



INNOVITA⁺ Empowering Respiratory Pathogens Diagnosis

2019-nCoV IgM/IgG Combo Test



Early diagnosis · early isolation · early treatment



2019-nCoV Ab Test (Colloidal Gold)

• NMPA approved product under National Emergency Assessment •



**Read results
in 15 minutes**

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.



IgM IgG

2019-nCoV Ab Test
(Colloidal Gold)

Features

Venous Whole
Blood/Serum/
Plasma

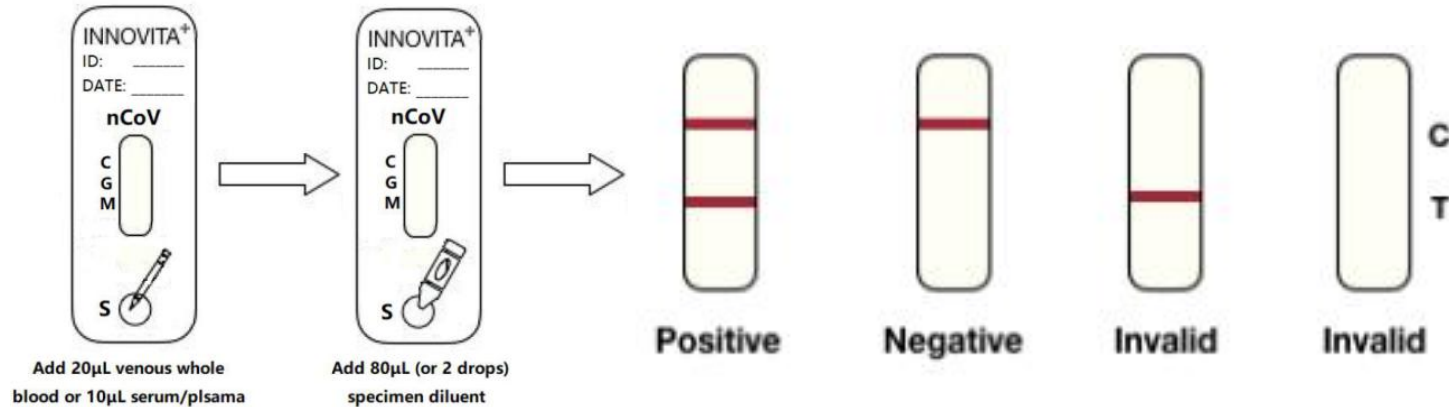
Result in
15 minutes

Equipment-free,
suitable for POCT

Assisting
confirmation of
positive cases

Innovita 2019-nCoV IgM/IgG Combo Test

The only IgM/IgG Rapid Combo Test approved by NMPA



2019-nCoV IgM/IgG Combo Test

Colloidal Gold (CG)

15 minutes

Whole Blood/Serum/Plasma



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.**

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

备注：
Remark:



附表

序号	产品名称	产品名称英文	规格型号	规格型号	注册证号	注册证号英文
	中文	/English	中文	英文	中文	/English
	/Chinese	/English	/Chinese	/English	/Chinese	/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 20203400 177	Registration of Medical Devices approved by China Food and Drug Supervision Administration No. 20203400177

Innovita Supporting Wuhan



Letter about the receipt of the 2019-nCoV Ab Test from Central Guidance Group

中央赴湖北等疫情严重地区指导组

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

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

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

八、鉴别诊断

(一) 新型冠状病毒感染轻型表现需与其他病毒引起的上呼吸道感染相鉴别。

(二) 新型冠状病毒肺炎主要与流感病毒、腺病毒、呼吸道合胞病毒等其他已知病毒性肺炎及肺炎支原体感染鉴别，尤其是对疑似病例要尽可能采取包括快速抗原检测和多重 PCR 核酸检测等方法，对常见呼吸道病原体进行检测。

(三) 还要与非感染性疾病，如血管炎、皮肤炎和机化性肺炎等鉴别。

Section 8. Differential Diagnosis

1. The mild manifestations of COVID-19 infections need to be distinguished from upper respiratory tract infections caused by other viruses.

