INNOVITA

2019-nCoV Ab Test (Colloidal Gold)

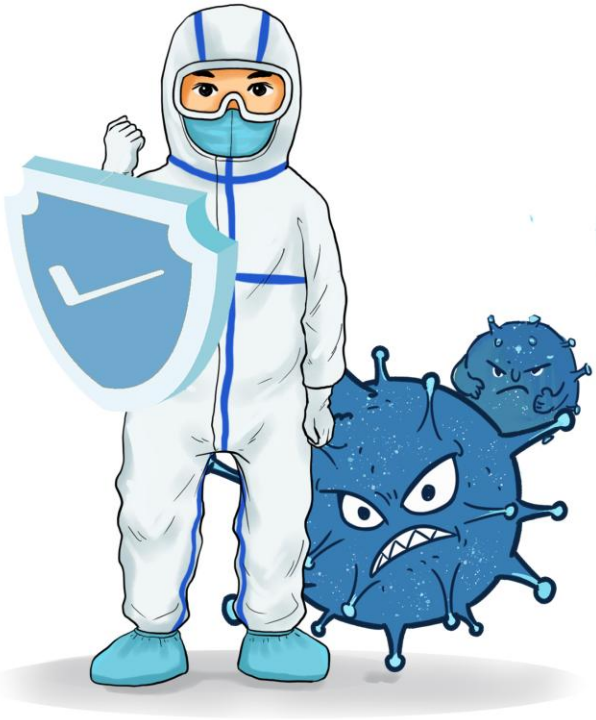
INNOVITA is a leading manufacturer of diagnostic solutions for respiratory pathogens diagnosis, striving for a more efficient healthcare system to enhance the health and well-being of people all over the world.

INNOVITA
No test too small, No matter too big.

Early diagnosis · early isolation · early treatment

2019-nCoV Ab Test (Colloidal Gold)

• NMPA approved product under National Emergency Assessment •



Read results in 15 minutes

INNOVITA

Characteristics of 2019-nCoV

Strong infectivity

Fast transmission

Long latent period

The latent period for 2019-nCoV is 1-14 days, with an average of 3-7 days. Mild patients only show symptoms such as low fever and mild fatigue without pneumonia. Some infected patients are asymptomatic but can also become a source of infection, which makes early diagnosis essential.

IgM and IgG Combined Detection

The clinical auxiliary diagnosis of 2019-nCoV requires simple, economical and feasible methods. The human immune system can produce specific IgM and IgG antibodies after virus infection. IgM is the earliest antibody that appears upon the first immune response. The detection of IgM antibody indicates a recent infection and can be used as auxiliary diagnosis of early infection. IgG is produced later and lasts long, which can be used as an indicator of previous or secondary infection.

The kit is intended for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human serum/plasma/venous whole blood specimen and for the auxiliary diagnosis of 2019-nCoV infection. The confirmation or exclusion of infection will be combined with the patient's clinical manifestations or further other methods.

2019-nCoV Ab Test
(Colloidal Gold)

Features

1. Venous Whole Blood/Serum/Plasma
2. Result in 15 minutes
3. Equipment-free, suitable for POCT
4. Assisting confirmation of positive cases

Empowering Respiratory Pathogens Diagnosis

CE

INNOVITA®

Instructions for 2019-nCoV Ab Test (Colloidal Gold)

INNOVITA (Tangshan) Biological Technology Co., Ltd.

Product Name

2019-nCoV Ab Test (Colloidal Gold)

Intended Use

The kit is intended for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human serum/plasma/venous whole blood specimen. It is only used as a supplementary detection indicator for suspected nucleic acid negative results or in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of COVID-19. It is not suitable for general screening.

A positive test result requires further confirmation. A negative test result does not rule out the possibility of infection.

This product is limited to clinical use and emergency reserve during the COVID-19 epidemic outbreak since December 2019, and cannot be used in the clinic as a conventional in vitro diagnostic reagent. The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

Laboratory testing of 2019-nCoV should meet the requirements of the "Technical Guidelines for Laboratory Testing of COVID-19 Infection" to do a better biosafety job.

Summary

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). 2019-nCoV is a new strain that has not been previously identified in humans.

Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

Current estimates of the incubation period range from 1-12.5 days with median estimates of 5-6 days. These estimates will be refined as more data becomes available. Based on information from other coronavirus diseases, such as MERS and SARS, the incubation period of 2019-nCoV could be up to 14 days. WHO recommends that the follow-up of contacts of confirmed cases is 14 days.

