One Step Test for Novel Coronavirus (2019-nCoV IgM and/or IgG Antibody)

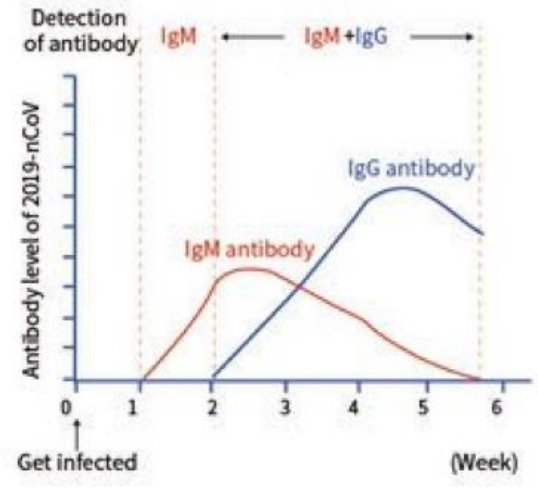
(Colloidal Gold Standard)

USER MANUAL

INTENDED USE

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

SUMMARY



When a person is firstly infected by 2019-nCoV, his or her immune system produces specific antibodies for the viral antigen one to two weeks after infection.

Detection of IgM and/or IgG of 2019-nCoV is an auxiliary diagnosis and screening method for COVID-19.

Potential patients can be diagnosed timely whether they are infected by 2019-nCoV.

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by 2019-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 antibodies are generated within 3 to 7 days after getting infected by 2019-nCoV, which can be used as a diagnostic indicator at the early stage. So, the detection of 2019-nCOV IgM and IgG antibodies in human blood can be used as an auxiliary means for early screening of COVID-19.

PRINCIPLE

The test uses an anti-human IgM and/or IgG antibody conjugated with colloidal gold and recombinant of 2019-nCoV nucleocapsid protein (N protein) and spike protein (S protein) coated on different test lines respectively. After the samples have been applied to the test strip, the gold-labelled anti-human IgM and/or IgG antibody will bind with IgM and/or IgG in the sample and form a marked antigen-antibody complex. These complexes are reflected to the test card detection zone by capillary action. The marked antigen-antibody complexes will be captured on different test lines by the recombinant 2019-nCoV N protein and S protein resulting in purplish red streaks on the test lines. The color intensity of each test line increases in proportion to the amount of 2019-nCoV IgM and/or IgG antibody in the sample.

CONTENTS

1. A kit contains:
    - Comes in a pack of 10 test kits: Option of Test Kit 1 (IgM) or Test Kit 2 (IgM and IgG)
    - Novel Coronavirus (2019-nCoV) Antibody test card in a sealed pouch with desiccant
    - Blood lancet
    - Sample diluent
    - User manual

    Note: Do not mix or interchange different batches of kits.

2. A test card consists of:
    - A plastic shell and a reagent strip which is composed of a sample pad
    - A colloidal gold pad (coated with gold-labelled anti-human IgM and/or IgG antibody)
    - Nitrocellulose membrane with two test lines (these two Ines are coated with recombinant 2019-nCoV N protein and S protein respectively)
    - The control line (coated with anti-recombinant protein tag protein), absorbent paper and liner.

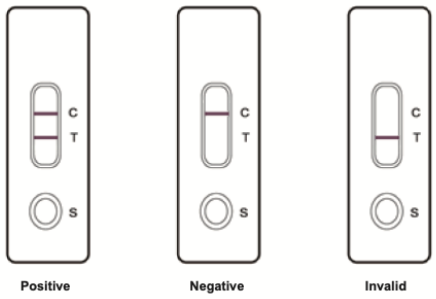
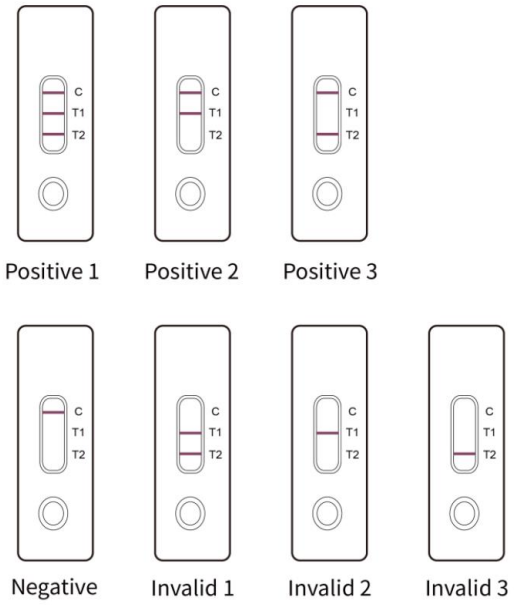
3. Storage and Stability
    - Test Card
        - Store the test card at 4-30℃ with a valid period of 24 months.
        - Use the test card within 1 hour once the foil pouch is opened.
    - Sample Diluent
        - Store the sample diluent at 0-30℃ with a valid period of 24 months.
        - Store the sample diluent at 2-8℃ for better results.
        - Use the sample diluent

4. Precautions
    - Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
    - The test cards can be stored in room temperature with sealed pouches and the test cards stored in low temperature should reach room temperature before testing.

