Declaration of Conformity

Declaration of Conformity for CE Certification of COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Declaration of Conformity

Manufacturer : **JOYSBIO (Tianjin) Biotechnology Co., Ltd.**
Tianjin International Joint Academy of Biotechnology &Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China

Whose single Authorized EU-Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049-1715605732
E-mail: info.m@luxuslw.de

Product Name: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 18113-2:2011	EN ISO 23640:2015
EN13975:2003	EN13612:2002

Signature: Sen Wang 2020.3.18
Name: Wang Sen
Title: General Manager
Position: TEDA Tianjin, China

EC Declaration of Conformity
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CE

Medical device export record certificate

天津市医疗器械出口备案凭证

备案号：津滨20200006

生产企业名称	正元盛邦（天津）生物科技有限公司		
生产地址	天津市开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层		
是否具有生产许可证或者备案	是	生产许可/备案编号	津食药监械生产许20100326
是否具有第三方认证	是	第三方认证机构	TUV莱茵检测认证服务（中国）有限公司
联系方式	13821759311		
出口产品名称	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)		
是否境内注册/备案	否	注册号/备案号	
出口企业名称	自营出口		
出口企业地址	自营出口		
销往国家（地区）	盟成员国：法国、德国、意大利、荷兰、比利时、卢森堡、丹麦、爱尔兰、希腊、葡萄牙、西班牙、奥地利、瑞典、芬兰、马耳他、塞浦路斯、波兰、匈牙利、捷克、斯洛伐克、斯洛文尼亚、爱沙尼亚、拉脱维亚、立陶宛、罗马尼亚，保加利亚、克罗地亚。EEA、瑞士、和土耳其，挪威，柬埔寨，越南，韩国，日本，菲律宾，黎巴嫩，泰国，新加坡，巴基斯坦，伊朗，澳洲，马来西亚，印度尼西亚，沙特，尼泊尔		
是否境外委托境内生产	否	是否获准境外上市	是
境外委托企业名称			
境外委托企业地址			
出口合同编号	无	出口合同期限	2021-03-31
产品规格	卡型、条型		
包装规格	20人份/盒（1人份/袋×20袋）、40人份/盒（1人份/袋×40袋）50条（1人份/袋×50袋）100条（1人份/袋×100袋）		
出口数量	2000000		
本企业承诺保证所生产出口的医疗器械符合进口国（地区）的要求，所提交的全部备案资料真实有效，并承担一切法律责任。 法定代表人（签字）：　　（企业盖章）			
备案部门（公章）： 备案日期：2020年03月20日			

Medical device export record certificate of COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-07
Certificate Registration No.:	SX 60143180 0001
An audit was performed. Report No.:	16806278 004
This Certificate is valid until:	2022-10-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland

Date 2020-06-05

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc 1/1, Rev 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60143180 0001
Report No.: 16806278 004

Organization:
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

Scope:
Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits used in the Detection of Cancer, Cardiac Markers, Fertility Testing, Pregnancy Testing, Drugs of Abuse, Sexually Transmissible Agents, Infection Diseases including Home Use In-vitro Diagnostic Medical Devices

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Date: 2020-06-05

Jing Zhang

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
R.A.C. Ori

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201797

Bijlagen
-

Uw aanvraag
29 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 12 mei 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 29 april 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam JOYSBIO (Tianjin) Biotechnology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-50908)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, JOYSBIO (Tianjin) Biotechnology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

Clinical Research Report

1.Name and Lot No. of the kit

Name: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Lot No.: Cassette： 2020022101

Strip： 2020022101

2. Manufacturer

Name: JOYSBIO(Tianjin) Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China

Summary of Research

Entrusted by JOYSBIO(Tianjin) Biotechnology Co., Ltd. (hereinafter referred to as "JOYSBIO"), Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital implemented clinical test on Diagnostic kit for COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)researched and produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd. according to Guiding Principle for Clinical Research Technology of In Vitro Diagnostics Reagent (CFDA MD(2014) 16).

The kit to be evaluated uses immunochromatography and the principle of Capture ELISA to qualitatively detect COVID-19 IgG/IgM Antibodies in human serum (or plasma or whole blood) for clinical auxiliary diagnosis. The test kit is produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd.
Lot No. 2020022101, Specification: 50 Test Kit /box, Type: Strip
Lot No. 2020022101, Specification: 20 Test Kit /box, Type: Cassette
Shelf life: 24 months

Strip Type

In this clinical study, a total of 300 samples were tested, including 160 confirmed samples of novel coronavirus and 140 negative samples. Result: among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of the assessed kits is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

Cassette Type

In this clinical study, a total of 300 samples were tested, including 160 confirmed samples of novel coronavirus and 140 negative samples. Result: among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of the assessed kits is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.The results of clinical study show that this kit is reliable, accurate, convenient, and has high clinical application value.

Introduction

1. Source, biological and physicochemical properties of analyte The 2019 novel coronavirus, known as the " COVID-19", was found due to viral pneumonia cases in Wuhan in 2019 and was named by the world health organization on January 12, 2020.Coronaviruses are a large family of viruses known to cause colds and more serious illnesses such as Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS). The novel coronavirus is a new strain of coronavirus that has never been found in humans before.China has reported tens of thousands of laboratory-confirmed cases, and the number is rising daily. Most reports have come from Hubei and surrounding provinces, while many cases have also been reported from other provinces and municipalities. Sporadic cases are also being reported in other countries, including Asian and European countries, Australia, the United States (Washington, Illinois, California, Arizona and Massachusetts) and Canada. Human-to-human transmission of COVID-19 has been confirmed in China and has been found in other countries, including the United States. So far the dissemination risk of this novel coronavirus is not clear. The main manifestations of the disease are fever,

cough, dyspnea, and chest imaging findings of double lung infiltration, and the incubation period is within 14 days after exposure. Although many of the cases reported so far are not severe, about 20% of those diagnosed are in critical condition, with respiratory failure, septic shock or other organ failure requiring intensive care. Most of the deaths were due to underlying complications.

Whole-genome sequencing and phylogenetic analysis showed that the COVID-19 is a novel β coronavirus, which belongs to a different evolutionary branch from the severe acute respiratory syndrome (SARS) and MiddleEast respiratory syndrome (MERS) related novel β coronavirus. The COVID-19 is very similar to the bat coronavirus, and bats are likely to be the main source, but it is unclear whether it is transmitted directly from bats to humans or through other mechanisms, such as with some intermediate hosts.

