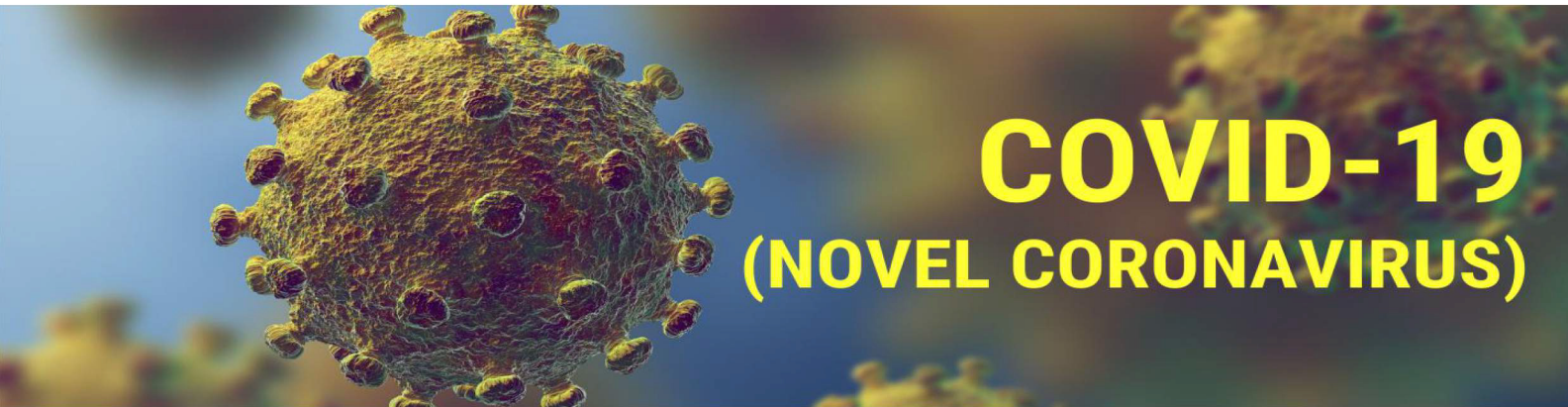




Novel Coronavirus Antigen Test Kit

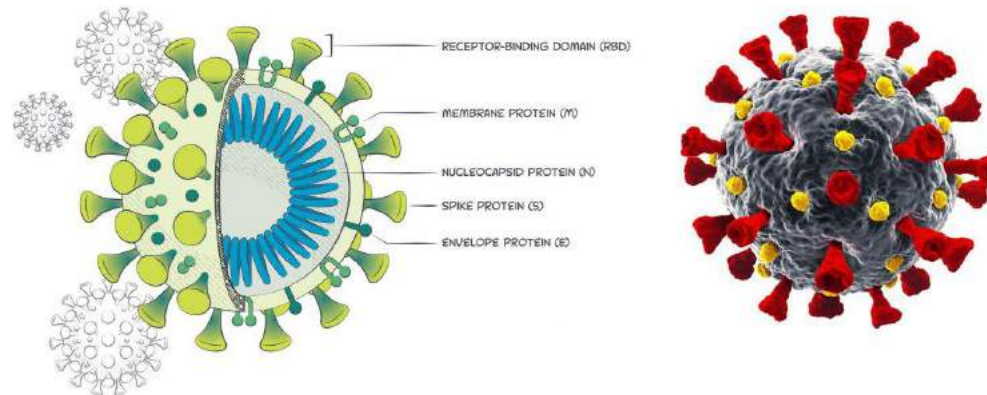
Specimen : Nasal swab



Hangzhou Laihe Biotech Co., Ltd.
Tel: 0571-87653090 www.lyherbio.com

COVID-19 & SARS-CoV-2

SARS-CoV-2 stands for severe acute respiratory syndrome coronavirus 2.
SARS-CoV-2 is the strain of coronavirus that causes the **COVID-19** disease.



What is a coronavirus antigen test?

An antigen test is a diagnostic test that checks to see if you're infected with the coronavirus. The test looks for proteins (antigens) in a sample taken from your nose or throat. Antigen tests are faster than PCR tests



Lyher Novel Coronavirus (COVID-19) Antigen Test Kit

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) is an in vitro immunoassay. The assay is for the direct and qualitative detection of antigen of SARS-CoV-2 from Nasal secretions specimens.

The kit is for in vitro diagnostic use.



