



COVID-19

Detection One-Stop Solutions



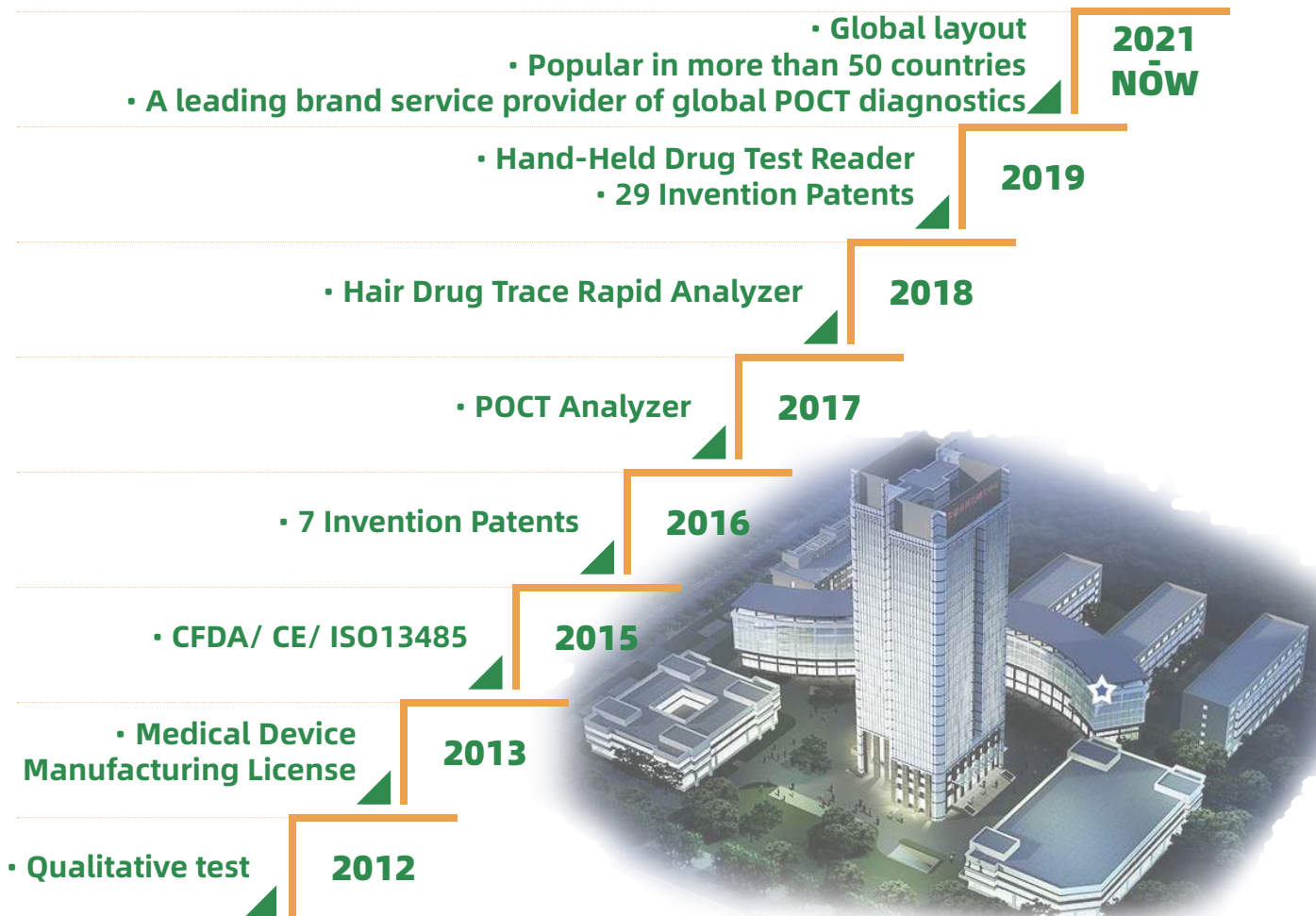
Company Profile

Founded in 2012, Hangzhou Laihe Biotech Co., Ltd., has always focused on the development and industrialization of POCT instant diagnosis, monitoring and health information technology field, and is committed to providing fast, accurate and reliable health detection products and services to the public.

LYHER® brand has been registered in more than 40 countries worldwide, including China, America, Australia, and many European and Asian countries, etc.

LYHER® Novel Coronavirus Test Kit has been certified by the US FDA EUA, Australian TGA, EU CE and some authorities of countries like German, France, Netherlands in Europe, like Brazil, Peru, Bolivia in South America, and Japan, Thailand, Indonesia, Malaysia, Vietnam in southeast Asia, and many other global authorities as well. LYHER kits have been shortlisted in the whitelist of importers, meanwhile some other synchronous registration in China NMPA, WHO and other authorities are also in progress. Our product is also the first batch of German novel coronavirus self-test products that have been entered into the BfArm list of enterprises.

Development Course





Are you still worried about COVID-19?



COVID-19 Infected now?



COVID-19 Ag test



COVID-19 or Influenza A/B infected?



COVID-19 and Influenza A/B Antigen Test Kit



COVID-19 Infected now?
COVID-19 Infected ever or after vaccination?
which stage have been recovered?



COVID-19 IgM/IgG Ab Test



Is there a protective effect after vaccination ?