2. Expected clinical using purpose and the diagnosis methods applied to such adaptation disease at present

At present, there are mainly nucleic acid detection (RT-PCR) and colloidal gold immunochromatography (GICA). Compared with nucleic acid detection, the rapid diagnostic kit for COVID-19 is suitable for samples of serum, plasma and whole blood. It is convenient, rapid and highly sensitive, and suitable for large-scale screening. Results can be obtained within 15 minutes. At the same time, cross contamination between samples can be avoided by using single reagent strips. In addition, it can reduce the exposure risk of health care workers and facilitate early diagnosis and exclusion of suspicious cases.

3. Testing principle and detection method of the product

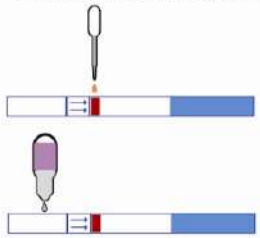
Test principle: This reagent uses immunochromatographic colloidal gold technique to detect 2019-ncov (COVID-19) IgG/IgM antibodies in samples.The detection card contains:

1) Recombinant COVID Antigen labeled colloidal gold Cellulose Membrane fixed with three lines (G line and M line) and one quality control line (C line) .The M line was coated with mouse anti-human IgM antibody for detection of 2019-ncov (COVID-19) IGM antibody .The G line was coated with mouse anti-human IgG antibody for detection of 2019-ncov (COVID-19) IgM antibody. The C line was coated with sheep anti-chicken antibody. When specimen is added to sample well, capillary effect causes the fluid to flow to the NC membrane, COVID IgM (if present) will bind with mouse anti-human IgM and the M line will be visible., COVID IgG (if present) will bind with mouse anti-human IgG and the G line will be visible. No matter whether the specimen is positive or negative, the C line should be visible, otherwise the test is invalid.

Test method:

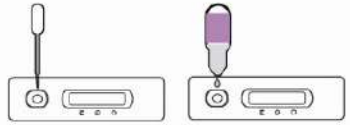
Completely read the manual of the products before test.

Strip Type (figure 1)



1. Restore the test strip (without opening the foil bag) to room temperature.
2. Remove the foil pouch from the box and open it, take out the strip, and lay it flat on a table.
3. Draw 10μl of serum/plasma sample or 20μl of whole blood sample with a quantitative dropper and add to the exposed purplish colloidal gold of the strip (arrow pointing). Then add 2 drops of diluent vertically to the sample pad at the lower end of the strip.
4. The experimental results were interpreted and recorded in 15～20 minutes, but were not valid in 20 minutes. (when a strongly positive sample is tested, a positive result can appear in 1-3 minutes.)

Cassette Type (figure 2)



1. Restore the test strip (without opening the foil bag) to room temperature.
2. Remove the foil pouch from the box and open it, take out the cassette, and lay it flat on a table.
3. Draw 10μl of serum/plasma sample or 20μl of whole blood sample with a quantitative dropper and add to hole A. Then add 2 drops of diluent vertically to hole B.
4. The experimental results were interpreted and recorded in 15～20 minutes, but were not valid in 20 minutes. (when a strongly positive sample is tested, a positive result can appear in 1-3 minutes.)

1. Test purpose

The purpose of the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) clinical trial is to verify the accuracy of this product in clinical test by verifying a certain number of confirmed samples of novel coronavirus, so as to judge whether the safety and effectiveness requirements of the marketed products have been met.

2. Test Management

The Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) is developed and produced by JOYSBIO(Tianjin) Biotechnology Co.,Ltd., and the clinical evaluation was conducted by Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital. Before implementation of the test, JOYSBIO(Tianjin) Biotechnology Co., Ltd. and representatives of

Hanyang District Central Health Examination Centre, Wuhan, Heilongjiang Hospital, Tianjin Center for Disease Control and Prevention admission hospital should discuss together. According to relevant regulations of "Clinical Research Technical Guidelines and Rules of IVD Reagents" etc., both parties should sign clinical test protocol and design clinical test scheme to clarify test purpose, content and responsibilities of both parties. Before the start of clinical research, participants in the research must be familiar with and master the operation of the product, technical performance, etc., so as to do their utmost to take control of the experimental error as well as unify record method and judgment standard; Researcher should fill in every item in detail and faithfully according to record chart to make sure content of record chart is complete, true and reliable; all observed results should be verified to ensure every conclusion in clinical trial is derived from the original records; there should be corresponding data management measures in clinical trial and data processing phases. During the clinical research any other situation outside the scheme shall be settled by the parties through negotiation.

3. Test Content

3.1. Selection of test subjects

1) Age and gender are not limited
2) Can provide enough test specimens as required
3) Confirmed samples of novel coronavirus
4) Consider cases of suspected influenza, respiratory syncytial virus, enterovirus, adenovirus and other viral infections

3.2. Information of the test reagent

The test reagent is Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced

by JOYSBIO(Tianjin) Biotechnology Co., Ltd.. There are two types, including strip-type and cassette-type, and one batch of each type is used. Strip type: specification is 50 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding. Cassette type: specification is 20 Test Kit/box; batch number is 2020022101, valid for 24 months, the preservation condition is 4-30 ° C, dry and light-avoiding.

3.3. Sample collection and serial number

Serum samples were collected intravenously in the conventional way. The samples to be tested within five days can be stored at 4 ℃, and the samples can be stored at -20 ℃ for at least six months.Avoid repeated freezing-thawing of samples as far as possible. Number the samples (001-100) to avoid sample disorder.

3.4. Test procedures

3.4.1. Read instruction book

Sample provider first should read the instructions for the diagnostic kit carefully, to learn about sample adding, time for result determination and the basis of result interpretation.

3.4.2. Specific operations

The researchers tested the numbered samples with the test reagent and recorded the test results faithfully after the corresponding number in the clinical trial registration form. Samples should be used as soon as possible after collection. Samples to be tested within five days can be stored at 4 ℃. The specimens can be stored at -20 ℃ for at least six months. Avoid repeated freezing-thawing of samples as far as possible.

4.Arrangement and analysis of clinical test results

4.1.Arrangement and analysis of strip-type diagnostic kit results

For the strip-type diagnostic kits assessed, the specification is 50 Test Kit/box, batch number is 2020022101,and the number of samples tested is 300. The results are as follows:

Assessed reagent-Strip-type diagnostic kits		Clinical diagnosis	
		+	-
	+	160	0
	-	3	140

The results indicate that among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of this kit is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

4.2.Arrangement and analysis of strip-type diagnostic kit results For the cassette-type diagnostic kits assessed, the specification is 20 Test Kit/box, batch number is 2020022101, and the number of samples tested is 300. The results are as follows:

Assessed reagent-Cassette -type diagnostic kits		Clinical diagnosis	
		+	-
	+	160	0
	-	3	140

The results indicate that among the 160 positive samples, 3 case was inconsistent according to the comparison of test kit results, while the results of 140 negative cases were all in conformance according to the comparison of test kit results. Through statistical analysis, the sensitivity of this kit is 98.12%, the specificity is 100%, the false positive rate is 0%, the false negative rate is 1.88%, and the total conformity rate is 99%.

