TEFANESO SERVICE

UNDER THE AUTORITY OF TEFANESO SWITZERLAND S. A.

Medical

TEST COVID-19

Coronavirus (2019-nCoV)
IgM/IgG Antibody
Test Kit (Colloidal Gold)

CE and FDA certified

COVID-19 can be screened and diagnosed by measuring the antibody IgG & IgM for novel coronavirus. Antibody IgM appears in the early stage of infection, while Antobody IgG in the late stage.

- Easy: only three steps to read results
- Efficient: reliable results in less than 15 minutes.

Ref. 11500-010

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IDE: CHE-274.734.952

Declaration of Conformity

Certificate No.:EU2020007

Product Name:

Novel Coronavirus（2019-nCoV）IgG Test Kit (Colloidal gold)
Novel Coronavirus（2019-nCoV）IgM Test Kit (Colloidal gold)
Novel Coronavirus（2019-nCoV）IgG/IgM Test Kit (Colloidal gold)

Model:

25T/kit, 50T/kit

Classification:

Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:

IVDD 98/79/EC Annex III (excludes section 6)
We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

General Applicable Directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016	EN ISO 23640:2015	EN ISO 14971:2012	EN ISO 18113-1:2011
EN ISO 15223-1:2016	EN 14136:2004	EN 13612:2002	EN ISO 18113-2:2011

CE

Place, Date of Issue: Shenzhen, Mar. 20th, 2020
Position Held in Company: Management Representative
Signature:

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空运 By Air

NO.2020042878

CNAS 中国认可 检验 INSPECTION CNAS C0071

货物运输条件鉴定书

Certification

for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新冠抗体胶体金法稀释液

Sample Name: (2019-nCoV) IgG/IgM Diluent

委托单位： 深圳市锦瑞生物科技有限公司

生产单位： 深圳市锦瑞生物科技有限公司

上海化工院检测有限公司 检验检测专用章

上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空运 By Air 空运 By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020042878

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样品名称 Sample Name	中文 Chinese	新冠抗体胶体金法稀释液
	英文 English	(2019-nCoV) IgG/IgM Diluent
委托单位 Consignor		深圳市锦瑞生物科技有限公司
生产单位 Manufacturer		深圳市锦瑞生物科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		无色透明液体，稍有气味 Colorless transparent Liquid, Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。 None.

2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR)

可按非限制性货物条件办理。 The substance is not subject to IATA DGR.

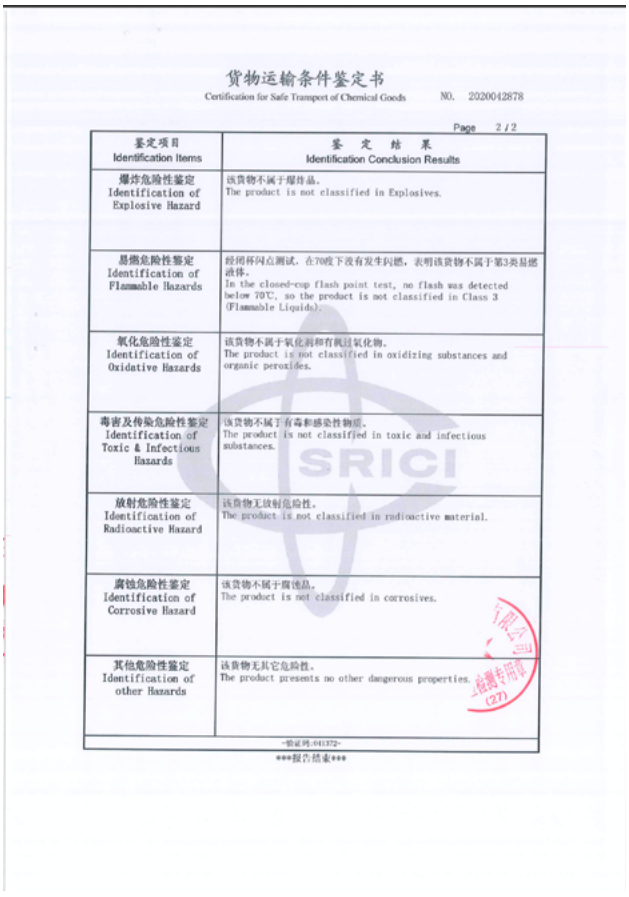
3. 包装要求(Packaging requirements)

无。 None.

检验日期: Inspection Date: 2020-04-09 签发日期: Issue Date: 2020-04-09 生效日期: Effective Date: 2020-04-09

备注 Comment	无。 None.