2. COVID-19 is mainly distinguished from other known viral pneumonia and mycoplasma pneumonia infections such as influenza virus, adenovirus and respiratory syncytial virus. Especially for suspected cases, common respiratory pathogens detection is required by using rapid antigen test and multiplex PCR nucleic acid test and other methods as soon as possible.

3. It should also be distinguished from non-infectious diseases such as vasculitis, dermatomyositis and organizing pneumonia.

Symptom	Virus	Mycoplasma/Chlamydia	Bacteria
Cold	PIV/RSV/ 2019-nCoV	Mycoplasma/Chlamydia	
Flu	Flu A/Flu B/PIV/ADV		
Acute tonsillitis	Flu A/Flu B/PIV/ADV	Mycoplasma/Chlamydia	
Acute laryngitis	Flu A/Flu B/PIV/ADV/RSV		
Otitis media	Flu A/Flu B/PIV		
Nasosinusitis	Flu A/Flu B/PIV/ADV	Chlamydia	
Pharyngo-conjunctival fever	ADV/COX B		
Bronchopneumonia	Flu A/Flu B/PIV/ADV/RSV	Mycoplasma/Chlamydia	
Pneumonia	Flu A/Flu B/PIV/ADV/RSV/COX B/ 2019-nCoV	Mycoplasma/Chlamydia	LP
Bronchiolitis	RSV/ADV/PIV/COX B	Mycoplasma/Chlamydia	
Myocarditis	Flu A/Flu B/PIV/ADV/COX B/ 2019-nCoV		
Meningitis	COX B		
Fever/Cough/Shortness of breath	Flu A/Flu B/PIV/ADV/RSV/COX B/ 2019-nCoV	Mycoplasma/Chlamydia	LP

Coinfections are common!

