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

REF 303002

22-202003/R2

Rx ONLY

IVD

REF 303002
22-202003/R2

For prescription use only.
For in vitro diagnostic use only.
For Emergency Use Authorization (EUA) only.

Instruction for Use

1. INTRODUCTION

1.1 INTENDED USE

The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is a lateral flow immunoassay intended for the qualitative detection of and differentiation of IgG and IgM antibodies to SARS-CoV-2 in serum and plasma (dipotassium-EDTA, lithium-heparin, or sodium-citrate). The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) early after infection in unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different as appropriate, IgG or IgM assay.

The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is only for use under the Food and Drug Administration's Emergency Use Authorization.

1.2 BACKGROUND

The novel coronaviruses belong to the β genus. COVID-19 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.

The *LYHER® Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit* is intended for qualitative detection of antibodies as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2 indicating recent or prior SARS-CoV-2 infection.

2. ABOUT THE LYHER KIT

2.1 TEST PRINCIPLE

The LYHER® Kit uses an immunochromatography based technique in which a colloidal gold-labeled antibody is used as a tracer to detect antibodies. The test panel contains (1) one colloidal gold-labeled recombinant COVID-19 S1 spike protein antigen and quality control antibody colloidal gold marker, (2) two detection lines: G and M, (3) one quality control line: C. The test area of nitrocellulose membrane is coated with mouse anti-human-IgM monoclonal antibody, mouse anti-human-IgG monoclonal antibody and goat anti-mouse antibody were immobilized at test M, G, and C, respectively.

When an appropriate amount of test sample is loaded to LYHER® Kit, it will move along the nitrocellulose membrane. If the specimen contains specific IgM/IgG antibodies against COVID-19, they will be captured by the mouse anti-human IgM/IgG monoclonal antibodies coated in the test area to form a visible strip. If neither antibody is present, a negative result is displayed. The Control Line is used as a procedural control. The control line should always appear if the test procedure is performed properly and the reagents are working as intended.

2.2 ASSAY KIT COMPONENTS

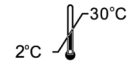
1. Test device: one plate per bag
    a. Sealed in an aluminum foil bag.
    b. Contains immobilized SARS-CoV-2 spike antigen protein and mouse IgG labeled with colloidal gold, respectively.
    c. Goat anti-mouse IgG antibodies as a control.
2. Specimen diluent buffer: 1 vial (4.5mL per vial for 40 tests)
    a. Contains 1.0% NaCl, 0.1% Na2HPO4 and 0.5% Casein.

Note: DO NOT mix components from different kit lots.

2.3 COMPONENTS REQUIRED BUT NOT INCLUDED WITH THE TEST KIT

1. Timer
2. Transfer pipet and pipette tips
3. Venipuncture specimen collection container

2.4 STORAGE INSTRUCTIONS



- Store in a dry place at 2-30 ℃, protected from light.
- The kit shall should be used within 30 minutes after the aluminum foil bag is opened.
- Testing should not be performed when the ambient temperature is higher than 30 ℃ or the relative humidity is higher than 70%.
- The date for the manufacturing and the expiration date are printed on the outside of the package.

2.5 SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle using standard biosafety procedures.

Plasma:

1. Collect blood specimen into a clean, unused tube.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

1. Collect blood specimen into a clean, unused tube.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.

4. Carefully withdraw the serum into a new pre-labeled tube.

Optimal performance of the kit depends upon the use of fresh plasma, serum samples (clear, non-hemolyzed, non-lipemic, non-icteric). The amount of specimen with a minimum volume of 50 μL is recommended in case repeat testing is required. Specimens should be collected aseptically by venipuncture.

Test specimens as soon as possible after collection. If specimens are not tested immediately, store at 2-8°C for up to 2 days. Samples that will not be tested within the time frame outlined above should be stored at ≤ -20 °C [≤ -4 °F]. For frozen samples, avoid more than 1 freeze-thaw cycle. Prior to testing, bring frozen specimens to room temperature slowly and mix gently.

Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

2.6 TEST PROCEDURE

1. For fresh samples, begin with Step 2. For frozen samples, bring the specimens and test components to room temperature, and mix the specimen well once thawed.
2. When ready to test, open the pouch and remove the test device. Place the test device on a clean, flat, dry surface.
3. Label the device with specimen ID number.
4. Add specimens:
    - Serum/Plasma: Take 10 μL of serum or plasma with a pipette into sample well (S), and then add vertically 2 drops (about 100 μL) of specimen diluent.
5. Set timer for 10 minutes.
6. Read the results at 10 minutes but no longer than 15 minutes.

3. WARNINGS AND PRECAUTIONS

⚠ **CAUTION:** The samples of this assay contains human sourced and/or potentially infectious components. As no known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. These human specimens should be handled as if infectious using laboratory safety procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories, OSHA Standards on Bloodborne Pathogens, CLSI Document M29-A4, and other appropriate biosafety practices. Therefore all human sourced materials should be considered infectious. These precautions include, but are not limited to, the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectants.
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.

The LYHER® Kit's specimen diluent buffer contains the following components:

- Sodium Chloride (EC no. 231-598-3)
- Disodium hydrogen phosphate (EC no. 231-448-7)
- Casein (EC no. 232-555-1)

The following warnings apply:

Warning

H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H315	Causes skin irritation
H402	Harmful to aquatic life*
H412	Harmful to aquatic life with long lasting effects
P261	Avoid breathing mist/vapors/spray
P264	Wash hands thoroughly after handling
P280	Wear protective gloves/protective clothing/eye protection
P273	Avoid release to the environment
P302 + P352	IF ON SKIN: wash with plenty of water
P333 + P313	If skin irritation or rash occurs: get medical advice/attention
P362 + P364	Take off contaminated clothing and wash before reuses
P305 + P351 + P338	IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: get medical advice/attention.
P501	Dispose of contents/container in accordance with local regulations.

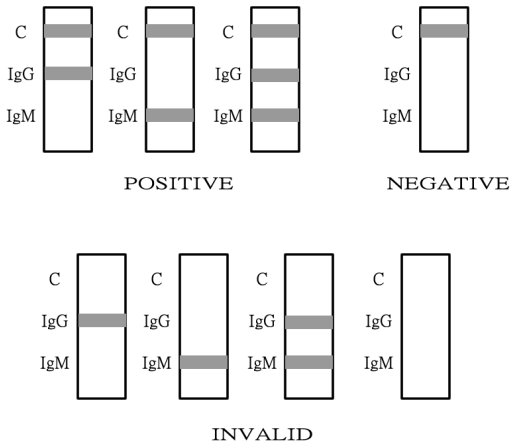
**** Not applicable where regulation EC 1272/2008 (CLP) has been implemented.**

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet. It is available from your local distributor.

1. As with any test procedure, good laboratory practice is essential to the proper performance of this test. The LYHER® Kit should be performed by qualified and trained staff to avoid the risk of erroneous results.
2. For in vitro diagnostic use only. For prescription use only.
3. This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
4. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
5. All patient samples should be handled as if infectious, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories and in the CLSI Document M29-A4.3 Only personnel proficient in handling infectious materials and the use of the Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit should perform this procedure.
6. Closely follow procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect optimal test performance.

