



新型冠状病毒IgM/IgG抗体检测试剂盒

COVID-19 IgM/IgG test kit

(胶体金法) & (稀土纳米荧光免疫层析法)

(Colloidal Gold) & (Rare earth nano fluorescence
immunochromatography)

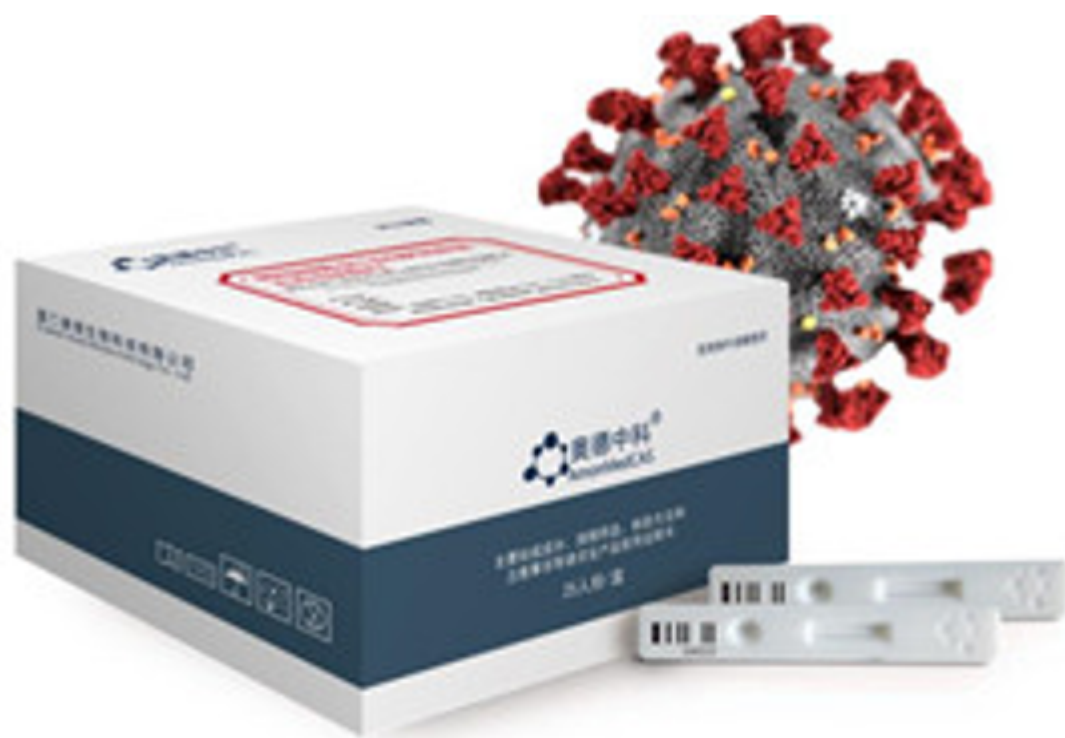
中科银昌(厦门)生物科技有限公司

Zhongke Yinchang (Xiamen) Biotechnology Co., Ltd

TEL +86 15359050780
+86 18559238739

新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）

COVID-19 IgM/IgG test kit (Colloidal Gold)



