
- No protein sequence homology was found between *M. tuberculosis*, however, cross-reactivity cannot be ruled out.

4) Endogenous Interference

To assess endogenous interference with the performance of the Nano-Check™ COVID-19 Antigen Test, positive and negative samples were tested with potentially interfering substances that may be found in the upper respiratory tract. This study was performed to demonstrate that sixteen (16) potentially interfering substances do not cross-react nor interfere with the detection of SARS-CoV-2 in Nano-Check™ COVID-19 Antigen Test.

Table 6. Endogenous Interference

Potential Interfering Substances	Concentration
Nasal Spray 1 - Afrin	15% v/v
Nasal Spray 2 - NasalCrom	15% v/v
Nasal Spray 3 - FLONASE	15% v/v
Sore Throat 1 - Oral Pain Reliever Spray	15% v/v
Sore Throat 2 - Lozenges	15% w/v
Nasal Drops	15% v/v
NasoGel (Gel Spray)	15% v/v
Nasal Allergy Relief	15% v/v
Homeopathic Allergy Nasal Spray	15% v/v
Zinc Lozenges	5% w/v
Mucin	0.5%
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Whole Blood	4%
Biotin	3500 ng/mL

5) High-Dose Hook Effect



The Nano-Check™ COVID-19 Antigen Test was tested up to 2.8×10^6 TCID₅₀/mL of gamma-irradiated SARS-CoV-2 and no high-dose hook effect was observed.

6) Point of Care Use

The Nano-Check™ COVID-19 Antigen Test demonstrated at near patient or Point of Care (POC) testing that non-laboratory personnel can perform the test accurately in the intended use environment. In addition, the robust use of the Nano-Check™ COVID-19 Antigen Test for near patient or Point of Care (POC) testing was verified by twelve (12) Flex studies.

12. REFERENCES

1. IFCC Information Guide on COVID-19 (<https://www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/>).
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Germany



For Use Under an Emergency Use Authorization (EUA) Only.

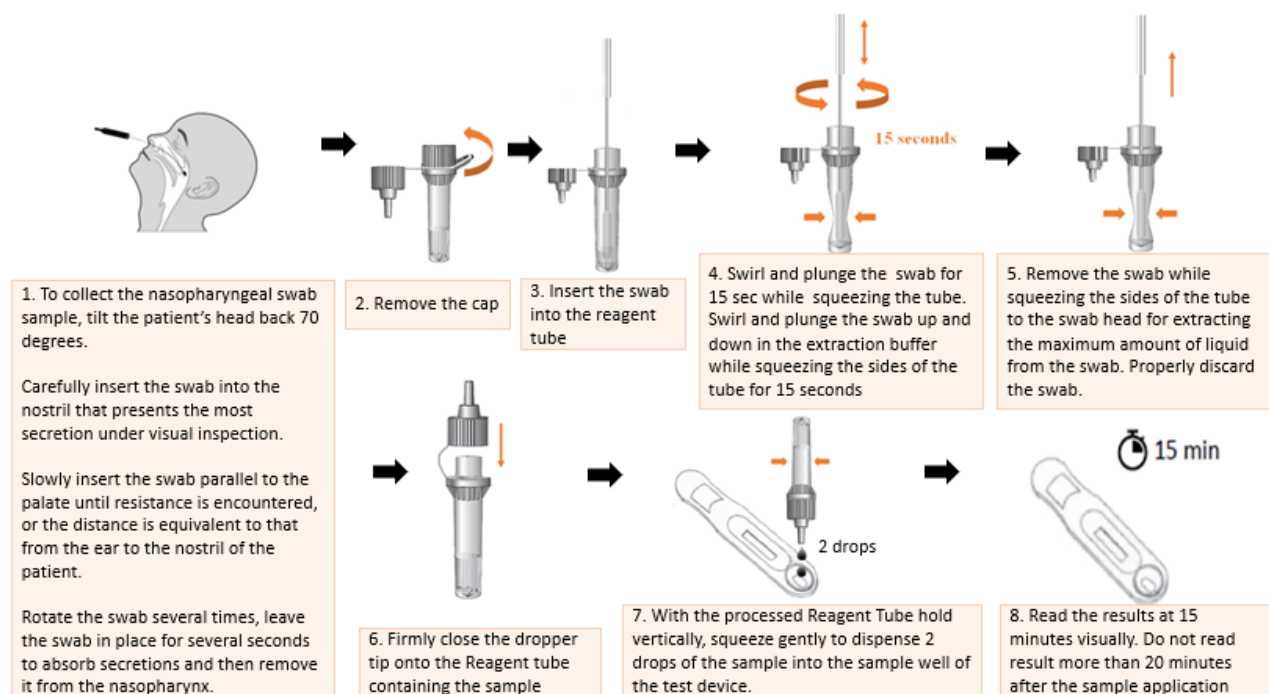
For *in vitro* diagnostic use, For prescription use only, For use with kit provided nasopharyngeal swab

The Nano-Check™ COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in direct nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptoms 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 48 hours between tests.

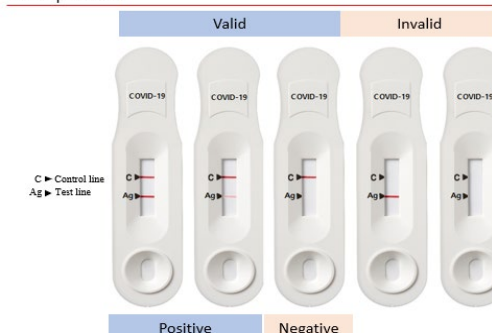
IMPORTANT:

- Refer to Product Insert, including QC section, for complete use instructions, warnings, precautions, and limitations.
- The test kit should be stored at 2°C - 30°C in the original sealed pouch. Do not freeze and bring to room temperature at least 30 minutes prior to use.
- The freshly collected nasopharyngeal swab specimen are recommended to be processed no later than one hour after specimen collection at room temperature (15°C - 30°C) or before 48 hours when stored at 2°C to 8°C.
- Refer to Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Nasopharyngeal Swab Sample Procedure



• Interpretation



Positive

Appearance of pinkish red colored bands at both the control line and the test line indicates positive result. The colored test line depending on the concentration of SARS-CoV-2 virus in the test specimen will appear. The line in the control region (C) is the control line, which is used to indicate proper performance of the device. The color intensity of the test lines may be weaker or stronger than that of the control line.

Negative

A single pinkish red colored band at the control line without visual test line is a negative result. Negative result does not indicate the absolute absence of SARS-CoV-2 virus in specimen or rule out COVID-19; it only indicates that the specimen does not contain the virus concentration at above the detection limit of the level.

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

Invalid














If no lines are seen or no colored line appears in the control region (C), the test result is invalid. If the invalid result is obtained during initial testing, the assay should be repeated with a new test device

External Quality Control Test Step Instructions

External positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as clinical sample swab, and conduct the assay as described in Test Procedure section. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user.

- 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 complexity, high complexity, or waived 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.
- 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 the declaration is terminated or the authorization is revoked sooner

Glossary

 Rx ONLY Prescription use only	 IVD For In Vitro use only	 Manufacturer	 CE CE mark of conformity	 EC REP Authorized Representative in the European Community
 LOT Batch code	 Use by	 Temperature limitation	 Consult instructions for use	 Contains sufficient for 20 determinations
 REF Catalog number	 CONTROL + Positive control	 CONTROL - Negative control		