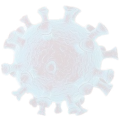
COVID-19 Neutralizing Antibody Test Kit
(Colloidal Gold)



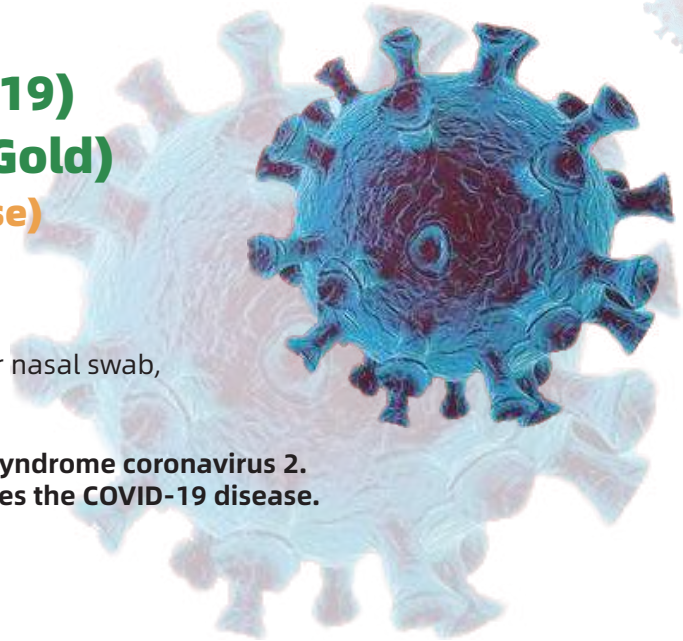
Still protective effect ?
Vaccinate again?



COVID-19 Neutralizing Antibody Test Kit (IFC)



Novel Coronavirus(COVID-19) Antigen Test Kit(Colloidal Gold) (for professional use and home use)



Specimen: nasopharyngeal or oropharyngeal or nasal swab, saliva, sputum

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.

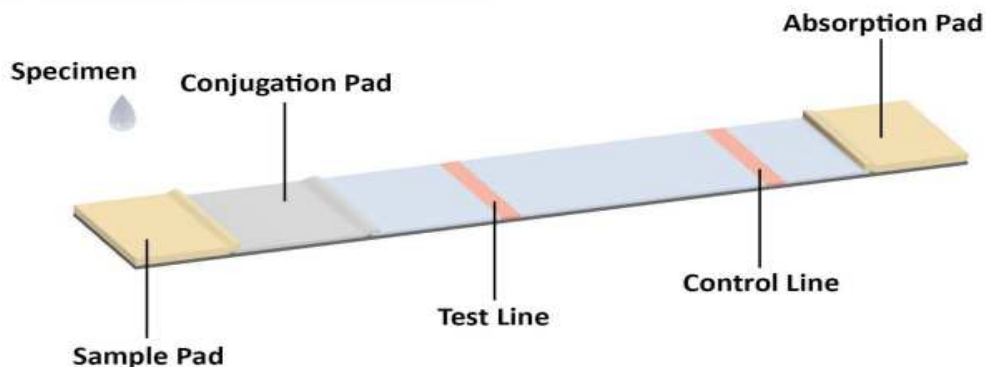
The test looks for proteins (antigens) in a sample taken from your nose or throat.

Antigen tests are faster than PCR tests.

LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) is an in vitro diagnostic kit. The assay is for the direct and qualitative detection of antigen of SARS-CoV-2 **Protein N** from nasopharyngeal, oropharyngeal, Nasal, Saliva and sputum secretions specimens.



Test 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

Product Features



CE Marked



Result in
15mins



Easy to
collect
samples



No
equipment
needed



Easy
to read
results



Room
temperature
storage

Product Portfolio

Nasopharyngeal or oropharyngeal (for professional use only)



Test device



Extraction buffer



Sterile swab



Work station

Test Procedure

1



Tear the foil out of the buffer tube and place extraction tube into box tube stand.

2



Remove the swab from the packet.
(Notice: Do not touch the swab tip with finger.)

3



Insert the swab into the nasal palate against the wall of the nostril slowly, and then rotate white wiping and remove gently.

or



open the mouth and gently rub the tonsils and the posterior pharyngeal wall back and forth with the swab at least 3 times each.

4



Insert the tip of the swab containing your sample into the tube pre-filled with diluent.

5



Squeeze the sample tube with the swab inserted 10-15 times to mix evenly. Allow the swab to stand in the tube for 1 minute by using the sample tube holder.

6



Remove the swab from the sample tube and fit the dropper ensuring it's well sealed.

7



Rip open the foil pouch and take out the test device. Place it horizontally on the table.

8



Invert the sample tube perpendicular to the sample hole(S) on the test cassette. Add 3 drops of sample to the sample hole(S).

9



Read the result after 15 MINUTES in good lighting. Results observed after 20 MINUTES are considered invalid.

Clinical data (For professional use only)

CLINICAL EVALUATION:

Clinical evaluation was performed to compare the results obtained by The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit and RT-PCR. The results were summarized below:

Table 1: COVID-19 Rapid Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	193	1	194
Negative(-)	10	381	391
Total	203	382	585

Clinical Sensitivity: 95.07% (91.13%-97.61%)*

Clinical Specificity: 99.74% (98.55%-99.99%)*

Total coincidence rate: 98.12% (97.02%-99.22%)*

*95% Confidence Interval

Pre-nasal area (for professional use and home use)



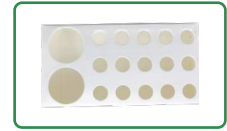
Test device



Extraction buffer



Nasal sterile swab



Work station

Test Procedure

- 1**

Tear the foil out of the buffer tube and place extraction tube into box tube stand.
- 2**

Remove the swab from the packet. (Notice: Do not touch the swab tip with finger.)
- 3**

Insert the swab gently into your nostril until resistance is felt. Roll the swab along the inside of one nostril 5 times within 7-10 seconds. Gently remove the swab.