批准 Approver: 审核 Checker: 主检 Appraiser:



货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020042878

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鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	经闭杯闪点测试，在70度下没有发生闪燃，表明该货物不属于第3类易燃液体。 In the closed-cup flash point test, no flash was detected below 70℃, so the product is not classified in Class 3 (Flammable Liquids).
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:041372-

报告结束

Declaration of Conformity

Product Name:
Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Test Kit (Colloidal gold)

Model:
1T/kit, 5T/kit, 10T/kit, 25T/kit, 50T/kit

Classification:
Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:
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EN ISO 15223-1:2016	EN 14136:2004	EN 13612:2002	EN ISO 18113-2:2011

CE

Place, Date of Issue: Shenzhen, Apr, 3rd, 2020
Position Held in Company: Management Representative
Signature:

FDA

U.S. FOOD & DRUG ADMINISTRATION

Submission Number: PEUA200209
Received: 3/25/2020

Device: Novel Coronavirus(2019-nCoV)IgG/IgM Test Kit (Colloidal gold)

GUIDANCE DOCUMENT

Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff

MARCH 2020

Download the Final Guidance Document | Read the Federal Register Notice

Final

C. Commercial Manufacturer Development and Distribution of Tests Prior to EUA Submission

The policy described in this subsection applies to commercial manufacturers that seek to develop and distribute diagnostic test kits to detect the SARS-CoV-2 virus to clinical laboratories or to healthcare workers for point-of-care testing. This policy does not apply to at home testing.

In light of the increasing numbers of COVID-19 cases throughout the country and the urgent need to expand the nation's capacity for COVID-19 testing during the public health emergency, FDA does not intend to object to a commercial manufacturer's development and distribution of SARS-CoV-2 test kits for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. Transparency can help mitigate potential adverse impacts from a poorly designed test by facilitating better informed decisions by potential purchasers and users.

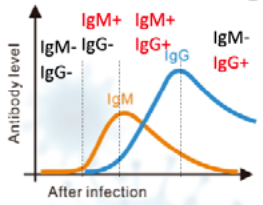
IgG and IgM

Antibody IgG and IgM belong to serological testing

The measured antibody IgG and IgM are specific to the novel coronavirus.

What's the difference between IgG and IgM?

- After the virus infection, the antibody IgM appears and rises in the early stage, while antibody IgG appears and rises in the late stage.
- By combining IgG and IgM, we can know if the body is infected and which stage it is.



单击此处编辑标题

- Colloidal gold is a kind of method to measure the antibody on a test card. Sometimes it's also called lateral flow method or similar.
- This method doesn't need any equipment to read results. Results can be read through eyes.
- Qualitative results

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Test Kit

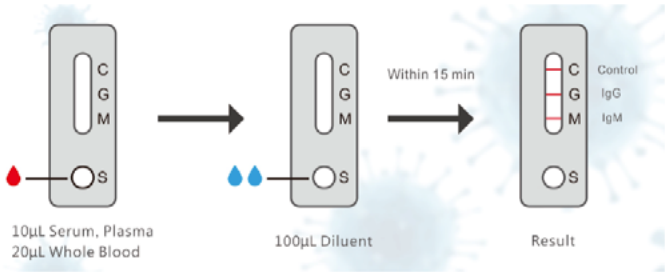
- 25 tests per kit
- Each card report both IgG and IgM results

Each test card is packed inside an individual pouch

Operation

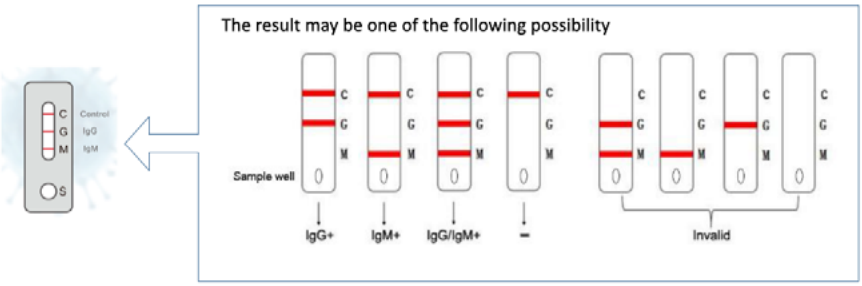
How to use:

- Take one pouch from the kit, open the pouch, put the test card on the table.
- Add 20uL of whole blood (or 10uL of serum/plasma) into the sample inlet by a pipette.
- Instantly add 4 drops of diluent into the sample inlet.
- Read the results within 15 minutes (no more than 15 minutes)



Read results

- Read results



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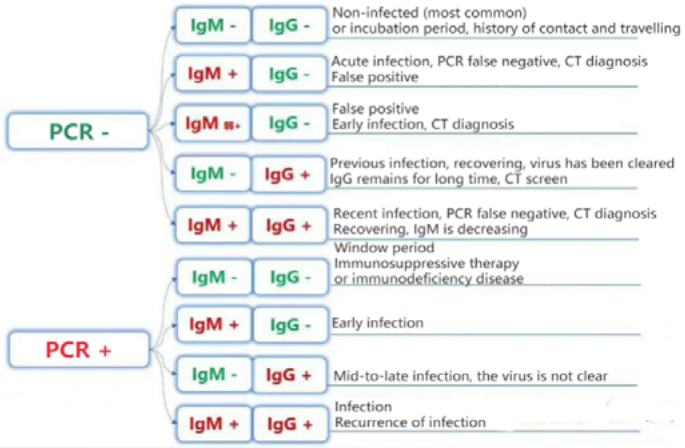
Interpretation



Why false negative?

