泽达精准（杭州）生物医药有限公司

Zeda Precision (Hangzhou) Biopharmaceutical Co.,Ltd

About us

Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd., established in 2019, is located in Binjiang District, Hangzhou, Zhejiang, and enjoys an ideal geographical and business environment. We are an in-vitro diagnostic(IVD) reagent manufacturer and innovator, focusing on clinical applications of mass spectrometry technology, immunological and molecular diagnostics. The company is led by medical experts and renowned scholars from top universities globally, including Zhejiang University. Equipped with cutting edge equipments, our R&D team is determined to advance diagnostic technology. Our latest production facility is built to be incredibly efficient,centered around a 10,000 sqft production line, and ready to provide our customers with the latest and best product in the industry.

Our goal is to become a leading company in promoting and advancing China's in-vitro diagnostic industry. Build a Chinese clinical diagnostics brand with a global presence.

统一社会信用代码

91330108MA2H00DC74 （1/1）

营业执照

（副 本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　泽达精准（杭州）生物医药有限公司

类　　型　有限责任公司(中外合资)

法定代表人　李家睿

经营范围　技术开发、技术咨询：生物技术、医药技术、医疗器械；生产、销售：医疗器械。（涉及国家规定实施准入特别管理措施的除外）（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）

注册资本　伍佰万人民币元

成立日期　2019年10月23日

营业期限　2019年10月23日 至 长期

住　　所　浙江省杭州市滨江区西兴街道江陵路88号7幢205室（自主申报）

登记机关　杭州高新技术产业开发区（滨江）市场监督管理局

2019 年 11 月 22 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
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Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204289

Bijlagen
-

Uw aanvraag
2 september 2020

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

Datum: 3 september 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 2 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Zeda Precision (Hangzhou) Biopharmaceutical Co.,ltd met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Novel Coronavirus S1 Protein Antigen Detection Kit(Latex) ,
Novel Coronavirus(2019-nCoV) IgG/IgM Antibody Detection Kit(Colloidal Gold) , Novel Coronavirus /Influenza Virus A/B Antigens Multiple Detection Kit(Latex)
(geen merknaam) (NL-CA002-2020-53278)
Serum Neutralizing Antibody Rapid Detection Kit For COVID-19 Quantum dot Fluorescence)
(geen merknaam) (NL-CA002-2020-53279)

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

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen 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).

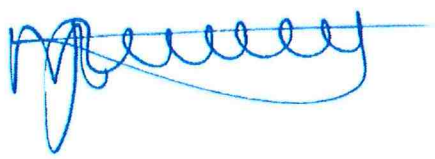
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Zeda Precision (Hangzhou) Biopharmaceutical Co.,ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen 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

Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

EC Declaration of Conformity

Doc#:CE-01/A0

Legal Manufacturer:	Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd
Legal Manufacturer's Address:	7-205, 88 Jiangling Rd, Binjiang Dist, Hangzhou, Zhejiang, China
EC Representative's Name:	Lotus NL B.V.
EC Representative's Address:	Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

We, the manufacturer, declare under our sole responsibility that the product
Product Name:
Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

standards, Applied	EN 23640-2015	EN 13640: 2002
	EN 980: 2016	EN 13641: 2002
	EN ISO 14971: 2019	EN ISO 18113-1 2011
	EN 13612: 2002	EN ISO 18113-4 2011

This self-declaration is according to Annex III (excluding Section 6) of the Directive.
For Medical Professional Use Only!

I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirement with sole responsibility.

CE

Date Signed: 9/21/2020

Jiarui Li
General Manager
Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

成品检验报告单

Certificate Of Analysis

产品名称/PRODUCT NAME: Novel Coronavirus S1 Protein Antigen Detection Kit（Latex）

产品批号/LOT: XGAG200501

生产日期/MFD: 2020-05-09

有效期/EXP. DATE: 2021-05-08

性能指标 Performance index	标准要求 Standard	检验结果 Result
物理检查 Physical Check	外观/Exterior	合格 /PASS
	膜条宽度/width	合格 /PASS
	爬速/Liquid moving speed	合格 /PASS
性能检查 Performance check	阴性符合率 coincidence rate of negative control products	合格 /PASS
	阳性符合率 coincidence rate of positive quality control products	合格 /PASS
	最低检测限/Minimum limit	合格 /PASS
	重复性/Repeatability	合格 /PASS
综合判定 Conclusion	合格 /PASS	

质检员/QC: 储素琴

浙江臻准(杭州)生物医药有限公司 检验专用章

日期/DATE: 2020/05/11


Novel Coronavirus
S1 Protein Antigen
Detection Kit (Latex)
20·Tests
ZEDA
CE IVD

Novel Coronavirus S1 Protein Antigen Detection Kit （Latex） Package Insert

For professional and in vitro diagnostic use only.

PRODUCT NAME

Novel Coronavirus S1 Protein Antigen Detection Kit （Latex）

PACKING

1. 1 piece/bag, 20pieces/box
2. 1 piece/box

INTENDED USE

This product is suitable for the qualitative detection of novel coronavirus in Sputum/Stool samples. It provides an aid in the diagnosis of infection with novel coronavirus.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The test kit contains a test strip, in which, on the nitrocellulose (NC) membrane, the rabbit anti-S1 protein of novel coronavirus antibodies is coated at the test area (T), and the goat anti-rabbit IgG polyclonal antibody is coated at the control area (C). Latex-labeled mouse anti-S1 protein of novel coronavirus antibody and Latex-labeled rabbit IgG are embedded in the reagent pad.

