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Wuhan UNscience Biotechnology Co.,Ltd

SARS-CoV-2 Antigen Rapid Test Kit

INTENDED USE

This product is used for in vitro qualitative detection of novel coronavirus (SARS-CoV-2) antigen in human oropharyngeal swabs, nasal swabs and nasopharyngeal swabs.

The SARS-CoV-2 is a new type of coronavirus and named by the World Health Organization. The SARS-CoV-2 has spread all over the world. It causes viral pneumonia with fever, fatigue, dry cough and sore throat as the main manifestations. The severe cases of viral pneumonia caused by it manifested as dyspnea, decreased blood oxygen saturation, and rapid development of acute respiratory distress syndrome, septic shock, etc. In serious cases, metabolic acidosis and coagulation dysfunction are difficult to be treated, which directly affect life and health.

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TEST PRINCIPLE

This kit adopts the sandwich method and the technical principle of colloidal gold immunochromatography to qualitative determine the SARS-CoV-2 antigen. During the test, the sample is dropped into the sample well, and chromatography is performed under the capillary effect. The SARS-CoV-2 antigen in the sample combined with the colloidal gold-labeled SARS-CoV-2 monoclonal antibody I, and then spread to the test area. It is captured by another coated antibody (SARS-CoV-2 monoclonal antibody II), to form a complex and gather in the test area (T line). The quality control area is coated with the goat anti-mouse antibody, and the colloidal gold-labeled antibody is captured to form a complex and aggregate in the quality control area (C line). If the C line does not show color, it indicates that the result is invalid, and this sample needs to be tested again.

MAIN COMPONENTS

1.Test reagent: 1 test/pouch.
2.Desiccant: 1 piece/pouch.
3.Swab: 1 piece/pack.
4.Sample treatment solution: 1 vial/pack.
5.Tube cap: 1 piece/pack.

STORAGE AND STABILITY

The test reagent is stored at 2℃ -30℃ , and the validity period is tentatively set for 18 months. See the label for the production date and expiration date.

SAMPLE REQUIREMENTS

a) Oropharyngeal swab: The head of the person is slightly tilted, with mouth wide open, exposing the pharyngeal tonsils on both sides. Use the swab to gently wipe the tonsils on both sides for at least 3 times, and then wipe the posterior pharyngeal wall up and down at least 3 times.
b) Nasal swab: Thoroughly blow and wipe your nose to clear thick mucus (snot). Insert the swab into one nostril, gently push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril), and then rotate the swab against the nasal wall 5 times. Remove the swab from the nostril, and repeat the previous steps in the second nostril.
c) Nasopharyngeal swab: Carefully insert the swab into the nostril with the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx (in case of reflex cough, stop for 1 minute).

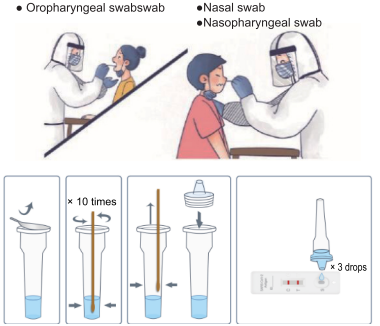
SAMPLE PREPARATION

a) Uncover the sealing membrane of the sample treatment solution.
b) Put the swab into sampling tube, make sure the swab soaked in the solution. Rotate and squeeze the swab on the wall and bottom of the tube 10 times, squeeze the swab tip along the inner wall of the sample tube to keep solution in the tube as much as possible.
c) Remove the swab and cover the tube cap. It is recommended to test immediately after sample collection and processing. If the test cannot be performed timely, the processed samples can be stored at 2-8℃ for 48h.

TEST PROCEDURE

Before use, please read the instructions carefully and operate in strict accordance with the instructions:

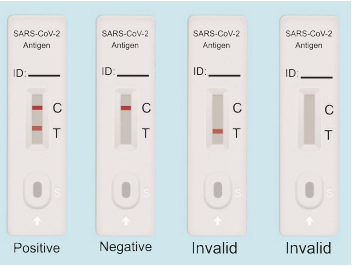
a) Bring the pouch to room temperature before use.
b) Take out the cassette, put it on a horizontal table.
c) Add 3 drops of the processed sample vertically into the sample well and start the timer.
d) Observe the result after 10 minutes, the result is valid within 30 minutes. Result after 30 minutes is invalid.



NOTE: This figure is only used as a reference.

INTERPRETATION OF RESULTS

1. Positive: Both the detection line (T line) and the quality control line (C line) appear colors.
2. Negative: The test line (T line) does not appear color, only the quality control line (C line) appears color.
3. Invalid: The quality control line (C line) does not appear color, which means that the test is invalid and the test should be repeated.