Factors that lead to PCR false negative results:

- poor quality of the specimen, containing little patient material (as a control, consider determining whether there is adequate human DNA in the sample by including a human target in the PCR testing).
- the specimen was collected late or very early in the infection.
- the specimen was not handled and shipped appropriately.
- technical reasons inherent in the test, e.g. virus mutation or PCR inhibition.

Antibody test

Is the antibody test result not good?

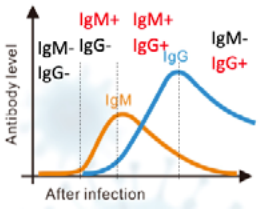
- There is window period to produce antibody.

  Specific IgM becomes detectable around 3-5 days after onset, while IgG about 10 to 15 days.

- Early infection

  The concentration of antibody is still very low in early infection. Qualitative test is not sensitive to extreme low level.

- Manual operation mistake



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Performance

- Clinical evaluation-Whole blood

IgG

		Comparison method		Sum
		Positive	Negative	
Genrui	Positive	129	3	132
	Negative	2	111	113
Sum		131	114	245

True positive rate (sensitivity)	129/131	98.47%
True negative rate (specificity)	111/114	97.37%
Positive predictive value	129/132	97.73%
Negative predictive value	111/113	98.23%
Accuracy	240/245	97.96%

Performance

- Clinical evaluation-Whole blood

IgM

		Comparison method		Sum
		Positive	Negative	
Genrui	Positive	134	4	138
	Negative	3	141	144
Sum		137	145	282

True positive rate (sensitivity)	134/137	97.81%
True negative rate (specificity)	141/145	97.24%
Positive predictive value	134/138	97.10%
Negative predictive value	141/144	97.92%
Accuracy	275/282	97.52%

Performance

- Clinical evaluation-Serum

IgG

		Comparison method		Sum
		Positive	Negative	
Genrui	Positive	226	12	238
	Negative	4	505	509
Sum		230	517	747

True positive rate (sensitivity)	226/230	98.26%
True negative rate (specificity)	505/517	97.68%
Positive predictive value	226/238	94.96%
Negative predictive value	505/509	99.21%
Accuracy	731/747	97.86%

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Performance

- Clinical evaluation-Plasma

IgG

		Comparison method		Sum
		Positive	Negative	
Genrui	Positive	115	2	117
	Negative	3	110	113
Sum		118	112	230

True positive rate (sensitivity)	115/118	97.46%
True negative rate (specificity)	110/112	98.21%
Positive predictive value	115/117	98.29%
Negative predictive value	110/113	97.35%
Accuracy	225/230	97.83%

Performance

- Clinical evaluation-Plasma

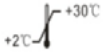
IgM

		Comparison method		Sum
		Positive	Negative	
Genrui	Positive	122	3	125
	Negative	3	116	119
Sum		125	119	244

True positive rate (sensitivity)	122/125	97.60%
True negative rate (specificity)	116/119	97.48%
Positive predictive value	122/125	97.60%
Negative predictive value	116/119	97.48%
Accuracy	238/244	97.54%

Transportation and storage

Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal Gold)



- Transport or store at room temperature from 2 to 30°C
- If individual pouch unopened, the kit can be stored for 12 months.
- Once the individual pouch is opened, this test card should be used within 1 hour.
- Once the diluent is opened, it can be store for 30 days at room temperature, and 6 months at 2 to 8 °C

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Packaging

Carton				Kit			Individual Pouch
Quantity (kits)	Gross weight (KG)	Net weight (KG)	Size (CM)	Quantity (tests)	Weight (KG)	Size (CM)	Size (CM)
30 kits	11.20	9.90	56*40*36cm	25	0.33	18*14*8	14*7
14 kits	5.40	4.62	37*32*32cm				

TEFANESO Services provide:

- Product sourcing,
- Quality control according to internal requirements,
- Order tracking,
- Support and assistance with customs and export formalities,
- Active search for solutions.

Our offices in Shanghai and Guangdong are located near the customs offices of these economic hubs. We are therefore able to intervene actively in the progress of customs formalities and procedures and thus help to speed up the finalization, if necessary.

TEFANESO Switzerland SA (hereinafter «Tefaneso») reserves the right to procure the product from supplier(s) different from the company indicated on the certificates mentioned in the appendix if such company cannot deliver the product. Tefaneso shall guarantee that the products from the other supplier(s) will scrupulously correspond to the product in terms of specifications, standards, tests and certifications.

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