During the test, add three drops of the sample, and the sample laterally flows from the bottom to the top under the capillary effect. If the sample contains the virus, the latex-labeled mAb of anti-S1 protein of novel coronavirus will be bound by the S1 protein of virus, and then captured by anti-S1 protein antibodies coated on the test area (T), the T line is appeared. If the sample does not contain the virus, the latex-labeled mAb of anti-S1 protein of novel coronavirus cannot be captured by anti-S1 protein antibodies coated on the test area (T), therefore, no T line appear. No matter whether there is a novel coronavirus in the sample, the latex-labeled rabbit IgG will be combined with the goat anti-rabbit IgG polyclonal antibody coated on the control area (C). A red latex line will appear in the control area.

At the end of the test, the amount of latex-mAb of anti-S1 protein of novel coronavirus bound on the T line is proportional to the concentration of novel coronavirus in the sample, while the amount of latex on the control line C bound is irrelevant to the amount of coronavirus in the sample.

COMPOSITION

Each piece contains：

1. Disposable test card
2. Disposable sample extraction tubes
3. Disposable paper cup

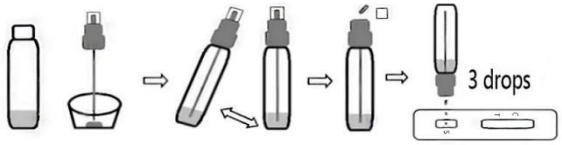
STORAGE AND STABILITY

1. Store as packaged in the hermetic bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date were printed on the labeling.

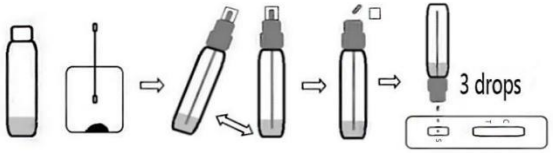
TEST PROCEDURE

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

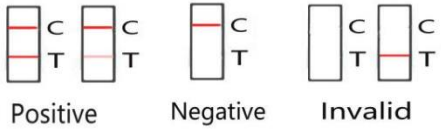
Stool Sample:



Sputum Sample:



1. **Stool Sample:** Unscrew the sampling bottle, use the sampling rod to pick up 10-50mg of fresh stool samples (equivalent to the size of a match head)；or swab the stool with a cotton swab. Put them into the tube and shake and mix completely.
2. **Sputum Sample:** Unscrew the sampling bottle, use the sampling rod or a cotton swab to pick up 10-50mg of fresh sputum samples. Put them into the tube and shake and mix completely.
3. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample into the sample hole vertically.
4. Wait for the appearance of the red stripe on T line, read the result in 15 minutes, and judge it invalid after 20 minutes.



RESULTS OF INTERPRETATION

Positive(+): Both of T and C lines are appeared in 3-15minutes.

Negative(-): C line is appeared while no T line appeared in 15 minutes after the sample added.

Invalid: As long as the C line does not appear, it indicates that the test result is invalid, and should retest with another test card.

NOTES

1. Please make sure that a proper amount of sample is added for testing. Too much or too little sample may cause deviations in results.
2. For positive judgement, it can be confirm as soon as both T and C line appeared. That may be in 3-15 minutes after the sample added. For negative judgement, please wait for 15 minutes after the sample added, C line is appeared while no T line appeared. The result is invalid after 20 minutes after sample added.
3. The test card is a disposable product. Please dispose properly after use.
4. This test device is disposable, please use within the validity period. After use, the test reagent, sample and other waste should be treated in accordance with the relevant national regulations.
5. If part of the test paper in the strip is out of the test window, or more than 2 mm of filter paper or latex pad is exposed in the test window, do not use. Otherwise, the test result is invalid and should replace with another new kit.

SPECIFIC PERFORMANCE DATA

Clinical evaluation

Table: Novel Coronavirus S1 Protein Antigen Detection Kit （Latex） vs. PCR Results (Stool Sample)

		Antigen detection kit		
		Positive	Negative	Total
PCR	Positive	98	3	101
	Negative	5	102	107
	Total	103	105	208
Sensitivity		95.15% (95%CI: 89.03%～98.41%)		
Specificity		97.14% (95%CI: 91.88%～99.41%)		
Accuracy		96.15% (95%CI: 92.56%～98.33%)		

Table: Novel Coronavirus S1 Protein Antigen Detection Kit （Latex） vs. PCR Results (Sputum Sample)

		Antigen detection kit		
		Positive	Negative	Total
PCR	Positive	99	2	101
	Negative	4	103	107
	Total	103	105	208
Sensitivity		96.12% (95%CI: 90.35%～98.93%)		
Specificity		98.10% (95%CI: 93.29%～99.77%)		
Accuracy		97.12% (95%CI: 93.83%～98.93%)		

PERFORMANCE CHARACTERISTICS

Limit of detection (LOD)

LOD studies determine the lowest detectable concentration of COVID-19 at which approximately 100% of all (true positive) replicates test positive. Heat inactivated COVID-19 virus, with a stock concentration of 4.6×10^5 $TCID_{50}$ / ml, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the Coronavirus Ag test..The Limit of Detection of the the novel Coronavirus S1 protein antigen detection kit (latex) is 1.5×10^2 $TCID_{50}$ / ml.

