AllChek™

SARS-CoV-2 Antigen Rapid Test
Package Insert

REF INCP-G502	English

SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen.

For in vitro diagnostic use only.

【INTENDED USE】

SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human Nasal Swab specimen from individuals who are suspected of COVID-19 within the first seven days of the onset of symptoms, when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms but suspected of COVID-19 with other epidemiological reasons, 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 protein antigen. Antigen is generally detectable in Nasal Swab 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 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.

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

This SARS-CoV-2 Antigen Rapid Test is intended for use by healthcare professionals in point of care settings. This assay is not intended for home testing (or self-testing).

【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.

【PRINCIPLE】

SARS-CoV-2 Antigen Rapid 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 binds with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and binds with COVID-19 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 antibody as the capture reagent and anti-SARS-CoV-2 antibody as the detection reagent.

【PRECAUTIONS】

1. This test is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
2. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
3. Do not use after expiration date.
4. Do not eat, drink or smoke in the area where the specimens or kits are handled.
5. Do not use test if pouch is damaged.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Wash hands thoroughly after handling.
9. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
10. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
11. The used test should be discarded according to local regulations.
12. Humidity and temperature can adversely affect results.
13. Swabs in the kit are approved for use with SARS-CoV-2 Antigen Rapid Test. Do not use other swabs.

【MATERIALS】

Material Provided

Materials		Quantity
Components	Kit size	20
	Test cassettes	20
	Extraction buffer filled tubes and tips	300μl*20
	Sterile swabs	20
	Workstation	1
	Procedure card	1
	Package insert	1

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

Materials required but not provided

• Timer

【STORAGE AND STABILITY】

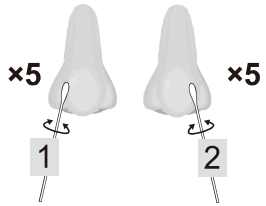
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. The extraction buffer tubes must be used immediately after opening. **DO NOT FREEZE.** Do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

【SPECIMEN COLLECTION, TRANSPORT AND STORAGE】

Nasal Swab Specimen Collection

Only the swab provided in the kit is to be used for nasal swab collection.

1. Unpack the swab. **DO NOT** touch the head of the swab.
2. Swab both nostrils carefully as shown. Insert the entire soft tip of the swab into a nostril (usually 1.3 to 2 cm). You do not need to go deeper.
3. Using medium pressure, rub the swab against all of the inside walls of the nostril. Make 5 full circles for each nostril. Swab each nostril for about 15 seconds.
4. Using the same swab, repeat step 3 with the other nostril.
5. Remove the swab from the nostril and immediately place into the extraction buffer tube.



Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

Specimen transport and storage

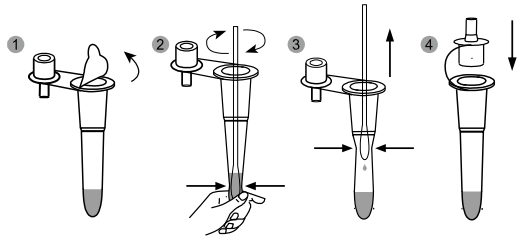
Specimens should be tested as soon as possible after collection.

If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8 °C.

【SPECIMEN PREPARATION】

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

1. Remove the cover of the extraction tube with buffer and place the tube in the workstation.
2. Insert the swab into the bottom of the extraction tube. Rotate the swab for 10-15s to mix the sample with the liquid in the tube.
3. Remove the swab while squeezing the swab head against the inside of the extraction tube. Throw the used swab into the trash.
4. Fit the tube tip onto the extraction tube.

