COVID-19 RAPID TEST
QUALITATIVE IgM / IgG DETECTION

#allagainstcoronavirus

SEPTEMBER 2020

To who may concern,

According to the World Health Organization (WHO), the diagnosis of those affected by coronavirus covid-19 is crucial to properly treat the disease and stop transmission.

Therefore, and in view of the vital need for this service to society, we offer you rapid qualitative detection tests for IgM / IgG antibodies to COVID-19 of proven quality.

From Grupo Arpa Médica we take care of making the following brands available to you in Argentina, all of them of proven quality and sensitivity.

All products have European accreditation as well as authorization from various Medicines Agencies in various countries.

Sincerely,

Dr. Ignacio Palomo Álvarez
Specialist Medical No. col .: 282.42.802 /
Managing partner of Grupo Arpa Médica
Honorary Consul of El Salvador

Content

01

EGENS

NANTONG EGENS BIOTECHNOLOGY CO., LTD

EGENS is a leading provider of diagnostic kits, developing, manufacturing and distributing diagnostic kits worldwide, with manufacturing sites in Beijing, Nantong and Wuxi, products ranging from rapid tests, Elisa kits, CLIA and POCT analyzer system , with registered trademark analysis system as EGENS®, so far, EGENS has certified with QMS of ISO9001, ISO13485 CMDR, ISO14001, OSHAS18001 and GMP, with large capacity production facilities of 19,500sqm2 class 10,000,100,000, 200,000, 300,000 rooms clean, 10 automatic production lines, more than a hundred sFDA licensed products and 7 FDA approved products, more than 40 CE marked products, exported to more than 106 countries and regions around the world.

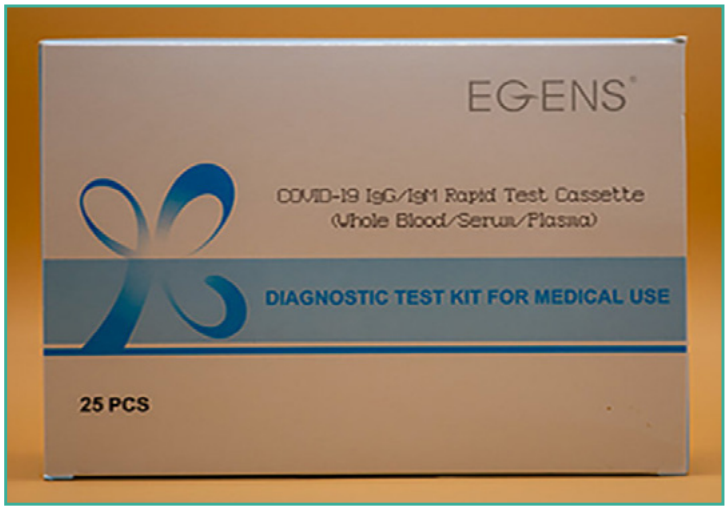
EGENS establishes R&D institute with South-East University, committed to providing new cutting-edge products to the market, totaling 2700 m2 of laboratories with comprehensive laboratory equipment, mainly develop IVD reagent, Nano antibodies, diagnostic equipment, recombinant antigen, monoclonal antibodies, etc. EGENS also establishes Nanobody (Nb) bioengineering postdoctoral research center, covering more than 2000 m2, mainly the development of diagnostic reagents and antibodies, has been approved to be the technical engineering center of Jiangsu province.