Cross-reactivity

The novel Coronavirus S1 protein antigen detection kit (latex) was evaluated with 8 viral isolates. Viral isolates were evaluated at a concentration of 20 μg/mL. None of the organisms or viruses listed

below gave a positive result in the novel Coronavirus S1 protein antigen detection kit (latex)

SARS-CoV Spike/S1 Protein	MERS-CoV Spike/S1 Protein
Human coronavirus (HCoV-229E) Spike/S1 Protein	Human coronavirus (HCoV-NL63) Spike/S1 Protein
Human coronavirus HKU1 (isolate N1) (HCoV-HKU1) Spike/S1 Protein	Human RSV (B1) glycoprotein G/RSV-G Protein
Influenza A H1N1 (A/Beijing/22808/2009) Hemagglutinin/HA Protein	Influenza B （B/Malaysia/2506/2004）Hemag glutinin/HA Protein

Interference substances studies

The novel Coronavirus S1 protein antigen detection kit (latex) was evaluated with 28 endogenous substances or exogenous drugs for stool sample and 27 for sputum sample. All protein interference substances were evaluated at a concentration of 20 mg/mL. None of the endogenous substances or exogenous drugs listed below gave a positive result in the novel Coronavirus S1 protein antigen detection kit (latex)

Sample Type	**Interference Substances**	**Sample Type**	**Interference Substances**
Stool	Aluminum hydroxide	Stool & Sputum	Ribavirin
	Sodium bicarbonate		Oseltamivir
	Sodium chloride		Paramive
	Qu Anide		Lopinavir
	Ritonavir		Abidor
Sputum	mucin		Tobramycin
	Triamcinolone	Stool & Sputum	Phenylephrine
	Ritonavir		Zanamivir
	Acetonide		Oxymetazoline
Stool & Sputum	Hemoglobin		Histamine hydrochloride
	Bilirubin		Beclomethasone
	Levofloxacin		Dexamethasone
	Azithromycin		Flunisolide
	Ceftriaxone		Budesonide
	Meropenem		Mometasone
	α-interferon		Fluticasone

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Manufacturer

Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd.
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Koningin Julianaplein 10 Tel: +31644168999
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The Hague, Netherlands

Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)

Accelerated and Transport Stability Study Report

Final report date: 2020.06.16

Management of the study: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

R&D Department

Quality Management Department

Place of study: Hangzhou

Sponsor: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Study Director Signature and Verification Dates

Company: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Position: Director of Quality Management Department

Study Director: Xiaonan Lu

Signature: Lu Xiao nan Date: 2020.06.16

Position: Director of R&D Department

Study Handlers: Menglei Guo

Signature: Menglei Guo Date: 2020.06.16

Reviewer: Runze Chen

Signature: Runze Chen Date: 2020.06.16

Study summary

Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) were stored at 45℃ for 41 days, the performance still met Evaluation Criteria. If opening the primary package,the in-use stability of the reagents was ideal within 1 hour, no matter what the conditions were. Reagents still preformed well after 10 days transport by express.

1. Purpose

The test was to indicate the product shelf-life,transport and storage condition , and in-use stability of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) after the first opening of the primary package.

2. Materials

Reagents: Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) (Lot#: XGAG200501, XGAG200502, XGAG200503)

Samples: 10 negative control products, 3 positive controls

3. Method

In the test, the stability was evaluated under the following three conditions:

Formula to indicate the shelf-life (according to Arrhenius's equation):

$AAF=Q_{10}^{(TAA-TRT)/10}$

AAF: Accelerated aging factor

Q_{10}: An aging factor for 10℃ increase or decrease in temperature (Q_{10} = 3 is a means of calculating an aging factor when Using the Arrhenius equation)

T_{AA}: Accelerated aging temperature (45℃)

T_{RT}: Ambient temperature (25℃)—Select a temperature that represent that the actual product storage and working condition (The room temperature is typically between 20℃ to 25℃. A temperature of 25℃ is considered a conservative approach.)

Where Q_{10} = 3, ambient temperature = 25℃ accelerated aging temperature = 45 ℃

$AAF = 3.0^{(45-25)/10}=3.0^{2.0}=9$

AAT = 365*1/9 ≈ 41

41 days at accelerated aging condition is equivalent to a product shelf-life of 12 months in real-time study.

Method: Set the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) from three sequential batches under 45℃ for 41 days. The relative humidity is normal.

Test frequency: Carry out a test after 5, 10, 15, 20, 25, 30, 35, 40, and 41 days from the beginning of the study.

Test duration date： 2020-05-05~ 2020-06-16

The amount of each test： 35 copies

4. Test item

Performance index		Quality control	Method content
Physical properties	Exterior	/	Visually check the appearance under natural light.
	width	/	Use a measuring ruler to check the width of the film strip.
	Liquid moving speed	Negative sample	Take 3 copies of the same batch of reagents, follow the instructions, count the time after the negative sample is added, record the time (t) for the liquid to travel to the top of the observation window, and measure the travel distance (L) with a measuring ruler, calculate L/t, which is the moving speed.
Specificity		10 negative control products N1~N10	Take 10 pieces of the same batch of reagents and follow the instructions to test the negative control products separately.
Sensitivity		Positive quality control	Take 3 copies of the same batch of reagents, follow the instructions, and test positive quality control products, repeat 3 times.

LOD	Quality control products with minimum detection	Take 3 pieces of the same batch of reagents, follow the instructions, and test the minimum detection quantity of quality control products, repeat 3 times.
Repeatability	Repetitive control	Take 10 pieces of the same batch of reagents and follow the instructions to test the repetitive properties of the control and repeat 10 times.