5. Discussion and Conclusion

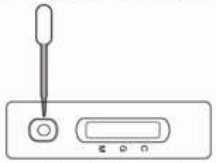
In the process of test, the researchers carefully read the instructions and independently completed the operation of the assessed reagent kits to avoid the result error caused by improper operation. They filled in the test record faithfully, thus ensuring the reliability of the data. Through the analysis of the test data, we can see that the two types (strip type, cassette type) of the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd.are highly consistent with the results of confirmed samples. A high coincidence rate indicates that the Diagnostic kit for COVID-19 IgM/IgG Antibodies (Colloidal Gold) produced by JOYSBIO(Tianjin) Biotechnology Co., Ltd. is reliable, accurate, safe, convenient, stable and has high clinical application value.

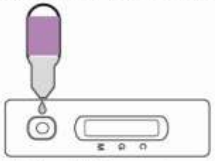
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
For in vitro diagnostic use only

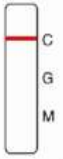
【PRODUCT NAME】
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
【PACKAGE AND SPECIFICATION】
Cassette : 20Test Kit/Box (1Test/Bag ×20 Bags)、40 Test /Box (1Test / Bag ×40 Bags)
【INTENDED USE】
This product is used for in vitro qualitative detection of 2019-ncov (COVID-19) IgG/IgM antibodies in human whole blood, plasma and serum samples.This product is suitable for the auxiliary diagnosis of 2019-ncov (COVID-19) infection.2019-ncov (COVID-19) , mainly transmitted by inhalation and direct contact, is one of the main pathogens causing upper respiratory tract infection and lung diseases.It can cause the changes of the extrapulmonary system, which has aroused great concern.Timely and effective laboratory diagnosis of 2019-ncov (COVID-19) infection becomes particularly important
【PRINCIPLE】
This reagent uses immunochromatographic colloidal gold technique to detect 2019-ncov (COVID-19) IgG/IgM antibodies in samples.The detection card contains: 1) Recombinant COVID Antigen labeled colloidal gold .2) Cellulose Membrane fixed with three lines (G line and M line) and one quality control line (C line) .The M line was coated with mouse anti-human IgM antibody for detection of 2019-ncov (COVID-19) IGM antibody .The G line was coated with mouse anti-human IgG antibody for detection of 2019-ncov (COVID-19) IgM antibody. The C line was coated with sheep anti-chicken antibody.When specimen is added to sample well, capillary effect causes the fluid to flow to the NC membrane,COVID IgM (if present) will bind with mouse anti-human IgM and the M line will be visible., COVID IgG (if present) will bind with mouse anti-human IgG and the G line will be visible.No matter whether the specimen is positive or negative, the C line should be visible, otherwise the test is invalid.
【COMPONET】

COMPONENT	20Test Kit/Box	40Test Kit/Box	Main components
Test Kit	20Test Kit/Box (1Test/Bag ×20 Bags)	40Test Kit/Box (1Test/Bag ×40Bags)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the quality control lines were coated with sheep anti-chicken antibody, and the colloidal gold pad contained recombinant COVID Antigen labeled colloidal gold .
Dryer	20Bags	40Bags	Silica Gel
Specimen Diluent	1Bottle(5mL)	1Bottle(8mL)	Solution of trimethylaminomethane hydrochloride(0.02M Tris-HCl)

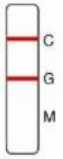
2.Plasma and serum :Collect the specimen with a pipettor, Add 10μl plasma and serum into sample well,Add 1~2 drops diluent into sample well .Whole blood: Collect the specimen with a pipettor, Add 20μl whole blood into sample well,Add 1-2drop diluent into sample well .
3.Start timing .The result should be read at 15-20minutes.The result is invalid after 20 minutes.


Add specimen into sample well

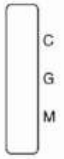

Add diluent into sample well

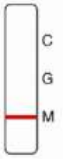


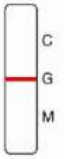
Negative (-)

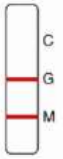


Positive (+) Positive (+) Positive (+)









