SARS-CoV-2 Antigen Rapid Test Kit

Product name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal gold Immunoassay)
Catalogue No: CoV2Ag-25
Packing specification: 25T/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.
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 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, each test consists of a test cassette and a desiccant. The cassette is composed of a test strip and a test strip shell. The test strip consists of a sample pad and a colloidal gold bonding pad (sprayed with colloid Gold-labeled SARS-CoV-2 monoclonal antibody I), nitrocellulose membrane (NC membrane) (the detection area is coated with SARS-CoV-2 monoclonal antibody II (T line) and goat anti- Mouse IgG (C line)), liner and absorbent pad.
2. **Desiccant:** 1 piece/pouch, silica gel.
3. **Swab:** 25 pieces/pack.
4. **Sample treatment solution:** 20 mL/bottle.
5. **Sampling tube:** 25 pieces/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

1. **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.
2. **Nasal swab**: Prior to collecting the nasal swab, the patient should be instructed to blow their nose. Carefully insert the swab into the nostril with the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril), and rotate the swab against the nasal wall several times and then remove it from the nostril.
3. **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).

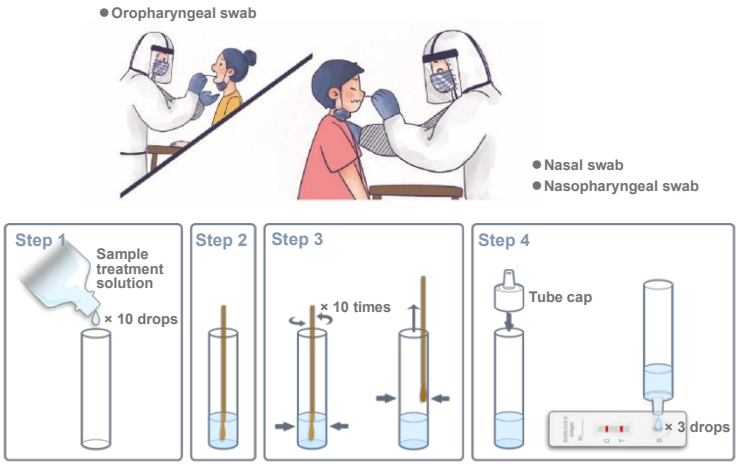
SAMPLE PREPARATION

1. Take out sampling tube and add 10 drops of sample treatment solution.
2. Put the swab into sampling tube, make sure the swab soaked in the solution.
3. **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 as much solution in the tube as possible.
4. Remove the swab. 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:

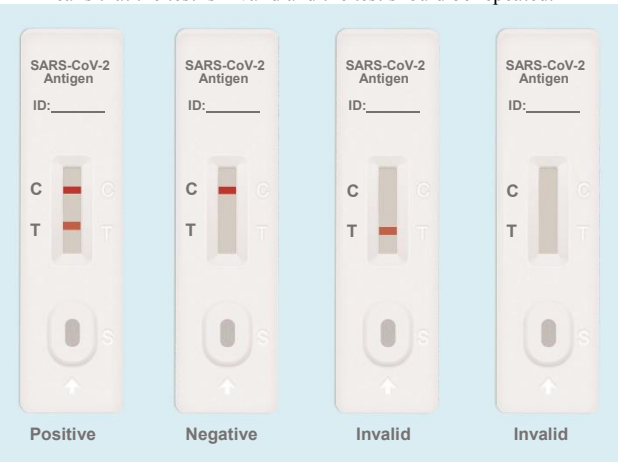
1. Bring the pouch to room temperature before use.
2. Take out the cassette, put it on a horizontal table.
3. Add **3 drops of the processed sample** vertically into the sample well and start the timer.
4. Observe the result after **10 minutes**, the result is valid within 30 minutes, read results after 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

1. This kit is a qualitative test for in vitro auxiliary diagnosis.
2. 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.
3. Unreasonable sampling, transportation and handling, or low virus content in the sample will lead to false negative results.
4. 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.