5. Evaluation Criteria

5.1 The appearance is smooth, the material is firmly attached, and the content is complete; the width of the film strip should not be less than 3mm; the liquid moving speed should not be less than 10mm/min.

5.2 The coincidence rate requirements of negative quality control products are verified by enterprise quality control products, and 20 negative quality control products are tested.

5.3 The test results of the coincidence rate requirements of positive quality control products are all positive.

5.4 The minimum detection requirement requires that the test results are positive.

5.5 Repeatability requires repeated testing with repetitive control materials 10 times, and the test results are positive.

5.6 If the result meets the requirement, it is judged as qualified; if the result does not meet the requirements, it is judged as unqualified.

6. Result

The test was carried out according to the test procedure of the reagent,and the results were read after 15 minnutes.

The results as follows("＋"＝Positive, "－"＝Negative)

6.1 Accelerated stability study

Lot#: XGAG200501

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
5th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
10th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
15th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
20th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
25th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
30th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
35th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
40th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
41th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified

Lot#: XGAG200502

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
5th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
10th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
15th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
20th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
25th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
30th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
35th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
40th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified
41th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified

Lot#: XGAG200503

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
5th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
10th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
15th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
20th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
25th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
30th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
35th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
40th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified
41th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified

6.2 In-use stability

Lot#: XGAG200501

	The normal conditions				The abnormal conditions			
	Physical properties	Specificity	Sensitivity	LOD	Physical properties	Specificity	Sensitivity	LOD
1st hour	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified	−(10/10)	+(3/3)	+(3/3)
2nd hour	Qualified	−(10/10)	+(3/3)	+(2/3)	Qualified	−(10/10)	+(3/3)	+(3/3)
3rd hour	Qualified	−(10/10)	+(3/3)	+(1/3)	Qualified	−(10/10)	+(3/3)	+(3/3)

Lot#: XGAG200502

	The normal conditions				The abnormal conditions			
	Physical properties	Specificity	Sensitivity	LOD	Physical properties	Specificity	Sensitivity	LOD
1st hour	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified	−(10/10)	+(3/3)	+(3/3)
2nd hour	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified	−(10/10)	+(3/3)	+(2/3)
3rd hour	Qualified	−(9/10)	+(3/3)	+(2/3)	Qualified	−(8/10)	+(3/3)	+(1/3)

Lot#: XGAG200503

	The normal conditions				The abnormal conditions			
	Physical properties	Specificity	Sensitivity	LOD	Physical properties	Specificity	Sensitivity	LOD
1st hour	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified	−(10/10)	+(3/3)	+(3/3)
2nd hour	Qualified	−(10/10)	+(3/3)	+(2/3)	Qualified	−(10/10)	+(3/3)	+(3/3)
3rd hour	Qualified	−(8/10)	+(3/3)	+(1/3)	Qualified	−(7/10)	+(3/3)	+(1/3)

6.3 Transport simulation

Lot#: XGAG200501

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
15th Day	Qualified	−(10/10)	+(3/3)	+(3/3)	Qualified

Lot#: XGAG200502

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
15th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified

Lot#: XGAG200503

	Physical properties	Specificity	Sensitivity	LOD	Repeatability
15th Day	Qualified	－(10/10)	＋(3/3)	＋(3/3)	Qualified

7. Conclusion

When set three sequential batchs of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) (Lot#: XGAG200501, XGAG200502, XGAG200503) under 45℃ for 41days, their performance still met the evaluation Criteria.

No matter what the conditions are,the in-use stability of the reagent after the first opening of the primary package is ideal in 1 hour.

The reagents keep good performance after transport to MoBei and back for 14Day.

Based on the result above,it should be reliable to define the condition for transport and storage of the test kit as the temperature range is 2℃~30℃ and the relative humidity is normal.The expirt date could be 12 months under the condition above. However, we recommend that operators use the reagent as soon as possible,just within 1hour after removal from pouch,specifically the room temperature is higher than 30℃ and the humidity is high.

Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)

Clinical Study Report

Final report date: 2020.10.15

Management of the study: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

R&D Department

Quality Management Department

Place of study: Hangzhou

Sponsor: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Study Director Signature and Verification Dates

Company: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Position: Director of Quality Management Department

Study Director: Xiaonan Lu

Signature: Lu Xiaonan Date: 2020.10.15

Position: Director of R&D Department

Study Handlers: Menglei Guo

Signature: Menglei Guo Date: 2020.10.15

Reviewer: Runze Chen

Signature: Runze Chen Date: 2020.10.15

Product name: Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)

Specifications: 20 Tests/Box

Start and end time of the test: August 20, 2020 ~October 15, 2020

Unit: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Address: 205, Building 7, Jiangling Road, Xixing Street, Binjiang District, Hangzhou, Zhejiang, P.R. China

List

1. Summary

The Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) is a lateral flow chromatographic immunoassay for the qualitative and quantitative detection of the COVID-19 in human samples. It provides and aid in the diagnosis of infection with 2019-nCOV.

