Introducción de los nuevos reactivos de detección de IgM / IgG de coronavirus nCoV de Longi

Clongene Biotech COVID-19 IGG/IGM Test Cassette

1. Introducción de la empresa
Hangzhou Longji Biotechnology Co., Ltd. es un país especializado en investigación y desarrollo, producción y venta de materias primas biológicas y reactivos de diagnóstico in vitro.
empresas de alta tecnología. La compañía está ubicada en el No. 1, Yichuang Road, Yuhang Street, Yuhang District, Hangzhou, con un área total de construcción de 19,000 metros cuadrados.
Longji Bio es un conocido proveedor de materias primas biológicas en China, especializado en la producción de antígenos, anticuerpos y enzimas. Los reactivos de diagnóstico in vitro de Longji Bio cubren reactivos de detección de oro coloidal, reactivos de detección de inmunofluorescencia, reactivos de detección de quimioluminiscencia, PCR Reactivos de detección.
Sus productos han sido aprobados por la Administración de Productos Médicos de China, la FDA de EE. UU. Y la CE de la UE, y han pasado la ISO
Certificación del sistema de gestión de calidad 13485 e ISO 9001.

Introducción de la empresa:

Clongene es una empresa de alta tecnología especializada en materias primas biológicas y productos de diagnóstico in vitro.

Fundada en 2004, Clongene está equipada con la certificación ISO 13485: 2016 de última generación: China
Instalaciones de fabricación y de I + D que cumplen con las normas GMP que cubren 19.000 metros cuadrados en Hangzhou, China. Nuestros productos han obtenido certificados CE, certificados FSC y autorizaciones 510 (k) de la FDA de EE. UU.

Somos un fabricante líder en tecnología y productos de diagnóstico in vitro, con una sólida reputación y servicios diversificados con una flexibilidad superior para distribuidores profesionales y afiliados asociados al mercado global.

二、产品介绍：

新型冠状病毒 2019-nCOV IgG/IgM 检测试剂盒(胶体金法)
使用说明书

【产品名称】

通用名称：新型冠状病毒 2019-nCOV IgG/IgM 检测试剂盒(胶体金法)

【包装规格】

40 人份/盒

【预期用途】

本品采用捕获法和胶体金免疫层析技术用于快速定性检测人全血、血清、血浆中的 2019-nCOV抗体。

【检验原理】

本品采用捕获法和胶体金免疫层析法原理定性检测人全血、血清、血浆中的 2019-nCOV 抗体，以金标 2019-nCOV 重组抗原和金标羊 IgG 作为指示标记物，在硝酸纤维素膜上的检测线 IgM、检测线 IgG 和控制线处分别包被抗 IgM 抗体、抗 IgG 抗体和鼠抗羊多抗。

检测时，样本在毛细效应下层析。如被检样本中含有抗 2019-nCOV IgM 抗体时，金标 2019-nCOV 重组抗原与 2019-nCOV IgM 抗体结合形成复合物，在层析过程中与固定在检测线处的抗 IgM 抗体结合形成“Au-2019-nCOV 重组抗原－2019-nCOV IgM 抗体－抗 IgM 抗体”夹心物，从而在检测区（IgM）出现一条紫红色条带；如被检样本中含有抗 2019-nCOV IgG 抗体时，金标 2019-nCOV 重组抗原与 2019-nCOV IgG 抗体结合形成复合物，在层析过程中与固定在检测线处的抗 IgG 抗体结合形成“Au-2019-nCOV 重组抗原－2019-nCOV IgG 抗体－抗 IgG 抗体”夹心物，从而在检测区（IgG）出现一条紫红色条带；反之，检测区（IgM）（IgG）不出现紫红色条带。无论被检样本中是否存在 2019-nCOV 抗体，复合物都会继续向上层析至控制区（C），与羊抗兔多抗反应出现一条紫红色条带。控制区（C）所呈现的紫红色条带是判断层析过程是否正常的标准，同时也作为试剂的内控标准。