产品特点 Product Features

便携——无需仪器设备，可肉眼观察

Portable---No instruments required for visual inspection

简单——操作简单，易上手

Simple---simple operation, easy to use

快速——10分钟可以判读结果

Fast---10 minutes to read the results

灵活——可使用指尖血、血清、血浆、全血样本

Flexible---Can use fingertip blood, serum, plasma, whole blood samples

操作步骤 Operating Procedure

➤检测卡恢复至室温。

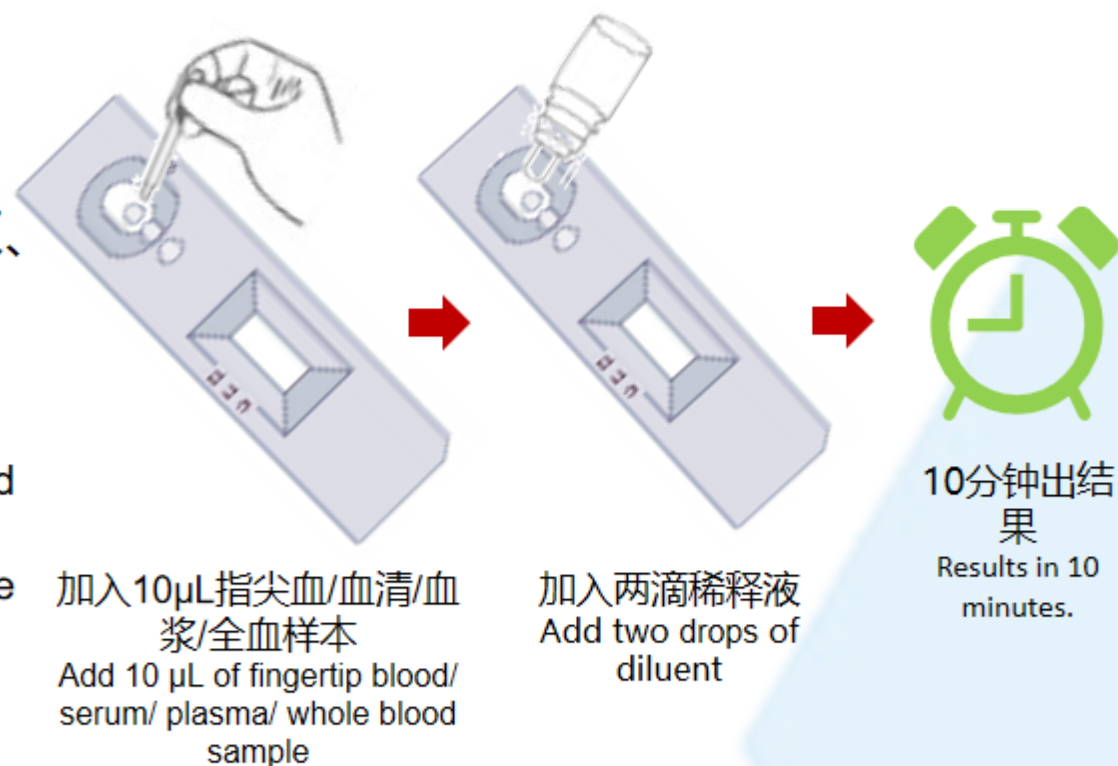
The test card is restored to room temperature.

➤在加样孔中加入10 μ L指尖血、血清、血浆、全血样本，再加入两滴稀释液（约80 μ L）。

10 μ L of fingertip blood, serum, plasma, whole blood sample and two drops of diluent (about 80 μ L) were added to that loading well.

➤等待10分钟后，判读结果。

After waiting for 10 minutes, read the results.



新型冠状病毒IgM/IgG抗体检测试剂盒（胶体金法）

COVID-19 IgM/IgG test kit (Colloidal Gold)