2. Acronyms

1) Test reagents: Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) developed by Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd.
2) 2019-nCOV/COVID-19: the Corona Virus Disease of 2019

3. Investigators

Name	Position	Responsibility	Institutions
Xiaonan Lu	Manager Representative	Study Director	Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd
Menglei Guo	R&D Supervisor	Study Handler	
Runze Chen	R&D Technician	Reviewer	

4. Fundamental contents

4.1 Instruction

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The test kit contains a test strip, in which, on the nitrocellulose (NC) membrane, the rabbit anti-S1 protein of novel coronavirus antibodies is coated at the test area (T), and the goat anti-rabbit IgG polyclonal antibody is coated at the control area (C). Latex-labeled mouse anti-S1 protein of novel coronavirus antibody and Latex-labeled rabbit IgG are embedded in the reagent pad.

During the test, add three drops of the sample, and the sample laterally flows from the bottom to the top under the capillary effect. If the sample contains the virus, the latex-labeled mAb of anti-S1 protein of novel coronavirus will be bound by the S1 protein of virus, and then captured by anti-S1 protein antibodies coated on the test area (T), the T line is appeared. If the sample does not contain the virus, the latex-labeled mAb of anti-S1 protein of novel coronavirus cannot be captured by anti-S1 protein antibodies coated on the test area (T), therefore, no T line appear. No matter whether there is a novel coronavirus in the sample, the latex-labeled rabbit IgG will be combined with the goat anti-rabbit IgG polyclonal antibody coated on the control area (C). A red latex line will appear in the control area.

At the end of the test, the amount of latex-mAb of anti-S1 protein of novel coronavirus bound on the T line is proportional to the concentration of novel coronavirus in the sample, while the amount of latex on the control line C bound is irrelevant to the amount of coronavirus in the sample.

4.2 Trial purposes

The Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) developed by Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd. was compared with the diagnosis results of the 2019-nCOV nucleic acid detection reagent approved for sale in China. The Statistical coincidence rate of the test results was used to verify that if it could be used as an aid for the diagnosis of suspected cases of 2019-nCoV.

4.3 Trial management

Clinical trials were completed in diagnostic laboratories regulated by clinical trial units. The main experimenters are subject leaders, and the participants are all professionally trained technical personnel. The clinical trial process was carried out strictly in accordance with relevant regulations such as the “Guidelines for Clinical Testing Techniques of In Vitro Diagnostic Reagents”. The clinical trial plans formulated by both parties, and no relevant technical issues occurred.

For any item in the clinical trial record form, the data is filled in truthfully, completely, and in accordance with statistical

significance.

4.4 Trial design

4.4.1 Trial overall design and program description

The clinical trial specimens were collected by the clinical trial institutions. The sample confirmed by Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd. before was tested by the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) developed by Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd. The clinical sensitivity, clinical specificity and total coincidence rate were counted based on the results.

4.4.2 Trial design and method selection

(1) The basis for determining the number of samples.

With reference to relevant regulations, and taking into account the uncertainty of obtaining samples, the number of samples for this clinical trial should not be less than 100, of which the number of positive samples should not be less than 30.

(2) Sample selection basis, inclusion criteria and exclusion criteria.

The clinical trial samples are sputum or stool samples collected by the Hangzhou Center for Disease Control and Prevention, the positive and negative results are confirmed by clinical diagnosis. A total of 208 samples were collected and 101 patients were infected 2019-nCoV pneumonia and the others are not.

(3) Sample collection, storage, transportation methods, etc.

In different stages of disease, the sputum or stool samples were collected with a collection tube respectively. Samples should be tested as soon as possible. Samples for testing within 24 hours can be stored at 2~8℃. If long-term storage is required, samples should be stored at -20℃ and below. The longest time is about 2 months.

(4) Establishment of the "Gold standard"

Nucleic acid testing is currently the "Gold standard" for the diagnosis of 2019-nCoV. The Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd. has mature methods. It mainly detects the ORFlab, N gene and E gene of the 2019-nCoV, and can be used as an auxiliary diagnosis and emergency reserve for pneumonia infected by the 2019-nCoV.

(5) The basic information of clinical trial reagents and the registration status of the "Gold standard" reagents.

Test reagent	Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)		
Specification	20 Tests/Box	Lot number	XGAG200501
			XGAG200502
			XGAG200503
Period of Validity	1 year	Storage Conditions	2~30℃
Manufacturer	Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd		

Gold Standard reagent	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR kit		
Approval Number	CFDA NO:20203400057		
Specification	50 Test/Box		
Period of Validity	6 months	Storage Conditions	Store at -20±5℃ away from light
Manufacturer	Shanghai ZJ Bio-Tech Co., Ltd.		

(6) Quality control methods

The clinical trial operation is strictly carried out in accordance with the corresponding instruction manual.

(7) Statistical analysis method of clinical trial data

		Contrast reagent		Total
		Positive	Negative	
Test reagent	Positive	a	b	a + b
	Negative	c	d	c + d
Total		a + c	b + d	a + b + c + d

Clinical sensitivity (%) = [a / (a + c)] × 100%

Clinical specificity (%) = [d / (b + d)] × 100%

Coincidence rate (%) = [(a + d) / (a + b + c + d)] × 100%

Average clinical sensitivity = Σ(clinical sensitivity)/n

Average clinical specificity =Σ(clinical specificity)/n

Average coincidence rate =Σ(coincidence rate)/n

95%CI: Ave-1.96*SD~Ave+1.96*SD

4.5 Clinical trial results and analysis

Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) (Lot#: XGAG200501, XGAG200502, XGAG200503) were tested. The test was carried out according to the test procedure of the reagent, and the results were read after 15 minutes.