7. False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.
8. The *LYHER® Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit* is only for use with serum, plasma that have been handled and stored as described in the Section 2.4 and 2.5 of this package insert.
9. Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality.
10. During preparation of samples, compliance with good laboratory practices is essential to minimize the risk of cross-contamination between sample.
11. Excessive or inadequate samples may yield false or invalid results.
12. Components contained in the LYHER® Kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the device from lot X with the specimen diluent buffer from lot Y.
13. Do not use kits or reagents after the expiration dates shown on the labels.
14. Work area must be considered potential sources of contamination. Change gloves after contact with potential contaminants (specimens) before handling unopened reagents, or specimens.
15. The test kit is sealed in a protective foil pouch. Do not use if pouch is damaged or open. Remove test kit from pouch just prior to use. Do not touch the reaction area of test kit.
16. Do not use damaged test kit. Do not reuse the test kit.
17. Decontaminate and dispose of all potentially biohazardous materials in accordance with local, state, and federal regulations. All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.
18. Humidity and temperature can adversely affect results.

3.1 INTERPRETATION OF THE RESULT



- IgG POSITIVE: * Two lines appear. The result is positive for IgG antibodies to the SARS-CoV-2. One colored line should be in the control line region (C), and a colored line appears in the IgG test line region.
- IgM POSITIVE: *Two lines appear. The result is positive for IgM antibodies to the SARS-CoV-2. One colored line should be in the control line region (C), and a colored line appears in the IgM test line region.
- IgG and IgM POSITIVE: *Three lines appear. The result is positive for both IgM and IgG antibodies to the SARS-CoV-2. One colored line should be in the control line region (C), and two-colored lines should appear in IgG test line region and IgM test line region.

  ***NOTE:** The intensity of the color in the test line regions will vary depending on the antibodies against the novel coronavirus present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
- NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the IgG or IgM

test region (T).

- INVALID: Control line fails to appear. Insufficient sample volume or incorrect procedural techniques 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, discontinue using the test kit immediately and contact your local distributor.

3.2 QUALITY CONTROL PROCEDURE

A built-in procedural control on the card ensures that the test has been performed correctly; this pink/red colored lines should always appear above the printed C line on the card. If a line does not appear in the control region, discard the card as this is an invalid test and perform the test again.

CFUS Series 1000 and LHZG Series 2000 have been validated for use with this test kit. External positive and negative controls should be tested consistent with good laboratory practice to confirm the test procedure and to verify proper test performance. Both CFUS Series 1000 and LHZG Series 2000 can be procured by contacting your local distributors or LYHER directly. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations.

4. LIMITATIONS

For use under an Emergency Use Authorization only.

1. Use of *LYHER® Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit* is limited to laboratory personnel who have been trained. Not for home use.
2. The test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
3. Performance has only been established with the specimen types listed in the Intended Use. This product is only used for testing of individual serum, plasma samples. Other specimen types have not been evaluated and should not be used with this assay.
4. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.
5. Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
6. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
7. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the qSARS-CoV-2 IgG/IgM Rapid Test early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings.
8. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
9. False positive results may be produced if the amount of the added specimens exceeds the amount specified in this instruction.
10. False negative results may arise from degradation of the antibodies during shipping/storage.
11. Serological antibody testing is of limited reference value in patients with impaired immune function or receiving immunosuppressive therapy.

12. The target detection object of this product is IgM/IgG antibodies to the SARS-CoV-2. The positive results do not directly reflect the presence of SARS-CoV-2 in the specimen of the patient.
13. The kit should be used within 30 minutes after the aluminum foil bag is opened.
14. Testing should not be performed when the ambient temperature is higher than 30 ℃ or the relative humidity is higher than 70%.
15. The test should not be used for screening of donated blood.
16. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

5. CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas
Authorized laboratories using the LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Hangzhou Laihe Biotech (email: office@lyher.com; toll-free number: 1-800-965-0679) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Hangzhou Laihe Biotech Co., Ltd., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

***The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."**

6. PERFORMANCE CHARACTERISTICS

6.1 CLINICAL PERFORMANCE

A total of 527 prospective and retrospective samples were obtained for this study. The PCR positive samples were collected at four medical centers. Prospective specimens include samples from patients who tested positive for SARS-CoV-2 using nucleic acid tests, samples from patients who recovered from COVID-19, and samples from individuals who had contact with COVID-19 patients but tested negative with a SARS-CoV-2 nucleic acid test. The SARS-CoV-2 negative specimens include specimens that tested negative by a local hospital, specimens from patients with other respiratory infections, and random specimens collected prior to August 2019.