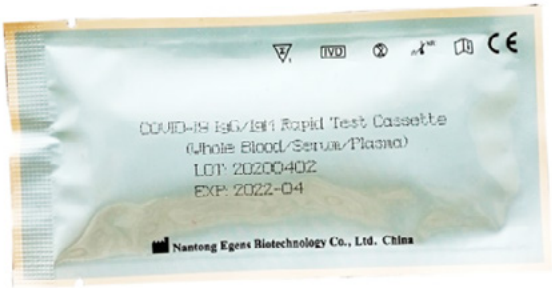
PRODUCT DESCRIPTION

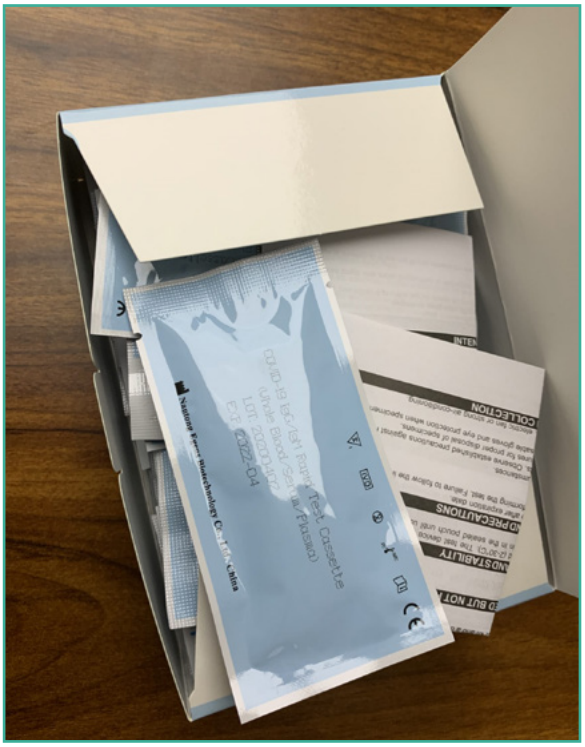
Complete kit for the diagnosis of the new Coronavirus IgG - IgM antibodies in the whole human body through independent measurements of IgG and IgM. This set consists of 25X tests, reagent, lancets, and pipette tubes.

Complete diagnostic set of a new rapid test for Coronavirus IgG / IgM antibodies including individual fluids, lancets and disinfectant wipes.

PRODUCT IMAGES







PROSPECT

INTENDED USE

COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirusi in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM) , anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anit-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS SUPPLIED

If whole blood test, sealed pouches each containing a test kit, a 5μL mini plastic dropper and a desiccant
1 Buffer
1 package insert
If serum/plasma test,sealed pouches each containing a test kit and a desiccant
1 Buffer
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Lancets (for fingerstick whole blood only)
2. Centrifuge and Pipette (for plasma/serum only)
3. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

For Serum or Plasma Specimens:

Allow test kit, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

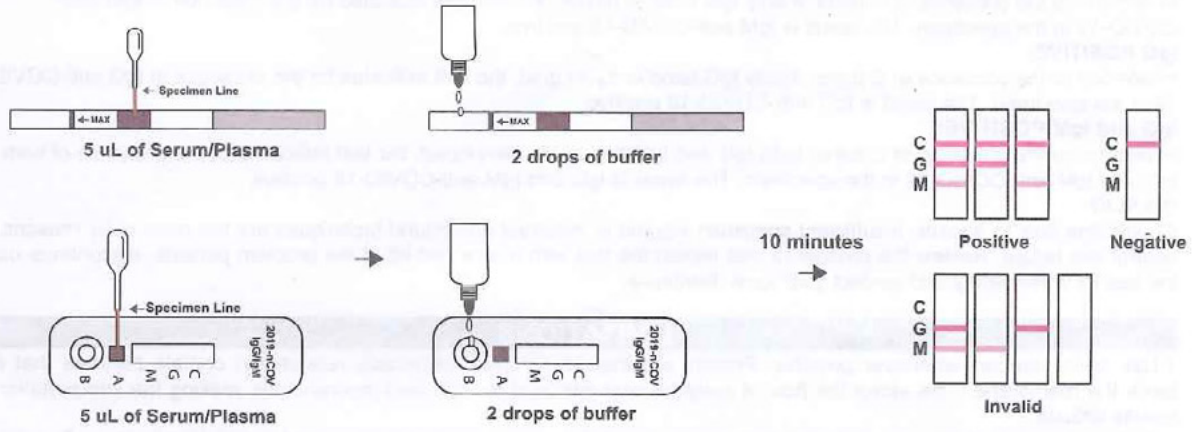
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test kit on a clean and level surface.