4.5.1 Test Results

LOT#: XGAG200501 Stool		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	98	5	103
	Negative	3	102	105
Total		101	107	208

LOT#:XGAG200501 Sputum		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	99	4	103
	Negative	2	103	105
Total		101	107	208

LOT#: XGAG200502 Stool		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	96	4	103
	Negative	5	103	105
Total		101	107	208

LOT#:XGAG200502 Sputum		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	101	10	111
	Negative	4	93	97
Total		101	107	208

LOT#: XGAG200503 Stool		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	95	7	102
	Negative	5	101	106
Total		100	108	208

LOT#:XGAG200503 Sputum		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	102	2	104
	Negative	5	99	104
Total		107	101	208

4.5.2 Result analysis

		Clinical Sensitivity	Clinical Specificity	Coincidence Rate
Stool	LOT#: XGAG200501	95.15%	97.14%	96.15%
	LOT#: XGAG200502	95.05%	96.26%	95.67%
	LOT#: XGAG200503	95.00%	93.52%	94.23%
Sputum	LOT#: XGAG200501	96.12%	98.10%	97.12%
	LOT#: XGAG200502	96.19%	90.29%	93.27%
	LOT#: XGAG200503	95.33%	98.02%	96.63%

The average clinical sensitivity = 95.05% (95%CI: 92.65%~97.45%)
The average clinical specificity = 96.74% (95%CI: 95.28%~98.2%)
The total coincidence rate = 95.56% (95%CI: 93.76%~97.36%)

4.6 Discussion and conclusion

The Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) is a lateral flow chromatographic immunoassay for the qualitative and quantitative detection of the Novel coronavirus in human samples. It provides an aid in the diagnosis of infection with 2019-nCOV.

In the clinic trial, the “Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit” produced by Shanghai ZJ Bio-Tech Co., Ltd., which has been approved for sale in China, is used as the “gold standard” reagent. For the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) developed by Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd., the average clinical sensitivity was 95.05% (95%CI: 92.65%~97.45%)， the average clinical specificity is96.74% (95%CI: 95.28%~98.2%), the coincidence rate is 95.56% (95%CI: 93.76%~97.36%).

In summary, the overall agreement rate between the test reagent and the “gold standard” reagent is relatively high, and satisfy the judgment criteria. The test reagent can be used as an aid for the diagnosis of suspected cases of 2019-nCOV.

5. Notes on special circumstances in clinical trials

No special circumstances.

6. Annex

1、References
2、Instruction manual
3、All trial data in clinical trials

References

[1] Population-based age-stratified seroepidemiological investigation protocol for coronavirus 2019 (COVID-19) infection

[2] Evaluation of nine commercial SARS-CoV-2 immunoassays

[3] Towards the next phase: evaluation of serological assays for diagnostics and exposure assessment

[4] Herd immunity is not a realistic exit strategy during a COVID-19 outbreak

Novel Coronavirus S1 Protein Antigen Detection Kit (Latex)

Real-time Stability Study Report

Final report date:_____

Management of the study: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

R&D Department

Quality Management Department

Place of study: Hangzhou

Sponsor: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Study Director Signature and Verification Dates

Company: Zeda Precision (Hangzhou) Biopharmaceutical Co., Ltd

Position: Director of Quality Management Department

Study Director: Xiaonan Lu

Signature:_____ Date: _____

Position: Director of R&D Department

Study Handlers: Menglei Guo

Signature:_____ Date: _____

Reviewer: Runze Chen

Signature:_____ Date: _____

Study summary

Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) were produced and placed in the product warehouse with temperature between 2℃ to 30℃ and the normal humidity. A series of tests are performed after1,2,3,6,9,12,15 months from production to confirm the shelf-life of the product in above condition.

1. Purpose

The test was to indicate the product shelf-life stability of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex).

2. Materials

Reagents: Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) (Lot#: XGAG200501, XGAG200502, XGAG200503)

Samples: 10 negative control products, 3 positive controls

3. Method

Three sequential batches of the Novel Coronavirus S1 Protein Antigen Detection Kit (Latex) are placed in the product warehouse with the temperature between 2℃ to 30℃ and the normal humidity. A series of tests are performed after each month until 15 months from production.

4. Test item

Performance index		Quality control	Method content
Physical properties	Exterior	/	Visually check the appearance under natural light.
	width	/	Use a measuring ruler to check the width of the film strip.
	Liquid moving speed	Negative sample	Take 3 copies of the same batch of reagents, follow the instructions, count the time after the negative sample is added, record the time (t) for the liquid to travel to the top of the observation window, and measure the travel distance (L) with a measuring ruler, calculate L/t, which is the moving speed.
coincidence rate of negative control products		10 negative control products N1~N10	Take 10 pieces of the same batch of reagents and follow the instructions to test the negative control products separately.
coincidence rate of positive quality control products		Positive quality control	Take 3 copies of the same batch of reagents, follow the instructions, and test positive quality control products, repeat 3 times.
LOD		Quality control products with minimum detection	Take 3 pieces of the same batch of reagents, follow the instructions, and test the minimum detection quantity of quality control products, repeat 3 times.
Repeatability		Repetitive control	Take 10 pieces of the same batch of reagents and follow the instructions to test the repetitive properties of the control and repeat 10 times.

5. Evaluation Criteria

5.1 The appearance is smooth, the material is firmly attached, and the content is complete; the width of the film strip should not be less than 3mm; the liquid moving speed should not be less than 10mm/min.

5.2 The coincidence rate requirements of negative quality control products are verified by enterprise quality control products, and 20 negative quality control products are tested.

