Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit

(REF:C3042)

Intended Use

The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit is a chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab or oropharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset.

The test provides preliminary test results. Negative results do not preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only.

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 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 periodis 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

The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit is composed of novel Coronavirus monoclonal antibody 2 and goat anti-mouse IgG polyclonal antibody fixed in the nitrocellulose membrane and Novel Coronavirus monoclonal antibody 1 latex-labeled fixed in the release pad.The kit tests Novel Coronavirus SARS-CoV-2 N antigen in human nasopharyngeal swabs or oropharyngeal swabs with the principle of double antibody sandwich method by latex immunochromatography.

When a specimen is added to the sample well, the sample is first mixed with the colored latex-labeled novel coronavirus monoclonal antibody 1 on the release pad, and then migrate on the nitrocellulose membrane. If SARS-CoV-2 N protein antigen presents in the sample, these antigens will bind to coronavirus monoclonal antibody 1 labeled with color latex forming antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex is captured by the SARS-CoV-2 monoclonal antibody 2 to form a red colored band in the T line, which is a positive result.If no antigen presents in the sample, there will be no red band appearing in the testing region, this is a negative result. The internal control (C band) fixing with goat anti-mouse antibody should exhibit a red band regardless of whether antigen presents in the test.

Materials

Materials Supplied

1) 25 Individual sealed pouches,each pouch
   contains: 1*Test Card
   1*Desiccant Pouch
2) 25 Sampling Tubes(Containing Sample Extraction Liquid)
3) 25 Sterile Swabs
4) 25 Biosafety Bags
5) Introduction Manual

Materials Required But Not Provided

1) Clock,timer,or stopwatch

Storage and Stability

1) Stored at 4～30℃ protected from light.
2) Do not freeze.
3) Properly stored kits are valid for 12 months.
4) See label for production date and validity.
5) The test card should be used within 1 hour after taking out from the packaging bag.

Specimen Collection and Handling

The test can be taken with nasopharyngeal swab or oropharyngeal swab.

1. Nasopharyngeal swab specimen collection:Carefully insert the swab into the nostril of the patient, hold the swab near the nasal septum, and gently push the swab into the posterior nasopharynx.Rotate the swab several times over the surface of the posterior nasopharynx, then withdraw the swab from the nasal cavity.
2. Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums..
3. It is recommended that the specimen is tested at the time of specimen collection. If the specimens cannot be tested immediately, they may be stored at 2~8℃ for up to 4 hours, or they may be stored at -70℃ for a long time.
4. The samples and the kit should be returned to room temperature before test.

Specimen Transport and Storage

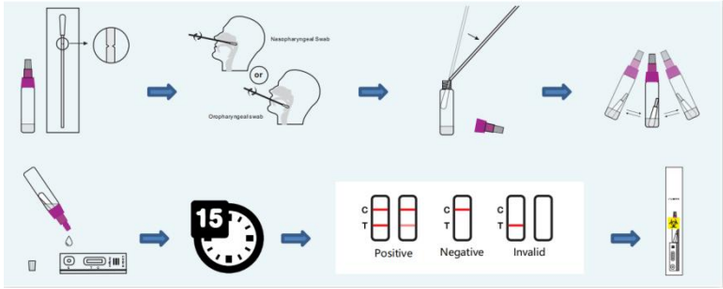
DOs and DON'Ts of Sample Collection

- Collect sample as soon as possible after onset of symptoms.
- Test sample immediately.
- Use only swabs provided with the kit.
- Refer to: Interim Guidelines for Collecting, Handling and Testing https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Freshly collected specimens should be tested within 1 hour

Test Procedure

1. After sample collection, remove the screw cap. Break off the head part of the swab and keep this part in the bottle.
2. Shake the sampling tube for several times and make sure that the sample is fully dissolved in the sample extration liquid.
3. Take out a test card from the packaging bag by tearing at the notch and place it on a level surface.
4. Unscrew the upper screw cap and add 2 drops of liquid to "S"(the sample well).
5. Wait for 15~20 minutes and read the results. Do not read results after 20 minutes.
6. After the test, put the medical wastes into the biosafety bag.



NOTE: Do not use sample tubes from any other product, including other products from Jinwofu or other manufacturers.

This kit IS NOT INTENDED for testing liquid samples such as wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.

Interpretation Of Results

Positive Result

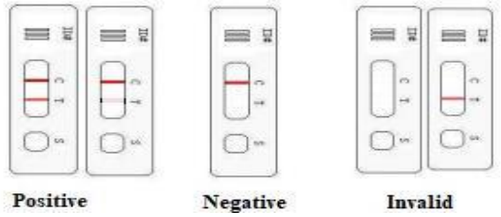
The present of red band in control C and T. It indicates that there is SARS-CoV-2 antigen in specimen.

Negative result

The control line appears in the window, but the test line is not visible. It indicates that the concentration of the SARS-CoV-2 antigen is zero or below the detection limit of the kit.

Invalid Result

Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. It is recommended. It is recommended to retest the specimen.