Repeat this step in your other nostril with the same swab.
- 4**

Insert the tip of the swab containing your sample into the tube pre-filled with diluent.
- 5**

Squeeze the sample tube with the swab inserted 10-15 times to mix evenly. Allow the swab to stand in the tube for 1 minute by using the sample tube holder.
- 6**

Remove the swab from the sample tube and fit the dropper ensuring it's well sealed.
- 7**

Rip open the foil pouch and take out the test device. Place it horizontally on the table.
- 8**

Invert the sample tube perpendicular to the sample hole(s) on the test cassette. Add 3 drops of sample to the sample hole(s).
- 9**

Read the result after 15 MINUTES in good lighting. Results observed after 20 MINUTES are considered invalid.

Clinical Data (Professional use clinical data)

Performance Characteristics

CLINICAL EVALUATION:

Clinical evaluation was performed to compare the results obtained by The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit and RT-PCR. The results were summarized below:

Table 1: COVID-19 Rapid Test vs. RT-PCR (Nasal)

Testergebnisse des Lyher-Kits	Klinische Diagnose (PCR-Ergebnisse)			Test results from the Lyher kit	Clinical diagnosis (PCR results)		
	Positive(+)	Negative(-)	Total		Positive(+)	Negative(-)	Total
Positive(+)	145	1	144	Positive(+)	193	1	194
Negative(-)	7	249	256	Negative(-)	10	381	391
Total	152	250	402	Total	203	382	585

Sensitivity: 95,39% (90,74%, 98,13%)* Specificity: 99,60% (97,79%, 99,99%)* Total Accurately: 98,01% (96,12%, 99,14%)

Self test clinical data

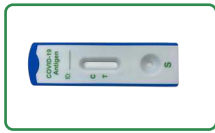
The LYHER® COVID-19 antigen self-test was examined with nasal mucus samples from individuals either infected or uninfected with SARS-CoV-2 and compared with a molecular test (RT-PCR test), in order to determine sensitivity and specificity. The study was done with 411 samples.

COVID-19 Antigen Self-Test Compared to RT-PCR			
Test results from the Lyher kit	Clinical Diagnosis (PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	152	1	153
Negative(-)	8	250	258
Total	160	251	411

Sensitivity: 95.0%
Specificity: 99.6%

A feasibility study showed that 100% of participants understood how the results should be interpreted. Of the participants, 70% found the instructions for use very clear and 30% clear. Of the participants, 76% found the reading of the test result very clear and 23% clear. Of the participants, 67% found the test very easy and 33% easy. 97.81% of different test results were interpreted accurately. 84.67% of participants completed the test without help.

Saliva/sputum (for professional use and home use)



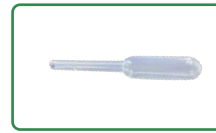
Test device



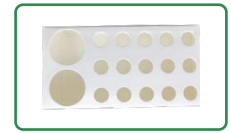
Extraction buffer



Specimen cup



disposable dropper



Work station

Test Procedure

1

Tear the foil out of the buffer tube and place extraction tube into box tube stand.

2

Rinse your mouth with water before sampling to remove food residue. (Notice: Don't clean your throat.)

Cough deeply, make the noise of "Kruuuua" from the throat to clear sputum/oropharyngeal saliva from deep throat.

Release it into the container once the sputum/oropharyngeal saliva is in your mouth.

3

Aspirate the saliva sample with a dropper to the scale line (about 0.2ml).

4

Drop the specimen into the tube pre-filled with diluent.

5

Cover the specimen tube tightly with dropper tip.

6

Shaking 10 times at least and then stand for 1 minute by using the sample tube holder.

7

Rip open the foil pouch and take out the test device. Place it horizontally on the table.

8

Shaking the tube 3-5 times again and invert the tube perpendicular to the sample hole(S). Add 3 drops (about 100µl) of sample.

9

Read the result after 15 MINUTES in good lighting. Results observed after 20 MINUTES are considered invalid.

Clinical Data(For professional use only)

Clinical evaluation was performed to compare the results obtained by The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit and RT-PCR. The results were summarized below:

Table 1: COVID-19 Rapid Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	63	0	63
Negative(-)	5	68	73
Total	68	68	136

Clinical Sensitivity: 92.65% (83.67%-97.57%)*
 Clinical Specificity: 100.00% (94.72%-100.00%)*
 Total coincidence rate: 96.32% (91.63%-98.80%)*

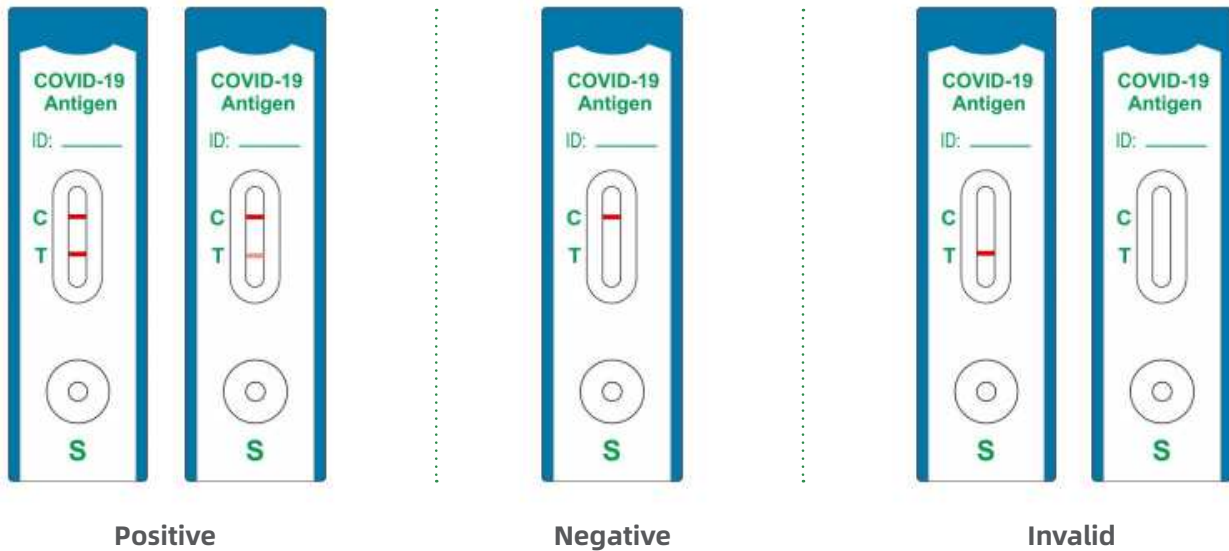
Self test clinical data

Clinical evaluation was performed to compare the results obtained by The LYHER® SARS-CoV-2 Antigen Rapid Test Kit for self-testing (Saliva) and RT-PCR. The results were summarized below:

COVID-19 Antigen Self-Test Compared to RT-PCR			
Test results from the Lyher kit	Clinical Diagnosis (PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	94	0	94
Negative(-)	16	460	476
Total	110	460	570

Clinical Sensitivity (true positive rate) : 85.45% (77.46%-91.45%)*
 Clinical Specificity (true negative rate) : more than 99% (99.20%-100.00%)*
 Total coincidence rate: 97.19%(95.48%-98.39%)*
 *95% Confidence Interval

Interpretation of Results



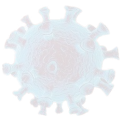
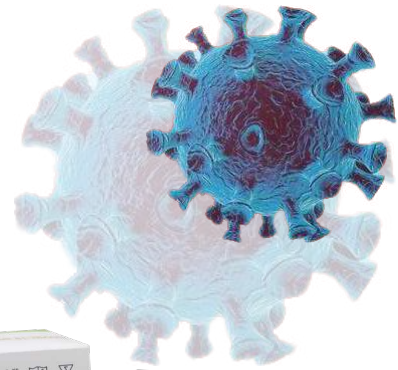
POSITIVE: Two colored lines appear on the membrane. One colored line appears in the control region (C) and the other line appears in the test region (T).

NEGATIVE: Only a single colored line appears in the control region (C). No visible colored line appears in the test region (T).

INVALID: The control line does not appear. The test results which do not show a control line after the specified reading time should be discarded. The sample collection should be checked and repeated with a new test. Stop using the test kit immediately and contact your local dealer if the problem persists.

CAUTION

1. The color intensity in the test region (T) may vary depending on the concentration of virus proteins present in the nasal mucus sample. Therefore, any color in the test region should be considered positive. It should be noted that this is only a qualitative test and cannot determine the concentration of viral proteins in the nasal mucus sample.
2. Insufficient sample volume, improper procedure or expired tests are the most likely reasons why the control line does not appear.



COVID-19 and Influenza A/B Antigen Test Kit

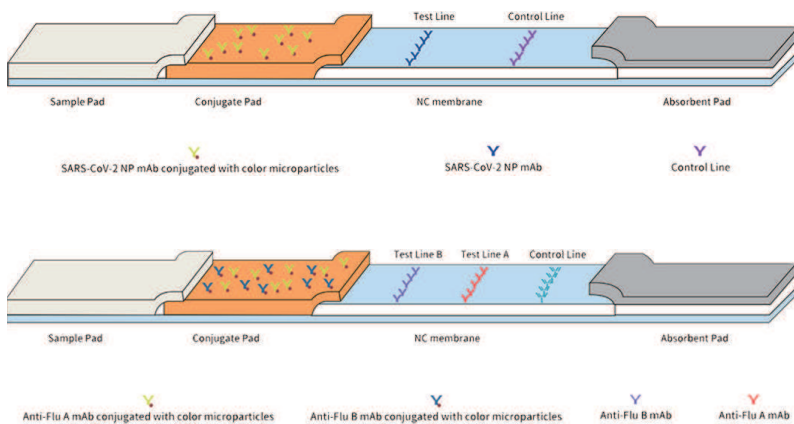
(for professional use and home use)

At present, the prevention and control of new coronavirus pneumonia (NPV) has entered a critical period, however, the prevalence of influenza A/B virus infection is gradually increasing, and its clinical manifestations are similar to npv pneumonia, it is difficult to be differentiated by clinical manifestation and chest imaging, and the treatment of the two infections is quite different.



The rapid differential detection protocol for influenza virus and new coronavirus infection is helpful for rapid, safe and labor-saving differential diagnosis of influenza A/B virus and new coronavirus infection, as well as identification of co-infection.

Test Principle



The immune colloidal gold technique is used in the assay to detect antigens of SARS-CoV-2 and Influenza A/B. The sample pad is coated with colloidal gold bound antibodies. The quality control area is coated with goat anti-mouse IgG, and test area with anti-SARS-CoV-2 or Influenza A/B antibodies. When testing, if there are any SARS-CoV-2 or Influenza A/B antigen, the T line will become visible red. The C line should be red after add sample.

Product Features



CE Marked



Result in 15mins



Easy to collect samples



No equipment needed



Easy to read results



Room temperature storage

Nasopharyngeal or oropharyngeal (for professional use only)



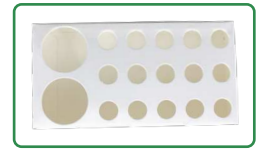
Test device



Extraction buffer



Sterile swab



Work station

Test Procedure

1

Wash your hands.

2

Tear the foil out of the buffer tube and place extraction tube into box tube stand.

3

Remove the swab from the packet. (Notice: Do not touch the swab tip with finger.)

4

Insert the swab into the nasal palate against the wall of the nostril slowly, and then rotate while wiping and remove gently. or open the mouth and gently rub the tonsils and the posterior pharyngeal wall back and forth with the swab at least 3 times each.

5

Squeeze the sample tube with the swab inserted 10-15 times to mix evenly. Allow the swab to stand in the tube for 1 minute.