PERFORMANCE

1. Positive coincidence rate: 8 national positive reference samples (P1-P8) diluted 1:10 for testing, and the results should all be positive.
2. Negative coincidence rate: 20 national negative reference materials (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 product S to dilute into three detection limit 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.
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 enterprise repeatable reference products, repeat 10 times for each batch, all the results are positive, and the color rendition of the same concentration is uniform without difference.
6. Hook effect: Within the titer range of clinically positive samples of the SARS-CoV-2 antigen, the test result of this product does not show a hook effect.
7. Clinical performance: Adopt the experimental IVD reagent and make comparison with the clinical diagnostic criteria of SARS-CoV-2 to verify the clinical performance of this product. Test and statistically analysis 158 clinical samples (including 31 positive and 127 negative) shows the sensitivity is 90.323% (95%CI: 74.246%, 97.958%) and specificity is 99.213% (95%CI: 95.691%, 99.980%). The comparison results of 158 clinical samples with nucleic acid test shows that the positive coincidence rate is 90.32% and the negative coincidence rate is 99.21%. In addition, select homologous oropharyngeal swabs, nasal swabs and nasopharyngeal swabs from 50 subjects to compare, it shows that the consistent detection rates between nasal swabs and oropharyngeal swabs, nasopharyngeal swabs and oropharyngeal swabs, nasal swabs and nasopharyngeal swabs are all 100% (95%CI: -100%, 100%). After preliminary evaluation, it's basically confirmed that the clinical performance of the product could meet the requirements of SARS-CoV-2 antigen detection.

NOTES

1. This kit is for clinical research use only, and only for in vitro detection. 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 disposal solution, swabs, test cassette and all wastes must be disposed of in accordance with 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 cannot be reused.
5. The test results of this kit 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		

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Version: A4.1 Date Adopted: 2020-10-21

Test Report

Inspection No.	AB3022020092401	Report No.	AC3022020092401
Description	SARS-CoV-2 Antigen Rapid Test Kit(Colloidal gold Immunoassay)		
Sample Type	Finished Product	Sample Code	CoV2Ag-25
Lot No.	20200918	Amount	514 Kits
Manuf. Date	Sept. 18. 2020	Exp. Date	2022.03.17
Sample Package	25 Test/Kit	Sampling No.	4 Kits
Check Dept.	Production Department	Sample Source	Production Workshop
Inspection Basis	Inspection regulation of SARS-CoV-2 Antigen Rapid Test Kit(Chromatographic Immunoassay)		

Inspection Result

No.	Inspection Item	Requirement	Result	Judgement
1	Appearance	Smooth and clean, no damage, no pollution, all components are complete, the position is correct, paste firmly without falling off.	Conformance To Requirements	Qualified
2	Components	The number of individual detection bags inside is correct, and the production batch number and validity period printed on the aluminum foil bags are clear and correct. Correct bag contents, complete instructions.	Conformance To Requirements	Qualified
3	Reagent strip width	3.0mm±0.10mm	Conformance To Requirements	Qualified
4	Fluid migration velocity	≥10mm/min	Conformance To Requirements	
5	Positive reference compliance rate	8 positive references are positive	8/8	Qualified
6	Negative reference compliance rate	20 negative references were negative	20/20	
7	Detection limit	S1 negative, S3 positive, S2 negative or positive	3/3	Qualified
8	Repeatability	10 repeatability tests for R1 and R2 reference	20/20	
9	Inter-batch difference	10 repeatability tests for R1 and R2 reference	20/20	Qualified
Conclusion	The test result of this sample meets the requirements, and the judgment result is qualified.			
Note				

武汉优恩生物科技有限公司 质量部

Inspector/Date: Ye 2020.09.24 Reviewer/Date: wang 2020.09.24 Quality Leader/Date: celery 2020.09.24