10分钟内实现新冠病毒筛查

Screening for coronavirus in 10 minutes

简单、便携、快速

Simple, portable and fast

👍 指尖采血

Fingertip blood collection

👍 肉眼判读结果

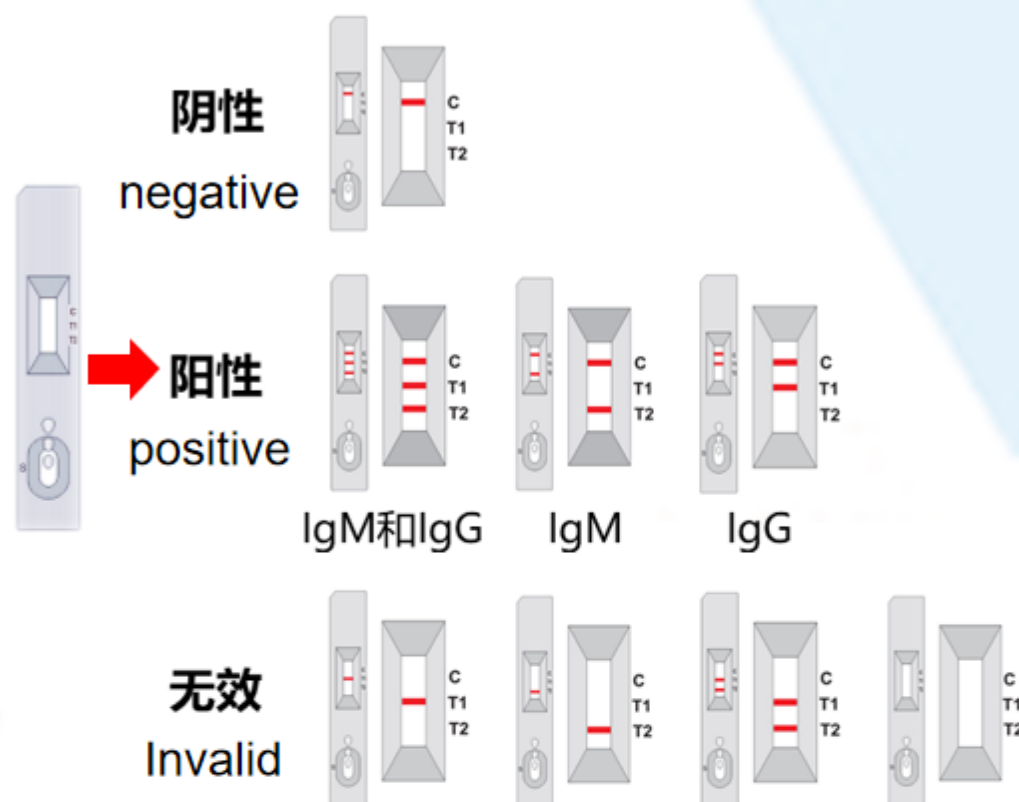
Visual interpretation results

👍 快速检测

Rapid detection

👍 社区筛查，家庭自诊

Community screening family self-diagnosis



仪器显示 Instrumental display	阳性 Positive				阴性 Negative				无效 Invalid			
IgM (T1)	+	-	+	-	+	-	+	-	+	-	+	-
IgG (T2)	-	+	+	-	-	+	+	-	-	+	+	-
C line	+	+	+	+	-	-	-	-	-	-	-	-

结果判读Result interpretation

- IgM/IgG双阳性，提示近期感染新冠病毒，血液检测双抗呈阳性。
IgM/IgG positive indicated recent infection with SRAS-COV-2 and positive blood test for double antibody.
- IgM阳性，提示最近感染新冠病毒，血液中已出现冠状病毒IgM，但尚未产生IgG。
IgM positive indicated recent infection with SRAS-COV-2, IgM has appeared in the blood.
- IgG阳性，提示已经感染过新冠病毒，血液中已出现冠状病毒IgG，IgM已消失。
IgG positive indicated that SRAS-COV-2 has been infected, IgM has disappeared.
- 阴性结果，提示血液中未检出新冠病毒抗体IgM/IgG。
negative result indicated neither antibody is present.

