LYHER®

CE

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)

REF 303035 Cassettes: 25 Tests/40 Tests

Intended Use

The LYHER® 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 nasopharyngeal secretions and oropharyngeal secretions specimens. The kit is **for *in vitro diagnostic use.***

Principle

The immune colloidal gold technique is used in the assay to detect antigens of COVID-19. The reagent binding pad is coated with anti-SARS-CoV-2 monoclonal antibodies which is labeled with colloidal gold marker, respectively. A nitrocellulose membrane in test area of a strip is coated with anti-SARS-CoV-2 antibodies. The quality control area within the nitrocellulose membrane is coated with goat anti-mouse IgG antibodies. When testing, the antibodies against COVID-19 form immuno-complexes with the antigen protein of the virus in the specimen to be tested. As a result of chromatography, immuno-complexes move along the membrane and will be captured by the anti-SARS-CoV-2 antibodies coated in the test area to form a visible line with red color (T line). The free colloidal gold marker or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the quality control area to form a visible line (C line). If the specimen does not contain the antigen of COVID-19, no test line will show, only quality control line(C line) will appear.

Kit Presentation

Materials Supplied

Test device: There are two different packages with 25 or 40 test cassettes containing immobilized anti-SARS-CoV-2 antibodies labeled which is labeled with colloidal gold, anti-SARS-CoV-2 monoclonal antibodies, goat anti-mouse IgG antibodies as a control.

Specimen Tube: There are 25 or 40 tubes, respectively.

Swabs: 25 or 40 Pcs

Specimen extraction buffer: 6 mL x 2 bottles for 25 Tests or 6 mL x 3 bottles for 40 Tests.

Specimen tube dropper tips: 25 or 40 Pcs

Tube Stand: 1 per box.

Note: The Specimen extraction buffer cannot be used with a mixed lot.

Materials Required But Not Provided

Timer, clock or stopwatch

Storage and Stability

1. Store in a dry place at 2-30 ℃, protected from light. The validity is 18 months.
2. In general, the kit shall be used within 30 minutes after the aluminum foil bag is opened. If the temperature is higher than 30 ℃ or the humidity of the environment is higher than 70%, the kit shall be used as soon as possible after opening of the aluminum foil bag.
3. The date for the manufacturing and the expiration date are printed on the outside of the package.

Precautions

- For in vitro diagnostic use only.
- Read this instruction prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Extraction Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin contact with buffer.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- Viral isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are NOT recommended, except in a BSL3 laboratory using BSL3 work practices.

Specimen Collection and Storage

1. Handle all specimens as if they are capable of transmitting infectious agents.
2. Collection of Specimens:

   - Oropharyngeal specimen: With the patient's head slightly lifted up, and the mouth wide open, the patient's tonsils are exposed. With a clean swab, the patient's tonsils are gently rubbed back and forth at least 3 times, and then the patient's posterior pharyngeal wall are rubbed back and forth at least 3 times.

   - Nasopharyngeal specimen: Let the patient's head relax naturally. Turn the swab against the wall of the nostril slowly into the nostril, to the nasal palate, and then rotate while wiping and remove slowly.

   Treatment of Specimen: Add 10 drops (about 0.3ml) of specimen extraction buffer to the specimen tube, insert the swab head into the extraction buffer after specimen collection, mix well, squeeze the swab 10-15 times by compressing the walls of the tube against the swab, and let it stand for 2 minutes to keep as many samples as possible in the specimen extraction buffer. Discard the swab handle.
3. Swab specimens should be tested as soon as possible after collection. Use freshly collected specimens for best test performance.
4. If not tested immediately, swab specimens may be stored at 2-8°C for 24 hours after collection. If long-term storage is required, it should be kept at -70℃ to avoid repeated freeze-thaw cycles.
5. Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.

Quality Control

The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored line located at the "C" region is present before reading the result.

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

Test Procedure

1. Preparing

a) The specimens to be tested and the required reagents shall be removed from the storage condition and be balanced to room temperature;

b) The kit shall be removed from the packaging bag and placed flat on a dry bench.

2. Testing

2.1 Place the test kit horizontally on the table.

2.2 Add specimen

Place the clean dropper tip on the specimen tube and invert the specimen tube so that it is perpendicular to the sample hole (S) and add 3 drops (about 100ul) of the sample. Set timer for 15 minutes.

2.4 Reading the result

The positive specimens can be detected at 15 minutes after sample addition.