6

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

7

Press the nozzle cap tightly onto the tube.

8

Rip open the foil pouch and take out the test device. Place it horizontally on the table.

9

Invert the sample tube perpendicular to the sample hole(S) on the test cassette. Add 3 drops of sample to both the sample hole(S).

10

Read the result after 15 MINUTES in good lighting. Results observed after 20 MINUTES are considered invalid.

Clinical data (For professional use only)

Performance Characteristics

CLINICAL EVALUATION:

Clinical evaluation was performed to compare the results obtained by The LYHER® Test Kit and RT-PCR. The results were summarized below:

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	51	0	51
Negative(-)	2	140	142
Total	53	140	193

Clinical Sensitivity: 96.23% (91.10%,100.00%)*
 Clinical Specificity: 100.00% (99.82%,100.00%)*
 Total coincidence rate:98.96% (97.53%,100.00%)*

Table 2: Lyher Test Kit - Influenza A

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	32	0	32
Negative(-)	0	161	161
Total	32	161	193

Clinical Sensitivity: 100.00% (99.64%,100.00%)*
 Clinical Specificity: 100.00% (99.84%,100.00%)*
 Total coincidence rate: 100.00% (99.85%,100.00%)*

Table 2: Lyher Test Kit - Inluenza B

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	17	0	17
Negative(-)	1	175	176
Total	18	175	193

Clinical Sensitivity: 94.44% (83.86%,100.00%)*
 Clinical Specificity: 100.00% (99.84%,100.00%)*
 Total coincidence rate: 99.48% (98.47%,100.00%)*
 *95% Confidence Interval

Pre-nasal area (for home use)



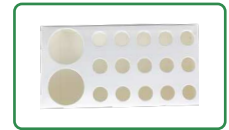
Test device



Extraction buffer

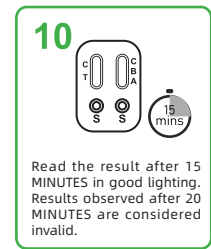
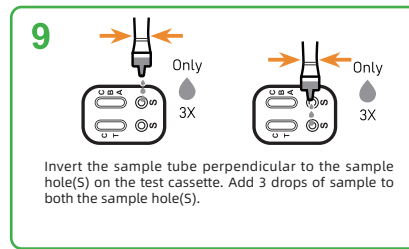
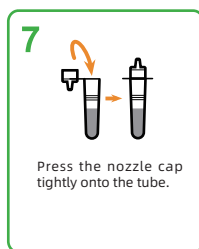
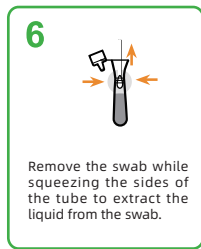
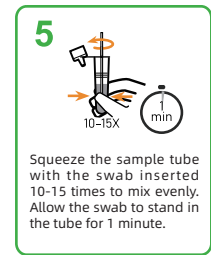
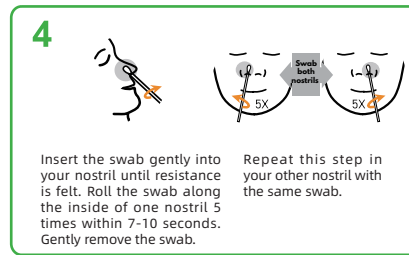
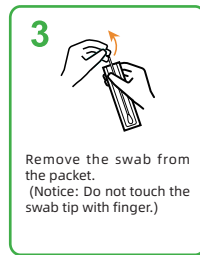
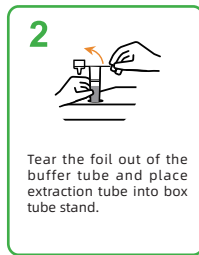


Nasal sterile swab



Work station

Test Procedure



Self test clinical data

Clinical evaluation was performed to compare the results obtained by The LYHER® COVID-19 and Influenza A/B Antigen Test Kit for self-testing and RT-PCR. The results were summarized below:

Table 2: COVID-19 Rapid Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	103	0	103
Negative(-)	7	460	467
Total	110	460	570

Clinical Sensitivity (true positive rate) : 93.67% (87.33%-97.40%)*

Clinical Specificity (true negative rate) : more than 99% (99.20%-100.00%)*

Total coincidence rate: 98.77%(97.49%-99.50%)*
*95% Confidence Interval

Table 2: Influenza A Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	72	0	72
Negative(-)	1	280	281
Total	73	280	353

Clinical Sensitivity (true positive rate) : 98.63% (92.60%-99.97%)*

Clinical Specificity (true negative rate) : more than 99% (98.69%-100.00%)*

Total coincidence rate: 99.72% (98.43%-99.99%)*
*95% Confidence Interval

Table 2: Influenza B Test vs. RT-PCR

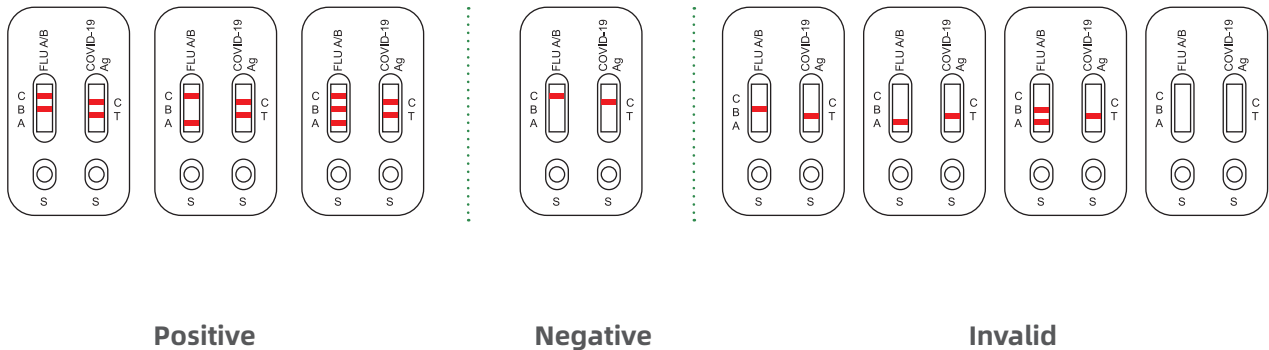
Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	30	0	30
Negative(-)	0	323	323
Total	30	323	353