适用于：临床辅助新冠病毒检测筛查、社区检测、居家自查、学校复学、企业复工、无症状或易感人群

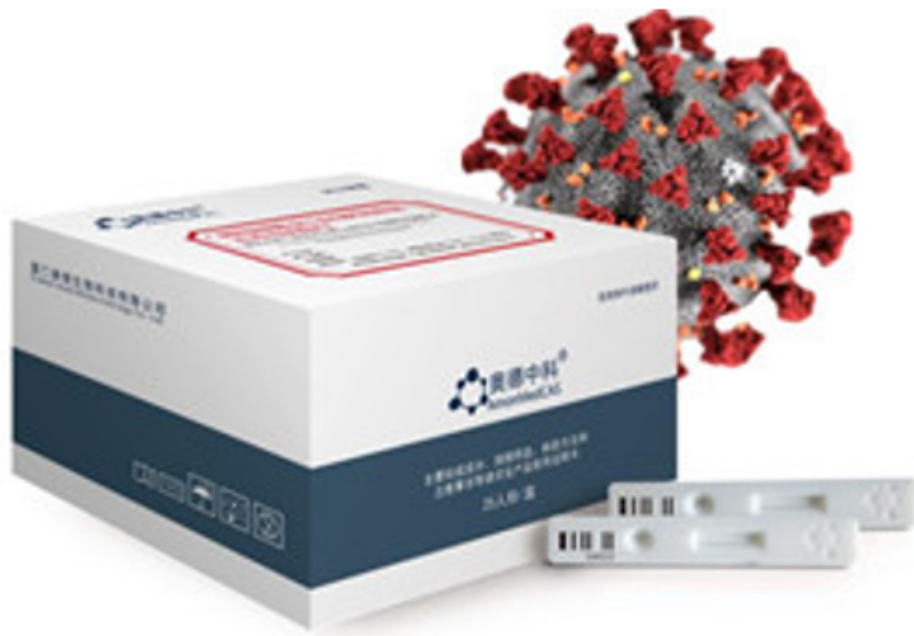
Applicable to: clinical coronavirus detection and screening, community testing, home self-examination, school resumption, enterprise resumption of work, asymptomatic or susceptible population

新型冠状病毒IgM/IgG抗体检测试剂盒

(稀土纳米荧光免疫层析法)

COVID-19 IgM/IgG test kit

(Rare earth nano fluorescence immunochromatography)



产品特点 Product Features

便携——无需仪器设备，可肉眼观察

Portable---No instruments required for visual inspection

灵活——可使用指尖血、血清、血浆、全血样本

Flexible---Can use fingertip blood, serum, plasma, whole blood samples

简单——操作简单，易上手

Simple---simple operation, easy to use

快速——10分钟可以判读结果

Fast---10 minutes to read the results

操作步骤 Operating Procedure

- 开启仪器，检测卡恢复至室温，取出ID卡插入检测仪。

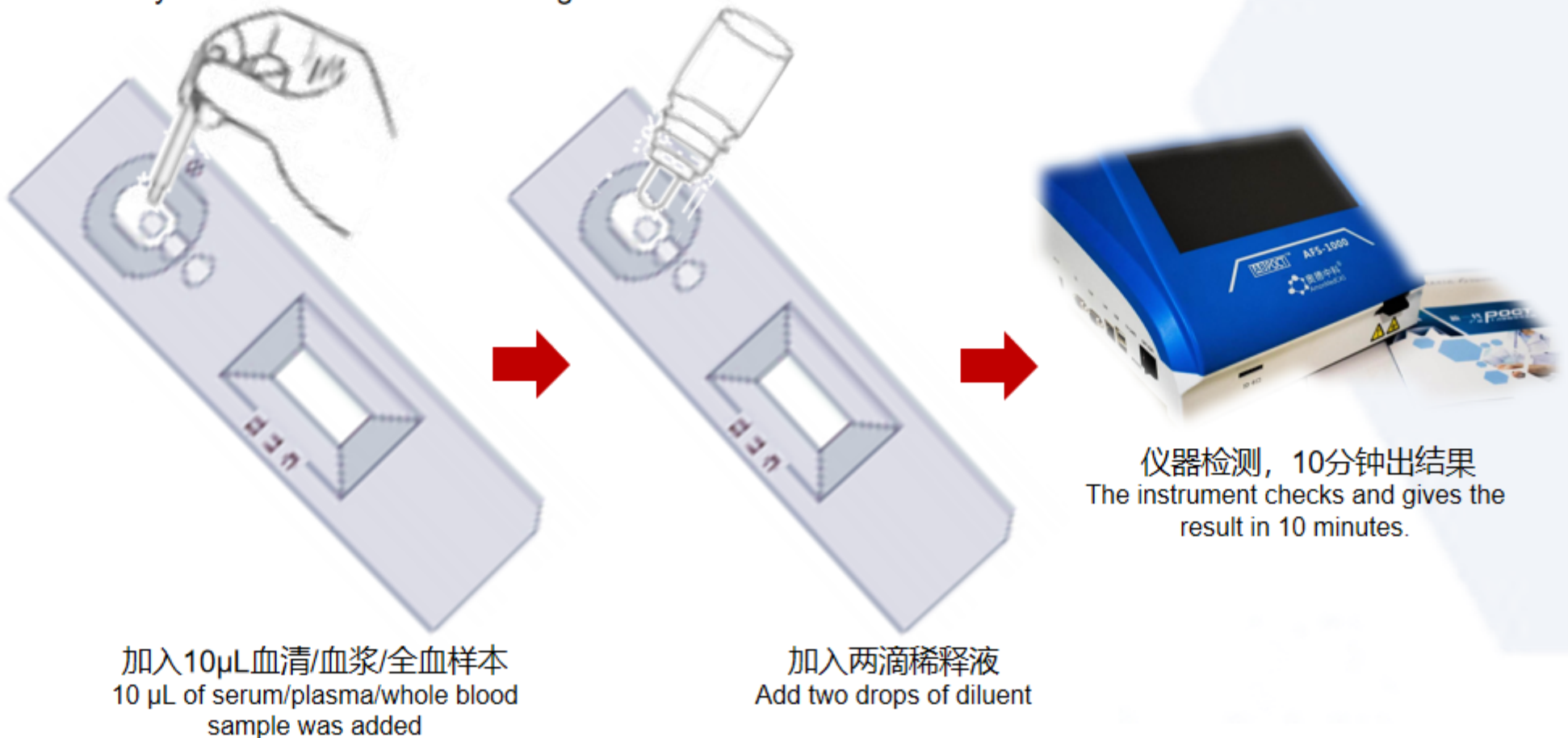
Turn on the instrument, restore the test card to room temperature, take out the ID card and insert it into the tester.