Kit Contents



Sterilized Swab



Test Cassette



Extraction Tube



Work Station

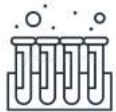
Product Features



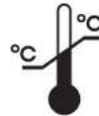
Result in 15 mins



No equipment needed



Easy to collect samples

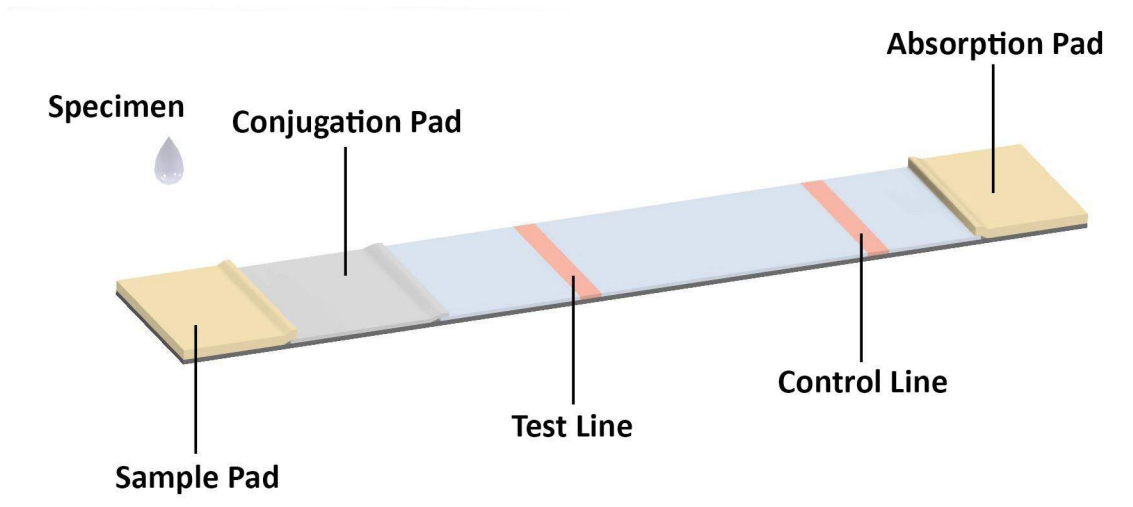


Room temperature storage



Results are easy to read

Principle



- The test line is coated with anti-SARS-CoV-2 antibodies
- The Control line is coated with goat anti-mouse IgG antibodies
- The conjugation pad is coated with anti-SARS-CoV-2 monoclonal antibodies

If the specimen contains the antigen of SARS-CoV-2, a colored test line(T line) will be visible in the result window. If the specimen does not contain the antigen of SARS-CoV-2, no test line will show, only quality control line(C line) will appear.

Specimen Collection

Nasal swab collection



- ① Make sure the nasal cavity is moist
- ② Carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
- ③ Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
- ④ Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
- ⑤ Withdraw the swab from the nasal cavity.

Table 3: COVID-19 Rapid Test vs. RT-PCR (Nasal)

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	145	1	144
Negative(-)	7	249	256
Total	152	250	402

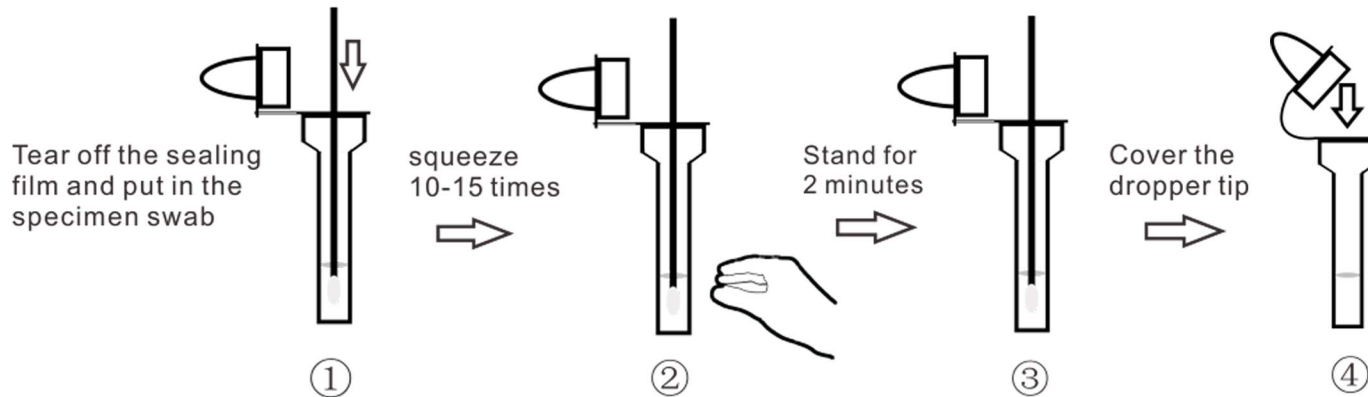
Clinical Sensitivity: 95.39% (90.74% , 98.13%)

