DrugPro
SARS-COV-2 Ag RAPID TEST

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DrugPro SARS-COV-2 Ag RAPID TEST

DrugPro Sars-CoV Ag Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigen to SARS-CoV-2.

- Rapid: results within in 15 mins
- Easy to use
- Specimen: Nasopharyngeal swab
- Visual interpretation of results
- Early diagnostics, early medical treatment and reduce the closed contacts
- high specificity, more than 95%
- Good coincidence rate with RT-PCR test, especially for samples that with Ct value less than 25
- Ideal testing tools for on-site test and places that with limited access to RT-PCR laboratory significantly improve the detection capability

Test Kit Performance Analysis

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	38	1	39
Detected Negative	8	87	105
Total	46	88	134

Sensitivity: 82.61% (38/46), 95%CI (69.28, 73.61).
Specificity: 98.86% (87/88), 95%CI (93.84, 99.80).

Coincidence Rate of Different CT Values

CT Value	PCR Result	Ag Rapid Test Results	PPA	95%CI
≤25	25	23	92%	(75.03%,97.78%)
>25	21	15	71.4%	(50.04%, 86.19%)

PS: The antigen rapid test kit shows good compliance rate with RT PCR test, especially when the RT-PCR CT value is less than 25.

Antigen rapid test is an ideal diagnostics tools for early diagnostics, especially for patient with symptoms onset between 3-10 days, so that the local health authority can quickly identify the infected patient on time, reduce the closed contacts, and take medical treatment immediately. At the same time, antigen rapid test is also an ideal diagnostics tools for on-site testing and also for places that with limited access to RT-PCR laboratory.

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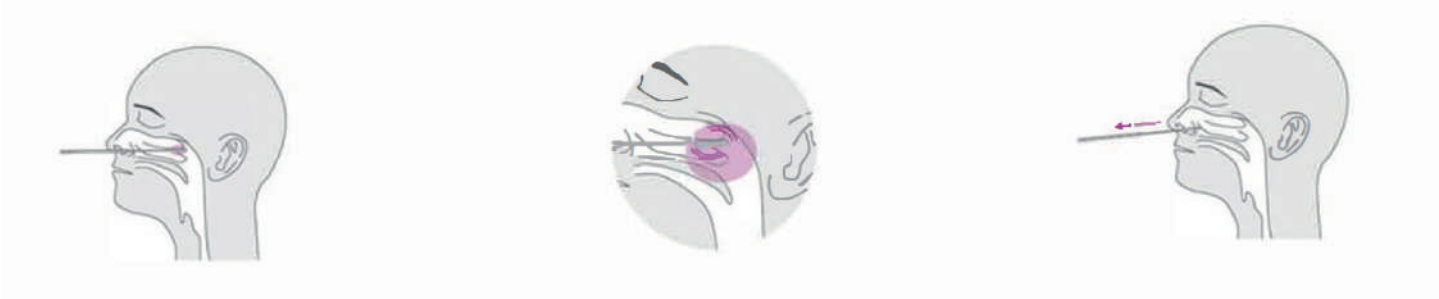
According to India ICMR, a positive test should be considered as true positive, whereas all symptomatic individuals testing negative through the rapid antigen test should be confirmed with real-time PCR test.

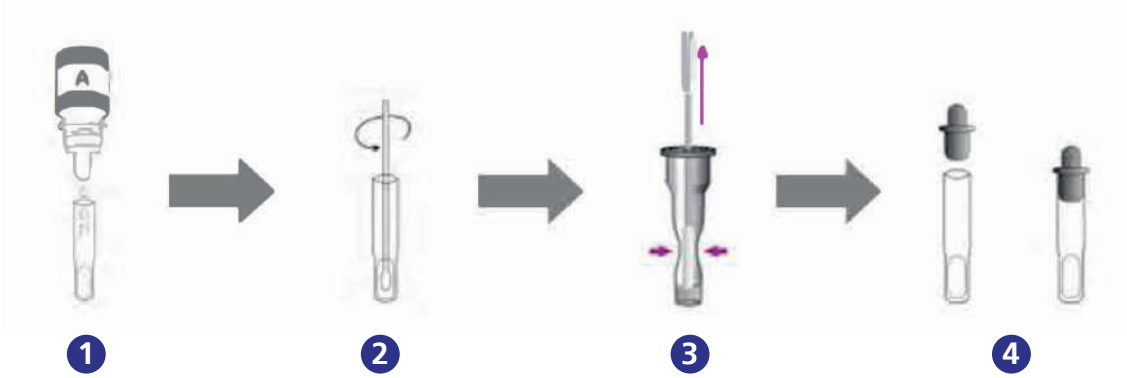
Sampling

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



PS: Correct sampling is quite important, otherwise the sampling sample might not have enough virus loading which might lead to false negative results.