5.3 The test results of the coincidence rate requirements of positive quality control products are all positive.

5.4 The minimum detection requirement requires that the test results are positive.

5.5 Repeatability requires repeated testing with repetitive control materials 10 times, and the test results are positive.

5.6 If the result meets the requirement, it is judged as qualified; if the result does not meet the requirements, it is judged as

unqualified.

6. Result

The test was carried out according to the test procedure of the reagent,and the results were read after 15 minnutes.

The results as follows("＋"＝Positive, "－"＝Negative)

Lot#: XGAG200501

	Physical properties	coincidence rate of negative	coincidence rate of positive	LOD	Repeatability
1th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
2th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
3th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
6th Month					
9th Month					
12th Month					
15th Month					

Lot#: XGAG200502

	Physical properties	coincidence rate of negative	coincidence rate of positive	LOD	Repeatability
1th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
2th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
3th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
6th Month					
9th Month					
12th Month					
15th Month					

Lot#: XGAG200503

	Physical properties	coincidence rate of negative	coincidence rate of positive	LOD	Repeatability
1th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
2th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
3th Month	Qualified	－(10/10)	＋(3/3)	＋(3/3)	＋(10/10)
6th Month					
9th Month					
12th Month					
15th Month					

7. Conclusion

The study is going to be finished on 2021.08.

新冠抗原&抗体检测试剂整体方案

COVID-19 Antibody & Antigene Test Solutions

泽达精准（杭州）生物医药有限公司
Zeda Precision (Hangzhou) Biopharmaceutical Co.,Ltd

目录

新冠产品简介

Novel Coronavirus (2019-nCoV) IgG/IgM Antibody Detection Kit

操作简单方便，适用于大量疑似病例和无症状感染者检测

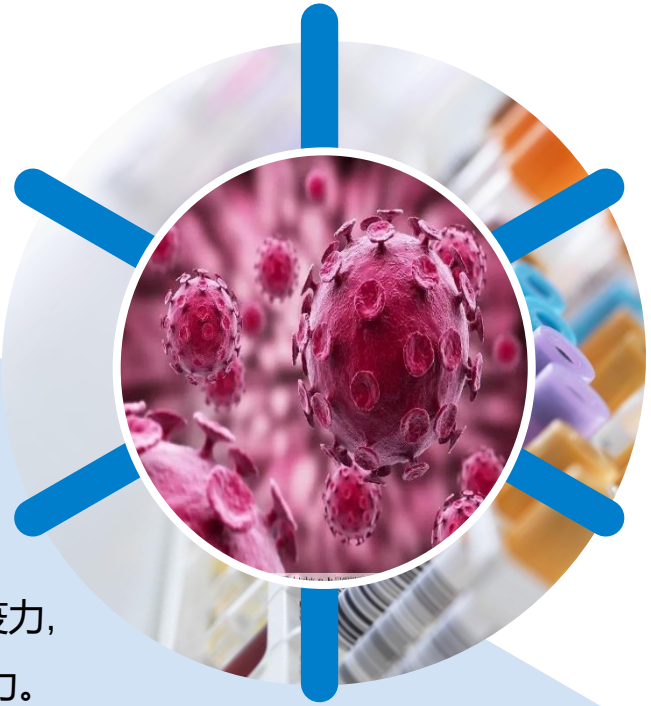
The operation is simple and convenient, suitable for the detection of a large number of suspected cases and asymptomatic infections

... ...

Serum Neutralizing Antibody Rapid Detection Kit For COVID-19

正确衡量病人是否已经具有免疫力，可用于确定疫苗的效力。

Correctly measure whether the patient has immunity, Can be used to determine the effectiveness of vaccines.



Novel Coronavirus S1 Protein Antigen Detection Kit

对实验室要求较低，可用于早筛查、早诊断，适合基层医院大规模筛查

Low requirements on the laboratory, can be used for early screening, early diagnosis, suitable for large-scale screening in primary hospitals

Novel Coronavirus Influenza Virus A/B Antigens Multiple Detection Kit

用于临床和检测人群的快速分流，在抗击新型冠状病毒肺炎疫情的同时警惕季节性流感的叠加效应。

Rapid diversion of clinical and test populations to combat COVID-19 while alerting the combined effects of seasonal influenza.

产品原理

Novel Coronavirus S1 Protein Antigen Detection Kit（Latex）

- 双抗体夹心法，识别不同抗原位点的一对抗体，一个包被在NC膜上，另一个标记指示剂（红色乳胶颗粒），当抗原存在时，分别于这两个抗体进行反应，形成一个三明治的结构，在检测区（T线）呈现色带。
- Double antibody sandwich method is used to identify a pair of antibodies with differentantigen sites.

Novel Coronavirus (2019-nCoV) IgGIgM Antibody Detection Kit (Colloidal Glod)

- 利用重组蛋白片段和抗体，通过间接法和和侧向免疫层析技术，定性检测样本中的抗新冠病毒IgM抗体和IgG抗体。
- The recombinant protein fragment and antibody were used to qualitatively detect IgM and IgG antibodies of 2019-nCoV by indirect method and lateral immunochromatography.