【主要组成成分】

1. 新型冠状病毒 IgG/IgM 检测试剂盒（40 人份）：每份铝箔袋单独包装。其中试剂盒由包被有金标 2019-nCOV 重组抗原和金标羊 IgG 的聚酯纤维素膜、包被有抗 IgM 抗体、抗 IgG 抗体及鼠抗羊多抗的硝酸纤维素膜、塑料背衬、塑料模板组成。
2. 一次性塑料吸管（40 人份）
3. 样本稀释液
4. 使用说明书（1 份）

【储存条件及有效期】

储存条件：原包装应储存于 4～30℃处，禁止冷冻。

有效期：24 个月。

试剂盒应在铝箔袋拆封后 1 小时内尽快使用；建议在周围温度高于 30℃或高湿度条件下，尽可能做到即开即用。

生产日期及失效日期详见标签。

【适用仪器】

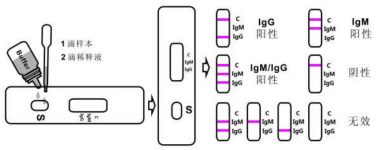
1. 标本收集器、离心机（仅用于血浆）
2. 计时器

【样本要求】

1. 可检测人全血、血清或血浆样本。
2. 将采集的静脉血收集在干净、干燥的容器中，可以采用 EDTA、肝素、枸橼酸钠作为抗凝剂。
3. 样本收集后应尽快分离血清/血浆以避免溶血，不能在室温下长时间存放。
4. 严重溶血的样本不能用于检测，需重新采集。
5. 全血样本采集后应尽可能立即使用，抗凝血应在 24 小时内使用，不得冻存。
6. 如果血清/血浆样本收集后 7 天内检测，样本须放在 2-8℃保存，如果大于 7 天则须冷冻（-20℃）保存。
7. 检测前，冷藏的样本必须恢复至室温，冷冻保存的样本须完全融化、复温、混合均匀后使用。避免反复冻融。

【检验方法】

1. 在进行检测前必须先完整阅读使用说明书，使用前将检测试剂盒和样本恢复至室温（20℃～30℃）。
2. 撕开铝箔袋，取出试剂盒，应在 1 小时内尽快使用。
3. 将试剂盒置于干净平坦的台面上，用塑料吸管垂直滴加 1 滴样本于加样孔（S）中，随即滴加 2 滴样本稀释液（约 70μL）于 S 孔中。
4. 等待紫红色条带的出现，15 分钟内读取结果，20 分钟后判定无效。



【检验结果的解释】

阳性（+）：在检测区（IgM）（IgG）和控制区（C）都出现了紫红色条带。结果表明：样本中含有 2019-nCOV IgM 抗体和 2019-nCOV IgG 抗体。

若只有两条紫红色条带出现。一条位于检测区（IgM）或（IgG），另一条位于控制区（C）。结果表明：样本中只含有 2019-nCOV IgM 抗体或 2019-nCOV IgG 抗体。

阴性（-）：仅在控制区（C）出现一条紫红色条带，在检测区（IgM）（IgG）无紫红色条带出现。

无效：控制区（C）未出现紫红色条带。表明操作不当或试剂盒已失效。在此情况下，应再次仔细阅读说明书，并用新的试剂盒重新测试。如果问题仍然存在，应立即停止使用此批号产品，并与当地供应商联系。

注意：检测区（IgM）（IgG）紫红色条带可呈现颜色深浅的现象。但是，在规定的观察时间内，不论该色带颜色深浅，即使只有非常弱的色带也应判定为阳性结果。

【检验方法的局限性】

1. 本品仅供研究使用，仅供检测人全血、血清、血浆样本。
2. 本品仅对样本中的 2019-nCOV IgG 抗体或 2019-nCOV IgM 抗体提供定性检测，不能用于定量。需要检测某一指标的具体含量请借助相关的专业仪器。
3. 本品用于初步筛查，任何测定阳性结果都须用确证方法作进一步的确认。

