Lumigenex

PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

For Use with Nasal Swab Samples
For In Vitro Diagnostic Use Only
For self-testing

Product Name: PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Intended Use

The PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) is used to qualitative detection of SARS-CoV-2 virus nucleocapsid protein, which is an important conserved structural protein of SARS-CoV-2 in human nasal samples. The detection of SARS-CoV-2 nucleocapsid protein antigen can be used to assist the diagnosis of novel coronavirus infection, and is helpful for the early detection of novel coronavirus pneumonia infection in the latent period.
The PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) is used for self-testing by layusers over 18 years old.
Children and adolescents of 6~18 years old should need help by adults when testing. Adults over 75 years should also be supported by an assistant. For children under 6 years old, please do not use this test.

The Contents of the product

Cat.No	Package	Strip	Nasal Swap	Extraction Tube	Extraction Reagent Bottle	Tube Holder
P23001	1 Test / Box	1	1	1	1	/
P23005	5 Tests / Box	5	5	5	5	1
P23025	25 Tests / Box	25	25	25	25	1

Materials Not Supplied With the PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) but required

Clock, Timer, or Stopwatch
Hand soap and water or hand sanitizer for cleaning your hands
Safety mask or other face covering
Gloves

Warnings and Precautions

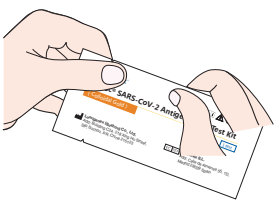
1. Read the package leaflet carefully. All instructions must be followed carefully.The reliability of the test results cannot be guaranteed if the user does not follow the instructions in this package leaflet exactly.
2. Do not use the kit beyond the expiration date printed on the outside of the box.
3. The test kit has been authorized only for the detection of nucleocapsid proteins from SARS-CoV-2 and SARS-CoV. This test does not differentiate between SARS-CoV and SARS-CoV-2. This test isn't used for any other viruses or pathogens.
4. The experiment should be carried out within 1 hour to avoid the inaccurate test result caused by extended exposure of strip in the air after the strip is taken out from the foil pouch.
5. The best detection temperature is 20°C ~ 30°C and humidity RH is 40% ~ 60%.
6. Discard all samples and materials resulted from the test as biohazardous waste.
7. The test buffer is composed of PBS buffer, Triton-100 and proclin300. Don't contact the test buffer.

Test Procedure

1. Before starting the test, wash your hands with soap and water or use hand sanitizer
2. Open the package and take out the test card.
3. Place the extraction tube on the tube holder (not be included in 1 test/box). Open the The extraction reagent bottle and pour the reagent into the extraction tube.
4. Now follow the instructions for sampling, remove the swab from its wrapper.

Note: Rip the package at the end with the arrow label / OPEN.Make sure the tip of the tip is not touched.

2



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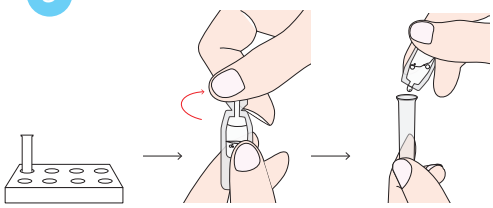
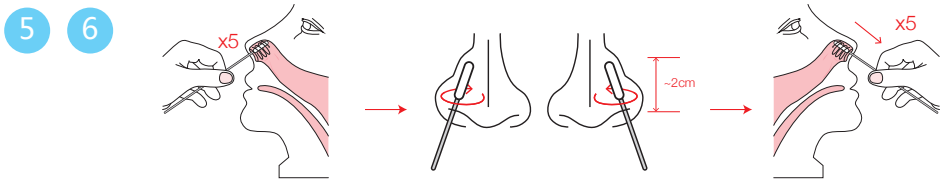


Collecting Samples

5. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the person. The swab tip should be inserted up to nostril about 2 cm until resistance is met.
6. Rub the swab around the inside wall of each nostril at least 5 times. Take approximately 15 seconds to collect the sample. This is done with the same swab in the other nostril.