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【STORAGE AND STABILITY】
The kit can be stored at cool ,dark place. (4-30°C). Valid for 24 months.After opening the inner package, the detection reagent will lose its efficacy due to moisture absorption and should be used within 30 minutes.
【SPECIMEN REQUIRMENTS】
1.Can be used to detect whole blood, plasma and serum specimen.
2. Specimen were collected as general manner.
3. The Specimen which need to be test within 5 days can be stored at 4℃, and if the plasma and serum specimen which need to be test more than 5days should be frozen at -20℃.The test kit should be carried out freeze-thaw in -20℃ no more than 6 times .Do not freeze and thaw samples repeatedly.
4. Whole blood, plasma and serum shall be collected and stored in sterile conditions .Avoid sample hemolysis , Samples contaminated with bacteria cannot be used for testing.
【TEST PROCEDURE】
1.Remove test kit, specimen to room temperature .Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface.
【TEST METHOD】
1.In the early stage of infection, no IgG/IgM is produced or the titer is very low, which will lead to negative results. The patient should be prompted to review within 7-14 days.
2.In patients with impaired immune function or receiving immunosuppressive therapy, serological antibody detection is of limited reference value.
3.IgG/IgM antibody positivity occurs not only in primary infection but also in secondary infection.
【PRODUCT PERFORMANCE 】
The performance of the product was tested with the enterprise new coronavirus-igg /IgM antibody for Internal control blood test, meeting the following requirements:
1.Negative reference product compliance rate: 10 negative serums in the internal control blood liquidation were tested, and the compliance rate was 10/10.
2.Positive reference product Compliance rate: 10 positive serums in the internal control blood liquidation were tested, and the compliance rate was 10/10.
3.Minimum detection amount: the minimum detection amount of serum in the internal control blood liquidation test, L1 should be negative, L2 and L3 should be positive.
4.Precision: 10 detection reagents were tested in parallel with the precision serum of internal controlled blood liquidation, and the detection results were consistent and the chroma was uniform.
5.Stability: after being placed at 37℃ for 14 days, the test should meet the above requirements.
6.Cross reaction: with mycoplasma pneumoniae (MP) - IgM, chlamydia pneumonia (CP) - IgM, syncytial virus (RSV), influenza virus that the IgM (FluV) and mycobacterium tuberculosis (TB), hepatitis c virus (HCV), syphilis antibodies (TP), hepatitis b surface antigen (HBsAg), the AIDS virus (HIV), rheumatoid factor (RF) and antinuclear antibody (ANA) positive samples basic no cross reaction.
7.Interference: there was no interference when compared with the samples containing 15mg/mL triglyceride, 6mg/mL hemoglobin and 0.2mg/mL bilirubin, respectively.
【 WARNINGS AND PRECAUTIONS】
1.Please operate in strict accordance with this instruction and strictly control the reaction time.
2.This kit is a disposable product, which is only used for external diagnosis.The test results should be judged synthetically with other test indexes and medical characteristics.
3.The test of samples must be carried out in a specific environment. The blood samples in contact during the test should follow the laboratory test procedures for infectious diseases.
4.The small cup containing the serum must be clean and not reusable to avoid contamination.Test samples should be avoided from repeated freeze-thaw, and samples contaminated with bacteria should not be used for testing, so as not to affect the test results.Samples stored at 4℃ must be balanced to room temperature before use.
5.Guard against moisture in the test strip. Use the test kit within 30 minutes after opening the inner package.
【REFERRENCE 】
1. 《China biological product code》
2. 《Guidelines for preparation of in vitro diagnostic reagent specifications》
3.Daxboeck F, Krause R, Wenisch C. Laboratory diagnosis of Mycoplasma pneumoniae infection[J]. Clin Blicrobiol Infect, 2003, 9(6): 263-273.
【MANUFACTURE 】
Name:JOYSBIO(Tianjin) Biotechnology Co., Ltd.
Add:Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China Tel: +0866-022-65378415 Fax: +0866-022-65378415

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Instructions for Use (IFU)

【PRODUCT NAME】

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

【PACKAGE AND SPECIFICATION】

20Tests/box (1Test/bag ×20 Bags) 、40 Tests /box (1Test / bag ×40 Bags)

【INTENDED USE】

For in vitro qualitative determination of the content of COVID-19 IgG/IgM antibody in human serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

For in vitro diagnostic use only. For professional use only

【TEST PRINCIPLE】

In this kit, IgG antibody and IgM antibody of novel coronavirus (COVID-19) were detected by immunocapture method. Mouse anti-human IgM antibody, mouse anti-human IgG antibody and goat anti-chicken IgY antibody were coated with cellulose nitrate membrane. Recombinant novel coronavirus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.

Add the sample to the sample loading well of test strip; and the sample flows through the blood filter film (filter red blood cells).If the sample contains the novel coronavirus IgM antibody, it can combine with colloidal gold labeled novel coronavirus antigen to form a complex, which is captured by the mouse anti-human IgM antibody coated with colored band (M line).If the sample contains the novel coronavirus IgG antibody, it can combine with colloidal gold labeled novel coronavirus antigen to form a complex, which is captured by the mouse anti-human IgG antibody coated with colored band (G line). The colloidal gold labeled chicken IgY antibody is bound to the goat anti- chicken IgY antibody coated with a colored band (C line), which acts as a control line.

【COMPONENT】

COMPONENT	20Tests/box	40Tests/box	Main components
Test Kit	20Tests/box (1Test/bag ×20 Bags)	40Tests/box (1Test/bag ×40Bags)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the control line was coated with goat anti-chicken antibody, Recombinant novel coronavirus antigen and chicken IgY antibody labeled by colloidal gold are as tracers.
Desiccant	20 pouchs	40 pouchs	Silica Gel
Sample Diluent	1Bottle(4mL)	2Bottles(8mL)	Solution of trimethylaminomethane hydrochloride(0.02M Tris-HCl)

【STORAGE AND STABILITY】

1. Store at 4~30ºC in the sealed pouch up to the expiration date, and the validity is tentatively 12 months. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the aluminum foil bag. Sample diluent should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.

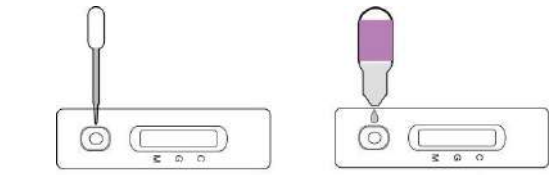
【SPECIMEN COLLECTION AND PREPARATION】

1. The recommended samples for this kit are serum, plasma, whole blood. Plasma and whole blood can be collected by blood collection tube or centrifuge tube with EDTA-2K or heparin sodium anticoagulant.

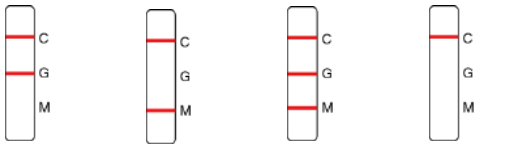
2. The samples collected with the correct medical technology should be returned to room temperature before testing. Jaundice, hemolysis, lipemia, and cloudy samples cannot be used. Severe hemolytic or heat-inactivated specimens are not recommended.
3. Samples should be tested as soon as possible. If the test cannot be completed within 8 hours, the samples can be stored at 4℃perature. Serum samples and plasma samples can be stored for 7 days at 4℃ or for 6 months at -20℃, and whole blood can be stored for 3 days at 4℃. Do not freeze and thaw samples repeatedly.

【TEST METHOD】

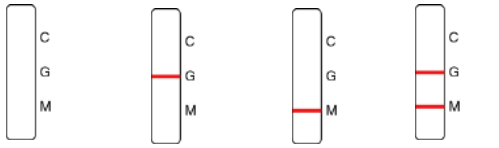
1. Remove test kit, specimen to room temperature. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface.
2. Add 20μL whole blood or 10μL serum (or plasma) into sample well using a calibrated pipet. Then add 70 μL (2 drops) of the Sample Diluent. For each individual's specimen, use a separate tip and Cassette.
3. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.



Add specimen into sample well Add diluent (70μL/2 drops) into sample well



Positive (+) Positive (+) Positive (+) Negative (-)



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(The picture is for reference only)

【INTERPRETATION OF TEST RESULTS】

1. IgG POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.
2. IgM POSITIVE:Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.
3. IgG and IgM POSITIVE: Three lines appear. 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. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.

   NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
4. NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).
5. INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your

local distributor.