Clinical Specificity: 99.60(97.79%, 99.99%)

Total coincidence rate: 98.01% (96.12%, 99.14%)

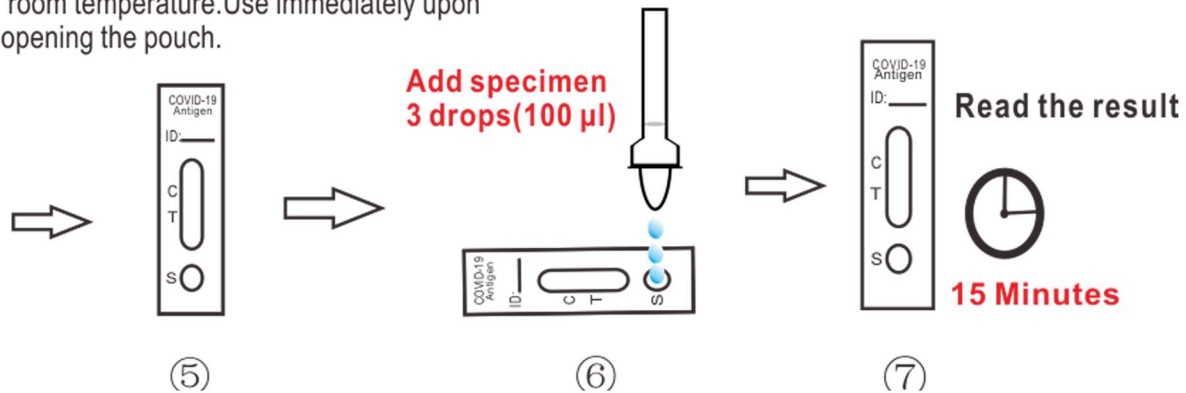
Test Procedure

Specimen Extraction:

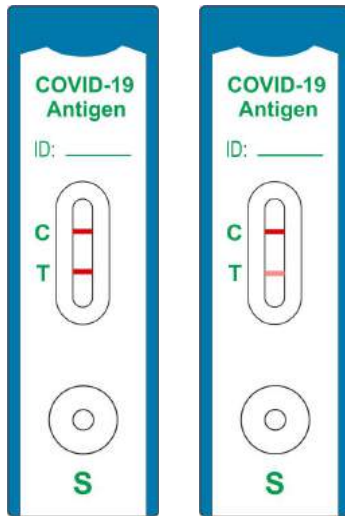


Preparation

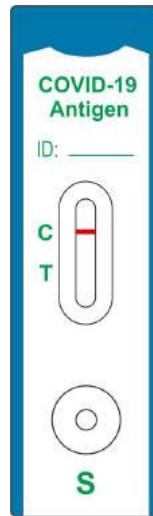
Do not open the test kit until it reaches room temperature. Use immediately upon opening the pouch.



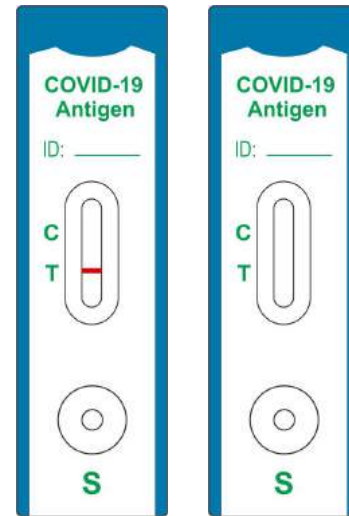
Interpretation of Results



Positive



Negative



Invalid

Ordering information



- **Component:** 25pcs test kits,
25pcs buffers
25pcs nasal swabs

- **Package Information:** 25pcs/kit 40kits/carton 1000pcs/carton
 - **Carton Size:** 63x35x30.5cm
-



- **Component:** 5pcs test kits
5pcs buffers
5pcs nasal swabs

- **Package information:** 5pcs/kit 100pcs/box 2000pcs/carton
-



- **Component:** 1pc test kit
1pc buffer
1pc nasal swab

- **Package information:** 1pc/kit 100pcs/box 2000pcs/carton
-



Limit of detection

The limit of detection has been evaluated at 0.5 ng/mL

Cross-Reactivity

We have evaluated 27 organisms, and samples positive for these organisms were found negative when tested with the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit.