Quality Control

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

Limitations

1) Results from the Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit should be correlated with the clinical history, epidemiological data, and other data available to the clinicians for the evaluation of patient.
2) 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.
3) The amount of antigen in a sample may decrease with the disease development. Specimens collected after day 7 of illness are more likely to be negative compared to a RT-PCR assay.
4) Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
5) Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterialinfections.
6) Negative results should be treated as presumptive and confirmed with an authorized molecular assay, if necessary, for clinical management, including infection control.
7) The testing personnel and who carry on the Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test should be specifically instructed and trained according to the techniques of in vitro diagnostic procedures and proper infection control procedures. Individuals that use the kit should receive similar training of point-of-care testing.

Warnings and Precautions

1) Do not use this kit beyond the expiration date printed on the outside carton.
2) This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens;
3) To avoid erroneous results, specimens must be processed as indicated in the test procedure section.Proper specimen collection, storage and transport are critical to the performance of this test
4) Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
5) The used Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test cards should be treated as biohazardous waste.

Performance Characteristic

Clinical Sensitivity and Specificity

The clinical performance of Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit was established with 850 samples enrolled from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. All these samples included 320 positive samples and 530 negative samples.

The performance was compared to results of an molecular (RT-PCR) test for detection of SARS-CoV-2.

Results of Jinwofu Novel Coronavirus(SARS-CoV-2) Antigen Rapid Test Kit	Result of the molecular (RT-PCR) test		Total
	Positive	Negative	
Positive	310	0	310
Negative	10	530	540
Total	320	530	850

Compare the sensitivity and specificity of Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit with the molecular (RT-PCR) test:

Sensitivity＝96.88% (95%C.I. 94.34%, 98.29%)

Specificity＝100% (95%C.I. 99.28%, 100.00%)

Total Coincidence Rate＝98.82% (95%C.I. 97.85%, 99.36%)

Limit of Detection(LoD)

In the limit of detection research, the inactivated coronavirus (with concentration of 1.85 x 10^5TCID$_{50}$/mL) was diluted in clinical negative samples.The lowest concentration that can be detected is the preset LoD.Setting several concentrations around the preset LoD, the concentration at which positive coincidence rate was ≥95% could be confirmed as the LoD.

The LoD of Jinwofu Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit is 100 TCID$_{50}$/mL.

Hook Effect

No hook effect was observed when testing up to a concentration of 1.85 x 10^5TCID$_{50}$/mL of inactivated coronavirus.

Cross-reactivity

In the cross-reactivity research, a certain concentration of the pathogens were added to the clinical negative samples. The negative tested result showed no cross-reactivity with the pathogens below in the table:

Pathogens	Concentration	Pathogens	Concentration
Common coronavirus(OC43)	1.0×10^{6}pfu/ml	Adenovirus-1/-2/-3/-4/ -5/-7/-55	1.0×10^{6}pfu/ml
Common coronavirus(NL63)	1.0×10^{6}pfu/ml	Enterovirus-A/-B/-C/-D	1.0×10^{6}pfu/ml
Common coronavirus(229E)	1.0×10^{6}pfu/ml	EB virus	1.0×10^{6}pfu/ml
Influenza A H1N1	1.0×10^{6}pfu/ml	Measles virus	1.0×10^{6}pfu/ml
Influenza A H3N2	1.0×10^{6}pfu/ml	Human cytomegalovirus	1.0×10^{6}pfu/ml
Influenza A H5N1	1.0×10^{6}pfu/ml	Rotavirus	1.0×10^{6}pfu/ml
Influenza A H7N9	1.0×10^{6}pfu/ml	Norovirus	1.0×10^{6}pfu/ml
Influenza B Yamagata	1.0×10^{6}pfu/ml	Mumps virus	1.0×10^{6}pfu/ml
Influenza B Victoria	1.0×10^{6}pfu/ml	Varicella-zoster virus	1.0×10^{6}pfu/ml
Respiratory Syncytial Virus	1.0×10^{6}pfu/ml	Mycoplasma pneumonia	1.0×10^{6}pfu/ml
Rhinovirus -A/-B	1.0×10^{6}pfu/ml	/	/

Interference

In the interference research, a certain concentration of the interfering substances was added to the inactivated coronavirus samples(in low concentration of 500 TCID$_{50}$/mL). The positive tested result showed no interference with the interfering substances below in the table:

Interfering Substances	Concentration	Interfering Substances	Concentration
Mucin	10 mg/ml	Beauty e.faecalis	1 μg/ml
Ribavirin	2.0 mg/ml	Palmer peramivir	20 μg/ml
Oseltamivir	375 μg /L	Ceftriaxone	100 mg/ml
Azithromycin	0.15 g/L	Times the chlorine beauty pine	200 μg/L
Tobramycin	0.125 mg/mL	Budesonide	0.64 nmol/L
Sodium chloride	0.9%	The hydroxy methyl thiazole moiety	500 μg/ml
Levofloxacin	5 μg/ml	Mucus	-
Alpha interferon	3×10^6 U	Whole blood	-

Index Of Symbol

Attention,see instruction for use	Do not reuse
IVD For in vitro diagnostic use only	REF Catalog#
Store between 4~30℃	EC REP Authorized Representative
Tests per kit	Keep dry
Expiry Date	Caution
LOT Lot number	Keep away from sunlight
Manufacturer	

Basic Information

Manufacturer

Beijing Jinwofu Bioengineering Technology Co.,Ltd.

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