COVCLEAR™ SARS-COV-2 (COVID-19) RAPID ANTIGEN TEST

For Emergency Use Authorization only
For in vitro diagnostic use only
For OTC use at Home and other non-laboratory sites

INTENDED USE

The CovClear COVID-19 Rapid Antigen Test is a single-use lateral flow immunoassay with an integrated swab, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. This test is authorized for OTC, non-prescription home use, and non-laboratory use with self-collected anterior nasal samples from individuals 18 years or older, or adult collected anterior nasal samples from individuals 2 years or older. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease.

Individuals who test positive with the CovClear COVID-19 Rapid Antigen Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary. Negative results should be treated as presumptive. Confirmation with molecular assay, if necessary for patient management, may be performed. Negative results do not rule out COVID-19 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 an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary for patient management. 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 COVID-19 or residing in communities with low prevalence of infection. Individuals who test negative and continue to experience COVID-19 symptoms such as fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their healthcare provider. Individuals should report results obtained with this product to their healthcare provider.

The CovClear COVID-19 Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRINCIPLES OF THE TEST

The CovClear COVID-19 Rapid Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in nasal swab specimens directly collected.

The CovClear COVID-19 Rapid Antigen Test is comprised of five components: polyester swab, lateral flow dipstick, polypropylene vials, locking caps, and chase buffer solution. Each dipstick contains a nitrocellulose membrane coated with antibodies against the SARS-CoV-2 nucleocapsid protein at the test line. A green-colored line will appear at the test line in the presence of the SARS-CoV-2 nucleocapsid protein. The nitrocellulose membrane is also coated with a printed control line that will appear as a 'blue' line until the dipstick has been exposed to the swab sample where it will then appear 'red.' This color change from 'blue' to 'red' will indicate that the test was run successfully.

Nasal swabs require a sample preparation step in which the sample is eluted from the swab and into the chase buffer solution. The CovClear COVID-19 Rapid Antigen Test dipstick is then placed into the chase buffer solution. When the swab sample migrates into the test strip the gold nanoparticles labeled with anti-SARS-CoV-2 antibodies will bind the SARS-CoV-2 viral antigens to form an antibody-antigen immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

Test results are interpreted at 20 minutes. The presence of two-colored lines, red at the control line and green at the test line, indicates a COVID-19 positive sample. The presence of one red colored line indicates a COVID-19 negative sample. A blue colored line or no line at 20 minutes after running the assay indicates an invalid test.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- The test has been validated but the FDA's independent review of this validation is pending.
- This test 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 authorization is terminated or revoked sooner.
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Immediately use after removing the test strip from packaging.
- In order to obtain accurate results, the test must follow this package insert.
- Do not interpret the test result before or after 20 minutes of starting the test.
- Do not use if the test device package or its contents are damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions in the collection, handling, storage, and disposal of samples and used kit contents.
- If the chase buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as though they contain infectious agents.

- Observe normal precautions against microbiological hazards and proper disposal of specimens.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.

REAGENTS AND MATERIALS PROVIDED

Materials Provided

KIT COMPONENT	AMOUNT PER KIT
Lateral Flow Assay Strip	1
Chase Buffer Ampule	1
Vial	1
Locking Cap	1
Individually Wrapped Swab	1
Instructions for Use	1

Materials not provided with your test

- Timer

STORAGE AND STABILITY

The reagents and materials in the CovClear COVID-19 Rapid Antigen Test are stable until the expiration date printed on the packaging. Do not use beyond the expiration date. Store at 15°C to 30°C (60°F to 86F) sealed. Do not freeze any contents of the kit.

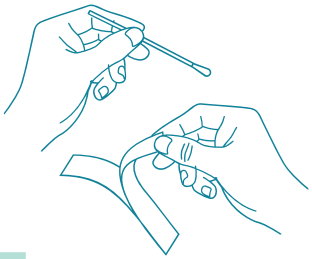
SPECIMEN COLLECTION AND HANDLING

The CovClear COVID-19 Rapid Antigen Test only use a direct nasal swab specimen. Only use the swab provided in the kit. It is essential that correct specimen collection and preparation methods be followed.

LOWER NOSTRIL SWAB SAMPLE COLLECTION

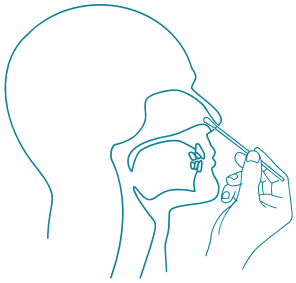
Procedural Notes:

- Process the test sample immediately after collection.
- Use only provided nasal swab for specimen collection.
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible after the onset of symptoms.



