AllChek™ COVID-19 Antigen Home Test Package Insert For Healthcare Provider

REF INCP-G502H01	**REF INCP-G502H02**	**REF INCP-G502H05**	**English**
REF INCP-G502H07	**REF INCP-G502H10**	**REF INCP-G502H20**	
REF INCP-G502H25			

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in anterior nasal swab specimens.

For in vitro diagnostic use only.

【INTENDED USE】

The Allchek™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from the SARS-CoV-2 in anterior nasal swab specimens directly from individuals aged 14 years and older, or with adult-collected anterior nasal swab specimens directly from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Individuals who test positive with the Allchek™ COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary. Negative results are presumptive and confirmation with a molecular assay, if necessary, may be performed.

The Allchek™ COVID-19 Antigen Home Test is authorized for self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.[1]

【PRINCIPLE】

Allchek™ COVID-19 Antigen Home Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in swab specimen. SARS-CoV-2 nucleocapsid protein antibodies are coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with SARS-CoV-2 nucleocapsid protein antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-SARS-CoV-2 antibodies as the capture reagent and anti-SARS-CoV-2 antibodies as the detection reagent.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test. Failure to follow directions may produce inaccurate test results.

- For *in vitro* diagnostic use.
- This product has been designed only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- To obtain accurate results, the test must be performed as indicated in this package insert.
- The test should not be performed if the extraction buffer is accidentally spilled.
- INVALID RESULTS, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test cassette. Gently squeeze the tube and dispense 3 drops of solution into the sample well of test cassette.
- Swabs in the kit are approved for use with Allchek™ COVID-19 Antigen Home Test. Do not use other swabs.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wash hands thoroughly before and after handling.
- Do not use on anyone under two years of age. Keep test kit and materials out of the reach of children and pets, before and after use.
- Children aged 2 to 13 years of age should be tested by an adult.
- Wear a safely mask or other face-covering when collecting a specimen from a child or another individual.
- Leave the test cassette sealed in its pouch until just before use. Once opened, the test cassette should be used within 60 minutes.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single use. Do not re-use. Do not use with multiple specimens.
- Make sure there is sufficient light when reading and interpreting test results.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test. Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may result in false negative test results.
- Do not touch the swab tip when handling the swab.
- Test samples immediately after collection, and no more than two hours after the swab is added to the reagent solution, if stored at room temperature.
- The test is intended to be read at 10 minutes. If the test is read before 10 minutes or after 20 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- Do not ingest any kit components.
- If the result is preliminary positive, share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.
- The used test should be discarded according to local regulations.
- The buffer solution in the tube contains a harmful chemical (see table below). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice.

Hazardous Ingredients for the Extraction Buffer

Chemical Name	Harms (GHS Code) for Each Ingredient	Concentration
Triton X-100	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage(H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.02%

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. The extraction buffer tubes must be used immediately after opening. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

			Materials				
	REF	Kit size	Test cassette (INCP-G502H-T)	Extraction buffer tube (INCP-G502H-B)	Sterile swab	Quick reference instructions	Tube holder
Quantity	INCP-G 502H01	1	1	1	1	1	/
	INCP-G 502H02	2	2	2	2	1	/
	INCP-G 502H05	5	5	5	5	1	/
	INCP-G 502H07	7	7	7	7	1	/
	INCP-G 502H10	10	10	10	10	1	1
	INCP-G 502H20	20	20	20	20	1	1
	INCP-G 502H25	25	25	25	25	1	1

Note: Sterile swabs are manufactured by Jiangsu Chang feng Medical Industry Co., Ltd, please refer to its package for detail information.

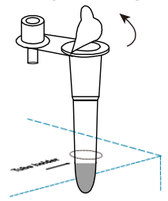
Materials Required But Not Provided

Clock, Timer, or Stopwatch

【PROCEDURE】

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

Insert the extraction buffer tube onto the tube holder. Remove the cover of the extraction buffer tube. Be careful to not spill the liquid inside the tube.