【注意事项】

1. 全部检测工作必须符合生物安全守则规定，严格防止交叉感染。
2. 每一份样本均应使用新的加样吸管，以避免样本受到污染。
3. 如果检测结果呈阴性并有临床症状存在，可建议使用其他临床方法进行测试。本品仅供研究使用，不能作为确诊依据。
4. 就阳性结果而言，检测区色带颜色的深浅并不完全和样本中的抗体滴度成正比关系。
5. 样本和所有用过的物品应按可能存在潜在的感染性物品处理。

【基本信息】

生产企业名称：杭州隆基生物技术有限公司

生产地址：杭州市余杭区余杭街道义创路 1 号

邮政编码：311121

电话号码：0571-88262113　　88262120

传真号码：0571-88262112　　88261752

网址：www.clongene.com

Introducción del producto:

COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with Novel coronavirus.

[SUMMARY]

Early January 2020, a novel coronavirus (SARS-CoV-2, formerly known as 2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.Six 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. The two other strains severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are zoonotic in origin and have been linked to sometimes fatal illness.
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.
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.

[PRINCIPLE]

The COVID-19 IgG/IgM Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. The test cassette consists of: 1) a burgundy colored conjugate pad containing Novel coronavirus recombinant envelope antigens conjugated with Colloid gold (Novel coronavirus conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with the Mouse anti-Human IgM antibody, IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM anti-Novel coronavirus, if present in the specimen, will bind to the Novel coronavirus conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a Novel coronavirus IgM positive test result. IgG anti-Novel coronavirus if present in the specimen will bind to the Novel coronavirus conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a Novel coronavirus IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with Mouse anti-Human IgM antibody and Mouse anti-Human IgG antibody on the test line, and a dye pad which contains colloidal gold coupled with Novel coronavirus recombinant antigen.
The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

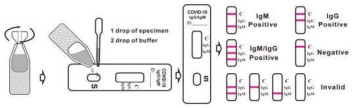
- Store as packaged in the sealed pouch at the temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The test can be used to test Whole Blood/Serum/Plasma specimens.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store specimens at 2-8℃ up to 7 days. The specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃or 59-86℉) prior to testing.
1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop of specimen (approximately 10μl) to the specimen well(S) of the test device, then add 2 drops of buffer (approximately 70μl) and start the timer. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive: Control line and at least one test line appear on the membrane. The appearance of IgG test line indicates the presence of Novel coronavirus specific IgG antibodies. The appearance of IgM test line indicates the presence of Novel coronavirus specific IgM antibodies. And if both IgG and IgM line appear, it indicates that the presence of both Novel coronavirus specific IgG and IgM antibodies.
Negative: One colored line appears in the control region(C).No apparent colored line appears in the test line 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

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

[LIMITATIONS]

- The COVID-19 IgG/IgM Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antibodies to Novel coronavirus are either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Summary data of COVID-19 IgG/IgM Rapid Test as below:
Regarding the IgM test,the result comparison to RT-PCR.
COVID-19 IgM:

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

A statistical comparison was made between the results yielding a sensitivity of 87.01%, a specificity of 98.89% and an accuracy of 93.41%

Regarding the IgG test, we have counted the positive rate of the 77 patients during the convalescence period.

COVID-19 IgG:

COVID-19 IgG		Number of patients during the convalescence period	Total
	Positive	75	75
	Negative	2	2
Total		77	77

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive specimens of other common infectious diseases were spiked into the Novel coronavirus positive and negative specimens and tested separately. No cross reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, TP, HTLV, CMV, FLUA, FLUB, RSV, MP, CP, HPIVs.

