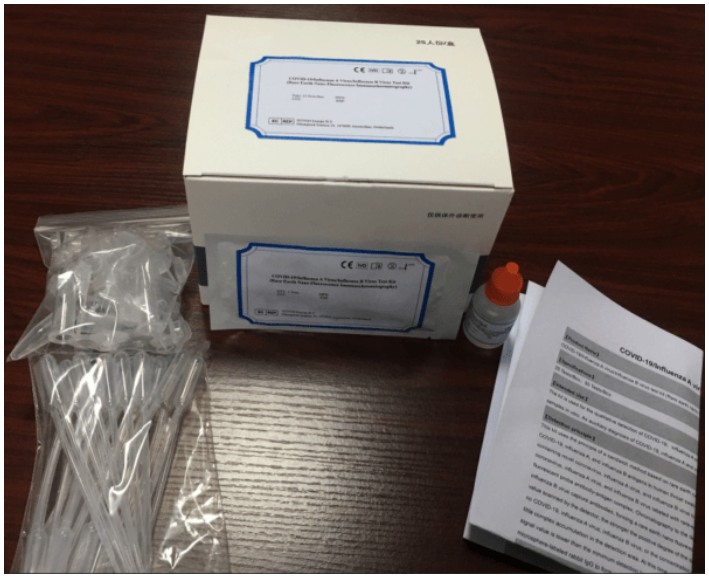

## TEST KIT IGM/IGG COVID19 (COLLOIDAL GOLD)

**€39.50**

**Packaging:** 25 Test Kits / Box

18 Box / Carton

**Carton dimensions and weight:** 40 * 33 * 34.5 cm / 0.046 CBM / 5.855 kg

Manufactured in China

Production capacity: 3-5 million / day

Minimum order: 100,000 Test Kits

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**SKU:** N/A
**Categories:** Bioide, Test Kits

## PRODUCT DESCRIPTION

**Product Description**: COVID-19 IgM/IgG Test Kit (Colloidal Gold)

**SKU/Product ID:** COVIF-19 – REF:JAS

**Feature:** 10 minutes to read the result, accuracy is >95-99%

Manufactured in China

# CE CERTIFICATION

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo
global service

# DECLARATION OF NOTIFICATION

As the EU Representative, SUNGO Europe B.V., hereby declare that:

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/97EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

| Name Device | Reference Numbers |
|---|---|
| COVID-19 IgM/IgG test kit (Colloidal Gold) | 20200534 |
| COVID-19/Influenza A virus/Influenza B virus test kit (Rare earth nano fluorescence immunochromatography) | 20200534 |

The notification to the Netherlands Competent Authorities has been carried out on March 8, 2020 by SUNGO Europe B.V., the appointed Authorized Representative of

Information on the notification to the competent Authorities of other European countries is available upon request.

SUNGO Europe B.V.
Authorized Representative

SUNGO Sungo CERTIFIED

SUNGO Europe B.V. | Office Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

# ISO13485:2016 CERTIFICATION

Certificate of Registration

nqa.

兹证明

的质量管理体系适用于

**体外诊断试剂的生产及销售（资质许可范围内，明细见附件）**

已经 NQA 根据标准

**ISO 13485: 2016**

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询
SNQA 查询网站：www.snqa.com.cn

Managing Director

Certificate Number **46652**

Date: 09 July 2019
Valid Until: 09 July 2022
EAC Code: 19

UKAS MANAGEMENT SYSTEMS 015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

nqa.