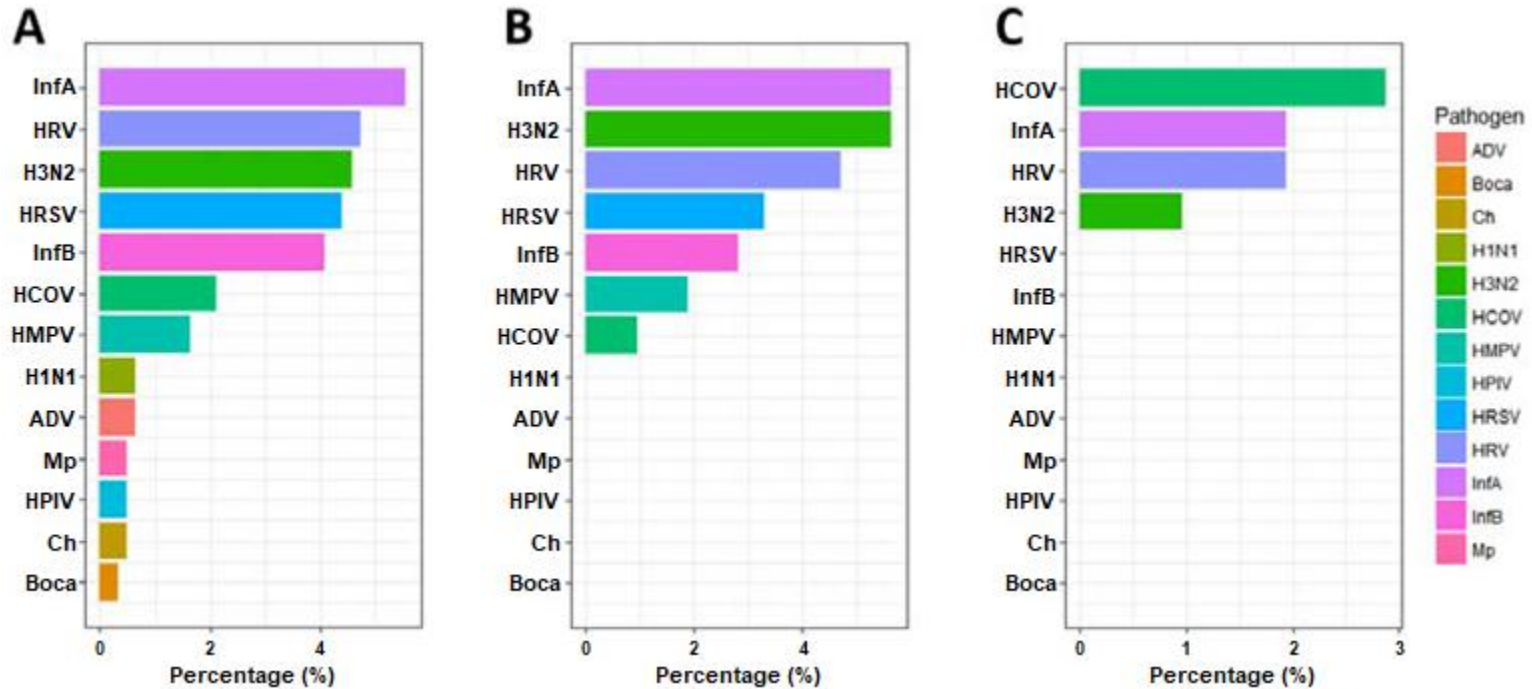


Figure 2 Comparison of 2019-nCov infection rates with infection rates of 13 other respiratory pathogens

A: Pathogen-positive rates for all 13 respiratory pathogens tested, n = 614;

B: 2019-nCov-negative subjects, 13 respiratory-pathogen-positive rates, n = 202;

C: 2019-nCov-confirmed subjects. Positive rate of 13 respiratory pathogens in the test population, n= 104.

ADV: Adenovirus;

Boca: Boca virus;

Ch: Chlamydia;

H1N1: H1N1 Influenza A

virus;

H3N2: H3N2 Influenza A virus;

HCOV: Human coronavirus;

HMPV: Human metapneumovirus;

HPIV: Human parainfluenza virus;

HRSV: Respiratory syncytial virus;

HRV: Human rhinovirus;

InfA: Influenza A virus;

InfB: Influenza B virus;

Mp: Mycoplasma pneumoniae

Similar symptoms, Different treatments

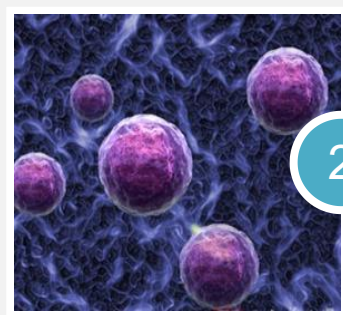
Viruses

Osetamivir/Antivirals



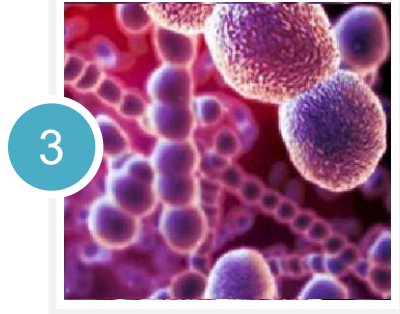
Mycoplasma/Chlamydia

Azithromycin



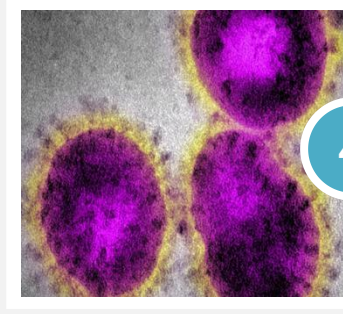
Bacteria

Antibiotics



2019-nCoV

Integrated
Chinese & Western
medicines



It's necessary to identify the exact pathogen.