6. Result determination time: The result should be judged within 15~20 minutes after the sample is added into the sample loading well, and the result displayed after 20 minutes is invalid.

【LIMITATIONS OF TEST METHOD】

1. This product is only suitable for qualitative test and auxiliary diagnosis.
2. The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptom, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information.
3. The hemolytic, lipemia, jaundice, and contaminated samples may affect the test results. Such samples should be avoided.
4. During early infection, when IgG/IgM isn't formed or the concentration is very low, it will cause a negative result. If there is a suspected infection, it's recommended to retest in 7-14 days. Test the second sample simultaneously with the first sample under the same conditions to determine whether exist seroconversion in first infection or an elevation in antibody titer.
5. We do not test all types of collection tubes that may be used for this kit; therefore, for blood sample collection tubes from different manufacturers, different results may be obtained due to different raw materials and additives. Each laboratory shall make its own judgment on the suitability of the blood collection tubes.

【PERFORMANCE CHARACTERISTICS】

1. Positive conformity rate: testing positive reference material of the company, there is no false negative result.
2. Negative conformity rate: testing negative reference material of the company, there is no false positive result.
3. Limit of detection: testing the the detection limit reference material of the company, S1 should be positive, S2 should be negative or positive, and S3 should be negative.
4. Repeatability: testing two copies of the repeatability reference materials of the company, each test is repeated 10 times, all should be positive.
5. Clinical Performance

The clinical performance of the COVID-19 IgG/IgM Rapid Test Kit was evaluated by testing a total of 400 clinical samples from individual patients: serum samples, plasma samples and whole blood samples (EDTA, heparin, and citrate). The samples were collected from patients at three sites in China at a time when the acute SARS-CoV-2 infection was prevalent.

Study Results

Across all study sites, serum and plasma samples from a total of 182 patients with positive PCR comparator results and 218 patients with negative PCR comparator results were tested with the Anti-SARS-CoV-2 Rapid Test. Overall study results are shown in Table 1 below.

Table 1. Overall Clinical Study Results for all time periods from symptom onset

Reagent test results		PCR Comparator		Subtotal
		positive	negative	
positive	IgG+/IgM+	148	0	148
	IgG-/IgM+	4	4	8
	IgG+/IgM-	18	5	23
negative	IgG-/IgM-	12	209	221
Subtotal		182	218	400

Positive Percent Agreement (PPA)= (IgM positive or IgG positive)/(PCR positive)

Positive Percent Agreement (PPA)= 170/182 (93.41%)

Negative Percent Agreement: (NPA) = (IgM negative and IgG negative)/(PCR negative)

Negative Percent Agreement (NPA)= 209/218 (95.87%)

6. Assay Cross Reactivity Cross-reactivity of the COVID-19 IgG/IgM Rapid Test Kit was evaluated using serum or plasma samples (collected before August 2019) which contain antibodies to the pathogens listed below. No IgM or IgG false positivity was found with the following:

Table 2: Cross-reactivity Results

IgM/IgG potential cross-reactant			
Potential cross-reactants	No. of samples	Potential cross-reactants	No. of samples
Anti-Flu A (IgM/ IgG)	10	Human coronavirus panel (IgM/ IgG)	10
Anti-Flu B (IgM / IgG)	10	EB Virus antibody (IgM/ IgG)	10
anti-HKU1 (beta coronavirus)	10	HIV-1 and HIV-2	10
anti-OC43 (beta coronavirus)	10	Adenovirus (IgM/ IgG)	10
anti-NL63 (alpha coronavirus)	10	Human Metapneumovirus (hMPV) (IgM/ IgG)	10
anti-229E (alpha coronavirus)	10	Parainfluenza virus 1-4 (IgM/ IgG)	10
anti-rhinovirus (IgM/ IgG)	10	Enterovirus (IgM/ IgG)	10
anti-HCV (IgM/ IgG)	10	Rhinovirus (IgM/ IgG)	10
anti-HBV (IgM/ IgG)	10	Streptococcus pneumoniae (IgM/ IgG)	10
ANA	10	Mycobacterium tuberculosis (IgM/ IgG)	10
anti-respiratory syncytial virus (IgM/ IgG)	10	Mycoplasma pneumoniae (IgM/ IgG)	10
anti-Haemophilus influenzae. (IgM/ IgG)	10		

7. Potentially Endogenous Interfering Substances Low titer COVID-19 antibody positive serum samples and COVID-19 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Bilirubin Conjugated	0.3 mg/mL	Antibody (HAMA) Human Serum Albumin	50 mg/mL
Hemoglobin	8 mg/mL	Levofloxacin	200 mg/L
Human Anti-mouse	780 ng/mL	α-IFN	200 mg/L
Bilirubin Unconjugated	0.4 mg/mL	Abidol	50 mg/L
Triglycerides	15 mg/mL	Tobramycin	10 mg/L
Cholesterol	5 mg/mL	Ribavirin	40 mg/L
Rheumatoid Factor	2000 IU/mL	Ceftriaxone	420 mg/L
Histamine hydrochloride	4 mg/L	Meropenem	210 mg/L
Oseltamivir carboxylate	1 mg/L	Human IgM	0.5 mg/mL

Zanamivir	1 mg/L	Human IgG	9 mg/mL

【PRECAUTIONS】

1. This product is only used for in vitro diagnosis, not for other purposes; do not use expired reagents.
2. All reagent components, samples and various wastes should be treated as infectious agents. At the same time, this product is a one-time use product, and it should be destroyed centrally in accordance with the local infectious disposal law or laboratory regulation.
3. Proper specimen collection, storage and transport are critical to the performance of this test.
4. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
5. Please read the instructions carefully before operation, and follow the instructions. During use, all laboratory reagent handling precautions must be followed.
6. Please use fresh samples as much as possible, and avoid using samples contaminated with bacteria, hemolysis, jaundice, or excessive blood lipid.
7. The results of this kit are invalid after 20 minutes.