NOTE: This figure is only used as a reference.

LIMITATIONS

a) This kit is a qualitative test for in vitro diagnosis.
b) Due to methodological limitations, the sensitivity of this kit is lower than that of PCR. Therefore, more attention should be paid to the negative results of this experiment, and a comprehensive judgment should be combined with other test results. It is recommended that the suspected results be supplemented with nucleic acid testing or virus isolation and culture in vitro for confirmation.
c) Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results.
d) The test results of this reagent are for clinical reference only and cannot be used as the only basis for clinical diagnosis. The tester should conduct a comprehensive evaluation based on the patient's clinical manifestations and other laboratory test results.
e) The substance the kit detected was SARS-CoV-2 nucleocapsid protein(NP). The variation of new coronavirus mutant B1.1.1.7 (SARS-CoV-2 VOC 202012/01) is mainly in spike protein receptor binding domain(RBD). There was no affection for diagnostic after mutation. So this kit could be used to detect the SARS-CoV-2 mutant, but could NOT distinguish the mutant from SARS-CoV-2.

PERFORMANCE

1.Positive coincidence rate: 8 national positive references (P1-P8) diluted to 1:10 for testing, and the results should all be positive.
2.Negative coincidence rate: 20 national negative references (N1-N20) for testing, the results should all be negative (Negative references include Staphylococcus aureus, Streptococcus pneumoniae, measles virus, mumps virus, adenovirus type 3, Mycoplasma pneumoniae, parainfluenza virus type 2, metapneumovirus, coronavirus OC43, coronavirus 229E, Bacillus parapertussis , Type B influenza virus Victoria line, Type B influenza virus Y line, Type A influenza virus H1N1, Type A influenza virus H3N2, Avian influenza virus H7N9, Avian influenza virus H5N1, Epstein-Barr virus, Enterovirus CA16, Rhinovirus).
3.Limit of detection: Use the LOD national reference S to dilute into three samples of 1:400 (S1), 1:800 (S2), and 1:1600 (S3), repeat the determination 3 times, of which S1 are all positive, S3 are all negative, and S2 results can be positive or negative.
The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time(i.e., concentration at which at least 19 out of 20 replicates tested positive).SARS-CoV-2 Antigen Rapid Test Kit LOD concentration chosen was 5×10^4 $TCID_{50}$/mL, also confirmed as 1.6×10^2 PFU/mL.
4.Repeatability: Apply with the national reference R, dilute it into 1:10 (R1) and 1:100 (R2) repeatable samples of both high and low concentrations. Repeatedly test 10 times, all the results are positive, and the color rendition of the same concentration is uniform without difference.
5.Inter-batch difference:Change the detection conditions, detect 3 batches of kits with 2 repeatable samples, repeat 10 times for each batch, all the results are positive,and the color rendition of the same concentration is uniform without difference.
6.Specificity analysis:
a) Cross-reaction: There was no cross-reaction when the concentration of the potential cross-reactive substance is lower than the value listed below:

Cross-reactive substance	Concentration
Staphylococcus aureus	5 x 10^4 PFU/mL
Streptococcus pneumoniae	2 x 10^4 PFU/mL
Measles virus	1 x 10^5 $TCID_{50}$/mL
Mumps virus	1 x 10^5 $TCID_{50}$/mL
Adenovirus type 3	5 x 10^5 $TCID_{50}$/mL
Mycoplasma pneumoniae	2 x 10^4 PFU/mL
Parainfluenza virus type 2	5 x 10^4 $TCID_{50}$/mL
Metapneumovirus	5 x 10^5 $TCID_{50}$/mL
Coronavirus OC43	2 x 10^4 $TCID_{50}$/mL
Coronavirus 229E	1 x 10^4 $TCID_{50}$/mL
Bacillus parapertussis	5 x 10^4 PFU/mL
Type B influenza virus Victoria line	2 x 10^5 $TCID_{50}$/mL
Type B influenza virus Y line	2 x 10^5 $TCID_{50}$/mL
Type A influenza virus H1N1	5 x 10^5 $TCID_{50}$/mL
Type A influenza virus H3N2	1 x 10^6 $TCID_{50}$/mL
Avian influenza virus H7N9	1 x 10^5 $TCID_{50}$/mL
Avian influenza virus H5N1	1 x 10^5 $TCID_{50}$/mL
Epstein barr virus	1 x 10^5 $TCID_{50}$/mL
Enterovirus CA16	1 x 10^5 $TCID_{50}$/mL
Rhinovirus	5 x 10^4 $TCID_{50}$/mL

b) There was no interference when the concentration of the potential interfering substance is lower than the value listed below:

Cross-reactive substance	Concentration
Mucin	100μg/mL
Whole Blood	5% (v/v)
Biotin	100μg/mL
Histamine dihydrochloride	100μg/mL
IFN-α	200μg/mL
Zanamivir	400μg/mL
Ribavirin	1000μg/ml

Cross-reactive substance	Concentration
Oseltamivir	500μg/mL
Paramivir	300μg/mL
Lopinavir	10μg/mL
Ritonavir	1000μg/ml
Arbidol	500ng/ml
Levofloxacin	200μg/mL
Azithromycin	100μg/mL
Ceftriaxone	1000μg/mL
Meropenem	10μg/mL
Tobramycin	10μg/mL
Antinuclear antibody (ANA)	1:240
Anti-mitochondrial antibody （AMA）	80U/mL
Mouse IgG	1000μg/mL

7.Hook effect: Within the titer range of clinically positive samples, the test result does not show a hook effect.

8. Clinical performance:Several studies using 341 direct oropharyngeal swabs or nasopharyngeal swabs were performed. The samples were sequentially enrolled from 3 locations and tested fresh. The SARS-CoV-2 Antigen Rapid Test Kit (CoV2Ag) was compared to the RT-PCR assay and the test results are listed below:

	POS by PCR	NEG by PCR	Total
POS by CoV2Ag	105	1	106
NEG by CoV2Ag	4	231	235
Total	109	232	341
Positive Coincidence Rate	96.33%		
Negative Coincidence Rate	99.57%		
Sensitivity	96.330% (95%CI: 90.870%, 98.991%)		
Specificity	99.569% (95%CI: 97.622%, 99.989%)		
Positive Predictive Value	99.057% (95%CI:93.690%, 99.866%)		
Negative Predictive Value	98.298% (95%CI:95.665%, 99.343%)		

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The test results of oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 50 subjects are compared. The results show that the consistent detection rate between oropharyngeal swabs, nasal swabs and nasopharyngeal swabs is 100% (95%CI: -100%, 100%).

109 positive samples ct values were analyzed, POS coincidence rates as follows:

Range of Ct value	POS by PCR	POS by CoV2Ag	POS Coincidence Rate
23-25	21	21	100%
26-29	37	37	100%
30-33	47	45	95.74%
34-35	4	2	50%

341 samples were analyzed, POS coincidence rates by age as follows:

Age	Amount	POS by PCR	POS by CoV2Ag	POS Coincidence Rate
0-20	67	19	19	100%
21-60	195	65	63	96.92%
61-90	79	25	24	96%

341 samples were analyzed, POS coincidence rates by symptom onset days as follows:

Days onset	Amount	POS by PCR	POS by CoV2Ag	POS Coincidence Rate
1	42	8	7	87.5%
2	51	6	5	83.33%
3	57	11	11	100%
4	64	23	21	91.3%
5	60	23	23	100%
6	31	18	18	100%
7	36	20	20	100%

NOTES

1. This kit is for in-vitro diagnostic. Please read the instruction carefully before test, and should operate in strict accordance with the instruction. Different batches of reagents and treatment solution should not be mixed.
2. Sample collection, storage and testing should be in strict accordance with the novel coronavirus related testing technical guide and biosafety guide etc.; The remaining sample treatment solution, swabs, test cassette and all wastes must be disposed of laboratory biosafety requirements.
3. It is recommended to use ethyl ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, chloroform and other solvents to soak the waste generated during the detection process, inactivate the virus, and treat the waste as the infectious material.
4. The test cassette is ready to use, valid within 1 hour after opening, and the test cassette can not be reused.
5. The test results are for clinical reference only. Diagnosis should be made after comprehensive judgment with the clinical symptoms, signs, medical history and other laboratory examination results of the patient.

BASIC INFORMATION

GLOSSARY OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	*In vitro* diagnostic medical device	2℃ 30℃	Temperature limitation
	Manufacturer		Use by date
	Date of Manufacture		Consult instructions for use
	Do not reuse	CE	Meet the requirements of EC Directive 98/79/EC
LOT	Batch code	EC REP	Authorized representative in the European Community

Wuhan UNscience Biotechnology Co., Ltd.

Address: Building B18, 2nd Phase of Biomedical Park, #858 GaoXin Road, Donghu Hi-Tech Development, Wuhan, Hubei, P.R. China

Tel: 86-27-87385095

E-mail: techsupport@uni-science.com

EC REP CMC Medical Devices & Drugs S.L

Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain

Email: info@cmcmedicaldevices.com

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Exclusive Distribution for Mauritius:
Azur Sense SAS

Address: 29 Chemin du Vinaigrier, 06300 Nice, France
www.azursense.com