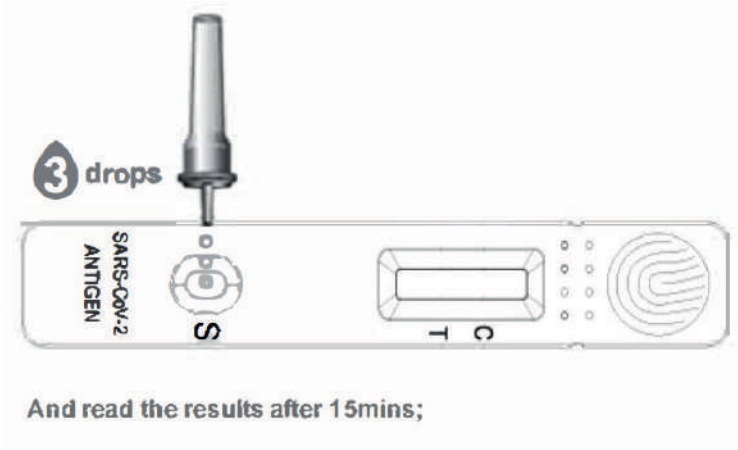
Samples Preparation



1) 500 µl (15 drop) Sample Extraction Buffer.
2) vigorously mix at least 10 times
3) remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4)Cover the dripper head.