Certificate of Registration

附件

1.D-二聚体（D-Dimer）测定试剂盒（荧光免疫层析法）
2.降钙素原（PCT）测定试剂盒（荧光免疫层析法）
3.尿微量白蛋白（U-ALB）测定试剂盒（荧光免疫层析法）
4.全程 C-反应蛋白（hsCRP+常规 CRP）测定试剂盒（荧光免疫层析法）
5.细菌唾液酸酶测定试剂盒（唾液酸酶法）
6.隐血（Hb/Tf）双联测定试剂盒（胶体金法）
7.肌钙蛋白 I（cTnI）测定试剂盒（荧光免疫层析法）
8.肌酸激酶同工酶（CKMB）测定试剂盒（荧光免疫层析法）
9.肌红蛋白（Myo）测定试剂盒（荧光免疫层析法）
10.胱抑素 C（CysC）测定试剂盒（荧光免疫层析法）
11.N 末端脑利钠肽前体（NT-proBNP）测定试剂盒（荧光免疫层析法）
12.糖化血红蛋白（HbAlc）测定试剂盒（荧光免疫层析法）

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Certificate Number **46652**

Date: 09 July 2019
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# CERTIFICATION FOR EXPOORTATION OF MEDICAL PRODUCTS

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：闽厦药监械出 20200031 号
Certificate NO.: Min Xia Yao Jian Xie Chu No.20200031

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： 厦门生物科技有限公司
Manufacturer: Xiamen Biotechnology Co.,Ltd.

医疗器械出口备案凭证号：见附件
Exportation Registration certificate(s):See Attachment

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 product(s) have been registered to be manufactured and exported in China.

证明有效日期至：2022 年 03 月 18 日
This certification valid until:2022-03-18

备注：
Remark:

2020 年 03 月 19 日
（出具单位盖章）

附件
Attachment

证书编号：
Certificate No.：

| 序号<br>No. | 产品名称<br>Product(s) | 规格型号<br>Model | 医疗器械出口备案凭证号<br>Exportation Registration certificate(s) |
|---|---|---|---|
| 1 | 中文：新型冠状病毒 IgM/IgG 抗体测定试剂盒（胶体金法）<br>英文：COVID-19 IgM/IgG test kit (Colloidal Gold) | 25 人份/盒，50 人份/盒。<br>25tests/kit,50tests/kit. | 闽厦 20200012<br>Min Xia<br>20200012 |
| 2 | 中文：新型冠状病毒/甲型流感病毒/乙型流感病毒 IgM 抗体测定试剂盒（胶体金法）<br>英文：COVID-19/Influenza A virus/Influenza B virus IgM combo test kit (Colloidal Gold) | 25 人份/盒，50 人份/盒。<br>25tests/kit,50tests/kit. | 闽厦 20200015<br>Min Xia<br>20200015 |
| 3 | 中文：新型冠状病毒 IgM/IgG 抗体测定试剂盒（稀土纳米荧光免疫层析法）<br>英文：COVID-19 IgM/IgG test kit (Rare earth nano fluorescence immunochromatography) | 25 人份/盒，50 人份/盒。<br>25tests/kit,50tests/kit. | 闽厦 20200012<br>Min Xia<br>20200012 |
| 4 | 中文：新型冠状病毒/甲型流感病毒/乙型流感病毒 IgM 抗体测定试剂盒（稀土纳米荧光免疫层析法）<br>英文：COVID-19/Influenza A virus/Influenza B virus IgM combo test kit (Rare earth nano fluorescence immunochromatography) | 25 人份/盒，50 人份/盒。<br>25tests/kit,50tests/kit. | 闽厦 20200012<br>Min Xia<br>20200012 |
| 5 | 中文：新型冠状病毒(ORF1ab-E-N 基因)核酸检测试剂盒（三重荧光 PCR 法）<br>英文：COVID-19 (ORF1ab / E / N Gene) Nucleic Acid Diagnostic Kit(Triple Fluorescence PCR Method) | 25 人份/盒，50 人份/盒。<br>25tests/kit,50tests/kit. | 闽厦 20200015<br>Min Xia<br>20200015 |

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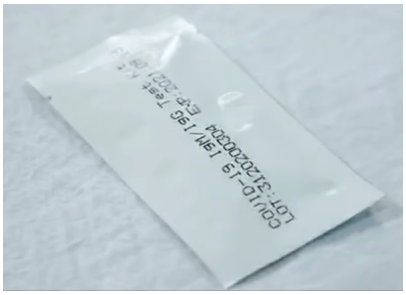
JAS TestKit Instruction

JAS COVID-19 IgMIgG test kit production