Clinical Sensitivity (true positive rate) : more than 99% (88.43%-100.00%)*

Clinical Specificity (true negative rate) : more than 99% (98.86%-100.00%)*

Total coincidence rate: more than 99% (98.96%-100.00%)*

Interpretation of Results



Influenza A POSITIVE: It is positive for Influenza A antigen if two Red lines appear. One Red line should be in the control line region (C), and the other one appears in the A test line region.

Influenza B POSITIVE: It is positive for Influenza B antigen if two Red lines appear. One red line should be in the control line region (C), and the other one appears in the B test line region.

Influenza A and B POSITIVE: It is positive for both the antigens of Influenza A and Influenza B if three Red lines appear. One Red line should be in the control line region (C), and another two should appear in A test line region and B test line region.

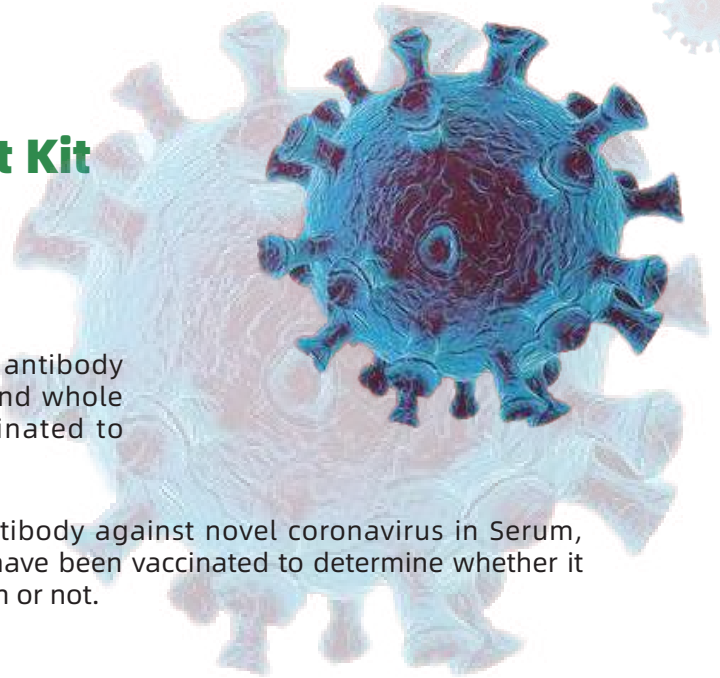
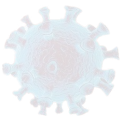
NEGATIVE: One Red line appears in the control region (C). No apparent red line appears in the influenza A and B test region (T).

CAUTION

1. The color intensity in the test region (T) may vary depending on the concentration of virus proteins present in the nasal mucus sample. It should be noted that this is only a qualitative test and cannot determine the concentration of viral proteins in the nasal mucus sample.
2. Insufficient sample volume, improper procedure or expired tests are the most likely reasons why the control line does not appear.
3. The true positive result should show a red line on the T line. If it is a very weak faint water mark (not red), it may be caused by too many samples, or there are interferences in the sample, or it is not time to read the result, so it should not be judged as positive.

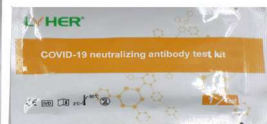
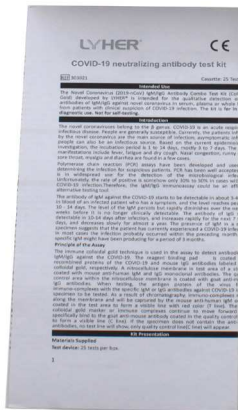


COVID-19 Neutralizing Antibody Test Kit



1. For qualitative detection of the neutralizing antibody against novel coronavirus in Serum, plasma and whole blood from the People who have been vaccinated to determine whether it has a protective effect.

2. Quantitative detection of the neutralizing antibody against novel coronavirus in Serum, plasma and whole blood from the People who have been vaccinated to determine whether it has a protective effect and should vaccinate again or not.



The vaccine of COVID-19 generally needs two injections, and usually produces protective neutralizing antibodies about 7 days after the second injection. However, due to the difference of individual immunity, not everyone who has been vaccinated will produce neutralizing antibodies.

Some people who have been infected with the COVID-19 also produce protective neutralizing antibodies.

There are no definite evidence whether neutralizing antibodies can protect the mutated COVID-19. There are still lack of sufficient research on the protection period of neutralizing antibody.

Timetable for the onset of 5 international vaccines

	Sinopharm	Pfizer	Moderna	Jassen	Novavax	AstraZeneca
Vaccine Technology	Inactivated vaccines	mRNA	mRNA	Adenovirus vector	Nano recombinant protein	Chimpanzee adenovirus vector vaccine
Inoculation dose	2 doses, 14-28 days apart	2 doses, 21 days apart	2 doses, 28 days apart	1 dose	2 doses, 28 days apart	2 doses, 28 days apart
Onset time of vaccine	14 days after inoculation	7 days after the second dose	14 days after the second dose	Get the most protection 14 days after inoculation	Start 14 days after the first injection	14 days after the second dose of vaccination; new data shows that there is a protective effect 22 days after the first dose