Among the 178 specimens that were PCR positive, 90 were from patients who were still in quarantine and 88 were from recovered patients. Among the 349 negative specimens in this trial, 239 of them were from patients with coronavirus infections not caused by SARS-CoV-2, and 110 of them were patients with other respiratory tract infections (all 110 cases were retrospective frozen specimens collected before August 2019).

Positive Results by Days After Onset of Symptoms (n=178)

Days from Symptoms Onset to Blood Collection	Number of PCR Positive Sample	LYHER IgM/IgG Antibody Combo Test Result				Positive Percent Agreement	
		IgM+	IgG+	Both IgM/IgG+	Both IgM/IgG-	IgM	IgG
≤ 6 days	23	23	0	0	0	23/23=100%	0/23=0.00%
7 – 14 days	21	5	0	13	3	18/21=85.71%	16/21=76.19%
>14 Days	134	2	1	131	0	133/134=99.25%	132/134=98.50%

Negative Results (n=349)

Number of PCR Negative Sample	LYHER IgM/IgG Antibody Combo Test Result				Negative Percent Agreement	
	IgM-	IgG-	Both IgM/IgG+	Both IgM/IgG-	IgM	IgG
349	347	347	0	347	347/349=99.43%	347/349=99.43%

Independent Clinical Agreement Validation

The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) was tested on 6/10/2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the COVID-19 IgG/IgM Rapid Test Cassette (Serum/Plasma). The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using one lot of the COVID-19 IgG/IgM Rapid Test Cassette (Serum/Plasma). Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

Summary Results

COVID-19 IgG/IgM Rapid Test Cassette (Serum/Plasma)		Comparator Method			
		Positive (IgM/IgG) +	Negative (IgM/IgG)-	Negative, HIV+	Total
Positive	IgM +/ IgG+	29	0	0	29
	IgM+, IgG-	0	0	0	0
	IgM-, IgG+	1	1	0	2
Negative	IgM- / IgG)-	0	69	10	79
Total (n=110)		30	70	10	110

Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
IgG Sensitivity	100% (30/30)	(95.4%; 100%)
(IgM+ or IgG+; Total) Sensitivity (PPA)	100% (30/30)	(88.7%; 100%)
(IgM-/IgG-; Total) Specificity (NPA)	98.8% (79/80)	(93.3%; 99.8%)
Cross-reactivity with HIV+	0% (0/10) not detected	

6.2 CROSS-REACTIVITY

Cross-reactivity of the LYHER® Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit was evaluated in two studies using a total of 137 serum or plasma samples which contain antibodies to the pathogens listed below. All 137 specimens were negative by the LYHER® Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit. The data are summarized in the following table:

No.	Type of Specimens	Number of Samples	LYHER IgM/IgG Antibody Combo Test Result	
			Total IgM Neg	Total IgG Neg
H1N1-1~H1N1-3	Anti-H1N1 IgM and IgG Positive	3	3	3
H3N2-1	Anti-H3N2 IgM and IgG Positive	1	1	1
H5N1-1~H5N1-2	Anti-H5N1 IgM and IgG Positive	2	2	2
H7N9-1~H7N9-2	Anti-H7N9 IgM and IgG Positive	2	2	2