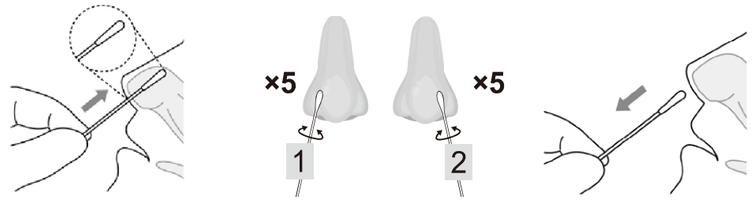
Nasal swab specimen Collection

<u>Only the swab provided in the kit is to be used for nasal swab collection.</u>

1. Open the swab packaging. Remove the swab from the stem. Be careful not to touch the soft tip of the swab
2. Insert the swab about 1.3 to 2 cm into the nostril. (Collect the anterior nasal swab specimen).
3. Gently twist the swab 5 times against the nasal wall. Do not just spin the swab. The swab should remain in the nostril for 15 seconds
4. Pull the swab out of the nose while twisting it slightly.
5. Repeat the process with the same swab in the other nostril, also for 15 seconds.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

Note: With children, the maximum depth of insertion into the nostril may be less than 2 cm, and you may need to have a second person to hold the child's head while swabbing.

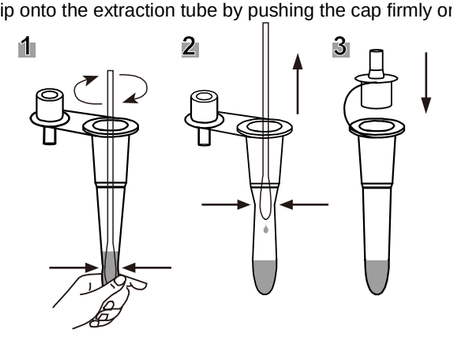


Process the Swab Sample

<u>Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.</u>

1. Place swab into the tube.
2. Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab. Then keep the swab in the extraction tube for **1 - 2 minutes**. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

   WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.
3. Fit the tube tip onto the extraction tube by pushing the cap firmly on.



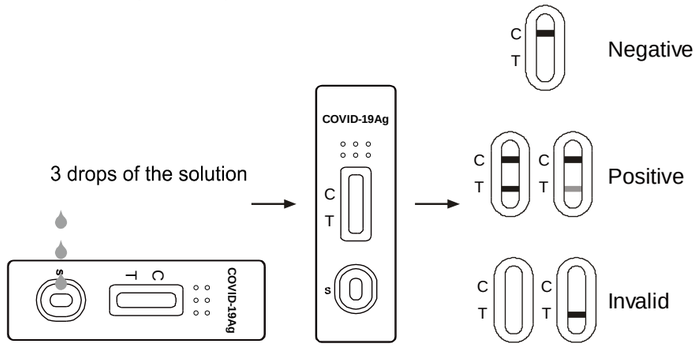
Testing

1. Remove the test cassette from the sealed foil pouch, put it on a flat surface and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the tube and add **3 drops of the solution** to the sample well(s) by gently squeezing the tube.

   Do not add test sample to the rectangular results window.

   WARNING: Adding other than the recommended number of drops may result in inaccurate results. If there isn't enough for 3 drops, please use a new kit, and re-do the previous steps again.
3. **Read the results after 10 minutes and within 20 minutes.** Do not read the result after 20 minutes.

WARNING: Do not read the result before 10 minutes or after 20 minutes.
After test is completed, dispose of used materials in trash.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE: One colored line appeared in the control line (C) region and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected. A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen.

To increase the chance that the negative result for COVID-19 is accurate, you should:

-Test again in 48 hours if you have symptoms on the first day of testing.

-Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.

POSITIVE:* Two colored lines appear in the test window, one on the test line region (T) and the other on the control line region (C). A positive test is interpreted as protein antigen from the virus that causes COVID-19 was detected in the specimen. The individual is positive for COVID-19. Test results should be considered in association with the patient's history and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations).

You do not need to perform repeat testing if you have a positive result at any time.

NOTE: The test line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Any faint visible Test line should be interpreted as positive, when the control line (C) is also present.

INVALID: Control line fails to appear. If a line does not appear on the control line position (C) in 20 minutes, the test result is invalid. Re-test with a new Allchek^{TM} COVID-19 Antigen Home Test.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

【CONTROL PROCEDURE】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens. 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.
2. Specimens should be tested as quickly as possible after specimen collection.
3. Failure to follow the package insert may adversely affect test performance and/or invalidate the test result.
4. A false negative result may occur if the level of antigen in a sample is below the detection limit of the test.
5. A false negative result may occur if the sample was collected incorrectly or handled.
6. A false negative result may occur if the swab is not rotated at least 15 seconds.
7. A false negative or invalid result may occur if less than 3 drops of fluid are added to the Sample Well.
8. A false negative or false positive result may occur if the test result is read before 10 minutes or after 20 minutes
9. This test detects both viable (live) and non-viable 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.
10. Test results should be correlated with other clinical data available to the physician.
11. A positive or negative test result does not rule out co-infections with other pathogens such as other viral or bacterial infections.
12. Negative results are presumptive, do not rule out COVID-19 and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
13. A negative test result is not intended to rule out other viral or bacterial infections.