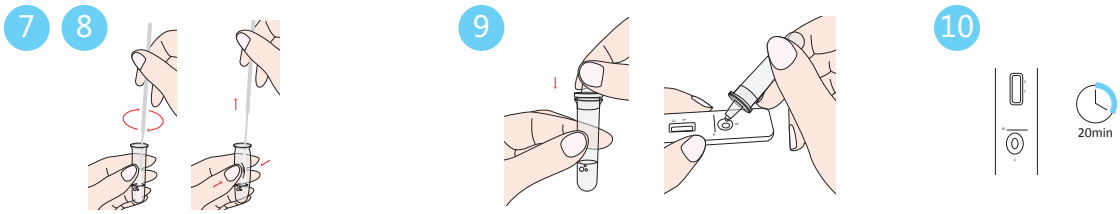


Note: Inadequate or inappropriate sample collection, may yield false negative test results.

Performing the Test

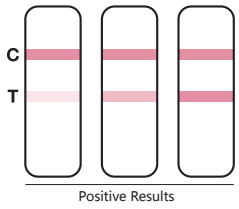
7.Put the swab sample into the extraction tube with extraction reagent, rotate the swab for about 10 seconds,
8. press the swab head several times against the tube wall to release the antigen in the swab as possible as can. Discard the swab according to local regulations of biohazard waste.
9. Install the beater on the extraction tube, drop 80μL（three drops） into the sample well of the test card, and start the timer.
10. Read the result in 20 minutes. A strong positive result can be reported within 20 minutes, but a negative result must be reported after 20 minutes.

⚠ **Warning: If the result is read after more than 30 minutes, the result may be invalid.**



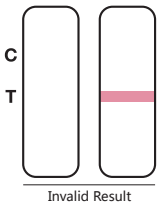
Interpretation of Results

Positive Results:
The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
In case of a positive test result:
-There is currently a suspicion of COVID-19 infection, Contact your doctor or local health authority immediately
-Comply with local self-isolation directives
-To have a PCR confirmation test performed



Negative Results:
One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).
In case of a negative test result:
-A negative result means that you probably do not have a COVID-19. Please note that a negative result does not completely exclude a COVID-19 infection and also negative test may present an infection.
-Continue to maintain all applicable rules regarding contact with others as well as protection and hygiene measures.
-Repeat the test after 1-2 days in case of suspicion, as the corona virus is not present at all stages

Invalid Result:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.
In case of invalid test result:
-Possibly invoked by faulty test execution
-Repeat the test
-Contact your doctor or a COVID-19 test centre if your test results are still invalid



Limitations

1. The test is intended for direct nasal swab samples only. Using another sample collection device or method may cause false results.
2. The contents of this kit are used only for the qualitative detection of SARS-CoV-2 antigens from nasal swab samples.
3. A negative tests 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 improperly.
4. This test detects both viable (live) and non-viable, 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.
5. Failure to follow the performing the test and Interpretation of results may adversely affect test performance and/or invalidate the test results.
6. Positive test results do not rule out co-infections with other pathogens.
7. Negative results should be treated as presumptive, and confirmation with another SARS-COV-2 assay, if necessary, should be done.
8. Adults with contraindications, such as color blindness, color weakness and other eye diseases. Someone else is needed to help with the test to avoid the wrong conclusion from the self-test.

Kit Storage and Stability

All reagents are ready to use as supplied. Unopened reagent kits are stable at 4°C~30°C for 24 months. It should be used within 1 hour once the pouch is opened. After that expiration date, the kit should be discarded in household waste.

Summary and Explanation

In December 2019, a new coronavirus emerged and caused an acute respiratory disease now known as coronavirus disease 2019 (COVID-19). The virus was identified to be a beta-coronavirus related to severe acute respiratory syndrome coronavirus (SARS-CoV) and thus was named SARS-CoV-2.

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 latent 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 procedure

The PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) is a double antibody sandwich immunoassay. The test strip contains Nitrocellulose membranes which are pre-coated with anti-SARS-CoV-2 virus Nucleocapsid protein (N protein) monoclonal antibodies on the test line. Another mouse anti- SARS-CoV-2 virus N protein monoclonal antibody which can specifically bind to SARS-CoV-2 N protein, are bound to colloidal gold and sprayed on conjugation zone. When the sample is added into the sample well, SARS-CoV N protein and labeled antibody complexes are formed and the complexes travel forward along the strip. Complex is captured by pre-coated antibody to form a visible red line. The presence of SARS-CoV-2 will be indicated by a visible red test line (T) in the result window. The Control Line is used as a procedural control. The control red line should always appear when the test procedure is performed properly and the testing kit is valid as intended.