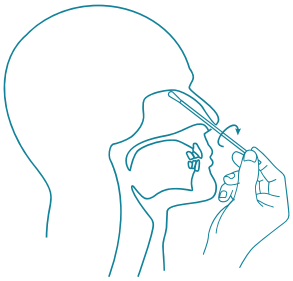
1

Remove a swab from the pouch.



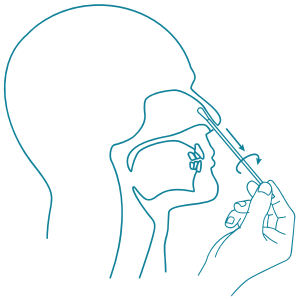
2

Place the dry swab into one nostril until it reaches resistance.



3

Slowly rotate the swab 7 times over the inside surface of the nostril.



4

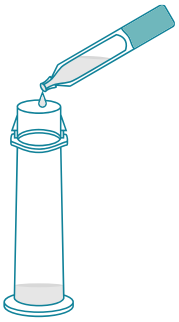
Slowly remove the swab from the nostril while still rotating.

Repeat steps 2-4 on other nostril using the same swab.

DIRECT SWAB TEST PROCEDURE

Procedural Notes:

- The test kit should be at room temperature (15-30°C) prior to use.
- Remove the CovClear COVID-19 Rapid Antigen Test strip, vial and locking cap, swab, chase buffer ampules from its kit immediately before testing.
- The CovClear COVID-19 Rapid Antigen Test kit IS INTENDED to be used only with a direct nasal swab specimen.
- The CovClear COVID-19 Rapid Antigen Test kit IS NOT INTENDED for testing other liquid samples such as nasal wash or aspirate samples as results can be compromised by over dilution.



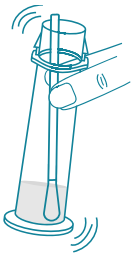
1

Pour entire buffer solution ampule into empty vial

2

Following the Lower Nostril Sample Collection Procedure, insert dry swab into one nostril until you meet resistance. Swirl 7 times.

Repeat with the same swab in other nostril.

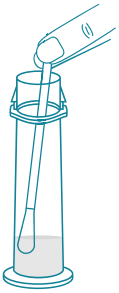


3

Place swab into prepared vial with buffer solution.

Slightly swirl the vial and swab for 30 seconds.

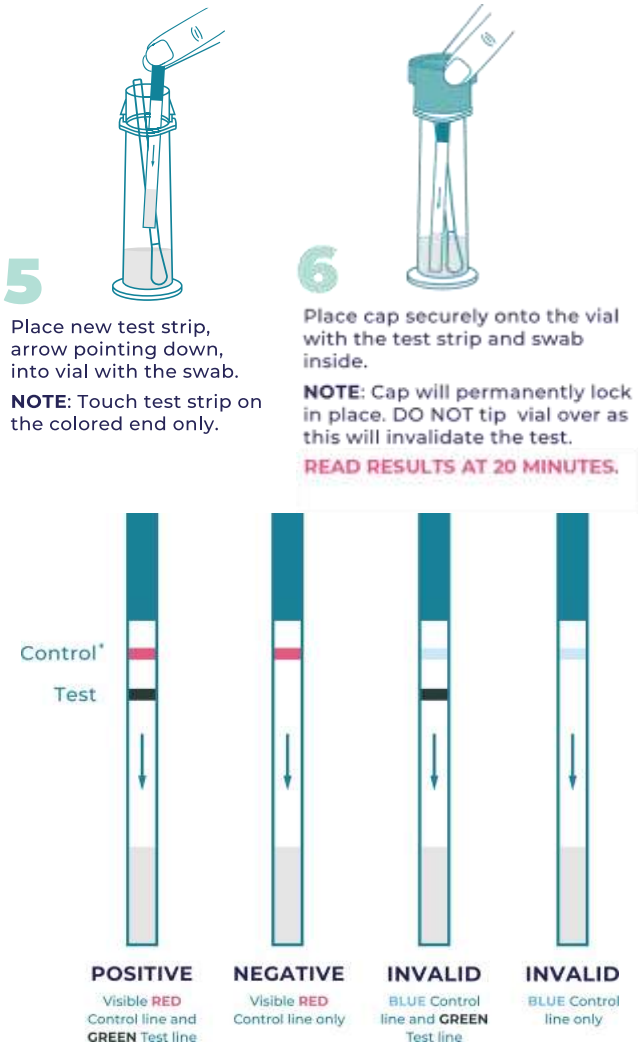
NOTE: DO NOT place the cap on the vial. DO NOT REMOVE SWAB.