Principle

The kit detects 2019-nCoV IgM and IgG antibodies by immuno-capture method. The nitrocellulose membrane is coated by mouse-anti human monoclonal IgM antibodies, mouse-anti human monoclonal IgG antibodies, and goat-anti-mouse IgG antibodies. The recombinant 2019-nCoV antigen and mouse IgG antibodies are labeled with colloidal gold as a tracer. After addition of the specimens, if 2019-nCoV IgM antibodies are present, the antibodies will bind to colloidal gold-coated 2019-nCoV antigens to form compounds, which are further captured by pre-coated mouse-anti human IgM antibodies to form new compounds, and generate purple line (T). If 2019-nCoV IgG antibodies are present in specimen, the antibodies will bind to colloidal gold-labeled 2019-nCoV antigens to form compounds, and further form new compounds by binding to pre-coated mouse-anti human monoclonal IgG antibodies, which give rise to purple line (T). The binding of colloidal gold-labeled mouse IgG antibodies with goat-anti-mouse IgG antibodies will present purple line, which is used as the control line(C).

Composition

1. Sealed foil pouches each containing:
   a. One cassette device
   b. One desiccant
2. Specimen diluent
3. Instructions for use

Storage and Stability

1. Store at 4℃~ 30℃（39.2℉~ 86℉）.
2. Use the test within 1 hour after opening the pouch under 60% humidity.
3. See production date and expiration date on label.

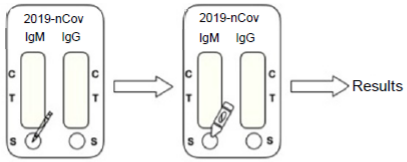
Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. The kit is intended for test only in serum/plasma/venous whole blood specimens.
2. Specimens should be collected by standard protocol.
3. The venous whole blood specimens could be stored at 2℃~ 8℃ (36℉~46℉) for up to 3 days, and it couldn't be frozen. Venous whole blood specimens can be anti-coagulated with routine dosage of heparin (9.8-28IU/mL), sodium citrate (3.8%, equivalent to 129mmol/L), ethylenediaminetetraacetic acid (EDTA) (4.55mmoL / mL ± 0.85 mmol/mL).
4. The serum or plasma specimen s could be stored at 2℃~ 8℃ (36℉~46℉) for up to 7 days, and could be frozen at -20℃（-4℉） for 6 months. The specimens are repeatedly frozen and thawed no more than 8 times; it should be the best to test the sample after collection immediately.
5. 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.

Test Procedure

1. Allow the test, specimen diluent and/or controls to reach room temperature 10℃~30℃ (50℉~86℉) prior to testing.
2. Remove the test device from the sealed pouch and use it as soon as possible.
3. Place the test device on a clean and level surface.
4. **FROM THE TOP OF THE SPECIMEN WELL:** Add 20μL venous whole blood or 10μL serum/plasma specimen into each specimen well.
5. **FROM THE BOTTOM OF THE SPECIMEN WELL:** Add 80μL or 2 drops of specimen diluent into each specimen well.
6. Wait for the colored line(s) to appear. Read results within 15 minutes. Do not read the result after 15 minutes.

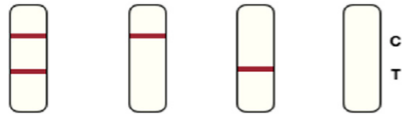


Add 20 μL venous whole blood or 10 μL serum/plasma

Add 80 μL(or 2 drops) of specimen diluent

Results Interpretation

1. **IgM Positive**: The presence of two purple bands (T and C) within the IgM result window indicates positive for 2019-nCoV IgM antibody.
2. **IgG Positive**: The presence of two purple bands (T and C) within the IgG result window indicates positive for 2019-nCoV IgG antibody.
3. **Negative**: Only one purple band appearing at the control line (C) indicates negative result.
4. **Invalid**: If control line (C) fails to appear, no matter whether the T line is visible or not, the test is invalid. Insufficient specimen 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 device. If the problem persists, you should immediately stop using the kit with the same LOT No. and contact your local distributor.