- 在加样孔中加入10 μ L指尖血、血清、血浆、全血样本，再加入两滴稀释液。

10 μ L of fingertip blood, serum, plasma, and whole blood sample were added to that sample well, and then two drops of the diluent were added.

- 将检测卡插入检测槽，设置检测时间为10min，按“检测”键，检测仪将自动对检测卡进行扫描，得出结果。

Insert the detection card into the detection slot, set the detection time to 10 minutes, press the "detection" button, the detector will automatically scan the detection card and get the result.



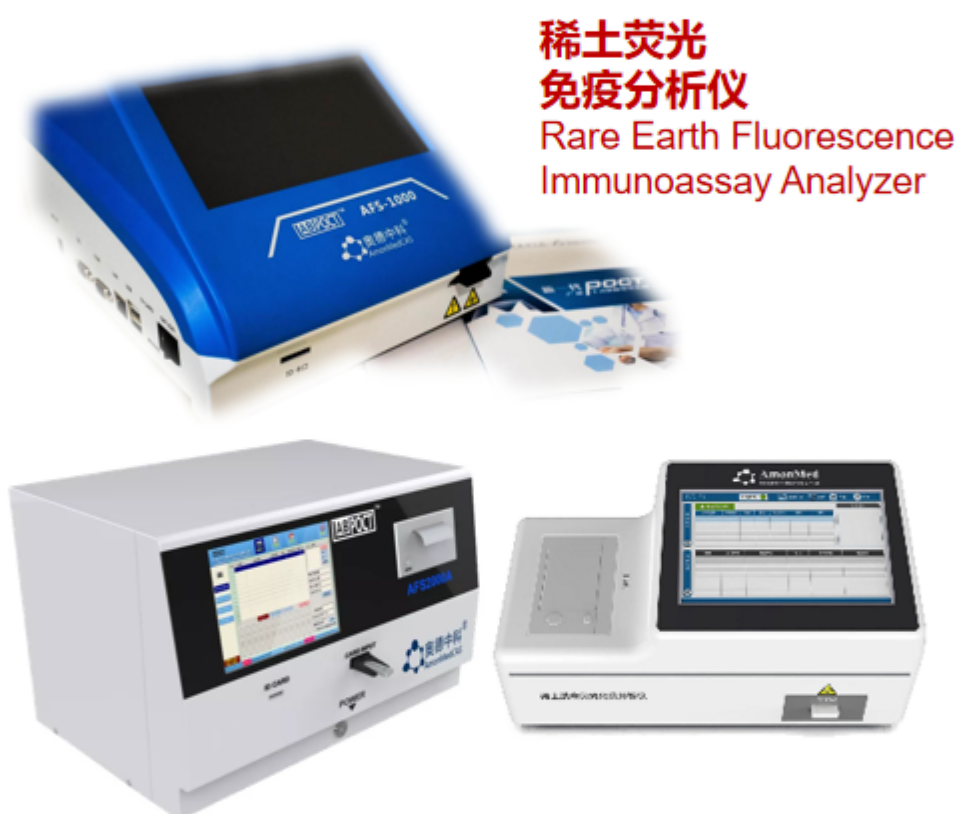
新型冠状病毒IgM/IgG抗体检测试剂盒 (稀土纳米荧光免疫层析法)