4

Press tip against side of vial to squeeze liquid from swab for 10 seconds. Then place swab back into the buffer solution.

NOTE: DO NOT REMOVE SWAB



INTERPRETATION OF RESULTS

NOTE: The test results should be read and interpreted 20 minutes after the sample application and the reading and interpretation of the results should not exceed 20 minutes. The test results should not be interpreted using any instruments.

NOTE: Before use, a blue control line will be visible. It will transition to red when a valid test is performed.

NOTE: The color intensity in the test line (i.e. green-colored line) will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line in the test region should be considered as positive.

POSITIVE: Two distinct colored lines appear: One red-colored line representing the control line and one green-colored line representing COVID-19 positive result.

NEGATIVE: One red-colored line indicates a negative result.

INVALID: If the red-colored line is not visible, the result is invalid. If the test Is Invalid, a new test should be performed with a new sample collection.

Persons who test positive with the CovClear COVID-19 Rapid Antigen Test should seek follow-up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.

Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

REPORTING RESULTS

Users should report their test results by completing a web form located at www.CovClearTest.com. This Registration Portal can be accessed via mobile phone or desktop web browser. Users will be provided with form fields including test result details and demographic information. These results will be shared with local, state, federal public health authorities, as well as other authorities to whom reporting is required. Reporting results is critical for informing the public health response to COVID-19.

LIMITATIONS

- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- 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 will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from 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.
- This device has been evaluated for use with human specimen material only.
- False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 292 subjects were tested in two investigational sites to evaluate the clinical performance of the CovClear COVID-19 Rapid Antigen Test strip. Subjects self-sampled and self-administered using the CovClear Test. The study was designed as an all comers study where subjects (both symptomatic and asymptomatic) over the age of 2 years, presenting to the site seeking COVID-19 testing for any reason, were eligible to enroll if they met all inclusion criteria and did not meet any of the exclusion criteria. All subjects also had a nasal swab sample collected by clinical study site staff for testing at a reference laboratory with an EUA high sensitivity molecular SARS-CoV-2 assay.

A total of 292 subjects were evaluated in this study. Fifty three (53) were symptomatic and two-hundred and thirty-nine (239) were asymptomatic at time of presentation. Symptomatic subjects were defined as those exhibiting at least one of the following signs and symptoms on day of presentation: Fever, cough, body aches, sore throat, chills, loss of taste or smell, congestion or runny nose.

Asymptomatic subjects were defined as subjects not experiencing COVID-like illness symptoms on day of testing.
Age distribution of the 292 subjects is presented below.

Age distribution (by CovClear COVID-19 Rapid Antigen Test) per age group

Age Group	Total Number of Subjects	N % (Number of subjects per age group/Total tested)
<18 years of age	14.73%	43
18-24 years of age	11.99%	35
25-29 years of age	11.99%	35
30 - 49 years of age	30.14%	88
50 - 64 years of age	24.66%	72
65+ years of age	6.51%	19
TOTAL	100.00%	292

The following table summarizes the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the CovClear COVID-19 Rapid Antigen Test when compared with an FDA EUA high sensitivity molecular SARS-CoV-2 assay.

Performance of the CovClear COVID-19 Rapid Antigen Test as compared to an FDA EUA high sensitivity molecular SARS-CoV-2 assay in SYMPTOMATIC subjects

CovClear COVID-19 Antigen	Comparator (RT-PCR)		
	Positive	Negative	Total
Positive	52	0	52
Negative	1	0	1
Total	53	0	53
Positive Percent Agreement (PPA)	98.1% (CI: 98%-100%)		
Negative Percent Agreement (NPA)	Not Applicable		

Performance of the CovClear COVID-19 Rapid Antigen Test as compared to an FDA EUA high sensitivity molecular SARS-CoV-2 assay in ASYMPTOMATIC subjects

CovClear COVID-19 Antigen	Comparator (RT-PCR)		
	Positive	Negative	Total
Positive	12	0	12
Negative	0	227	227
Total	12	227	239
Positive Percent Agreement (PPA)	100% (CI: 93%-99.8%)		
Negative Percent Agreement (NPA)	100% (CI: 98.9%-100%)		

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct swab was established using heat-inactivated SARS-CoV-2 isolate Hong Kong/VM20001061/2020). The strain was spiked into 0.5% saline solution prepared in accordance with BAM R66. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 1.29 x 10^5 $TCID_{50}$/ml.