【WARNINGS】

1. This test has not been reviewed by the FDA.
2. Negative results do not rule out COVID-19 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-COVID-19 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
5. Not for the screening of donated blood .
6. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
7. Dispose of all specimens and materials used to perform the test as biohazardous waste.
8. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
9. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

【EXPLANATION OF LABELS】

IVD	In Vitro Diagnostic Use		See Instruction for Use	REF	Catalog #
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse	30℃ 4℃	Store between 4～30℃		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative
CE	CE Mark				

【BASIC INFORMATION】

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Tel：+86-022-65378415

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EC REP

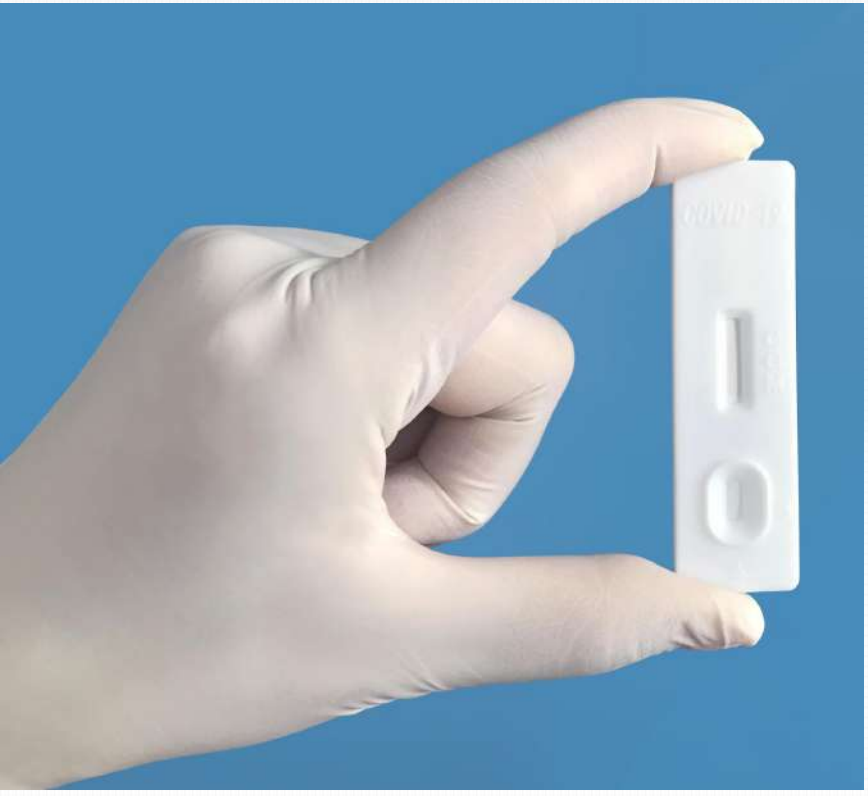
Lotus NL B.V.

Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

【DATE OF APPROVALAND AMENDMENT OF IFU】： June-2020

我公司胶体金新冠检测产品与核酸检测方法对比，其优势在于

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit Advantages



取样简单，无需处理	Simple sample collection ， no processing required
弱阳性结果清晰明了	Weak positive result is clear
操作简单	Simple operation
常温运输	Normal temperature transport
4~30 摄氏度储存	Storage at 4℃ -30 ℃
价格低	Competitive price
15分钟出检测结果	Test result will come out in 15 minutes
检测结果直观可见	The test results are clear and intuitive
根据说明书即可操作	Operate according to the instruction

我公司双抗体新冠检测产品优势

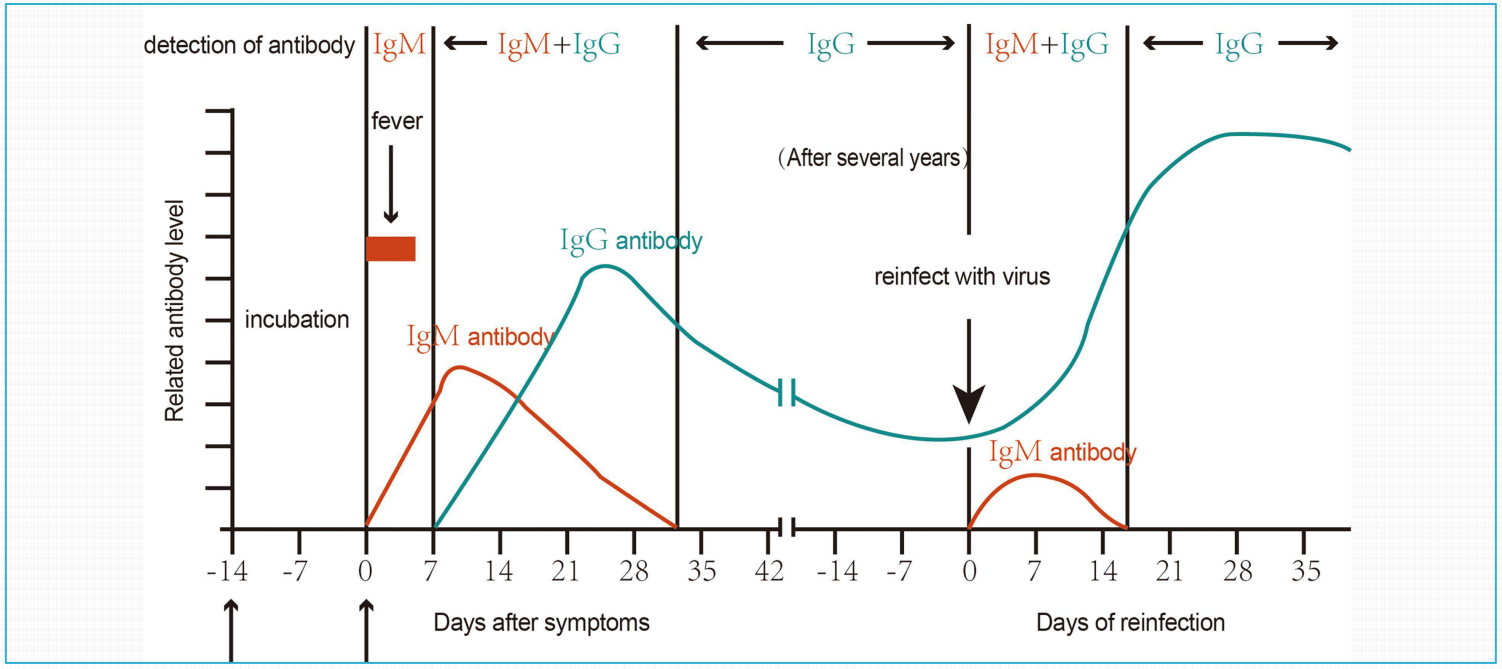
JOYSBIO COVID-19 IgG/IgM Rapid Test Kit Advantages

为什么用抗体检测?