Positive **Negative** **Invalid** **Invalid**

Performance Characteristics

1. Use the national or enterprise reference controls for testing, and the results meet the detection requirements of national or enterprise reference controls.
2. Test the samples with a titer of 1:320 at the original concentrations with the 2019-nCoV IgM antibody and 2019-nCoV IgG antibody. No hook effect was observed.
3. The clinical trial of this product is based on the clear diagnosis / exclusion criteria of the disease identified in the "COVID-19 Diagnosis and Treatment Program". Clinical research was conducted in 5 institutions and the total cases were 447. Using this kit, 110 cases out of 126 clinically confirmed cases are positive, with the sensitivity of 87.3% (95% CI: 80.40% to 92.0%); 62 cases of clinically excluded cases are totally negative with the specificity of 100% (95% CI: 94.20% to 100%).
4. Avoid using special samples: red background may appear in the hyperlipemia (triglyceride concentration higher than 25mg/ml), icteric samples (Bilirubin concentration higher than 0.2mg/mL) and hemolytic specimen (hemoglobin concentration more than 5.0mg/mL). which may affect the test result.
5. The 2019-nCoV IgM test was also evaluated with samples that are IgM positive for other diseases as listed in the following table. No cross reactivity was observed.

Coronavirus HKU1-IgM	Coronavirus OC43-IgM
Coronavirus NL63-IgM	Coronavirus 229E-IgM
Influenza A virus H1N1 (new type influenza A virus H1N1 2009, seasonal influenza virus H1N1) IgM	H3N2-IgM
H5N1-IgM	H7N9-IgM
Influenza B virus IgM	Respiratory Syncytial Virus IgM
Adenovirus IgM	Rhinovirus IgM
Enterovirus A-IgM	EB virus IgM
Measles virus IgM	Cytomegalovirus IgM
Rotavirus IgM	Mumps IgM
Varicella-zoster virus IgM	Parainfluenza virus IgM
Mycoplasma pneumoniae IgM	Chlamydia pneumoniae IgM
Coxsackievirus group B IgM	

6. The 2019-nCoV IgG test was also evaluated with samples that are IgG positive for other diseases as listed in the following table. No cross reactivity was observed.

Coronavirus HKU1-IgG	Coronavirus OC43-IgG
Coronavirus NL63-IgG	Coronavirus 229E-IgG
IInfluenza A virus H1N1 (new type influenza A virus H1N1 2009, seasonal influenza virus H1N1) IgG	H3N2-IgG
H5N1-IgG	H7N9-IgG
Influenza B virus IgG	Respiratory Syncytial Virus IgG
Adenovirus IgG	Rhinovirus IgG
Enterovirus A-IgG	EB virus IgG
Measles virus IgG	Cytomegalovirus IgG
Rotavirus IgG	Mumps IgG
Varicella-zoster virus IgG	Parainfluenza virus IgG
Mycoplasma pneumoniae IgG	Chlamydia pneumoniae IgG
Coxsackievirus group B IgG	

7. RF, ANA and AMA don't exhibit cross reactivity with the test.
8. Common antivirals such like Epistine hydrochloride (≤4mg/L), Ribavirin (≤40mg/L), Interferon (≤200mg/L), Oseltamivir (≤30mg/L), Abidol (≤40mg/L), Levofloxacin (≤200mg/L), Azithromycin (≤100mg/L), Ceftriaxone (≤400mg/L), Meropenem (≤200mg/L) have no interference effect on the detection of this kit.
9. Systemic lupus erythematosus has no interference effect on the detection of this kit.
10. Non-specific IgM antibody (≤0.8mg/mL) and non-specific IgG antibody (≤4mg/mL) have no interference effect on the detection of this kit.
11. Heparin, sodium citrate, EDTA and other anticoagulants have no interference effect on the detection of this kit.
12. The precision experiments were carried out by different experimenters, at different times and at different places, and the results met the product performance requirements.
13. After the specific IgM positive sample was destroyed by β-mercaptoethanol, the IgM test result was negative.
14. After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic. The product will further collect clinical data to confirm the clinical performance of the product after it is marketed.

Limitations

1. The kit is for qualitative detection and auxiliary diagnosis use only.
2. In the early phase of infection, no IgM or IgG antibody will be produced, or the titer will be very low, thus, negative result will occur. Re-testing will be conducted in 7-14 days, and the sample that is collected last time will be detected in parallel during re-testing to confirm whether the serology turns positive or the titer increases significantly.
3. The reference value of serological antibody detection is limited for the immune-compromised patients or patients who receive immunosuppressive therapy.
4. IgM antibody positive will occur not only in primary infection, but also in secondary infection.
5. IgG antibody positive indicates previous infection or secondary infection.
6. The confirmation or exclusion of infection will be combined with the patient's clinical manifestations or other further methods.

Precaution

1. Use fresh specimens whenever possible.
2. Results after 15 minutes are considered invalid.
3. The product should be used as soon as possible once the foil pouch is open, in case of long-term exposure to environment.
4. Follow standard biosafety guidelines for handling and disposal of potential infective material.

INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD.
No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, Hebei, 064400, China.

EC REP SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.
TEL: +31 (0) 2021 11106

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
EC REP	Authorized Representative in the European Community		
CE	CE Mark		

No.: Q/JSRDY373-1.0-05
Effective Date:Mar. 8, 2020

COVID-19 Diagnosis and Treatment Program (7th Edition)

五、诊断标准

（二）确诊病例。

疑似病例同时具备以下病原学或血清学证据之一者：

1. 实时荧光 RT-PCR 检测新型冠状病毒核酸阳性；

2. 病毒基因测序，与已知的新型冠状病毒高度同源；

3. 血清新型冠状病毒特异性 IgM 抗体和 IgG 抗体阳性；
   血清新型冠状病毒特异性 IgG 抗体由阴性转为阳性
   或恢复期较急性期 4 倍及以上升高。

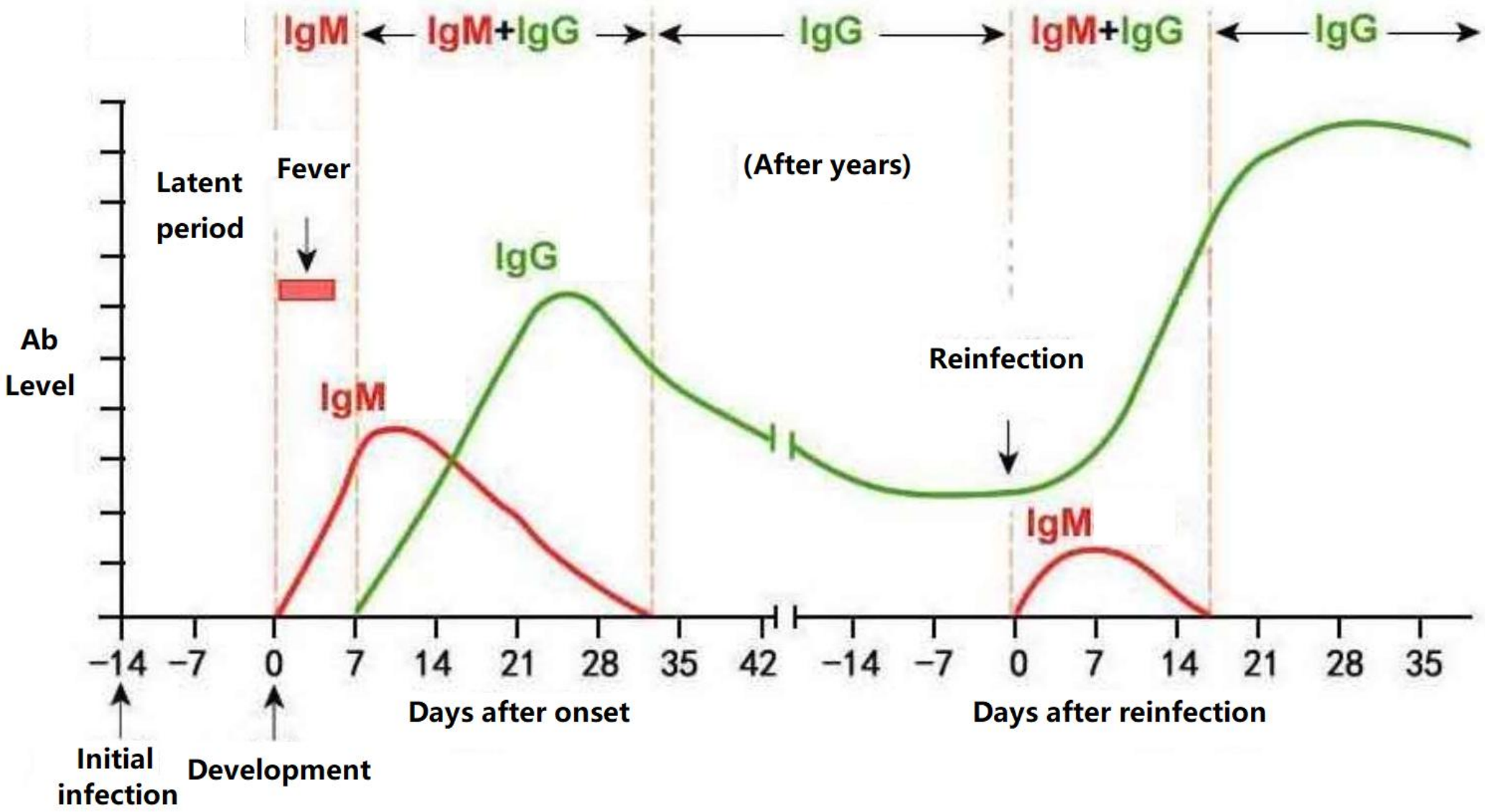
Section 5. Diagnosis Criteria

II. Confirmed Cases

Suspected cases having either one of the following etiology or serological evidences:

1. Nucleic acid positive by real-time fluorescence RT-PCR;
2. Highly homologous to known SARS-COV-2 by gene sequencing;
3. Specific IgM and IgG antibodies both positive; or
   Specific IgG antibody changed from negative to positive; or
   Specific IgG antibody increased by at least 4 times in recovery phase compared to acute phase.

Significance of IgM & IgG



Test Result Reference

Nucleic acid	IgM	IgG	Nucleic acid and antibody test results reference
Positive	-	-	Probably in "window period" of infection.
	+	-	Probably in the early stage of infection, but no IgG is produced or the IgG concentration does not reach the lowest limit of detection.
	-	+	Probably in the advanced stage of infection or recurrent infection.
	+	+	Active phase of infection. But the human body has developed immunity with persistent IgG antibody being produced.
Negative	+	-	Highly probably in the acute stage of infection. At this time, it is necessary to consider cases where the nucleic acid test result is suspect or the patient has other diseases. Rheumatoid factor has been found to result in weak positive or positive in IgM.
	-	+	Probably previous infection. But the body has recovered or the virus has been cleared. IgG produced by the immune response maintains for a long time and is still detectable in blood.
	±	-	Initial infection with very low virus load at early stage; When the viral load is lower than the lowest detection limit of nucleic acid, a small amount of IgM was produced, and no IgG was produced; Or rheumatoid factor positive of the patient resulted in IgM false positive.
	+	+	The patient has recently been infected and is in the recovery phase. The virus in the body has been cleared and IgM has not been reduced to the lowest limit of detection; Or the nucleic acid test result is false negative and the patient is in active phase of infection.

中华人民共和国

医疗器械注册证（体外诊断试剂）

注册证编号：国械注准20203400177

注册人名称	英诺特（唐山）生物技术有限公司
注册人住所	迁安高新技术产业开发区聚鑫街699号
生产地址	迁安高新技术产业开发区聚鑫街699号
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体金法）
包装规格	20人份/盒，40人份/盒。
主要组成成分	检测卡、样本稀释液、干燥剂（具体内容详见产品说明书）
预期用途	本试剂盒用于体外定性检测人血清、血浆样本中新型冠状病毒（2019-nCoV）IgM/IgG抗体。仅用作对新型冠状病毒核酸检测阴性疑似病例的补充检测指标或疑似病例诊断中与核酸检测协同使用，不能作为新型冠状病毒感染的肺炎确诊和排除的依据，不适用于一般人群的筛查。 仅限医疗机构使用。
附件	产品技术要求、说明书
产品存储条件及有效期	10～30℃保存，有效期暂定6个月。
其他内容	/
备注	请注册人在产品上市后继续完成以下工作： 1.本产品仅为新型冠状病毒（2019-nCoV）感染的肺炎的辅助诊断及应急储备，注册证有效期为一年。 2.延续注册时应按照如下要求提交临床应用数据的总结报告：应在三家以上临床医疗机构（包括各级疾病预防控制中心）收集该产品连续临床应用数据。临床应用数据应具有完善的信息，样本量符合统计学要求，签字盖章符合要求。 3.企业应当在延续注册时按照体外诊断试剂注册管理办法的要求完善所有注册申报资料。

批准日期：二〇二〇年三月二十二日

审批部门：国家药品监督管理局　　有效期至：二〇二一年三月二十一日

中华人民共和国

医疗器械注册变更文件(体外诊断试剂)

注册证编号：国械注准20203400177

产品名称	新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体金法）
变更内容	增加临床测定用样本类型“静脉全血”，说明书相应内容变化及其他文字变化，变更内容见附页。 请注册人依据变更批件自行修订产品说明书、产品技术要求及标签的相应内容。
备注	本文件与“国械注准20203400177”注册证共同使用。

审批部门：国家药品监督管理局　　批准日期：二〇二〇年三月二十七日

PEOPLE'S REPUBLIC OF CHINA
REGISTRATION CERTIFICATE FOR MEDICAL DEVICE
(IN-VITRO DIAGNOSTIC TEST)