Specimen Stability:

The specimen stability was established using heat-inactivated SARS-CoV-2 isolate Hong Kong/VM20001061/2020. Nasal swabs spiked with the heat-inactivated SARS-CoV-2 isolate Hong Kong/VM20001061/2020 at 3X LOD were Incubated at room temperature for 0, 2, 5, and 24 hours respectively prior to testing. All samples tested produced no qualitative impact on test line signal intensity as compared to the 0-hour condition, demonstrating that the CovClear COVID-19 Rapid Antigen Test performance was not affected by sample Instability for up to 24 hours at room temperature.

Analytical Specificity: Cross Reactivity and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the CovClear COVID-19 Rapid Antigen Test. Potential microbial interference was evaluated with samples containing heat-inactivated SARS-CoV-2 isolate Hong Kong/VM20001061/2020 at approximately 3x LoD. 4.1. A total of twenty-five (25) potential cross-reactant samples were evaluated for cross-reactivity at predefined concentrations in accordance with the EUA guidelines Antigen Template for Test Developers (version October 26, 2020). No cross-reactivity was observed with the CovClear COVID-19 Rapid Antigen Test.

Viral Pathogens	Bacterial Pathogens
Coronavirus OCN43 (Culture Fluid)	Mycoplasma pneumoniae
Coronavirus 229E (Heat inactivated)	Bordetella pertussis
Coronavirus NL63 (Heat inactivated)	Candida albicans
Parainfluenza Virus Type 3 (Culture Fluid)	Streptococcus pyogenes
Parainfluenza Virus Type 2 (Culture Fluid)	Streptococcus pneumoniae
Parainfluenza Virus Type 1 (Culture Fluid)	Hemophilus influenza
Human Metapneumovirus 16 (Culture Fluid)	Legionella pneumonia
Adenovirus (Culture Fluid)	Staphylococcus epidermidis
Parainfluenza Virus Type 4A (Culture Fluid)	Staphylococcus aureus
Influenza A H1N1 Virus (Culture Fluid)	Nasal Wash
Influenza B Virus (Culture Fluid)	Chlamydophila pneumoniae
Enterovirus Type 68 (Culture Fluid)	
Respiratory Syncytial Virus Type A (Culture Fluid)	
MERS-CoV (Culture Fluid, Heat Inactivated)	
Coronavirus OCN43 (Culture Fluid)	
Coronavirus 229E (Heat inactivated)	

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms 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 homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein is relatively low, at 36.7% across 86.4% of sequences, but cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and Mycobacterium tuberculosis total protein (3,991 proteins) is relatively low, homology-based cross-reactivity can be ruled out.

- The homology between SARS-CoV-2 nucleocapsid protein and Pneumocystis jirovecii total protein (3,745 proteins) is relatively low, homology-based cross-reactivity can be ruled out.

This test has not been evaluated to determine if the CovClear COVID-19 Rapid Antigen test is able to distinguish between SARS-CoV and SARS-CoV-2.

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the CovClear COVID-19 Rapid Antigen, positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 3x LoD. All samples tested produced no qualitative impact to test line signal intensity, demonstrating that the CovClear COVID-19 Rapid Antigen Test performance was not affected by any of the 14 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Whole Blood	4%	Zicam	5% v/v
Mucin	0.5%	Homeopathic (Alkalol)	1:10 dilution
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Sore Throat Phenol Spray	15% v/v
NasoGEL (NeilMed)	5% v/v	Tobramycin	4 µg/mL
CVS Nasal Drops (Phenylephrine)	15% v/v	Mupirocin	10 mg/mL
Afrin (Oxymetazoline)	15% v/v	Fluticasone Propionate	5% v/v
CVS Nasal Spray (Cromolyn)	15% v/v	Tamiflu (Oseltamivir Phosphate)	5 mg/mL

High-dose Hook Effect

The CovClear COVID-19 Rapid Antigen was tested up to 1.75×10^6 $TCID_{50}$/ml of heat-inactivated SARS- CoV-2 strain and no high-dose hook effect was observed.

Technical Support

For questions, or to report a problem, please call Empowered Diagnostics at 954-354-2768.

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800-FDA-1088; fax: 1-800-FDA-1078: or http://www.fda.gov/medwatch).