【SERIAL TESTING (REPEAT TESTING) INFORMATION AND LIMITATIONS】

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat testing at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.
- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of *Massachusetts Chan Medical School in collaboration with the US FDA.*
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-*19, however you should follow-up with a healthcare provider.*

【PERFORMANCE CHARACTERISTICS】

Clinical performance

The COVID-19 Antigen Home Test was evaluated with clinical nasal swab specimens whose status was confirmed using RT-PCR.

The results are presented in the following tables.

Table 1: Clinical Performance with all specimens

Method		PCR		Total Results
COVID-19 Antigen Home Test	Results	Positive	Negative	
	Positive	64	2	66
	Negative	6	268	274
Total Results		70	270	340
Relative Sensitivity		91.4%(95CI*:82.3%-96.8%)		
Relative Specificity		99.3%(95CI*:97.3%-99.9%)		
Accuracy		97.6%(95CI*:95.4%-99.0%)		

Table 2: PPA and NPA stratified by days since onset of symptoms

Group	PPA（95%CI）	NPA（95%CI）
Asymptomatic	72.7%(8/11) (95%CI* : 39.0% to 94.0%)	>99.9%(64/64) (95%CI* : 94.4% to 100%)
0-1 day	>99.9%(3/3) (95%CI* : 29.2% to 100%)	>99.9%(44/44) (95%CI* : 92.0% to 100%)
0-2 days	91.7%(11/12) (95%CI* : 61.5% to 99.8%)	>99.9%(92/92) (95%CI* :96.1% to 100%)
0-3 days	97.1%(34/35) (95%CI* : 85.1% to >99.9%)	99.3%(147/148) (95%CI* : 96.3% to >99.9%)
0-4 days	95.3%(41/43) (95%CI* : 84.2% to 99.4%)	99.4%(173/174) (95%CI* : 96.8% to >99.9%)
0-5 days	96.4%(54/56) (95%CI* : 87.7% to 99.6%)	98.9%(184/186) (95%CI* : 96.2% to 99.9%)
0-6 days	96.6%(56/58) (95%CI* : 88.1% to 99.6%)	99.0%(189/191) (95%CI* : 96.3% to 99.9%)
0-7 days	94.9%(56/59) (95%CI* : 85.9% to 98.9%)	99.0%(204/206) (95%CI* : 96.5% to 99.9%)

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

Limitation of Detection

COVID-19 Antigen Home Test can detect out SARS-CoV-2 heat-inactivated virus strain as low as 7.20 x 10^3 $TCID_{50}$/ml.

Dose Hook Effect

SARS-CoV-2 Antigen Rapid Test was tested up to 1.15 x 10^7 $TCID_{50}$/ml of heat-inactivated SARS-CoV-2 strain and no high-dose hook effect was observed.

Cross Reactivity (Analytical Specificity) and Microbial Interference

Potential cross-reactive pathogens and microorganisms were evaluated with SARS-CoV-2 negative samples and inactivated USA-WA1/2020 SARS-CoV-2 at a final concentration of 1.44 x 10^4 $TCID_{50}$/mL (2 x LoD). Each of the pathogens and microorganisms were tested in 3 replicates.

The performance of the COVID-19 Antigen Home Test was not affected by any of the potential interfering substances listed in table 3 at the concentration tested.

Table 3:

Test items	Test Level	Cross-reactivity Result	Interference result
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
MERS-coronavirus	1.05 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
SARS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Adenovirus 1	3.09 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Human Metapneumovirus 16 (hMPV-16) Type A1	1.26 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 1	1.26 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 3	8.51 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 4A	1.15 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza A H3N2 texas/50/12	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza A H1N1pdm California/07/2009	5.2 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza B Colorado/6/17	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza B Utah/9/14	3.80 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Influenza B Washington/02/19	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference

Enterovirus Type 68 Major Group	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Respiratory syncytial virus Type A	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Rhinovirus Type 1A	1.0 x 10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
Haemophilus influenzae, type b	6.97 x 10^6 CFU/mL	No cross-reactivity	No interference
Streptococcus pneumoniae	1.34 x 10^6 CFU/mL	No cross-reactivity	No interference
Streptococcus pyogenes	2.39 x 10^6 CFU/mL	No cross-reactivity	No interference
Pooled human nasal wash –representative of normal respiratory microbial flora	N/A	No cross-reactivity	No interference
Bordetella pertussis	1.96 x 10^7 CFU/mL	No cross-reactivity	No interference
Mycoplasma pneumoniae	2.70 x 10^6 CCU/mL	No cross-reactivity	No interference
Chlamydia pneumoniae	1.70 x 10^6 IFU/mL	No cross-reactivity	No interference
Legionella pneumophila	1.91 x 10^7 CFU/mL	No cross-reactivity	No interference
Staphylococcus aureus	2.51 x 10^6 CFU/mL	No cross-reactivity	No interference
Staphylococcus epidermidis	6.07 x 10^6 CFU/mL	No cross-reactivity	No interference
Candida albicans	4.76 x 10^6 CFU/mL	No cross-reactivity	No interference

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

In-silico:

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in-silico* analysis was used to assess the degree of protein sequence homology.

- Human coronavirus HKU1: 44.85% homology was found between the amino acid sequences of SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein. Therefore, the cross-reactivity with human coronavirus HKU1 cannot be completely ruled out.
- Pneumocystis jirovecii: No significant similarity was found between P. jirovecii and amino acid sequences of SARS-CoV-2 nucleocapsid protein. The probability of cross-reactivity with P. jirovecii is unlikely. However, cross-reactivity cannot be ruled out.
- Mycobacterium tuberculosis: No significant similarity was found between M. tuberculosis and amino acid sequences of SARS-CoV-2 nucleocapsid protein. The probability of cross-reactivity with M. tuberculosis is unlikely. However, cross -reactivity cannot be ruled out.

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance except Biotin was tested in the absence or presence of SARS-CoV-2 virus (USA-WA1/2020) at a 2 x LoD concentration, i.e. 1.44 x 10^4 $TCID_{50}$/mL. Biotin was tested in the absence or presence of SARS-CoV-2 virus (BetaCoV/Wuhan/IPBCAMS-WH-01/2019) at a 3 x LoD concentration, i.e. 234 $TCID_{50}$/mL.

All samples were tested negatives in the absence of SARS-CoV-2, and positive in the presence of SARS-CoV-2.

The results showed no cross-reactivity and no interference. The performance of the COVID-19 Antigen Home Test was thus not affected by any of the potential interfering substances listed in table 4 at the concentration tested.

Table 4:

Substance	Concentration	Cross-reactivity Result	Interference result
Whole Blood	4% v/v	No cross-reactivity	No interference
Mucin	0.5% v/v	No cross-reactivity	No interference
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No cross-reactivity	No interference
Naso GEL (NeilMed)	5% v/v	No cross-reactivity	No interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
CVS Nasal Spray (Cromolyn)	15% v/v	No cross-reactivity	No interference
Zicam	5% v/v	No cross-reactivity	No interference
Biotin	1 mg/mL	No cross-reactivity	No interference
Homeopathic Nasal Wash	1:10 dilution	No cross-reactivity	No interference
Sore Throat Phenol Spray	15% v/v	No cross-reactivity	No interference
Tobramycin	4 µg/mL	No cross-reactivity	No interference
Mupirocin	10 mg/mL	No cross-reactivity	No interference
Fluticasone Propionate	5% v/v	No cross-reactivity	No interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No cross-reactivity	No interference
Potential Interfering Household Items	**Concentration**	No cross-reactivity	No interference
Body & Hand Lotion with 1.2% dimethicone	0.5% v/v	No cross-reactivity	No interference
Daily Moisture Lotion	5% v/v	No cross-reactivity	No interference
Purell Hand Sanitizer	5% v/v	No cross-reactivity	No interference
Hand sanitizer, 75% isopropyl alcohol, fast drying	15% v/v	No cross-reactivity	No interference
Hand soap liquid gel	10% v/v	No cross-reactivity	No interference
Dial Complete	10% v/v	No cross-reactivity	No interference

SERIAL-TESTING CLINICAL PERFORMANCE

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 5.

Table 5: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

【BIBLIOGRAPHY】

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.

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	Consult instructions for use		Contains sufficient for <n> test
IVD	*In vitro* diagnostic medical device		Use-by date
35.6°F 2°C / 86°F 30°C	Store between 35.6-86 °F (2-30 °C)	LOT	Batch code
	Do not use if package is damaged and consult instructions for use		Manufacturer
REF	Catalogue number		Do not reuse

Hangzhou AllTest Biotech Co.,Ltd.
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Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Number: 146976200
Revision: C
Date: 2023-05-31