Strip:Add 5μl of serum/plasma to the sample pad(purple place with Colloidal gold) of the test strip,then add 2 drops (about 60 μL) of sample buffer to the buffer pad (top of the strip) immediately.

Cassette:
Add 5μl of serum/plasma to the specimen well(A) of the test cassette, then add 2 drops (about 60 μL) of sample buffer to the buffer well (B) immediately.

3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



SUPPORTING DOCUMENTATION

Declaration of Conformity

Manufacturer: Nantong Egens Biotechnology Co.,Ltd
Building 15 , Building 12(west) ,
No. 1692 Xinghu Avenue,
Nantong Economy&Technology
Development Zone, 226010 Nantong,
People's Republic of China

European Representative: Shanghai International Holding Corp.
GmbH (Europe)
Eiffestrasse 80, 20537
Hamburg, Germany

Product Name: **COVID-19 IgG/IgM Rapid Test Kit**

Model: Strip, Cassette

Classification (IVDD, Annex II): Others

Conformity Assessment Route: **Annex III**

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives 98/79/EC and Standards EN ISO13485:2016, under our sole responsibility.
All supporting documentations are retained under the premises of the manufacturer.

Signature: Su Lingling 苏灵玲

Name: Su Lingling

Position: Management Representative

Nantong Egens Biotechnology Co.,Ltd

CE

EC Declaration of Conformity
EGENS/CE-01, A/1

Date: 13-March-2020

SUPPORTING DOCUMENTATION

OHSAS18001

HEAD CERTIFICATION

职业健康安全管理体系认证证书

证书编号：19S1286R2M

兹证明:

南通伊仕生物技术股份有限公司

统一社会信用代码：91320600718557959C

职业健康安全管理体系符合:

GB/T28001-2011 / OHSAS18001:2007 标准

证书覆盖范围:

三类 6840 体外诊断试剂的设计开发、生产（医疗器械生产许可范围内）及相关管理活动

注册地址：江苏省南通开发区星湖大道 1692 号 15 号厂房 A 座

实际地理地址：江苏省南通开发区星湖大道 1692 号 15 号厂房、12 号厂房西侧

颁证日期：2019-05-14

有效期至：2021-03-11

初次颁证日期：2013-05-26

证书签发人

北京海德国际认证有限公司 证书专用章

此认证证书的有效性以左下角二维码扫描结果为准。

同时可登陆认证机构网站：www.hicchina.com.cn查询。

也可登陆中国国家认证认可监督管理委员会网站：www.cnca.gov.cn查询。

北京海德国际认证有限公司

中国・北京・朝阳区北苑东路19号院5号楼1601室（100012）

SUPPORTING DOCUMENTATION

OHSAS18001

HEAD CERTIFICATION

职业健康安全管理体系认证证书

证书编号：19S1286R2M

兹证明:

南通伊仕生物技术股份有限公司

统一社会信用代码：91320600718557959C

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北京海德国际认证有限公司

中国・北京・朝阳区北苑东路19号院5号楼1601室（100012）

SUPPORTING DOCUMENTATION

ISO9001

HEAD CERTIFICATION

质量管理体系认证证书

证书编号：19Q1280R3M

兹证明:

南通伊仕生物技术股份有限公司

统一社会信用代码：91320600718557959C

质量管理体系符合:

GB/T19001-2016 / ISO9001:2015 标准

证书覆盖范围:

三类 6840 体外诊断试剂的设计开发、生产（医疗器械生产许可范围内）

注册地址：江苏省南通开发区星湖大道 1692 号 15 号厂房 A 座
实际地理地址：江苏省南通开发区星湖大道 1692 号 15 号厂房、12 号厂房西侧

颁证日期：2019-05-14
有效期至：2022-05-13
初次颁证日期：2011-07-06

证书签发人

北京海德国际认证有限公司 证书专用章

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同时可登陆认证机构网站：www.hicchina.com.cn查询。
也可登陆中国国家认证认可监督管理委员会网站：www.cnca.gov.cn查询。