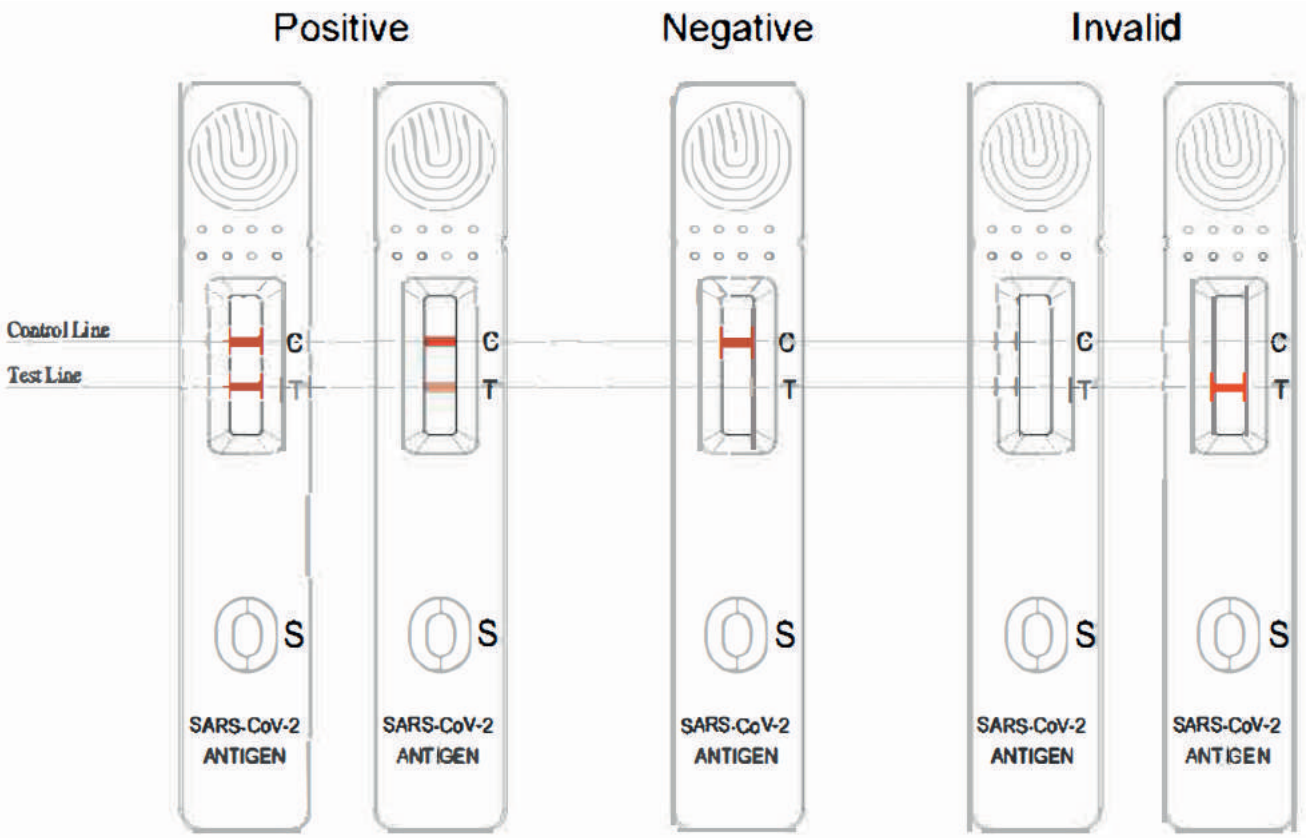
Testing

Apply 3 drops of extracted specimen to the specimen well of the test device.



Result interpretation

Read the result after 15 mins, don't read the results after 20 mins, the result is invalid after 20 mins, repeat the test again.



Intended Use

This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen. It is a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly. This test is only for clinical laboratory use or for immediate inspection by medical personnel, not for home testing, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by new coronavirus infection, and is not suitable for screening by the general population. A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection. The kit and test results are for clinical reference only. It is recommended to combine the patient's clinical manifestations and other laboratory tests for a comprehensive analysis of the condition. This Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Summary and Explanation

The novel coronaviruses belong to the β genus. SARS-COV-2 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 of the Test

This reagent uses double-antibody sandwich to legally detect the antigen of novel coronavirus (SARS-CoV-2) in nasopharyngeal swab and oropharyngeal swab samples. During detection, the gold labeled anti-SARS-CoV-2 monoclonal antibody in the labeling pad binds to the SARS-CoV-2 antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, It is captured by the anti-SARS-CoV-2 monoclonal antibody pre-coated by the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain SARS-CoV-2
antigen, a red color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a red reaction line will always form in the quality control area (C).

Materials and Components

Materials provided with the test kits

1. Test Card, 25 kits/box.
2. Tube, 25 units/box.
3. Dripper, 25 units/box.
4. Swab, 25 units/box.
5. Tube holder, 1 unit/box.
6. Sample buffer, 1 bottle/ box.
7. Manual instruction for use. Note: The components in different batches of the kit cannot be mixed.

Materials required but not provided

1. Transfer pipette
2. Timer

Storage and Stability

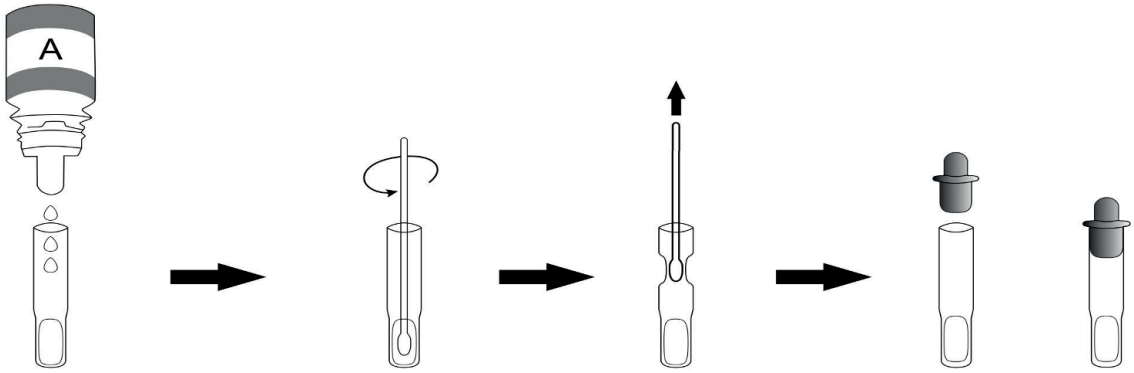
1. Store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products.
2. The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use.
3. The buffer should be used immediately after dropping into the dropper.
4. MFG date and EXP date: marked on the label. The product will be expired after 12 months.