Product Features



CE Marked



Result in 15mins



Easy to collect samples



Easy to read results



Room temperature storage

Clinic Evaluation

Sensitivity and Specificity

In order to test the sensitivity and specificity of the COVID-19 neutralizing antibody test kit (IFC), blood samples were collected from COVID-19 Vaccinated people from 3 hospitals. The results were summarized below:

Table 1: COVID-19 Test vs. Vaccinated results

Vaccinated	positive	negative	Sensitivity	95%CI		Specificity
Healthy people without inoculation	0	256	/	/	/	100%
7 days after first inoculation	41	215	16.02%	11.47%	21.09%	/
7 days after second inoculation	232	24	90.63%	86.37%	93.90%	/
14 days after second inoculation	249	7	97.27%	94.45%	98.89%	/

Kit Contents

- 25pcs Test Cassettes
- 25pcs Droppers
- 25pcs lancets
- 25pcs Extraction buffer
- 25pcs Alcohol pad



Test Procedure

-
-
-
-
-
-
-

Interpretation of Results

Positive	Negative	Invalid	

POSITIVE: There are no line in the test line region (T), or the color of T-line is lighter then R-line. And the control line region (C) is appeared.

NEGATIVE:The color of T-line is redder then R-line. And the control line region (C) is appeared.

INVALID: Control line fails to appear. Insufficient sample volumes or incorrect procedures are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, the test kit should be discontinued of using immediately and your local distributor should be contacted.



Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)



For the qualitative detection of the antibodies of IgM/IgG against novel coronavirus in serum, plasma or whole blood from patients with clinical suspicion of COVID-19 infection.

The antibody test kit is a product of the human immune response after infection with virus. In general, IgM antibodies appear early in the infection and IgG antibodies appear in middle and late stages on infection. Titers have a continuous increasing process and stay in blood circulation for longer time. The test for specific antibodies can determine whether a patient has “ recently or previously infected 2019-nCoV” .It helps to avoid “ False Negatives” to complementary to nucleic acid test.

In the past 2020 LYHER® Novel Coronavirus(2019-nCov) IgM/IgG Antibody Combo Test Kit have been popular in more than 40 countries all over the world and passed a series of the certifications like EU CE, US FDA EUA, WHO EUL, French Ministry of Health, Malta MCCA, Australia TGA, the Philippines FDA, Thai FDA, Brazil ANVISA and registered in Bolivia, Peru, Chile etc.

Product Features



CE Marked



Result in 10mins



Easy to collect samples



No equipment needed



Easy to read results



Room temperature storage

Clinical trials:

Sensitivity: 96.37%,
Specificity: 99.05%,
Total coincidence rate: 97.88%(Kappa=0.957, P < 0.001)

FDA EUA NCI Serology Test Evaluation repor

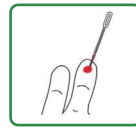
Measure	Estimate	Confidence Interval
IgM Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
IgM Specificity	100% (80/80)	(95.4%; 100%)
IgG Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined PPV for prevalence = 5%	80.8%	(40.9%; 96%)
Combined NPV for prevalence = 5%	100% (99.4%; 100%)	(99.4%; 100%)
Cross-reactivity with HIV+	0.0% (0/10) not detected	

Specimen Collection



Whole Blood/
Serum/
Plasma

or



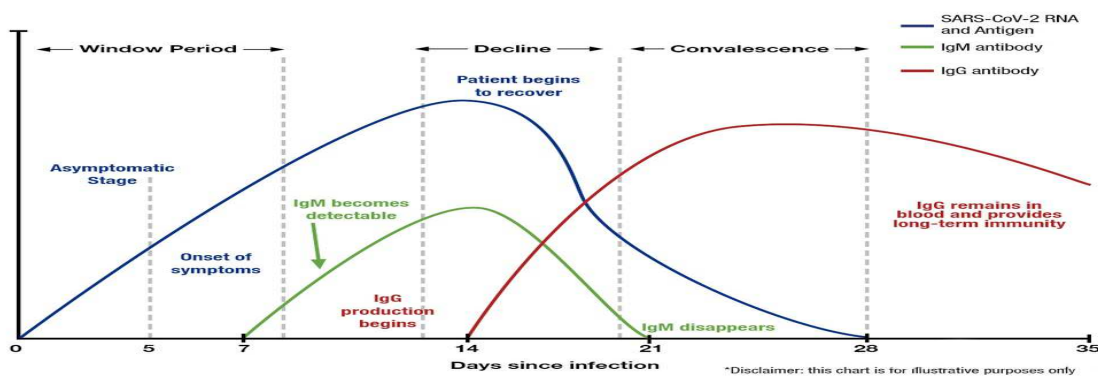
Fingertip blood

Interpretation of Results

Cross-Reactivity


A series of 63 serum specimens confirmed positive for the different antinuclear antibodies (ANA), rheumatoid factor (RF), and other common viruses, such as Influenza (H1N1, H3N2, H5N1, H7N9, Yamagata, Victoria), RSV, RUB, CMV, HSV, VZV, HIV, EBV, adenovirus, rotavirus, mumps, enterovirus, and measles), and Legionella were obtained from outside clinical laboratories. All of the specimens were negative for COVID-19 antibodies. These specimens were then run in the LYHER® IgM/IgG Test Kit for Novel Coronavirus Antibody. The results of this study indicate that the LYHER® IgM/IgG Test Kit for Novel Coronavirus (2019-nCoV) Antibody contains no cross-reacting proteins to other common viruses, Legionella, ANA or rheumatoid factor.