2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Novel coronavirus positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	20μg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200μg/ml	+	-
Lipids	20mg/ml	+	-

3. Some other common biological analytes were spiked into the Novel coronavirus positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (μg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

Reproducibility

Reproducibility studies were performed for Novel coronavirus IgG/IgM Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100 %.

Index of Symbol

Do not reuse	For in vitro diagnostic use only
Store between 4-30℃	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

Version No.: 1.0
Effective Date: Mar. 04, 2020

INSTRUCCIONES DE OPERACIÓN

Uso correcto, cómodo y rápido

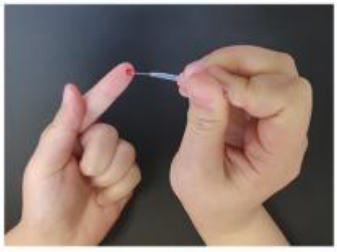
1 - Temperatura constante y posición estática

2 - Masajear la pulpa del dedo

3 - Desinfectar la tableta con alcohol

4 - Toma de muestras de sangre y acupuntura en el abdomen de los dedos

5 - Limpie la primera gota de sangre con una bola de algodón seca estéril.



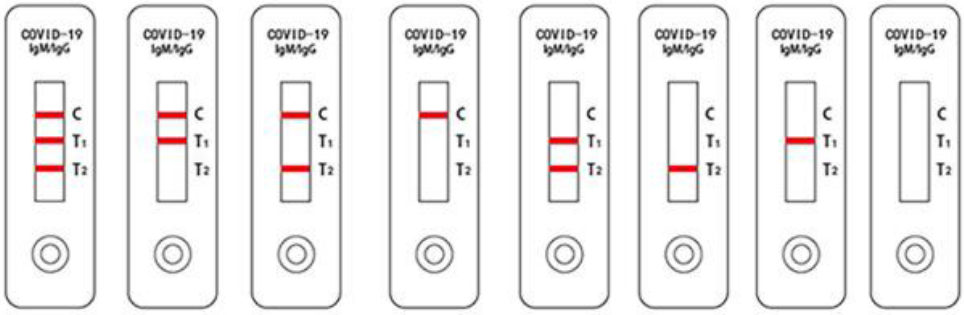
6 - Utilice una micropipeta desechable para succionar sangre.

7 - Se agregan las gotas de sangre a la tarjeta de prueba.

8 - Agregue diluyente y comience a cronometrar

9 - Deje reposar durante 20 minutos para leer el resultado

INTERPRETACIÓN DE RESULTADOS



T_1 Positivo T_2 Positivo	T_1 Positivo T_2 Negativo	T_1 Negativo T_2 Positivo	T_1 Negativo T_2 Negativo	Invalido	Invalido	Invalido	Invalido

三、公司资质 Calificación y certificados:

杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co.,Ltd
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou 311121,China
Tel: +86-571-88262120 Fax: +86-571-88261752
Web: www.clongene.com Email:marketing@clongene.com

BUSINESS LICENSE

(DUPLICATE)

Unified Social Credit Code: 913301107620252127
Company Name: Hangzhou Clongene Biotech Co.,Ltd
Type: Limited Company
Legal Representative: ZHENG SHU JIAN
Registered Capital: FIFTY MILLION ONE HUNDRED THOUSAND RMB
Founded Date: 9 June,2004
Business Term: From 9 June, 2004 to Long term
Business Scope: Technology development, technical consultation, technical services and achievements transfer of biological products: production; Food safety rapid detection reagent products , second and third class 6840 in vitro diagnostic reagents of Medical Device; Non-medical use biological raw materials, laboratory reagents (except hazardous chemicals and precursor chemicals), primary edible
agricultural products (except food, medicine), laboratory instrument&equipment sales; The import and export of goods (except those which are prohibited by laws and administrative regulations, can operate only after obtain a permission license). (the projects which need be approved by law, operational activities only can be carried out after approval by relevant departments)

Registration authority ： Hangzhou Yuhang district Market Supervision Administration.

Aug.06,2019