因为人体感染病毒后,人体免疫系统会自动产生免疫球蛋白, 人感染后七天内会产生免疫球蛋白M,检测方法是IgM检测法,七天后会产生免疫球蛋白G,也就是IgG检测法,我们就是IgM和Ig G双联检测,一个试剂盒同时测两种抗体,更加方便快捷，同时更有助于推算感染时间，精确筛查感染期间接触人群。在感染初期，体内抗体比较少的时候，俗称弱阳，这是很多产品容易漏检的时候，我公司检测试剂能够检测出来，这也是我公司产品的过硬之处，综合准确率95%以上!

Why should we choose antibody test kit ?

After infection, the body's immune system will produce immunoglobulin automatically , within seven days after infection can produce immunoglobulin M, What we called this detection method is IgM test, After seven days or a second infection to produce immunoglobulin G, what we called this is IgG test .We are double detection of IgM and IgG,one kit can detect two antibodies simultaneously , its more convenient. At the same time, it is more helpful to calculate the time of infection and accurately screen the people exposed during the infection. In the early stage of infection, antibodies are less , commonly call as weak Positive At this stage which is easy to miss diagnosis , however we can detect out, that is our test kit s Selling point and advantage, what s more， comprehensive accuracy can up to more than 95% .

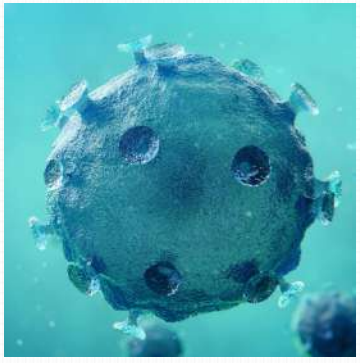


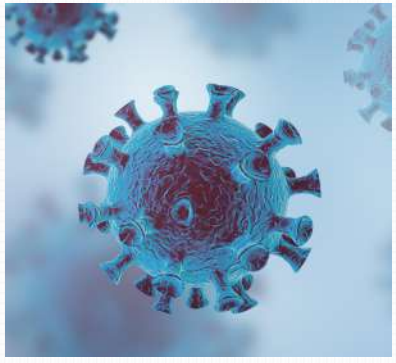
针对病毒变异的特性，我们采取的解决方案

For the characteristics of virus variation, we take the solution ， as follows:

9999999冠状病毒有不断变异的特性，而市面上大部分抗体检测产品均有单一性限制，无法及时更新技术及原料，容易导致病毒变异后漏检的现象出现。针对这一现象，我公司生产的抗体检测试剂盒针对变异及非变异进行了独家技术的双向融合，保证了产品的稳定性，同时针对感染病毒的变异非变异均可及时检测出来，避免了漏检现象出现！

Due to coronaviruses have the property of constantly mutating, Most antibody test kits on the market have a single limitation ,which is easy to lead to missing detection due to virus mutation .However, the antibody test kit produced by our company has the exclusive technology of bidirectional fusion for mutation and non-mutation.This can gurantee the absolute stability of the test kit, at the same time for the virus infection of the variation and non-variation can be timely detected, to avoid missing detectio.





正元盛邦新冠抗体检测试剂盒 预期用途

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit **Intended Use**

供体外定性检测人全血、血浆和血清样本中的新型冠状病毒（COVID-19）IgG/IgM 抗体用。本检测法 仅供临床实验室或医护人员即时检测使用，不作家居检测使用。 若结果呈阳性，则需进一步确诊；若结果呈阴性，则不能排除感染的可能性。本试剂盒的检测结果仅 供临床参考。建议结合临床表现及其他化验对患者状况进行综合分析。

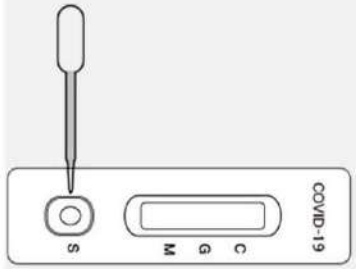
For in vitro qualitative determination of the content of COVID-19 IgG/IgM antibody in human serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing. A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. The test results of this kit are only for clinical reference. It is recommended to conduct a comprehensive analysis of the patient's condition in combination with clinical manifestations and other laboratory tests.

Rapid
Sensitive
Accurate
Convenient

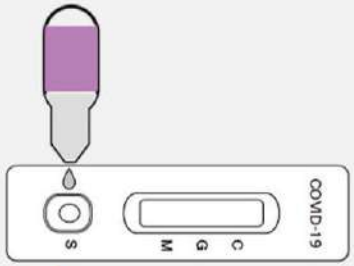
使用方法图解

JOYSBIO COVID-19 IgG/IgM Rapid Test Kit **Test Method**

全血样本检测法方图
Whole Blood Test Method

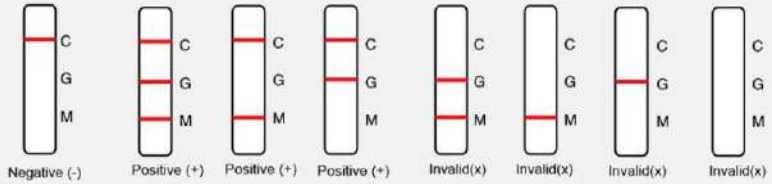


1 Add 20μl Whole Blood into sample well
在加样窗加入20μL全血样本



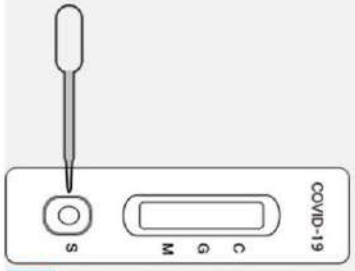
2 Add diluent into sample well
在加样窗加入样品稀释液

With in 15~20 minutes
等待15-20分钟

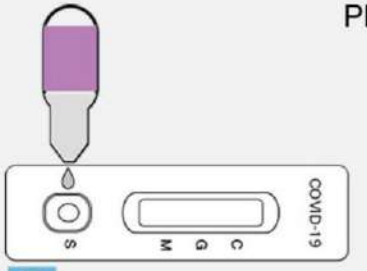


3 The results were observed at room temperature for 15-20 minutes.
在室温下，15至20分钟内读取检测结果

血清或血浆样本检测法方图
Plasma or Serum Test Method

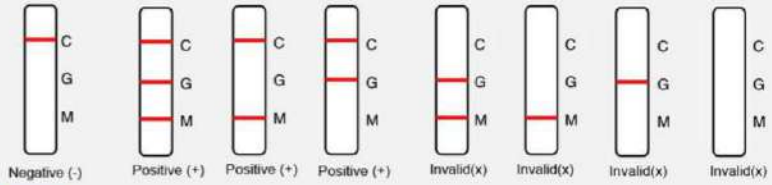


1 Add 10μl Plasma or serum into sample well
在加样窗加入10 μL全血样本



2 Add diluent into sample well
在加样窗加入样品稀释液

With in 15~20 minutes
等待15-20分钟



3 The results were observed at room temperature for 15-20 minutes.
在室温下，15至20分钟内读取检测结果

TEST REPORT

Report No.: 2020-GJ-0375

Entrusting Party: JOYSBIO (Tianjin) Biotechnology Co., Ltd.