Sample Requirements

1. Collection of nasopharyngeal secretion: Insert the sterile swab into the place where the nasopharyngeal secretions are the most and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
2. Collection of oropharyngeal secretion: Insert the sterile swab from mouth completely into the oropharyngeal swelling, centering on the red part of the throat wall, epicondylitis, and tonsils, wipe and rotate 10 times with moderate force to avoid touching the tongue and remove the swab.
3. The samples should be used as soon as possible after collected (within half an hour). 4. Samples should not be inactivated.

Test Procedure

Sample processing:
1. Take out the tube, add about 500μL of sample buffer (or 15 drops vertically) to the tube.
2. Completely immerse the swab head of the collected sample into the buffer in the tube.
3. Rotate the sample against the inner wall of the tube approximately 10 times or squeeze the tube 10 times to elute the sample to ensure that the sample on the swab is fully eluted into the buffer.
4. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.
5. Discard the swab and cover the drip head to mix the liquid thoroughly.
6. Samples should be eluted and used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.



Note: Recommend to use a pipette to transfer the samples to reduce deviations.

500μL (~15 drops) Extraction Buffer	Vigorously mix at least 10 times	Squeeze liquid from swab	Cover the dripper head

Test operation

Before test, please read the instruction manual.

1. Take the required reagents and test cards to equilibrate to room temperature.
2. Unpack the aluminum foil bag, place the reagent card horizontally on the table and mark it.
3. Add 100μL (3 drops) of the processed sample to the sample well, and timed. Recommended to use a pipette to take buffer/samples to reduce deviations.

Interpretation of Test Results

This product can only perform qualitative analysis on the detection object.

Positive Result:

If both C and T lines are visible within 15 minutes, the test result is positive and valid.

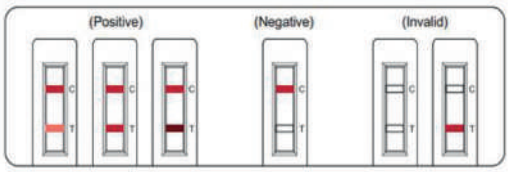
Note: Specimens containing very low levels of target antibodies may develop two colored lines over 15 minutes.

Negative Result:

If test area (T line) has no color and the control area displays a colored line, the result is negative and valid

Invalid Result:

The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test cassette.



Limitations

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab and nasopharyngeal swab. This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. The Sample buffer and test card must be equilibrated to room temperature (18C~26C) before used, otherwise the results may be incorrect
4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
5. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
6. React less than 10 minutes may lead a false negative result; React more than 10 minutes may lead a false positive result.
7. Positive test results do not rule out co-infections with other pathogens.
8. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
10. Negative results should be treated as presumptive and confirmed with a molecular assay.
11. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
12. Users should test specimens as quickly as possible after specimen collection.
13. ID CHIP and test card is matched. Please carefully check the consistency of lot number on ID CHIP and test card before use.
14. If the sample volume is not enough, the chromatography cannot be carried out successfully. Please pay attention to the prompt information of the instrument. It is recommended to use a pipette to add samples.

Interpretation of Test Results

1. Clinical Verification

Sampling from 46 RT-PCR positive patients, eluting with the sample extract of this reagent, and then detecting with this reagent, 38 samples was detected as positive; sampling from 88 RT-PCR negative patients, using this reagent Test, 87 samples were detected as negative.
Sensitivity: 82.61% (30/46), 95%CI (69.28, 73.61).
Specificity: 98.86% (87/88),95%CI (93.84, 99.80).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	38	1	49
Detected Negative	8	97	105
Total	46	88	134

2. Limit of Detection

When the virus culture concentration was 400 TCID50/mL and above, the positive rate was greater than or equal to 95%. At virus culture concentration of 200 TCID50/mL and below, the positive rate is not higher than 95%, so the minimum detection limit of the SARS-CoV-2 Ag Rapid Test Kit is 400 TCID50/m.

3. Cross-reactivity

Cross-reactivity of the Kit was evaluated. The results showed no cross reactivity with the following specimen.