COVID-19 IgM/IgG test kit (Rare earth nano fluorescence immunochromatography)

10分钟内实现新冠病毒筛查
Screening for coronavirus in 10 minutes

简单、便携、快速、准确
Simple, portable, fast and accurate

- 👍 全血、血清、血浆检测
Detection of whole blood, serum and plasma
- 👍 仪器检测 高灵敏度
Instrument detection, high sensitivity
- 👍 快速检测
Rapid detection
- 👍 临床辅助筛查
Clinically assisted screening



稀土荧光
免疫分析仪
Rare Earth Fluorescence
Immunoassay Analyzer

仪器显示 Instrumental display	阳性 positive			阴性 negative		无效 null and void		
IgM (T1)	+	-	+	-		+	-	+
IgG (T2)	-	+	+	-		-	+	+
C line	+	+	+	+		-	-	-

适用于：临床辅助新冠病毒检测筛查、无症状或易感人群筛查

Applicable to: clinical detection of new coronavirus screening, asymptomatic or susceptible population screening

稀土荧光免疫分析仪检测领域

Rare Earth Fluorescence Immunoassay Analyzer Detection Field

心脑血管系列
cTnI | CKMB | Myo | NT-proBNP | D-Dimer
H-FABP | S-100β | cTnI/CKMB/Myo联检

肾脏系列
炎症系列
NGAL | CysC | U-ALB | β2-MG
CRP | PCT | SAA | IL-6

健康筛查
糖尿病系列
AMH | 25-OH VD | PGI/PGII
HbA1c

心脑血管系列Cardiovascular series, 肾脏系列Kidney series, 炎症系列Inflammation series, 健康系列Health series, 糖尿病系列Diabetes series



DECLARATION OF NOTIFICATION

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

Xiamen AmonMed Biotechnology Co., Ltd.
Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian China.

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 Xiamen AmonMed Biotechnology Co., Ltd.

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



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

· 获欧盟CE认证

The product has obtained European CE certification

新型冠状病毒IgM/IgG抗体检测试剂盒 COVID-19 IgM/IgG test kit



To whom it may concern

SUNGO Europe B.V. located in Olympisch Stadion 24, 1076DE Amsterdam, Netherlands is appointed as the European Representative by Xiamen AmonMed Biotechnology Co., Ltd. located in Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian China.

The "Business Area" and "Product Categories" for the EU REP are COVID-19 IgM/IgG test kit (Colloidal Gold), COVID-19/Influenza A virus/Influenza B virus test kit (Rare earth nano fluorescence immunochromatography) in Europe market. And the formal contact of SUNGO Certification Company Limited is as following:

Contact: SUNGO Secretary
Tel: +31 (0)20 21 11 106
E-mail: ec.rep@sungoglobal.com

Signature and Stamp
SUNGO Europe B.V.

