SARS-CoV-2 IgM/IgG
Antibody test kit
(Colloidal Gold Method)

One step test for

SARS-CoV-2 IgM/IgG Antibody

Features

1. Test result can get within 15 min

2. Sample types: fingertip blood/whole blood/serum/plasma

3. Test both IgM and IgG to improve sensitivity

Instruction

Applicable people:

One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody(Colloidal Gold) is intendedfor the qualitative detection of 2019-Novel Coronavirus IgM and IgG antibody in serum, plasma, fingertip blood or wholeblood samples of pneumonitis patients or suspected cases.

Instruction

Summary:

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by2019-nCoV, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread between people via respiratory droplets from infected individuals when they cough or sneeze.Time from exposure to onset of symptoms is generally between 2 and 14 days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness. Further development may include pneumonia and acute respiratory distress syndrome.IgM and IgG antibody are generated within 3 to 7 days after people getting infected by 2019-nCoV, which can be used as diagnostic indicator on the early stage. So, the detection of 2019 n-COV IgM and IgG antibodies in human blood can be used as an auxiliary means for early screening ofC OVID-19.

Instruction

Principle:

The test uses mixed recombinant 2019-nCoV nucleocapsid protein (N protein) and spike protein (S protein), which are coated with colloidal gold and anti-human IgM and IgG antibodies on different test lines, respectively. Will sample After the product is coated on the test paper, the gold-labeled recombinant 2019-nCoV N protein and S protein will bind to the IgM or IgG antibody in the sample and form a labeled antigen-antibody complex with 2019-nCoV. These complexes move to the test card detection area by capillary action. The labeled antigen- antibody complexes will then be captured in different tests by strains produced by anti-human IgM and IgG antibodies producing purple-red striped test lines. The color intensity of each test line is related to the amount of 2019-nCoV IgM and IgG antibodies in the sample.

Instruction

Kit Components:

Each test kit contains the test card, sample diluent (2.2mL/bottle), and a manual.

Waring and Precautions:

Samples for human serum plasma or whole blood, should be considered as potentially infectious.Operators should wear protective clothing, masks, gloves and take other appropriate safety precautions to avoid or reduce the risk of infection.

Material required but not provided:

Sample vortex mixer

10-100µl pipette and tips

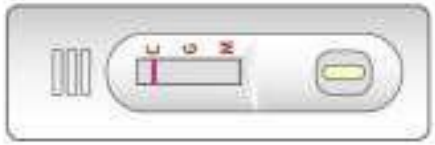
Test tubes

Sample collection tubes

Timer

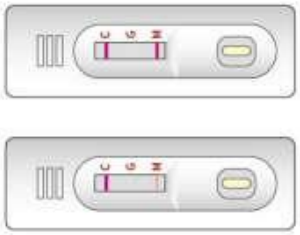
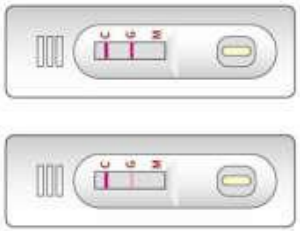
Instruction

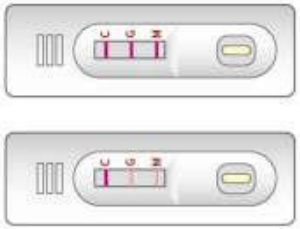
Interpretion of results:Negative

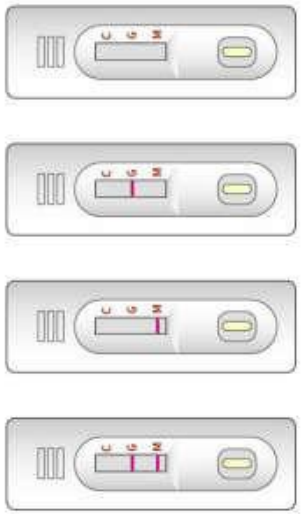
Negative: If only C-line appears, indicating that SARS-CoV-2 antibody is not detected, and the result is negative:	

Instruction

Interpretion of results: Positive

If both the C-line and the M-line appear, it means that the IgM antibody against SARS-CoV-2 is detected, and the result is that the IgM antibody is positive:	
If both the C-line and the G-line appear, it means that the IgG antibody against SARS-CoV-2 is detected, and the result is that the IgG antibody is positive:	