北京海德国际认证有限公司

中国・北京・朝阳区北苑东路19号院5号楼1601室（100012）

02

TESTSEALABS

HANGZHOU TESTEA BIOTECHNOLOGY CO. LTD

TESTSEALABS is a Chinese national high-tech enterprise, located in Hangzhou. TESTSEALABS has many researchers and workers who graduated from Zhejiang University and abroad. The company specializes in the research, development, production and sale of raw materials for medical diagnosis and food safety testing. They have 28 kinds of patents covering medical diagnosis, rapid food safety tests, food enzyme immunoassay and the preparation of new enzymes. TESTSEALABS provides perfect raw material solutions for scientific research institutions, companies, research institutes and other institutions around the world.

The company strictly follows the ISO13485 and ISO9001 quality management system operation with research, production, quality control, finance, domestic and international sales with good business relationship with many domestic universities and in vitro diagnostic production enterprises, even with Southeast Asia, Europe, Africa, Latin America and other countries.

TESTSEALABS has a physician and teacher led R&D team with professional workers and well equipment installations. The recombinant antigen production capacity has reached 18 g / month. TESTSEALABS is specialized in the production of rapid diagnostic tests applied to fertility, infectious diseases, drugs of abuse and different veterinary uses.

PRODUCT DESCRIPTION

The TESTSEALABS Covid-19 IgG / IgM Test Cassette takes 15 minutes to give us the result, has a sensitivity of 96.1%, a specificity of 96%, a sensitivity of 94%, is stored at 4-30ºC and has a 12 month life. Each box contains 20 units of test cassettes complete with a 4 ml diluent bottle and 1 instruction manual.

PRODUCT IMAGES

PROSPECT

COVID-19 IgG/IgM Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

A rapid test for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimens.

For professional medical institutions use only. Not for self testing.

【INTENDED USE】

The COVID-19 IgG/IgM Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum or plasma specimen.

【SUMMARY】

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.[1] Six coronavirus species are known to cause human disease.[2] Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.[3] The two other strains — severe acute respiratory syndrome coronavirus and Middle East respiratory syndrome coronavirus—are zoonotic in origin and have been linked to sometimes fatal illness.[4]

Coronaviruses are zoonotic, meaning they are transmitted between animals and people.

Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.[5]

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.[5]

【PRINCIPLE】

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/ Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to COVID-19, A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains COVID-19 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-human IgM and anti-human IgG as the capture reagent,COVID-19 antigen as the detection reagent. A mouse anti-goat IgG is employed in the control line system.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
7. The used test should be discarded according to local regulations.
8. Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C). The test is stable to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/ Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect <u>Fingerstick Whole Blood Specimens</u>:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using <u>a capillary tube</u>:
    - Touch the end of the capillary tube to the blood until filled to approximately 10μL. Avoid air bubbles.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the

anticoagulant for collecting the specimen.

【MATERIALS 】

Materials provided

Test cassettes Droppers Package insert Buffer

Materials required but not provided

Specimen collection containers	Centrifuge (for plasma only)	Capillary tubes
Lancets (for fingerstick whole blood only)	Timer	Pipette

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

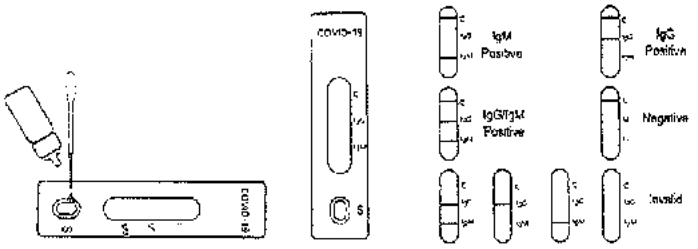
1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

   For **Serum or Plasma** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 10µL), and transfer the specimen to the specimen well (S). Then add 2 drops of buffer (approximately 70 µL), and start the timer.
   - To use a pipette: To transfer 10 µL of specimen to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

