

SARS-CoV-2 Antigen Rapid Test Kit

Catalogue No.: CP04009



INTENDED USE

This product is used for in vitro qualitative detection of novel coronavirus (SARS-CoV-2) antigen in human saliva.

This product is used under medical institutions only.

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.

TEST PRINCIPLE

This kit adopts the sandwich method and the technical principle of colloidal gold immunochromatography to qualitatively 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

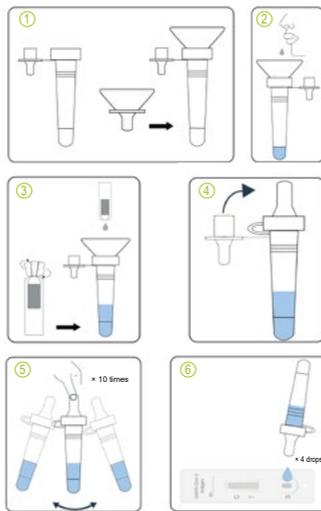
1. Test reagent
2. Desiccant
3. Saliva collector
4. Sample treatment solution
5. Collection tube

STORAGE AND STABILITY

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

SAMPLE PREPARATION

- Remove the tube cap, use the collection tube and saliva collector to collect saliva.
- Put the saliva collector close to lips and let the saliva flow into the tube. The volume of saliva needs to be at the scale mark (approximately 0.3 mL).
- Unscrew the lid of a sample treatment solution and add all of the sample treatment solution into the collection tube.
- Remove the saliva collector and cover the tube cap. Shake the tube more than 10 times vigorously to mix the saliva and sample treatment solution well.



NOTE: This figure is only used as a reference.

TEST PROCEDURE

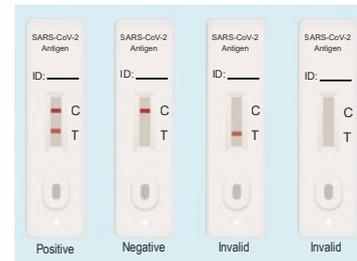
Before use, please read the instructions carefully and operate in strict accordance with the instructions:

- Bring the pouch to room temperature before use.
- Take out the cassette, put it on a horizontal table.
- Add 4 drops of the processed sample vertically into the sample well and start the timer.
- Observe the result after 15 minutes, the result is valid within 30 minutes, read results after 30 minutes is invalid.

INTERPRETATION OF RESULTS

- Positive: Both the test line (T line) and the quality control line (C line) appear color.
- Negative: The test line (T line) does not appear color, only the quality control line (C line) appears color.

- 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

- This kit is a qualitative test for in vitro diagnosis.
- 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.
- Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results.
- 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.
- 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

- Positive coincidence rate: 8 national positive references (P1-P8) diluted to 1:10 for testing, and the results should all be positive.
- 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).
- 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 $\geq 95\%$ 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 TCID₅₀/mL, also confirmed as 1.6×10^2 PFU/mL.

- 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.
- 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.
- Specificity analysis:
 - 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 ⁵ 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: 442 individual symptomatic patients and asymptomatic patients who were suspected of COVID-19. The saliva specimens were detected by SARS-CoV-2 antigen rapid test kit and RT-PCR. The test results showed as the tables below:

	POS by PCR	NEG by PCR	Total
POS by CP04009	134	2	136
NEG by CP04009	11	295	306
Total*	145	297	442
Positive Coincidence Rate	92.41%		
Negative Coincidence Rate	99.33%		
Sensitivity	92.414% (95%CI: 86.832%, 96.152%)		
Specificity	99.327% (95%CI: 97.589%, 99.918%)		
Positive Predictive Value	98.529% (95%CI: 94.389%, 99.627%)		
Negative Predictive Value	96.405% (95%CI: 93.825%, 97.931%)		

*CI≤37, a total of 442.



	POS by PCR	NEG by PCR	Total
POS by CP04009	104	2	106
NEG by CP04009	5	295	300
Total*	109	297	406
Positive Coincidence Rate	95.41%		
Negative Coincidence Rate	99.33%		
Sensitivity	95.413% (95%CI: 86.619%, 98.494%)		
Specificity	99.327% (95%CI: 97.589%, 99.918%)		
Positive Predictive Value	98.113% (95%CI: 92.886%, 99.519%)		
Negative Predictive Value	98.333% (95%CI: 96.163%, 99.285%)		

*CI≤30, a total of 406.

145 positive samples ct values were analyzed, POS coincidence rate as follows:

Range of Ct value	POS by PCR	POS by CP04009	POS Coincidence Rate
23-25	28	28	100.0%
26-29	63	60	95.2%
30-33	49	42	85.7%
34-35	5	4	80.0%

442 samples were analyzed, POS coincidence rate by symptom onset days as follows:

Days onset	N	POS by PCR	POS by CP04009	POS Coincidence Rate
1	72	19	17	89.5%
2	77	35	31	88.6%
3	73	28	26	92.9%
4	56	17	18	105.9%
5	55	18	18	100.0%
6	57	15	14	93.3%
7	52	13	12	92.3%

NOTES

1. FOR PROFESSIONAL USE ONLY.

2. This kit is for in-vitro diagnostic, it is recommended to use by professionals. 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.

3. 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, saliva collector, collection tube, test cassette and all wastes must be disposed of laboratory biosafety requirements.

4. 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.

5. The test cassette is ready to use, valid within 1 hour after opening, and the test cassette can not be reused.

6. 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
	In vitro diagnostic medical device		Temperature limitation
	Manufacturer		Use by date
	Date of Manufacture		Consult instructions for use
	Do not reuse		Meet the requirements of EC Directive 98/79/EC
	Batch code		Caution
	Authorized representative in the European Community		Contains sufficient for 1 test

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