产品优势

	核酸检测试剂	抗原检测试剂	抗体检测试剂
用途	诊断	诊断、筛查	辅助诊断，流行病学分析
灵敏度	高	高	较高
特异性	假阳性：0%～5%	假阳性0% ～2%	假阳性 2%～10%
检出时间	感染后1～5天	感染后1～5天	症状发作后3～5天
样本类型	鼻/鼻咽拭子，微创采样，患者不耐受	粪便/痰液，无创采样	有创采样，血清、血浆、全血
分析程度	定量，准确度高，可追溯	定性，肉眼判断	定性，肉眼判断
检测设备	高端、精密、昂贵	简单、低廉、无需特殊设备	简单、低廉、无需特殊设备
检测要求	专业的实验室（P3、P4）	相对独立通风场所	相对独立通风场所
检测速度	4~6小时，一般需第二天才能拿到检验报告	15~30分钟，现场即时检测	15~30分钟，现场即时检测
应用范围	大型医院、体检中心、第三方检测机构	医院、机场、车站等需要疫情防控的场所	医院、机场、车站等需要疫情防控的场所

Advantage

	Nucleic acid detection reagent	Antigen detection reagent	COVID-19 IgG/IgM Rapid Test Device
Using	On-site diagnosis，mass screenin	clinical diagnosis	Auxiliary diagnosis，epidemiological analysis
Sensitivity	higher	higher	High
Specificity	False Positive：0~5%	False Positive：0~2%	False Positive：2%~10%
Detection period	1~5 days after infection	1~5 days after infection	3~5 days after Symptoms attack
Sample	Nasal swab or Throat swab, minimally invasive sampling,Patient intolerance	Feces/sputum, non-invasive sampling	Whole blood or serum or plasma, Invasive sampling
Analysis	quantitative，high accuracy，objective result，Data traceability	qualitative，visual interpretation	qualitative，visual interpretation
Detection requirement	Professional P3 P4 laboratory, trained professionals and a variety of high-end equipment	Relatively independent Well Ventilated places	Relatively independent Well Ventilated places
Turnaround Time	4-6 hours, reports out next day	15~30min，on-site real time detection	15~30min，on-site real time detection
Applicable scenarios	Large hospitals, centers for disease control, third party independent medical laboratories, etc	Public places such as airports, railway stations, hospitals at all levels	Public places such as airports, railway stations,, hospitals at all levels

解决方案

抗原检测试剂	抗体检测试剂		结果说明	临床意义
	IgM（早期）	IgG（中晚期）		
-	-	-	体内病毒含量未达到检测限	未感染新冠病毒
+	-	-	病毒通过复制增殖，产生大量蛋白	患者处于病毒感染的“窗口期”
+	+	-	初次感染，人体产生IgM抗体	患者处于病毒感染早期
+	+	+	人体对病毒产生一定的免疫力	患者处于病毒感染活跃期
+	-	+	患者感染病毒超过1个月	患者处于病毒感染中晚期或者二次感染
-	+	+	患者近期感染，但体内病毒被清除	患者处于恢复期
-	-	+	患者既往感染过病毒，但体内病毒被清除	患者处于恢复期

Solution

Antigen	Antibody		Result	Clinical significance
	IgM (Early)	IgG (Middle/later)		
-	-	-	The virus load is below detection limit	Not infected
+	-	-	Viruses produce a large number of proteins through replication and proliferation	Window period
+	+	-	The human body produces IgM antibodies	early virus infection
+	+	+	The paitient is immune to virus	Active period
+	-	+	The patient was infected with the virus for more than 1 month	Late infection or secondary infection
-	+	+	The patient was recently infected, but the Virus is cleared	Recovery period
-	-	+	The patient was infected before, but the Virus is cleared	Recovery period

整体解决方案

➢1.检出率提高，减少漏检率。由于抗体是间接法法检测，人体产生抗体的时间有空窗期。使用抗原抗体双项检测可提高准确率。

➢2.判读方便快速，相较于核酸检测，抗体抗原检测均可以当场15分钟出结果。

➢3.抗原检出率与核酸相近，只要采样准确，均可检测出是否被病毒感染。

➢4.价格经济实惠，无大型传染病实验室等现场设备技术需求。普通检验科人员即可操作，适用场景广泛。

➢5.甲型流感病毒、乙型流感病毒等相关病毒感染致病的临床表现与新型冠状病毒肺炎相似，快速检测和精准鉴别对疫情防控具有 重要作用。新型冠状病毒SARS-CoV-2、甲型流感病毒及乙型流感病毒联合检测试剂盒可实现一次性检测三种病毒，用于临床和检测人群的快速分流，在抗击新型冠状病毒肺炎疫情的同时警惕季节性流感的叠加效应。

Comprehensive Test Solution

1. Improve the detection rate and reduce the missed detection rate. Since antibodies are detected by an indirect method, there is a window of time for the body to produce antibodies. The use of antigen- antibody dual detection improve accuracy.
2. Interpretation is easy and fast. Compared with nucleic acid detection, antibody and antigen detection can produce results on-site within 15 minutes.
3. The detection rate of antigen is similar to that of the Nucleic acid Method. As long as the sampling is accurate, It can provides a diagnosis on infection.
4. The price is Affordable and there is no need for Professional biosafety or other field equipment technology. It can be operated by ordinary laboratory personnel and has a wide range of application scenarios.
5. The clinical manifestations of diseases caused by influenza A virus, influenza B virus and other related viruses are similar to those of SARS-COV-2. Rapid detection and accurate identification play an important role in epidemic prevention and control. Novel Coronavirus SARS-COV-2, Influenza A virus and influenza B virus combined detection kit can detect three viruses at once, which can be used for rapid triage of clinical population, and alert the superposition effect of seasonal flu while fighting COVID-19 pandemic .


谢谢！
Thank you!