Interpretation of Results

POSITVE **NEGATIVE** **INVALID**

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

NEGATIVE: Only one colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Limitations

1. This product is only used for testing of individual nasopharyngeal secretions and oropharyngeal secretions specimens.
2. A negative result does not rule out the possibility of COVID-19 infection.
3. The test results of this product are for clinical reference only and shall not be taken as the sole basis for clinical diagnosis and treatment. The clinical management of patients shall be considered in combination with their symptoms, signs, medical history, other laboratory tests (especially pathogen detection), response to treatment , epidemiology and other information.
4. The LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit is for professional in vitro diagnostic use, and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of color in a positive line should not be evaluated as "quantitative or semi-quantitative".
5. Both viable and nonviable SARS-CoV-2 viruses are detectable with the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit.
6. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
7. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.

Version 3: 10162020

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

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

LIMIT OF DETECTION

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

PRECISION

Tested three specimens with 3 different lots of the product and each specimen was tested for 20 times to demostrate the repeatability of the product. Another study was conducted at 2 different sites by different operators using 3 different lots of product to demonstrate thereproducibility of the product. The results are given below:

Table 2:Repeatability

Specimen	Test Time	Results		
		Lot 1	Lot 2	Lot3
Negative Specimens	20	20/20	20/20	20/20
Cut-off Specimens	20	20/20	20/20	20/20
Positive Specimen	20	20/20	20/20	20/20

Table 3:Reproducibility

Specimen	n	Site 1	Site2
Negative Specimens	20	20/20	20/20
Cut-off Specimens	20	20/20	20/20
Positive Specimen	20	20/20	20/20

CROSS-REACTIVITY

Cross reactivity with the following organism and virus has been studied. Samples positive for the following organisms were found negative when tested with the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit.

Table 4: Cross-Reactivity

Organism	Organism	Organism
Influenza A (H1N1,H3N2,H5N1, H7N9)	Rotavirus	Haemophilus influenzae
Influenza B (Yamagata, Victoria)	Norovirus	Streptococcus pneumoniae
Rhinovirus (Group A,B,C)	Cytomegalovirus	Streptococcus pyogenes
Adenovirus (Type 1,2,3,4,5,7,55)	Measles virus	Candida albicans
Enterovirus (Group A,B,C,D)	Mumps virus	Bordetella pertussis
Respiratory syncytial virus	Legionella pneumonila	Mycoplasma pneumoniae
Varicella zoster virus	Coronavirus (HKU1,OC43,NL63,229E MERS,SARS)	Chlamydia pneumoniae
Herpes simplex virus	Human Metapneumovirus (hMPV)	Mycobacterium tuberculosis
Epstein-Barr virus	Parainfluenza virus (Type 1,2,3,4)	Pneumocystis jirovecii (PJP)

INTERFERING SUBSTANCES

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of the LYHER® Novel Coronavirus (COVID-19) Antigen Test Kit.

Table 5 : Substances having no interfering with Lyher Kit

Substance	Substance	Substance
α-interferon	Ceftriaxone	Hemoglobin
Zanamivir	Meropenem	White blood cells
Ribavirin	Tobramycin	Mucin
Paramivir	Phenylephrine	Mouthwash
Lopinavir	Oxymetazoline	Toothpaste
Ritonavir	Sodium chloride	Dexamethasone Acetate Adhesive Tablets
Abidol	Beclomethasone	Caoshanhu Spray
Levofloxacin	Dexamethasone	Mirabilitum praeparatum
Azithromycin	Flunisolide	Golden Throat Lozenge

Ordering Information

Catalogue No. 303035
Item: Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)
Specimen: Nasopharyngeal and oropharyngeal swab specimens
Format: Cassette

Hangzhou Laihe Biotech Co., Ltd.
1st Floor, Room 505 - 512, 5th Floor, No.2B Building, No.688 Bin'an Road, Changhe Jiedao, Binjiang District, Hangzhou, Zhejiang, People's Republic of China
Tel: 0571-86658001 Fax: 0571-86658000
www.lyherbio.com

EC REP SUNGO Europe B.V.
Add: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Guide to Symbols

	Caution		Keep away from sunlight
	Manufacturer	LOT	Batch Code
	Consult instructions for use		Do not reuse
	Keep dry		Use-by date
REF	Catalogue number	IVD	In vitro diagnostic
	Do not use if package is damaged	30℃ 2℃	Temperature Limitation (2-30℃)
CE	European Conformity	EC REP	Authorized Representative
	Date when manufactured		