- Sodium azide is used as preservative which may react with copper drainage pipe or lead drainage pipe and cause explosive substance. Please cope with the preservative properly according to relevant local regulations.
- There should be appropriate bio-safety assurance procedure for infectious sources or potential infectious sources. Relevant precautions are showed below:
    - Wear disposable gloves to deal with samples, or sterilize reagents.
    - Sterilize spilled samples or reagents with sanitizer.
    - Sterilize and cope with all of samples, reagents and potential contaminant with relevant local regulations.

5. Test Procedure: Read the manual carefully before using and operate according to the manual to avoid incorrect results.
    I. Collect specimens according to user manual.
    II. Test card, sample and reagent should reach to room temperature (15-30 ℃) before test.
    III. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
    IV. Put the test card on a clean table, horizontally placed.
    V. Load sample (ensure sufficient blood sample; at least one drop) into the sample port on the test card. Then add 3 drops of sample diluent immediately.
    VI. Wait for results (takes at least 10 minutes)

6. Test Results:

Kit 1 **One step test for 2019-nCoV IgM ONLY Antibody (Colloidal Gold)**	**Kit 2** **One step test for 2019-nCoV IgM/IgG Antibody (Colloidal Gold)**
Positive (+): Two purplish red bands appear, one at the control area (C) and the other at the test line. The result indicates that the sample contains IgM antibodies of 2019-nCoV. **Negative (-):** Only one purplish red band appears at the control area (C), no apparent purplish line appears in the test region (T). The result indicates that the sample does not contain IgM antibody of 2019-nCoV. **Invalid:** If no colored band appears in the control area (C) in 10-20 min, the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.	**Positive (+):** (1) 3 purplish red bands appear, one at the control area (C) and two at the test lines (T1, T2). The result indicates that the sample contains both 2019-nCoV IgM and IgG antibody. (2) 2 purplish red bands appear, one at the control area (C) and one at the test line (T1). The result indicates that the sample contains 2019-nCoV IgM antibody. (3) 2 purplish red bands appear, one at the control area (C) and one at the test line (T2). The result indicates that the sample contains 2019-nCoV IgG antibody. **Negative (-):** A single purplish red band appears at the control area (C) without any other band at test lines. The result indicates that the sample does not contain 2019-nCoV IgM or IgG antibody. **Invalid:** If no colored band appears in the control area (C) in 10-20 min, the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.
 **C: Control Area** **T: IgM antibody**	 **C: Control Area** **T1: IgM antibody** **T2: IgG antibody**

7. Certifications and Clinical Reports

Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
Authorized Representative (Name, Address)	**Lotus NL B.V.** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Medical device	One Step Test for Novel Coronavirus(2019-nCoV) IgG antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)
Classification	Others
Applicable coordination standards	EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13485:2016, EN 13612:2002, EN ISO15223-1:2012, EN ISO 18113-2:2011, EN 1041:2008, EN ISO 18113-1:2011, EN ISO 18113-3:2011, IEC 61010-1:2010, IEC 61010-2-101:2015, IEC 61010-2-081:2015, IEC 61326-1:2013, IEC 61326-2-2:2013

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager Enben Su

Nanjing, 4th, Mar, 2020

(place and date of issue)

(name and signature or equivalent marking of authorized person)