No.	Specimen type	Conc.
1	HCoV-HKU1	10^5 $TCID_{50}$/mL
2	Staphylococcus aureus	10^6 CFU / mL
3	Streptococcus pyogenes	10^6 CFU / mL
4	Measles virus	10^5 $TCID_{50}$/mL
5	Paramyxovirus parotitis	10^5 $TCID_{50}$/mL
6	Adenovirus 3	10^5 $TCID_{50}$/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 $TCID_{50}$/mL
9	Human Metapneumovirus (hMPV)	10^5 $TCID_{50}$/mL
10	Human coronavirus OC43	10^5 $TCID_{50}$/mL
11	Human coronavirus 229E	10^5 $TCID_{50}$/mL
12	Bordetella parapertussia	10^6 CFU / mL
13	Influenza B (Victoria strain)	10^5 $TCID_{50}$/mL
14	Influenza B (Ystrain)	10^5 $TCID_{50}$/mL
15	Influenza A (H1N1 2009)	10^5 $TCID_{50}$/mL
16	Influenza A (H3N2)	10^5 $TCID_{50}$/mL

No.	Avian influenza virus (H7N9)	10^5 $TCID_{50}$/mL
18	Avian influenza virus (H5N1)	10^5 $TCID_{50}$/mL
19	Epstein-Barr virus	10^5 $TCID_{50}$/mL
20	Enterovirus CA16	10^5 $TCID_{50}$/mL
21	Rhinovirus	10^5 $TCID_{50}$/mL
22	Respiratory syncytial virus	10^5 $TCID_{50}$/mL
23	Streptococcus pneumoniae	10^6 CFU / mL
24	Candida albicans	10^6 CFU / mL
25	Chlamydia pneumoniae	10^6 CFU / mL
26	Bordetella pertussis	10^6 CFU / mL
27	Pneumocystis jirovecii	10^6 CFU / mL
28	Mycobacterium tuberculosis	10^6 CFU / mL
29	Legionella pneumophila	10^6 CFU / mL

4. Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Interference substances	Conc.
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3μg / mL
4	Chloramphenicol	3μg / mL
5	Erythromycin	3μg / mL
6	Tobramycin	5%
7	Throat spray（Menthol）	15%

5. Precision

1. Test 10 replicates of negative and positive by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.

2. Test three different lots kits including positive and negative reference materials of enterprises. The negative results and the positive results were 100%

6. Hook Effect

There was no Hook effect detected when the concentration of inactivated virus stock solution raised up to 4.0×105 TCID50/ml.

Precautions

1. For in vitro diagnostic use.
2. Do not use the kit contents beyond the expiration date printed on the outside of the box.
3. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
4. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
5. Do not reuse the used Test Card, Reagent Tubes or Swabs.
6. The user should never open the foil pouch of the Test Card exposing it to the ambient environment until the Test Card is ready for immediate use.
7. Discard and do not use any damaged or dropped Test Card or material.
8. The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
9. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
10. Sample collection and handling procedures require specific training and guidance.
11. Use the appropriate Fixed Volume Pipette in accordance with test procedures.
12. To obtain accurate results, do not use visually bloody or overly viscous samples.
13. Do not write on the barcode of the Test Card.
14. As the detection reagent is a fluorescent compound, novisible results will form on the test strip.
15. To obtain accurate results, an opened and exposed Test Card should not be used inside a laminar flow hood or in a heavily ventilated area.
16. Testing should be performed in an area with adequate ventilation.
17. Wear suitable protective clothing, gloves, and eye/faceprotection when handling the contents of this kit.
18. Wash hands thoroughly after handling.

Key to Symbols Used

COMPONENT	Materials Included	ID CHIP	ID Chip
TEST CARD	Test Card	HOLDER	tube holder
TUBE	Tube	DRIPPER	Dripper
SWAB	Swab	DILUENT	Sample Buffer
IFU	Instruction for Use		Date of Manufacturer
	Consult Instructions For Use		Do Not Reuse
	Store at 2°C~30°C	REF	Catalogue Number
	Expiration Date		Keep away from Sunlight
	Manufacturer		Tests per Kit
LOT	Lot Number		Keep Dry
EC REP	Authorized Representative	IVD	In Vitro Diagnostic Medical Device

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CE

DrugPro Diagnostic Kit for SARS-CoV-2 Ag (Colloidal Gold) Clinical Report

1.Clinical Evaluation Purpose

Test oropharyngeal and nasopharyngeal swab samples
from patients with pneumonia with positive nucleic acid test results (suspected of SARS-CoV-2 infection) and patients with other diseases or normal persons with negative nucleic acid test results by using Diagnostic Kit: DrugPro SARS-CoV-2 Antigen Detection Kit (GICA), developed by Vesaş, and compare the test result with the nucleic acid test result blindly.
The trial purpose is to verify the consistency of the test results of the tested reagents with the nucleic acid test results.