Clinical significance and change of the IGM, IgG antibody levels

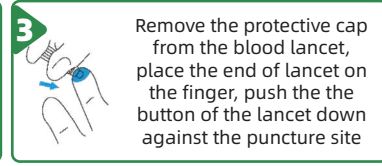


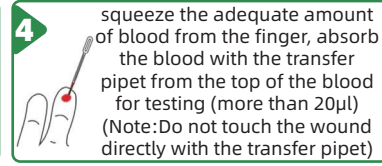
Test Results			Clinical Significance
PCR	IGM	IgG	
+	-	-	Patient may be in the window period of infection.
+	+	-	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	-	+	Patient may be in the late or recurrent stage of infection.
-	+	-	Patient may be in the early stage of infection. PCR result may be false-negative.
-	-	+	Patient may have a past infection, and has recovered.
-	+	+	Patient may be in the recovery stage of infection. Or the PCR result may be false-negative.

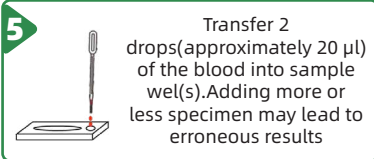
Test Procedure

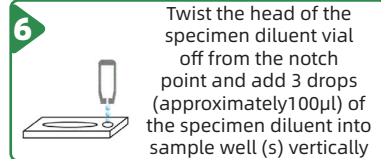
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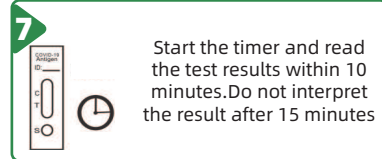
1 Preparation: After the kit reach 20 ~26°C , open the pouch just before test
- 

2 Use the alcohol pad provided to clean the subject's finger
- 

3 Remove the protective cap from the blood lancet, place the end of lancet on the finger, push the the button of the lancet down against the puncture site
- 

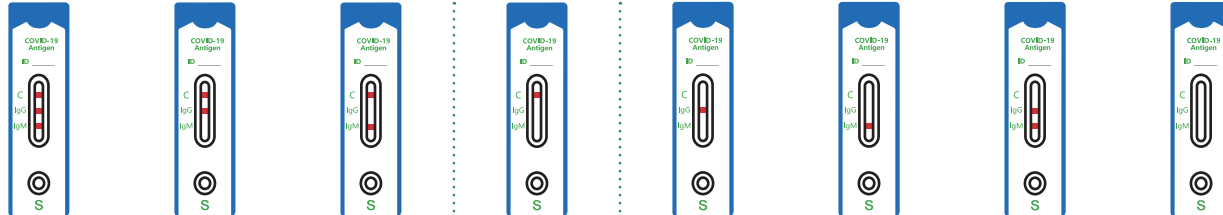
4 squeeze the adequate amount of blood from the finger, absorb the blood with the transfer pipet from the top of the blood for testing (more than 20µl) (Note:Do not touch the wound directly with the transfer pipet)
- 

5 Transfer 2 drops (approximately 20 µl) of the blood into sample well(s). Adding more or less specimen may lead to erroneous results
- 

6 Twist the head of the specimen diluent vial off from the notch point and add 3 drops (approximately 100µl) of the specimen diluent into sample well (s) vertically
- 

7 Start the timer and read the test results within 10 minutes. Do not interpret the result after 15 minutes

Interpretation of Results



IgG & IgM Positive **IgG Positive** **IgM Positive** **Negative** **Invalid**

POSITIVE: Two or three colored lines appear on the membrane. One colored line appears in the control region (C) and the other line appears in the test region (IgM or IgG or both).

NEGATIVE: Only a single colored line appears in the control region (C). No visible colored line appears in the test region (IgM or IgG).

INVALID: The control line (C) does not appear. The tests results which do not show a control line after the specified reading time should be discarded. The sample collection should be checked and repeated with a new test. Stop using the test kit immediately and contact your local dealer if the problem persists.

Packing information

Code: 303002

Component: 40pcs test kits,
2 bottles of buffers(4.5ml/bottle)

Package Information: 25 boxes/carton 1000 pcs/carton

Carton Size: 63x35x30.5cm

G.W: 9.5kg **N.W:** 9kg



Code: 303021

Component: 25 pcs test kits,
25 pcs buffers, or 2 bottles of buffers
25 pcs Lancets
25 pcs alcohol pads

Package Information: 40 boxes/carton 1000 pcs/carton

Carton Size: 63x45x30.5cm

G.W: 14.5kg **N.W:** 13kg



Ordering information

Item	Product name	Product code	Specimen	Specification/Box
1	Novel Coronavirus (COVID-19) Antigen Test Kit	303035	Nasopharyngeal / Oropharyngeal	25Tests
2	Novel Coronavirus (COVID-19) Antigen Test Kit	303036	Nasal	25Tests
3	Novel Coronavirus (COVID-19) Antigen Test Kit for self-testing	303036	Nasal	1Test/2Tests/5Tests/ 7Tests/25Tests
4	Novel Coronavirus (COVID-19) Antigen Test Kit	303034	Saliva/Sputum	5Tests/25Tests
5	SARS-CoV-2 Antigen Rapid Test Kit for self-testing (Saliva)	303107	Saliva/Sputum	1Test/5Tests/ 7Tests/25Tests
6	COVID-19 and Influenza A/B Antigen Test Kit	303050	Nasopharyngeal / Oropharyngeal	20Tests/25 Tests
7	COVID-19 and Influenza A/B Antigen Test Kit for self-testing	303051	Nasal	1Test/5Tests/ 20Tests/25Tests
8	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) with lancet/Alcohol pad	303021	Whole blood /Serum/Plasma	25Tests
9	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	303002	Whole blood /Serum/Plasma	40Tests
10	COVID-19 neutralizing antibody test kit(Colloidal Gold)	303057	Whole blood /Serum/Plasma	1Test/5Tests /25Tests/40Tests
11	COVID-19 neutralizing antibody test kit (Immunochromatography technique)	303060	Whole blood /Serum/Plasma	25Tests
12	COVID-19 neutralizing antibody test kit immunochromatography Analyzer	311001	/	1 Set



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