REGISTRATION OF MEDICAL DEVICES APPROVED BY NMPA NO. 20203400177

Registrant Name	Innovita (Tangshan) Biological Technology Co., Ltd.
Registrant Address	No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.
Manufacturing Site	No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.
Agent Name	/
Agent Address	/
Product Name	2019-nCoV Antibody Test (Colloidal Gold)
Packing Specification	20T/box, 40T/box
Components	Test kit, specimen diluent, desiccant (details as per IFU)
Intended Use	The test kit is intended for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human serum/plasma specimen and for the auxiliary diagnosis of 2019-nCoV infection. It is only used as a supplementary detection indicator for suspected cases of negative results from nucleic acid detection or in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonia infected by 2019-nCoV infection. It is not suitable for general population screening.
Annexes	Technical specifications, IFU
Storage & Expiry Date	Store at 10-30℃, valid for 6 months (temporarily).
MISC	/
Remark	Registrants are required to complete the following tasks after the product is launched: 1. This product is only an auxiliary diagnosis and emergency reserve for pneumonia infected by the 2019 Novel Coronavirus (2019-nCoV). The registration certificate is valid for one year. 2. When renewing the registration, a summary report of clinical application data should be submitted in accordance with the following requirements, and continuous clinical application data of the product should be collected at three or more clinical medical institutions (including all levels of disease prevention and control centers). The clinical application data should have complete information, the sample size meets the statistical requirements, and the signature and seal meet the requirements. 3. When renewing registration, the enterprise shall complete all registration application materials in accordance with the requirements of the administrative measures for the registration of in-vitro diagnostic tests.

APPROVED BY: NATIONAL MEDICAL PRODUCTS ADMINISTRATION

DATE OF APPROVAL: 22 FEB. 2020
DATE OF EXPIRY: 21 FEB. 2021

PEOPLE'S REPUBLIC OF CHINA
AMENDMENT CERTIFICATE FOR MEDICAL DEVICE
(IN-VITRO DIAGNOSTIC TEST)

REGISTRATION OF MEDICAL DEVICES APPROVED BY NMPA NO. 20203400177

Product Name	2019-nCoV Antibody Test (Colloidal Gold)
Amendment	The specimen type "venous whole blood" was added for clinical diagnosis, and the corresponding changes take effect in the instructions and other text. See the attachment for the amendment. The registrant is requested to revise the corresponding contents of the product instructions, product technical requirements and labels according to the amendment approval.
Remark	This document is used in conjunction with the " REGISTRATION OF MEDICAL DEVICES APPROVED BY NMPA NO. 20203400177" registration certificate.

APPROVED BY: NATIONAL MEDICAL PRODUCTS ADMINISTRATION

DATE OF APPROVAL: 27 FEB. 2020

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council directive 98/79/EC, SUNGO Europe B.V. performed all notification duties and responsibilities as the European authorized representative of:

Applicant: Innovita (Tangshan) Biological Technology Co., Ltd.

Address: No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.

The Manufacturer has provided SUNGO Europe B.V. with all the appropriate declarations according to the 98/79/EC Directive requirements including the EC Declaration of Conformity confirming that his In vitro diagnostic medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 98/79/EC.

Product(s): 2019-nCoV Ab Test (Colloidal Gold)

Type(s): (IgM/IgG Whole Blood/Serum/Plasma Combo)

Product Classification: IVDD Other

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration.

SUNGO
Executive Director
Sungo global service
CERTIFIED

Issued: Mar. 20 2020

Cert. No.: EU208518

Expiration Date: Mar. 19 2025

CE

This is not a CE mark and is only provided as a template for informational purpose.

SUNGO CONTACT INFORMATION
Email: info@sungoglobal.com Website: www.sungoglobal.com

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：冀唐药监械出 20200007
Certificate NO.：Certificate of medical device exports made in Tangshan issued by Hebei Drug Supervision Administration No. 20200007

产品名称：详见附表
Product(s)：**Details as per attached list.**

规格型号：详见附表
Model：**Details as per attached list.**

产品注册或备案凭证号：详见附表
Registration certificate(s)：**Details as per attached list.**

生产企业：英诺特（唐山）生物技术有限公司
Manufacturer：Innovita (Tangshan) Biological Technology Co., Ltd.

生产企业住所：河北省迁安市高新技术产业开发区聚鑫街 699 号
Address of manufacturer: No. 699, Juxin Street, High-tech Industrial Development Zone, Qian'an, Hebei.