CE

Figure 1.0 Declaration of Conformity


空运
By Air

NO.2002055707

CNAS

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： 样本稀释液

Sample Name: Sample Diluent

委托单位： 基蛋生物科技股份有限公司

生产单位： 基蛋生物科技股份有限公司

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

Figure 2.0 Certification for Safe Transport of Chemical Goods

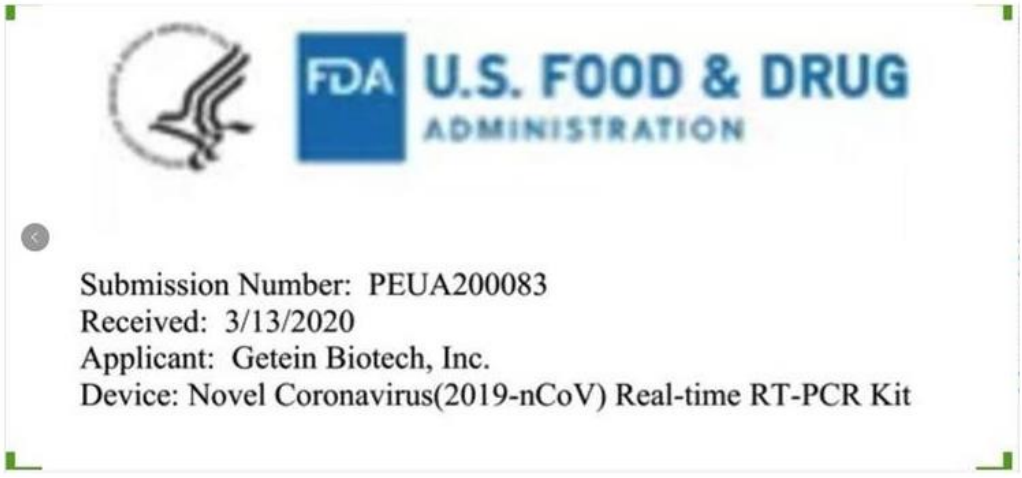
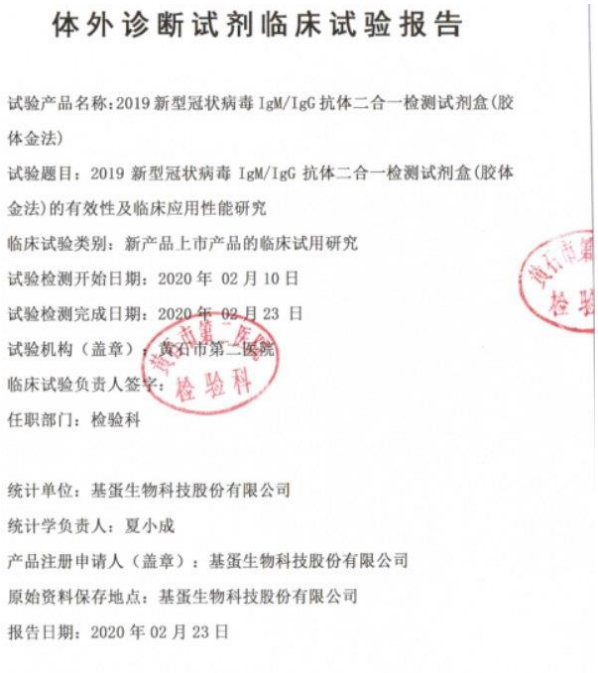


Figure 3.0 FDA Emergency Use Authorization



体外诊断试剂临床试验报告

试验产品名称：2019 新型冠状病毒 IgM/IgG 抗体二合一检测试剂盒(胶体金法)

试验题目：2019 新型冠状病毒 IgM/IgG 抗体二合一检测试剂盒(胶体金法)的有效性及临床应用性能研究

临床试验类别：新产品上市产品的临床试用研究

试验检测开始日期：2020 年 02 月 10 日

试验检测完成日期：2020 年 02 月 23 日

试验机构（盖章）：黄石市第二医院

临床试验负责人签字：

任职部门：检验科

统计单位：基蛋生物科技股份有限公司

统计学负责人：夏小成

产品注册申请人（盖章）：基蛋生物科技股份有限公司

原始资料保存地点：基蛋生物科技股份有限公司

报告日期：2020 年 02 月 23 日

Figure 4.0 Certified Clinical Report

检 验 报 告

Test Report

（2020）QW 类第 0506 号

样品名称 Product Name	2019 新型冠状病毒 IgM/IgG 抗体二合一检测试剂盒(胶体金法)
规格型号 Specifications	25 人份/盒
检验类别 Test Category	委托检验
委托单位 Entrusting Unit	基蛋生物科技股份有限公司

江苏省医疗器械检验所

Jiangsu Testing and Inspection Institute for Medical Devices

Figure 5.0 Certified Test Report from China Regulatory

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： 苏宁食药监械出20200007号

Certificate: 苏宁食药监械出20200007号

产品名称： 见附件

Product(s):SEE ATTACHMENT

规格型号：见附件

Model:SEE ATTACHMENT

生产企业： 基蛋生物科技股份有限公司

Manufacturer: Getein Biotech,Inc.

生产企业住所： 南京市六合区沿江工业开发区博富路9号

Address of manufacturer: No.9 Bofu Road,Luhe District, Nanjing, 211505, China

医疗器械出口备案凭证号： 苏宁20190069

Exportation Registration certificate(s): 苏宁20190069

兹证明上述产品已准许在中国生产和出口。

This is to certify that the above products have been registered to be manufactured and exported in China.

证明有效日期至： 2022年2月23日

This certification valid until: February 23th 2022

备注：

Remark:

2020 年 2 月 24 日

（出具单位盖章）

Figure 6.0 Certificate of Exportation of Medical Products