Sample Name: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Model No.: /

Kind of Testing: Registered Test( )

Registered Supplementary Test( )

Other Test (√) Entrusted Test

Tianjin Medical Devices Quality Supervision and Testing Center,

China Food and Drug Administration

(seal): Special seal for detection of Tianjin Medical Devices Quality Supervision and Testing Center,

China Food and Drug Administration

First Page of Test Report

Report No.: 2020-GJ-0375

Sample Name:	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) Sample presentation() | On-site() | Sampling(√)	Sample No.:	1# ~ 30#
Trademark:	/	Model Specification:	20 T/box
Entrusting Party:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Test Category:	Entrusted Test
Address of Entrusting Party:	Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China	Product Serial / Batch No.:	See remarks.
Manufacture:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Sampling Sheet No.:	122068400003024
Subject Company:	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Date of Production:	See remarks.
Sampling Institution:	Tianjin Medical Products Administration	Sample Quantity:	Thirty boxes(six hundred T)
Sampling Site:	Warehouse	Sampling Basic No.:	Seven hundred and thirty-eight T
Sampling Date:	April 30, 2020	Testing Site:	Quality Control Room of JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Date Received:	April 30, 2020	Test Date:	April 30, 2020 ~ May 15, 2020
Testing Item:	All the items		
Testing Basis:	*Technical Requirements for the COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)* of JOYSBIO (Tianjin) Biotechnology Co., Ltd.		
Testing Conclusion:	The tested samples conform to the specifications of the *Technical Requirements for the COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)* of JOYSBIO (Tianjin) Biotechnology Co., Ltd. Date of Issue: May 20, 2020		
Remarks:	(1) The "——" in this Test Report indicates that this item is not applicable. The "/" in this Test Report indicates that this item is blank. (2) Sample No. / Production Batch No. / Date of Production 1# ~ 10 # / 2020031906 / March 18, 2020 11# ~ 20# / 2020032107 / March 20, 2020 21# ~ 30# / 2020032408 / March 23, 2020 Samples 6#~10# were placed in 37℃ incubator on April 30, 2020 for stability test after 14 days. (3) This Report only provides test data of the enterprise's reference products.		

Approved by: _____ Checked by: _____ Tested by: _____

Position: _____

Contents of Test Report

Report No.: 2020-GJ-0375

Serial No.	Tested Item	Article	Requirements	Sample No.	Testing Conclusion	Single Conclusion	Remarks
1	Appearance	2.1.1	The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components shall be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	1#; 11#; 21#	Conform to Requirements	Conform	/
2	Membrane Strip Width	2.1.2	The membrane strip shall not be less than 3mm.	1#; 11#; 21#	3.00~3.02	Conform	/
3	Migration Velocity	2.1.3	The migration velocity shall not be less than 10mm/ min.	1#; 11#; 21#	40.70~50.00	Conform	/
4	Coincidence Rate of Negative Reference	2.2	The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	1#; 11#; 21#	1#; 11#; 21# IgG: 20/20 20/20 20/20 IgM: 20/20 20/20 20/20	Conform	/
5	Coincidence Rate of Positive Reference	2.3	The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	2#; 12#; 22#	2#; 12#; 22# IgG: 10/10 10/10 10/10 IgM: 10/10 10/10 10/10	Conform	/
6	Min. Detection Limit	2.4	The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	3#; 13#; 23#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative	Conform	/
7	Precision	2.5	Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform	/
8	Inter-batch Variation Coefficient	2.6	IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) in enterprise reference products were used to detect 10 detection reagents in each batch of the three batches of products, and the reaction results of 30 detection reagents were consistent, with uniform color rendering.	4#; 5#; 14#; 15#; 24#; 25#;	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.	Conform	/

9	Stability (use the product placed in a 37℃ incubator for 14 days.)	2.7	Appearance: The appearance of the kit shall be intact; The aluminum foil bag in the kit shall be sealed without air leakage; The desiccant shall be packed completely without leakage. Diluent components should be clear and transparent without flocculent, granular and other impurities; The detection reagent shall be flat without flaw, and the material of it shall be firmly attached with complete contents.	6#	Conform to Requirements	Conform	/
			The membrane strip shall not be less than 3mm.	6#	3.00 3.01 3.02		
			Migration velocity: The migration velocity shall not be less than 10mm/ min.	6#	41.98 41.28 45.28		
			Coincidence Rate of Negative Reference: The negative coincidence rate was 20/20 when tested with 20 IgG negative reference products from enterprise's reference products(internal control plate). The negative coincidence rate was 20/20 when tested with 20 IgM negative reference products from enterprise's reference products(internal control plate).	6#	IgG: 20/20 IgM: 20/20		
			Coincidence Rate of Negative Reference: The positive coincidence rate was 10/10 when tested with 10 IgG positive reference products (P1 - P10) from the enterprise's reference products(internal control plate); The positive coincidence rate was 10/10 when tested with 10 IgM positive reference products (P11 - P20) from the enterprise's reference products(internal control plate);	7#	IgG: 10/10 IgM: 10/10		
			Min. Detection Limit: The L1-IgG and L2-IgG shall be positive and the L3-IgG shall be negative when tested with 3 IgG reference products of min. detection limit from the enterprise's reference products(internal control plate). The L1-IgM and L2-IgM shall be positive and the L3-IgM shall be negative when tested with 3 IgM reference products of min. detection limit from the enterprise's reference products(internal control plate).	8#	L1-IgG: All positive L2- IgG- All positive L3- IgG - All negative L1- IgM: All positive L2- IgM: All positive L3- IgM: All negative		
			Precision: Ten detection reagents were tested in parallel with IgG(J1-IgG positive, J2 IgG negative) and IgM(J1-IgM positive, J2-IgM negative) precision reference products from enterprise's reference products, and the reaction results were consistent and the color rendering was uniform.	9#; 10#	J1-IgG: All positive. Uniform color rendering J2-IgG: All negative. J1-IgM: All positive. Uniform color rendering J2-IgM: All negative.		

Photo Page of Test Report

Photos and Descriptions

Sample Description
/
Model Specification or other Description
/