   For **Venipuncture Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
   - To use a pipette: To transfer 10 µL of whole blood to the specimen well(S), then add 2 drops of buffer (approximately 70 µL), and start the timer

   For **Fingerstick Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70 µL) and start the timer.
   - To use a capillary tube: Fill the capillary tube and transfer approximately 10 µL of fingerstick whole blood specimen to the specimen well (S) of test cassette, then add 2 drops of buffer (approximately 70 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM region.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to COVID-19 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to COVID-19 can be determined by this qualitative test.
2. The COVID-19 IgG/IgM Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to COVID-19 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.
3. As with all diagnostic tests, all results must be considered with other clinical information

PROSPECT

available to the physician.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of COVID-19 infection.
5. The test process and scope of the test must follow the principle of the instruction manual.
6. The results obtained with this test should be s, and the results should be interpreted in conjunction with clinical finding, and the results from other laboratory tests and evaluation.
7. This test should not be used for screening of donated blood.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR; the results show that COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

IgG Result

Method		PCR		Total Results
COVID-19 IgG/IgM Test Cassette	Results	Positive	Negative	
	Positive	48	0	48
	Negative	2	50	52
Total Result		50	50	100

Relative Sensitivity: 96% (95%CI*: 86.3%-99.5%) *Confidence
Interval Relative Specificity: 100% (95%CI*: 94.2%-100%)
Accuracy: 98% (95%CI*: 92.9%-99.7%)

IgM Result

Method		PCR		Total Results
COVID-19 IgG/IgM Test Cassette	Results	Positive	Negative	
	Positive	44	0	44
	Negative	6	50	56
Total Result		50	50	100

Relative Sensitivity: 88.0% (95%CI*: 75.7%-95.5%) *Confidence
Interval Relative Specificity: 100% (95%CI*: 94.2%-100%)
Accuracy: 94% (95%CI*: 87.4%-97.8%)

Cross-reactivity

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 50 mg/dL Ascorbic Acid: 20mg/dL
Hemoglobin 1000mg/dL Bilirubin:
60mg/dL Total cholesterol : 8mmol/L

【BIBLIOGRAPHY】

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9

World Health Organization (WHO). Coronavirus. https://www.who.int/health-topics/coronavirus

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C	LOT	Lot Number	REF	Catalog #

HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD.
3rd Floor, Building 6, No. 8-2 Keji Road, Yuhang District, HangZhou, China.

EC REP
LOTUS NL B.V.
Koningin Julianaplein 10, Le Verd, 2595AA,The Hague, Netherlands.

Number: 20200005
Effective Date: 2020-03-02

SUPPORTING DOCUMENTATION

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 24 maart 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 20 maart 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD. met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 IgG/IgM Test Cassette(Colloidal gold),SARS-CoV-2RT–qPCR Detection kit
(geen merknaam) (NL-CA002-2020-49844)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
F.J.J. de Bas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20200790

Bijlagen
-

Uw aanvraag
20 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Pagina 1 van 2

SUPPORTING DOCUMENTATION

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 104467 0001 Rev. 00

Holder of Certificate: **Hangzhou Testsea Biotechnology Co., Ltd.**
3rd Floor, Building 6 north, No. 8-2 Keji Avenue
Yuhang District
311121 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Testsea Biotechnology Co., Ltd.
3rd Floor, Building 6 north, No. 8-2 Keji Avenue, Yuhang District,
311121 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Kits for Fertility, Drug of abuse and Infectious Diseases**

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.: SH19155901

Valid from: 2020-02-21
Valid until: 2023-02-20

Date, 2020-02-21

Christoph Dicks
Head of Certification/Notified Body

A4 / 07.17

TÜV®

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

SUPPORTING DOCUMENTATION

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD.
No. 8-2 Science-Tech Road, Bldg. 6, Yuhang District
Hangzhou, Zhejiang, 311121, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration
Owner/Operator Number: 10064636

Listing No.	Product Code:	Device Name:
D379560	QKP	Coronavirus antigen detection test system
D379567	QKO	Reagent, coronavirus serological(SARS-CoV2 (COVID-19) IgG/IgM TEST).

Confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. we makes no other representations or warranties, nor does this certificate make sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder`s device or establishment by the U.S. Food and Drug Administration. we assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. we are not affiliated with the U.S. Food and Drug Administration.

US Food & Drug Administration.
W: www.fda.gov E: 547538132@qq.com

jimmy engineer
Issued: March. 28, 2020
Expiration Date: Dec31, 2020

Web: http://www.fda.gov Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov

03

GRUPO ARPA MÉDICA

International medical cutting edge services, from the heart of Spain

The Arpa Médica Group (GAM) was born as a center specialized in Gynecology, Obstetrics and Fertility in 1995. Today it is a recognized benchmark of Assisted Reproduction in Spain, a world leader in the industry. As a result of its success, the demands of its patients and the spirit of continuous improvement to offer women and families comprehensive care, the GAM progressively becomes a center for medical specialties. Currently, the medical group offers a portfolio of more than 20 medical specialties in its clinics.

You can breathe art and avant-garde when entering the group's clinics. Beyond that first perception, the medical team is made up of specialists of recognized national and international prestige who continue to prove innovation in health, human quality and professionalism with facts. In short, the medical craftsmanship of the GAM.

In addition, our medical group is equipped with equipment equipped with the latest advances in technology to optimize the diagnosis and treatment of each patient.

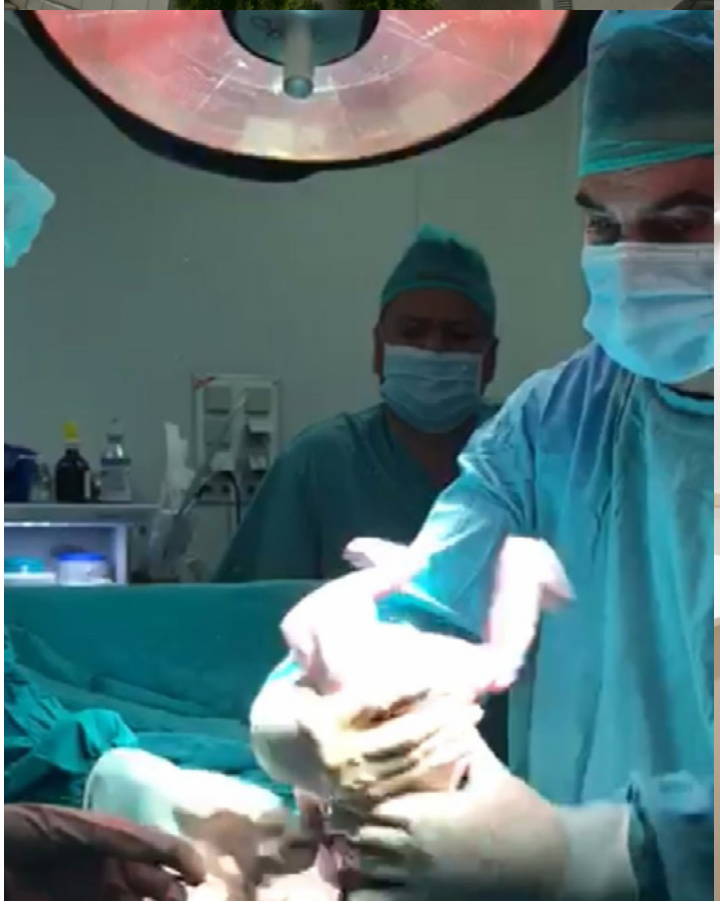
FAMILY BUSINESS WITH FREEDOM OF MANEUVER