If the C-line, M-line and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is that IgG and IgM antibody are positive:	

Invalid result: if C- line is not observed, it is invalid whether there is a detection line or not, and the detection shall be carried out again:	

Company ISO Certificate

Medical Device Export Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 094093 0003 Rev. 00

Holder of Certificate:
[redacted]td
Building D9 floor1-4, Innovation Park
West Wangjiang Road No.800
High-Tech Zones
230088 Hefei
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
[redacted]althcare [redacted]Co., Ltd
Building D9 floor1-4, Innovation Park, West Wangjiang Road No.800, High-Tech Zones, 2[redacted]PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:
Design, Development, Production and Distribution of Assay Kits for PEPSINOGEN I, PEPSINOGEN II, GASTRIN-17 Assay with ELISA, Fluorescence Immunochromatographic and Chemiluminescent Method, and Fluorescence Immunoassay Analyzer

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18103204_RA

Valid from: 2019-04-06
Valid until: 2022-04-05

Date, 2019-02-11

Stefan Preiß

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TÜV®

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：[redacted]药监械出 20200009 号
Certificate NO.: 皖合食药监械出 20200009 号

产品名称：新型冠状病毒（SARS-CoV-2）IgM/IgG 检测试剂盒（胶体金法）
Product(s): SARS-CoV-2 IgM/IgG antibody test kit（Colloidal Gold Method）

规格型号：**20/25/50/100** 人份/盒（或按客户要求定制）
Model: 20/25/50/100 pcs per box (or customzied)

产品注册或备案凭证号：皖合 **20200002** 号
Registration certificate(s):皖合 20200002 号

生产企业：[redacted]
Manufacturer: [redacted]**Co.,Ltd.**

生产企业住所：[redacted]三四层
Address of manufacturer: Building D9 floor 1-4, Innovation Park, No.800 West Wangjiang [redacted]

生产许可或备案凭证号：/
Manufacturing License(s):/

兹证明上述产品未在中国注册，尚未进入中国市场。出口不受限制。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至： **2022** 年 **03** 月 **17** 日
This certification valid until: March 17th, 2022

备注：/
Remark: /

2020 年 03 月 18 日

EC Declaration of Conformity

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: [redacted]

Address: Building D9 floor 1-4,Innovation Park,[redacted]wangjiang Road, High-Tech Zones, Hefei[redacted]hina

European Representative: Wellkang Ltd

Address: 16 Castle St,Dover,CT16 1PW, UK

Product: SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)

Classification: Others

We, the manufacturer, herewith declare with sole responsibility that our product mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council 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

The above declaration of conformity is issued under the sole responsibility of the manufacturer.

General Manager: Liu Feng

CE

Hefei, March 18th, 2020
(Place and Date of Issue)

Liu Feng
(Signature and Seal)

中华人民共和国海关

出/入境特殊物品卫生检疫审批单

审批单号：皖准202000007

申请单位			
单位性质	销售		
单位名称	[redacted]公司	组织机构代码	913401000822[redacted]
单位地址	[redacted]江西路800号[redacted]园D9栋	联系人	张小伟
E-mail	952[redacted]n	联系电话	182[redacted]01
特殊物品信息			
出/入境方式	出境	发货人	[redacted]限公司
运输存储条件	常温	运输方式	货运
特殊物品监管级别	D级	是否后续监管	否
查验拆检注意事项			
审批意见及检疫要求			
审批意见：	符合特殊物品卫生检疫行政许可要求		
检疫要求：	（一）检查出入境特殊物品名称、成分、批号、规格、数量、有效期、运输存储条件、输出/输入 国和生产厂家等项目是否与《特殊物品审批单》的内容相符。 （二）检查出入境特殊物品包装是否安全无破损、不渗、 不漏，存在生物安全风险的是否具有符合相关要求的生物危险品标识。		
审批有效期：	2020年03月19日-2021年03月19日		
签发时间：2020年03月19日		审批机构(盖章)：中国海关	
备注：			

CE Certificate

Health quarantine approval form

THANKS