2.Tested Reagents

2.1 Product information to be evaluated

2.1.1 Product name: DugPro SARS-CoV-2 Antigen Detection Kit (Colloidal Gold)

2.1.2 Comparison reagent: q-PCR 2019-nCoV Test Kit from BGI

3.Experiment Design

3.1 Sample selection: In order to examine the sensitivity and specificity of the product from a clinical perspective, this clinical trial selected (1) patients with pneumonia with positive nucleic acid test results (suspected of SARS-CoV-2 infection) as the "case group";
(2) patients with other diseases or normal persons with negative nucleic acid test results as the "control group".
In this trial, the results of nucleic acid detection of SARS-CoV-2 were selected as a control. The blind method and the comparative test design were used. The tested reagent was used to blindly test the test samples, and the complete and real clinical trial data were recorded. After submitting the data to the person in charge of statistics, the person in charge made statistics according to the statistical method in the clinical trial plan, and evaluated the coincidence rate and consistency of the tested reagent and the nucleic acid detection result based on the statistical results.

3.2 Sample size

3.2.1 33 PCR positive specimens collected from UTM tubes and 78 PCR negative specimens collected from UTM tubes

3.3.2 The PCR positive specimens eluted from 46 matched sample extracts and 88 PCR negative specimens eluted from matched sample extracts.

3.3 Test: test according to the instruction

3.4 Statistical interpretation

A. Please refer to 2x2 Contingency Table in EP12-A2（User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition, 2008）for statisticalinterpretation.

	qPCR			
DrugPro Coronavirus (SARS-CoV-2) Antigen Detection Kit (GICA)		Positive	Negative	Total
	Positive	A True positive	B False positive	A+B
	Negative	C False negative	D True negative	C+D
	Total	A+C	B+D	A+B+C+D

B. Please refer to computing method in EP12-A2（User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition , 2008）to calculate negative coincidence rate, positive coincidence rate, and 95% confidence interval for negative coincidence rate and 95% confidence interval for positive coincidence rate.

4.Statistical Interpretation

Clinical Evaluation 1 (with fresh samples)

(1) Sampling from 46 RT-PCR positive patients, eluting with the sample extract of this reagent, and then detecting with this reagent, 38 samples was detected as positive; sampling from 88 RT-PCR negative patients, using this reagent Test, 87 samples were detected as negative.

(2) Sensitivity: 82.61% (38/46), 95%CI (69.28, 73.61).

(3) Specificity: 98.86% (87/88),95%CI (93.84, 99.80).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	38	1	39
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Total	46	88	134

(4) Coincidence rate of different Ct values

Ct Value	PCR Result	Ag Rapid Test Results	PPA	95%CI
≤25	25	23	92%	(75.03%,97.78%)
>25	21	15	71.4%	(50.04%,86.19%)

Clinical Evaluation 2 (with VTM samples)

(1) With 33 UTM positive samples, 20 samples were detected as positive; With 78 UTM negative samples, 77 samples were detected as negative.

(2) Sensitivity:60.61% (27/65), 95%CI (43.68, 75.32).

(3) Specificity: 98.72% (77/78),95%CI (93.09, 99.77).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	20	1	21
Detected Negative	13	77	90
Total	33	78	111

5. Discussion and Conclusion

5.1 Discussion

1) In this clinical trial with fresh samples, 134 samples were taken from RT-PCR positive or negative patients, and the samples were eluted using the sample extraction solution matched with this reagent. Among them, 46 cases of "case group" samples and 88 samples of "control group" were determined by nucleic acid detection. example. Among them, 38 positive samples and 87 negative samples were detected by the assessment reagent. The positive coincidence rate of the assessment reagent was 82.61%, and the negative coincidence rate was 98.86%.

2) In this clinical trial with VTM samples, a total of 111 oropharyngeal swab samples were tested, of which 33 samples were identified in the "case group" confirmed by nucleic acid test, and 78 samples were in the "control group" . The evaluated reagent detected 20 positive samples and 77 negative samples. The positive coincidence rate of the reagent was 60.61%, the negative coincidence rate was 98.72%.

5.2 Conclusion

In summary, the detection results of Diagnostic Kit for SARS-CoV-2 Ag (Colloidal Gold) developed by Vesaş and the nucleic acid detection results are in good agreement, and the SARS-CoV-2 antigen detection function can meet the needs of clinical application

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