生产许可或备案凭证号：冀食药监械生产许 20150033 号
Manufacturing License(s): Hebei Province Food And Drug Supervision Administration of Medical Device Manufacturing License No.20150033

兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2021 年 02 月 21 日
This certification valid until：Feb.21,2021

备注：
Remark：

2020 年 02 月 27 日
（出具单位盖章）

附表

序号	产品名称中文 /Chinese	产品名称英文 /English	规格型号中文 /Chinese	规格型号英文 /English	注册证号中文 /Chinese	注册证号英文 /English
1	新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体法）	2019-nCov Ab Test (Colloidal Gold)	20 人份/盒，40 人份/盒	20T/box, 40T/box	国械注准 20203400177	Registration of Medical Devices approved by China Food and Drug Supervision Administration No. 20203400177

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Innovita (Tangshan) Biological Technology Co., Ltd.
No. 699 Juxin Street, High-tech Industrial Development Zone
Qian'an
064400 Hebei
China

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

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Test Kits used in the Detection of Infectious Diseases, Fertility Testing and Pregnancy Testing including Home Use In-vitro Diagnostic Medical Devices

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:	2019-09-19
Certificate Registration No.:	SX 60139531 0001
An audit was performed. Report No.:	16806309 004
This Certificate is valid until:	2022-09-18

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 2019-09-19

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

医疗器械生产许可证

许可证编号：冀食药监械生产许20150033号

企业名称：英诺特（唐山）生物技术有限公司　　生产地址：迁安高新技术产业开发区聚鑫街699号

法定代表人：张秀杰

生产范围：2002分类目录
II类:6840-10-临床医学检验辅助设备，6840-体外诊断试剂
III类:6840-体外诊断试剂

企业负责人：张秀杰

住　　所：迁安高新技术产业开发区聚鑫街699号

发证部门：河北省药品监督管理局

有效期限：至　2024年 12 月26 日　　发证日期：2019年 12 月 27 日

国家药品监督管理局制

People's Republic of China

Manufacturing License of Medical Device

Registration Number: Hebei FDA Production License Number: 20150033

Legal Representative: Zhang Xiujie

Company Name: Innovita (Tangshan) Biological Technology Co., Ltd.

Enterprise Principal: Zhang Xiujie

Address of Registration: No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.

Address of Manufacturing: No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.

Scope of Manufacturing: 2002 Categories
Class II: 6840-10 Clinical medical examination auxiliary equipment, 6840 in-vitro diagnostic test
Class III: 6840 in-vitro diagnostic test

License Issuing Authority: Hebei NMPA

Valid Until: 26 Dec. 2024

Issued Date: 27 Dec. 2019

Supervised by China NMPA

营业执照

副本编号：1－1

（副　本）

统一社会信用代码　91130283568909612G

名　　称　英诺特（唐山）生物技术有限公司

类　　型　有限责任公司

住　　所　迁安高新技术产业开发区聚鑫街699号

法定代表人　张秀杰

注册资本　壹仟万元整

成立日期　2011年01月21日

营业期限　2011年01月21日　至　2061年01月20日

经营范围　Ⅱ类：6840体外诊断试剂、Ⅲ类：6840体外诊断试剂生产；货物和技术进出口。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

登记机关　迁安市工商行政管理局

2015　年　10　月　30　日

企业信用信息公示系统网址：www.hebscztxyxx.gov.cn

中华人民共和国国家工商行政管理总局监制

Business License

(Copy)

Registration number: 91130283568909612G

Name of enterprise	INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD
Type of enterprise	Company with limited liability
Address	No. 699, Juxin Street, Modern Equipment Manufacturing Industry Areas, Qian'an, Hebei, China
Legal representative	Zhang Xiujie
Registered capital	RMB 10 million yuan in whole
Date of establishment	January 21, 2011
Business time limit	From January 21, 2011 until January 20, 2061
Business scope	Manufacturing in-vitro diagnostic test of Category II (6840) and Category III (6840), import & export of goods and technology. Any business activities should be carried out only after being approved by the authorities concerned.