Yamagata-1	Anti-Yamagata IgM and IgG Positive	1	1	1
Victoria-1~Victoria-4	Anti-Victoria IgM and IgG Positive	4	4	4
RSV-1~RSV-2	Anti-RSV IgM and IgG Positive	2	2	2
RUB-1~RUB-4	Anti-RUB IgM and IgG Positive	4	4	4
CMV-1~CMV-5	Anti-CMV IgM and IgG Positive	5	5	5
VZV-1~VZV-3	Anti-VZV IgM and IgG Positive	3	3	3
HSV-1~HSV-6	Anti-HSV IgM and IgG Positive	6	6	6
EBV-1~EBV-5	Anti-EBV IgM and IgG Positive	5	5	5
Rotavirus-1~Rotavirus-10	Rotavirus Antigen Test Positive	10	10	10
Adenovirus-1~Adenovirus-2	Anti-Adenovirus IgM and IgG Positive	2	2	2
Measles-1	Anti-Measles IgM and IgG Positive	1	1	1
Enterovirus-1~Enterovirus-3	Anti-Enterovirus IgM and IgG Positive	3	3	3
Mumps-1~Mumps-3	Anti-Mumps IgM and IgG Positive	3	3	3
HIV-1	Anti-HIV IgM and IgG Positive	1	1	1
Bacterium.P-1~Bacterium.P-2	Bacteriologic Test Positive	2	2	2
Chlamydia-1~Chlamydia-3	Anti-Chlamydia IgM and IgG Positive	3	3	3
M.P-1	Anti-Mycoplasma Pneumoniae IgM and IgG Positive	1	1	1
Legionella-1~Legionella-2	Anti-Legionella IgM and IgG Positive	2	2	2
Strep.P-1	Streptococcus Pneumoniae Antigen Test Postive	1	1	1
Staphyl.-1~Staphyl.-2	Bacteria culture result Positive	2	2	2
RF-1~RF-2	Anti-RF IgM and IgG Positive	2	2	2
ANA-1	ANA Positive	1	1	1

Sample Category	**Number of Samples**	**LYHER IgM/IgG Antibody Combo Test Result**					
		IgM			**IgG**		
		Pos	**Neg**	**%CR**	**Pos**	**Neg**	**%CR**
Anti-influenza A IgG Positive	5	0	5	0%	0	5	0%
Anti-influenza A IgM Positive	5	0	5	0%	0	5	0%
Anti-influenza B IgG Positive	5	0	5	0%	0	5	0%
Anti-influenza B IgM Positive	5	0	5	0%	0	5	0%
Anti-HCV IgG Positive	5	0	5	0%	0	5	0%
Anti-HCV IgM Positive	5	0	5	0%	0	5	0%
Anti-HBV IgG Positive	5	0	5	0%	0	5	0%
Anti-HBV IgM Positive	5	0	5	0%	0	5	0%
ANA Positive	5	0	5	0%	0	5	0%

Anti-respiratory syncytial virus IgG Positive	5	0	5	0%	0	5	0%
Anti-respiratory syncytial virus IgM Positive	5	0	5	0%	0	5	0%
Anti- Haemophilus influenzae IgG Positive	5	0	5	0%	0	5	0%
Anti- Haemophilus influenzae IgM Positive	5	0	5	0%	0	5	0%

Key to Symbols Used

For Prescription Use Only


Caution


Warning


Manufacturer

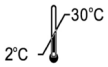

Date when the medical device was manufactured


Consult Instructions For Use

In Vitro Diagnostic Medical Device

Lot number


Use by



Temperature Limitation(2-30℃)

Catalogue Number


Corrosive


Do not reuse


Do not use if package is damaged


Keep dry

IN VITRO DIAGNOSTIC MEDICAL DEVICE TECHNICAL ASSISTANCE

For technical assistance, call Laihe Technical Services at +86 571 8665 8001or +1 (888) 291-2286, email office@lyher.com or chenyaohua9569@dingtalk.com, or visit Laihe website at http:// www.lyherbio.com

Hangzhou Laihe Biotech Co., Ltd.

1st Floor, Room 505 - 512, 5th Floor, No.2B Building, No.688, Bin'an Road, Changhe Jedao, Binjiang District, Hangzhou, Zhejiang, People's Republic of China.

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