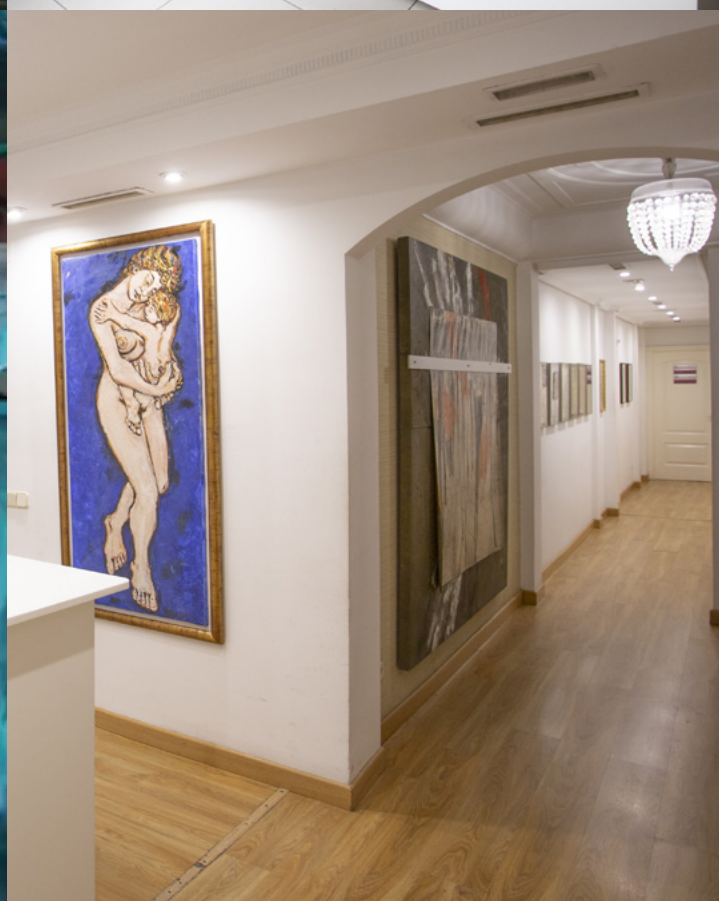
The GAM offers privately operated medical services collaborating with the main national and international medical insurers. 100% of the shareholders belong to Dr. Palomo, the entity's medical leader, which facilitates and speeds up decision-making.

TWO SPACES IN THE BEST AREAS OF MADRID

The two medical centers, owned by Dr. Palomo, are located in the Madrid neighborhoods of Salamanca and El Viso, where they offer Gynecology and Fertility Center and Medical Specialties Center services.


GRUPO ARPA MÉDICA





SERVICES

- Internal Medicine
- Enfermería
- Physiotherapy and Osteopathy
- Gynecology
- Clinical analisys laboratory
- Aesthetic Medicine
- Diagnostic imaging
- Nutrition and diet
- Assisted reproduction
- Obstetrics
- Otorhinolaryngology
- Pediatrics
- Psychology
- Odontology
- Urology
- Vaccination

CLUB

The comprehensive care unit for GAM patients*

*more information in www.arpamedica.es

03 Covid-19 team

Experience and youth with a variety of medical specialties and professionals

Our medical team specialized in COVID-19 is led by the internist Dr. Jorge Del Toro (current head of the Gregorio Marañón hospital section), the also internist Dr. José Ignacio Peralba (ex-general director of the Health of the Air Force , among other things) and Dr. Ignacio Palomo, physician-leader and founder of Grupo Arpa Médica. In addition, the team has other doctors.

Led by Dr. Palomo, the GAM team is made up of specialists in different subjects: nurses, biologists, health managers, etc. We highlight Mr. José Miguel Sanabria (general coordinator of several COVID-19 units)

DR. JORGE DEL TORO
Internal Medicine

DR. JOSÉ IGNACIO PERALBA
Internal Medicine

D. JOSÉ MIGUEL SANABRIA
Sanitary Management

GRUPO ARPA MÉDICA

VANGUARDIA EN SALUD desde Madrid.

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Centro de Ginecología y Fertilidad
OYALA
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CENTRO PALOMO
Gynecology & Fertility Clinic
www.centro-palomo.com

FUNDACIÓN
DR. PALOMO
www.fundaciondoctorpalomo.org

Colaboration

UNIVERSIDAD
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