Media Report

TV Asahi



CDC Begins to Test Patients with Flu-like Symptoms for Coronavirus

CDC Begins to Test Patients with Flu-like Symptoms for Coronavirus

FEB 18, 2020 | RACHEL LUTZ



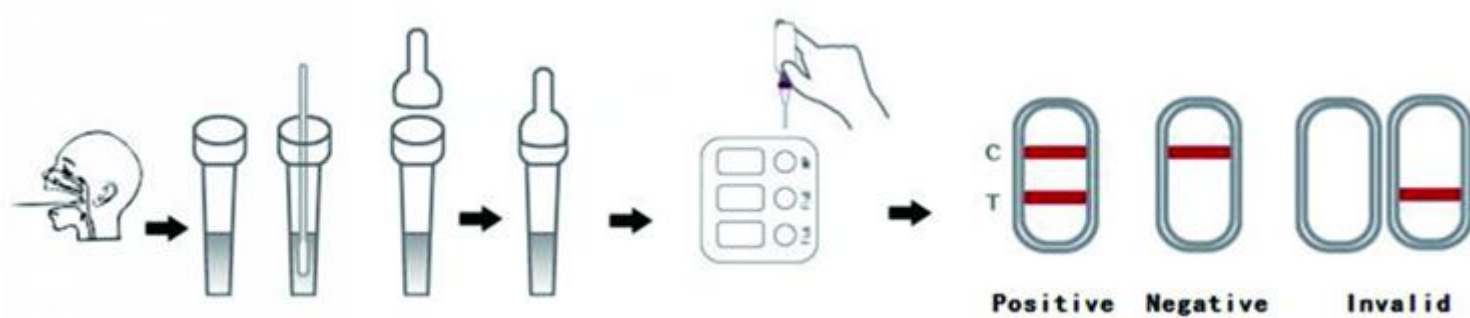
In a call with members of the media on Friday, February 14, 2020, the US Centers for Disease Control and Prevention (CDC) said they will begin to test individuals with influenza-like-illness for the novel coronavirus. This will take place at public health labs in Los Angeles, San Francisco, Seattle, Chicago, and New York City.

The CDC plans to expand this initiative to more cities in the coming weeks with the goal of eventually conducting national surveillance in order to guide response strategy.

Current laboratory diagnostic methods

	Advantages	Limitations
Isolation & Culture	Golden Standard	<ul style="list-style-type: none"> • Time-consuming (about 1 week) • Easily polluted
Nucleic Acid Detection	Early diagnosis with high sensitivity and specificity	<ul style="list-style-type: none"> • High requirements for lab condition • Expensive
Antigen Detection	Direct evidence of infection	<ul style="list-style-type: none"> • High skills required for operators • Specimen quality may affect the result easily.
IgM Antibody Detection	Earliest serum antibody with high sensitivity and specificity	<ul style="list-style-type: none"> • Individual differences and low immunity may delay antibody emergence.
IgG Antibody Detection	<ul style="list-style-type: none"> • Past/Secondary infection • Retrospective diagnosis reference 	<ul style="list-style-type: none"> • Developed later

Innovita Respiratory Ag Combo Test



Flu A/Flu B/MP Ag 3 in 1

Colloidal Gold (CG)

15 minutes


Swab

Innovita Respiratory IgM Combo Tests

PNEUMONONA
MP/CP/Flu A/Flu B/PIV/RSV/ADV/COX B/LP
IgM 9 in 1 Combo Test (IFA)

Indirect immunofluorescence assay to simultaneously detect antibodies against the main viruses and bacteria causing atypical pneumonia in serum samples

- Mycoplasma Pneumonia (MP)
- Chlamydia Pneumonia (CP)
- Influenza Virus A
- Influenza Virus B
- Parainfluenza Virus (PIV)
- Respiratory Syncytial Virus (RSV)
- Adenovirus (ADV)
- Coxsackievirus Group B (COX B)
- Legionella Pneumophila (LP)



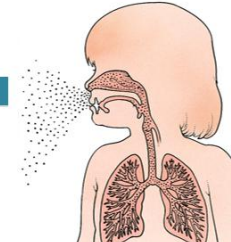
PNEUMOPENTA
MP/CP/RSV/ADV/COX B IgM 5 in 1 Combo Test

The first choice rapid test
of respiratory pathogens in early diagnosis

Simpler . Faster

Improve the prevention of severe respiratory diseases and protect the health of children.

Read results in 15 Minutes




FLUTRIO
Flu A/Flu B/PIV IgM 3 in 1 Combo Test

VANGUARD
of Screening And Diagnosis

Simpler . Faster

Early screening, early diagnosing, early treating... ..

Read results in 15 Minutes



PNEUMONONA 9 in 1	PNEUMOPENTA 5 in 1	FLUTRIO 3 in 1
Indirect immunofluorescence assay (IFA)	Colloidal Gold (CG)	Colloidal Gold (CG)
About 3 hours	15 minutes	15 minutes
Serum/Plasma	Whole blood/Serum/Plasma	Whole blood/Serum/Plasma

Hospitals In Cooperation

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

Thanks for listening!