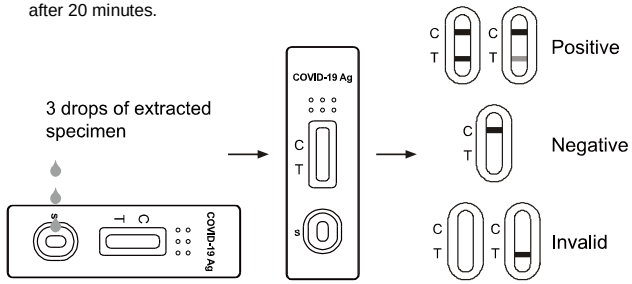


***NOTE**: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2~8°C.

【DIRECTIONS FOR USE】

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch 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 specimen extraction tube and add **3 drops of extracted specimen** (approx.75-100 μL) into the sample well (S) on the test cassette and then start the timer.
3. Wait **10 minutes** and read the results. Do not read the result before 10 minutes or after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the test region indicates detection of SARS-CoV-2 antigens in the sample.

Repeat testing does not need to be performed if the patient has a positive result at any time.

***NOTE**: The intensity of the color in the test region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of color in the test region (T), even a faint line, should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

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

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay 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. 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.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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.

【QUALITY CONTROL】

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Positive and Negative Controls

Positive and negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.1 Positive and negative control should be tested to ensure the proper performance of the assay. It is a recommended to test those positive and negative controls when a new lot of tests is open. When performed properly, in addition to the presence of C line, no line should be visible for the negative control and the T line is visible for the positive controls. Additional controls may be qualified and tested by the user. Please contact + 86-571-56267891 or email: info@alltests.com.cn to purchase SARS-CoV-2 Antigen Control (REF: SCSCO-S).

SARS-CoV-2 Antigen Control swabs are available separately for use only with the SARS-CoV-2 Antigen Rapid Test. The controls are used to verify test performance and interpretation of results. Refer to the SARS-CoV-2 Antigen Control kit Package Insert for additional information on the use of these swabs.

【LIMITATIONS】

1. The performance of SARS-CoV-2 Antigen Rapid Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. VTM should not be used with this test; extracted specimens for PCR tests cannot be used for the test.
2. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
3. SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 nucleocapsid protein antigens with nasal swab specimens. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
4. SARS-CoV-2 Antigen Rapid Test will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions:
   a) The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
   b) The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting samples at different times for the same patient may avoid false negatives.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
10. Statement: The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of 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.

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.
- A negative result should be followed up with repeat, or serial testing at least twice over three days with at least 48 hours between tests for symptomatic individuals and/or at least three times over five days with at least 48 hours between tests for asymptomatic individuals. A self-test may be used for this additional testing.
- The performance of this test was not clinically validated for serial testing. 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】

Sensitivity, Specificity and Accuracy

The SARS-CoV-2 Antigen Rapid Test was evaluated with clinical nasal swab specimens from symptomatic individuals whose status was confirmed using RT-PCR (Nasopharyngeal swab). The results are presented in the following tables.

Table 1: FOR CLINICAL SPECIMEN FROM SYMPTOMATIC INDIVIDUALS

Method		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test	Positive	138	2	140
	Negative	5	247	252
Total		143	249	392
Relative Sensitivity		96.50% (95%CI*: 92.03%~98.86%)		
Relative Specificity		99.20% (95%CI*: 97.13%~99.90%)		
Accuracy		98.21% (95%CI*: 96.36%~99.28%)		

The SARS-CoV-2 Antigen Rapid Test was evaluated with clinical nasal swab specimens from asymptomatic individuals whose status was confirmed using RT-PCR (Nasopharyngeal swab). The results are presented in the following tables.

Table 2: FOR CLINICAL SPECIMEN FROM ASYMPTOMATIC INDIVIDUALS

Method		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test	Positive	12	0	12
	Negative	2	58	60
Total		14	58	72
Relative Sensitivity		85.71% (95%CI*: 57.19%~98.22%)		
Relative Specificity		100% (95%CI*: 93.84%~100%)		
Accuracy		97.22% (95%CI*: 90.32%~99.66%)		

Totally 464 specimens: 157 SARS-CoV-2 positive specimens and 307 SARS-CoV-2 negative specimens with clinical symptoms and asymptomatic were used in the clinical study, commercial RT-PCR (Nasopharyngeal swab) served as the reference method, all the results were summarized as below:

Table 3:

Method		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test	Positive	150	2	152
	Negative	7	305	312
Total		157	307	464
Relative Sensitivity		95.54% (95%CI*: 91.03%~98.19%)		
Relative Specificity		99.35% (95%CI*: 97.67%~99.92%)		
Accuracy		98.06% (95%CI*: 96.35%~99.11%)		

*Confidence Intervals

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

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

Cross Reactivity (Analytical Specificity) and Microbial Interference

The microorganisms below were spiked with negative, 1.44×10^4 $TCID_{50}$/ml (2xLoD) positive sample. No cross-reactivity was observed for any microorganisms tested here. And the performance of the SARS-CoV-2 Antigen Rapid Test was not affected by any of the potential interfering substances listed in table 4 at the concentration tested.

Table 4:

Test items	Test Level
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
MERS-coronavirus	1.05×10^5 $TCID_{50}$/mL
SARS-coronavirus	1.0×10^5 $TCID_{50}$/mL
Adenovirus 1	3.09×10^5 $TCID_{50}$/mL
Human Metapneumovirus 16 (hMPV-16) Type A1	1.26×10^5 $TCID_{50}$/mL
Parainfluenza virus 1	1.26×10^5 $TCID_{50}$/mL
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
Parainfluenza virus 3	8.51×10^5 $TCID_{50}$/mL
Parainfluenza virus 4A	1.15×10^5 $TCID_{50}$/mL
Influenza A H1N1	1.0×10^5 $TCID_{50}$/mL
Influenza A H3N2 texas/50/12	1.0×10^5 $TCID_{50}$/mL
Influenza A H1N1pdm California/07/2009	5.2×10^5 $TCID_{50}$/mL
Influenza B Colorado/6/17	1.0×10^5 $TCID_{50}$/mL
Influenza B Utah/9/14	3.80×10^5 $TCID_{50}$/mL
Influenza B Washington/02/19	1.0×10^5 $TCID_{50}$/mL
Enterovirus Type 68 Major Group	1.0×10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type A	1.0×10^5 $TCID_{50}$/mL
Rhinovirus Type 1A	1.0×10^5 $TCID_{50}$/mL
Haemophilus influenzae, type b	6.97×10^6 CFU/mL
Streptococcus pneumoniae	1.34×10^6 CFU/mL
Streptococcus pyogenes	2.39×10^6 CFU/mL
Pooled human nasal wash –representative of normal respiratory microbial flora	N/A
Bordetella pertussis	1.96×10^7 CFU/mL
Mycoplasma pneumoniae	2.70×10^6 CCU/mL
Chlamydia pneumoniae	1.70×10^6 IFU/mL
Legionella pneumophila	1.91×10^7 CFU/mL
Staphylococcus aureus	2.51×10^6 CFU/mL
Staphylococcus epidermidis	6.07×10^6 CFU/mL
Candida albicans	4.76×10^6 CFU/mL

$TCID_{50}$ = 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. 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. However, cross-reactivity cannot be ruled out.

Interfering Substances

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. No substances showed any interference with SARS-CoV-2 Antigen Rapid Test.

Table 5:

Substance	Concentration
Whole Blood	4% v/v
Mucin	0.5% v/v
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Biotin	1 mg/mL
Homeopathic Nasal Wash	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Potential Interfering Household Items	**Concentration**
Body & Hand Lotion with 1.2% dimethicone	0.5% v/v
Daily Moisture Lotion	0.5% v/v
Purell Hand Sanitizer	5% v/v
Hand sanitizer, 75% isopropyl alcohol, fast drying	15% v/v
Hand soap liquid gel	10% v/v
Dial Complete	10% v/v

【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 6.

Table 6: 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.

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.

【BIBLIOGRAPHY】

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

Index of Symbols

	Consult instructions for use		Contains sufficient for <n> test
IVD	*In vitro* diagnostic medical device		Use-by date
	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.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Number: 146703500
Revision: B
Date: 2023-05-31