Registration institution:

(as sealed the Qianan Administration for Industry and Commerce)

October 30, 2015

Innovita Supporting Wuhan

Innovita Supporting Epidemic Countries

Innovita 2019-nCoV Ab Test reported in CCTV-1

Letter about the receipt of Innovita 2019-nCoV Ab Test

中央赴湖北等疫情严重地区指导组

指导组医〔2020〕18号

关于新型冠状病毒抗体检测试剂盒接收与分配情况的函

英诺特（唐山）生物技术有限公司：

近日，中央指导组医疗救治组收到你司捐赠新型冠状病毒抗体检测试剂盒5万份，并将其分配至新冠肺炎患者有关定点收治医院（具体分配情况见附表），用于患者的血清抗体检测工作，有效帮助临床诊断，提高医疗救治效率，在抗击新冠肺炎疫情工作中发挥了积极作用。

感谢你司大力支持！

附表：新型冠状病毒抗体检测试剂盒分配情况表

中央指导组医疗救治组

2020年3月11日

附表

新型冠状病毒抗体检测试剂盒分配情况表

序号	领取机构	数量（份）
1	华中科技大学同济医学院附属协和医院	7000
2	华中科技大学同济医学院附属同济医院	7000
3	武汉大学人民医院	7000
4	武汉大学中南医院	7000
5	武汉市第一医院	2000
6	武汉市中心医院	1000
7	武汉市第三医院	2000
8	武汉市第四医院	2000
9	武汉市儿童医院	1000
10	武汉市中医医院	1000
11	武汉市汉口医院	2000
12	武汉市武昌医院	2000
13	武汉市肺科医院	2000
14	武汉市金银潭医院	2000
15	武汉市红十字会医院	1000
16	武汉市第九医院	1000
17	东西湖区人民医院	1000
18	武汉市精神卫生中心	1000
19	武汉市武东医院	500
20	武汉市东湖医院	500
总计		50000

CENTRAL GUIDANCE GROUP TO HUBEI AND OTHER PLACES WITH SEVERE EPIDEMICS

Guidance Team Medical [2020] No. 18

Letter about the receipt of the 2019-nCoV Ab Test

Innovita (Tangshan) Biological Technology Co., Ltd .:

Recently, the medical treatment team of the Central Guidance Group received a donation of 50,000 pcs of 2019-nCoV Ab Tests from your company and have distributed them to designated hospitals that specially receive patients with COVID-19 for antibody diagnosis (for details, see the attached table). It effectively helped clinical diagnosis and improved the efficiency of medical treatment, and has played an active role in fighting the COVID-19 epidemic.

Thank you for your big support!

Attached Table: Distribution Table of 2019-nCoV Ab Test

Medical Treatment Team of Central Guidance Group
March 11, 2020

Annex

Distribution Table of 2019-nCoV Ab Test

No.	Receiving agency	Quantity (PCS)
1	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology	7,000
2	Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology	7,000
3	People's Hospital of Wuhan University	7,000
4	Zhongnan Hospital of Wuhan University	7,000
5	Wuhan First Hospital	2,000
6	Wuhan Central Hospital	1,000
7	Wuhan Third Hospital	2,000
8	Wuhan Fourth Hospital	2,000
9	Wuhan Children's Hospital	1,000
10	Wuhan Hospital of Traditional Chinese Medicine	1,000
11	Wuhan Hankou Hospital	2,000
12	Wuhan Wuchang Hospital	2,000
13	Wuhan Pulmonary Hospital	2,000
14	Wuhan Jinyintan Hospital	2,000
15	Wuhan Red Cross Hospital	1,000
16	Wuhan Ninth Hospital	1,000
17	Dongxihu District People's Hospital	1,000
18	Wuhan Mental Health Center	1,000
19	Wuhan Wudong Hospital	500
20	Wuhan Donghu Hospital	500
Total		50,000

Hospitals using Innovita 2019-nCoV Ab Test

Peking University Third Hospital	Hubei Provincial Hospital of Integrated Traditional Chinese and Western Medicine
Beijing Friendship Hospital	Wuhan Xiehe Hospital
Beijing Youan Hospital	Hubei Provincial Hospital of Traditional Chinese Medicine
Beijing Chaoyang Hospital	Wuhan Children's Hospital
Beijing Armed Police General Hospital	Wuhan Fangcai Hospital
Children's Hospital of Fudan University	Beijing Children's Hospital
Shanghai Xinhua Hospital	Capital Institute of Pediatrics
Shanghai Children's Medical Center	Shanghai Xinhua Hospital
Shanghai Children's Hospital	Affiliated Children's Hospital of Fudan University
Henan Provincial Center for Disease Control	Shanghai Children's Hospital
Guangdong Provincial Center for Disease Control	Suzhou Children's Hospital
Sichuan Provincial Center for Disease Control	Xuzhou Children's Hospital
Beijing Centers for Disease Control	Tianjin Children's Hospital
Disease Control Center of Shanxi Province	Shenyang Children's Hospital
Wuhan Tongji Hospital	Children's Hospital of Hebei Province