Clinical Performance

1. Clinical Evaluation:

Clinical evaluation was performed to compare the results obtained by the PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and 2019-nCoV Nucleic Acid Test Kit (RT-PCR). All the observation results and findings in the clinical trial are verified to ensure the reliability of the data and ensure that the conclusions in the clinical trial come from the original data. There are corresponding data management measures in clinical trial and data processing stage.

The results were summarized as below:

SARS-CoV-2		RT-PCR(Ct value ⩽35)		Total Results
PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Results	Positive	Negative	
	Positive	98	2	100
	Negative	7	347	354
Total Results		105	349	454

Sensitivity (PPA): (Ct ⩽35): 93.33% (98/105), (95%CI* 86.87%~96.73%)

Specificity (NPA): 99.43% (347/349), (95%CI* 97.93%~99.84%)

*Confidence Interval

Analytical Performance

1. Limit of Detection (LoD):

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. The LoD for The PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was established using limiting dilutions of gamma-irradiated SARS-CoV-2. The final LoD was determined to be the lowest concentration resulting in positive detection of twenty (20) out of twenty (20) replicates. Based on this testing the LoD for nasal swab samples was confirmed as: 121 $TCID_{50}$ /mL.

2. High dose hook effect:

Strong positive samples of Novel Coronavirus Antigen were diluted in a gradient, then gradient samples from low concentration to high concentration were tested, and were repeated in 5 times. The concentration when the colour density decreased with increased concentration was used as the minimum concentration of Novel Coronavirus Antigen when the hook effect appeared. A testing up to $10^5 TCID_{50}$ /mL of inactivated SARS-CoV-2 to demonstrate that a high dose affect will not occur.

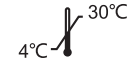
3. Cross-Reactivity:
Cross-reactivity of the PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was evaluated by testing various viruses as below, the final results show that the kit does not cross react with any other viruses and microorganisms except SARS-CoV (2003).

Substances	Concentration	Substances	Concentration
Coronavirus OC43	10^5PFU/mL	Parainfluenza virus 2	10^5PFU/mL
Coronavirus NL63	10^5PFU/mL	Parainfluenza virus 3	10^5PFU/mL
Coronavirus 229E	10^5PFU/mL	Parainfluenza virus 4	10^5PFU/mL
Coronavirus HKU1	10^5PFU/mL	Human Metapneumovirus (hMPV)	10^5PFU/mL
Influenza A	10^5PFU/mL	Adenovirus C1	10^5PFU/mL
Influenza B	10^5PFU/mL	Adenovirus 71	10^5PFU/mL
SARS-coronavirus	10^5PFU/mL	Rhinovirus A16	10^5PFU/mL
MERS-coronavirus	10^5PFU/mL	Streptococcus pneumoniae	10^5CFU/mL
Respiratory syncytial virus	10^5PFU/mL	Legionella pneumophila	10^5CFU/mL
Parainfluenza virus 1	10^5PFU/mL	Mycoplasma pneumoniae	10^5CFU/mL

4. Endogenous Interference Substances Studies:
A list of substances that tested for endogenous substances interference study with inactivated SARS-CoV-2 at 3xLoD. The results are shown in the following table; there was no interference between the test reagents and the potential interference substances.

Substances	Concentration	Substances	Concentration
Whole Blood	5%(V/V)	Zicam	5%(V/V)
Mucin	100 μg/mL	Homeopathic (Alkalol)	1:10dilution
HAMA Serum	3.78 μg/mL	Sore Throat Phenol Spray	15%(V/V)
Chloraseptic(Menthol/Benzocaine)	1.5 mg/mL	Tobramycin	4 μ g/mL
Naso GEL (NeilMed)	5%(V/V)	Mupirocin	10 mg/mL
CVS Nasal Drops (Phenylephrine)	15%(V/V)	Fluticasone Propionate	5%(V/V)
Afrin (Oxymetazoline)	15%(V/V)	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
CVS Nasal Spray (Cromolyn)	15%(V/V)		

GLOSSARY:

	Consult Instructions for Use		Batch Code
	Do not reuse		Manufacturer
	In-vitro diagnostic device		Do not use if package damaged
	Temperature limitation		Expiry date
	European Representative		Fragile. Handle with care
	Set up		Protect from moisture
	Caution, consult accompanying documents		Date of manufacture

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