

TEST RÁPIDO PARA DETECCIÓN DE COVID - 19 / SEROLÓGICA

Esta **PRUEBA SEROLÓGICA**, se realiza con **UN CASETE DE PRUEBA RÁPIDA IGG / IGM 2019-NCOV**, el cual es un inmunoensayo cromatográfico de flujo lateral para la detección cualitativa de anticuerpos IgG e IgM contra 2019-nCoV en una muestra de sangre entera humana/suero/plasma de punción digital in vitro, esta muestra que se utiliza es similar a un examen de glicemia, basta solo una gota de sangre sobre un dispositivo que marca positivo o negativo.

El tiempo de lectura que arroja los resultados del test demora 15 minutos aproximadamente, con un margen de sensibilidad mayor al 90%.

APLICACIONES DEL TEST :

- Cribado de población general
- Permite un examen y diagnóstico rápidos cerca del punto de atención
- Diseñado para profesionales del sector sanitario, como lo son hospitales, farmacias, consultorios médicos, laboratorios.

MATERIALES PROPORCIONADOS:

- Cassette de prueba.
- Buffer
- Pipeta
- Lanceta (solo para sangre entera por punción digital)
- Almohadilla de lana o gasa (solo para sangre entera por punción digital)
- Instrucciones de Uso.

MATERIALES REQUERIDOS PERO NO PROPORCIONADOS:

- Contenedor de recogida de muestra
- Temporizador
- Contenedor para desechos biopeligrosos.



Imagen Referencial

FICHA TÉCNICA DEL PRODUCTO

TEST RÁPIDO PARA DETECCIÓN DE COVID - 19 / SEROLÓGICA

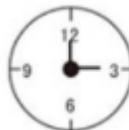
ADVERTENCIAS Y PRECAUCIONES:

- Sólo para uso diagnóstico in vitro.
- Para profesionales de la salud y profesionales en los puntos de atención.
- No lo use después de la fecha de vencimiento.
- El casete de prueba debe permanecer en la bolsa sellada hasta su uso.
- Todas las muestras deben considerarse potencialmente peligrosas y manipularse de la misma manera que un agente infeccioso.
- El casete de prueba usado debe desecharse de acuerdo con las reglamentaciones federales, estatales y locales.

MODO DE USO

Con Sangre

Ponga dos gotas de sangre en la cubeta y una gota de reactivo.



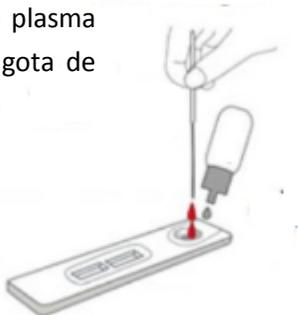
Espere 15 minutos



Resultado

Con Plasma

Ponga una gotas de plasma en la cubeta y una gota de reactivo.



Espere 15 minutos



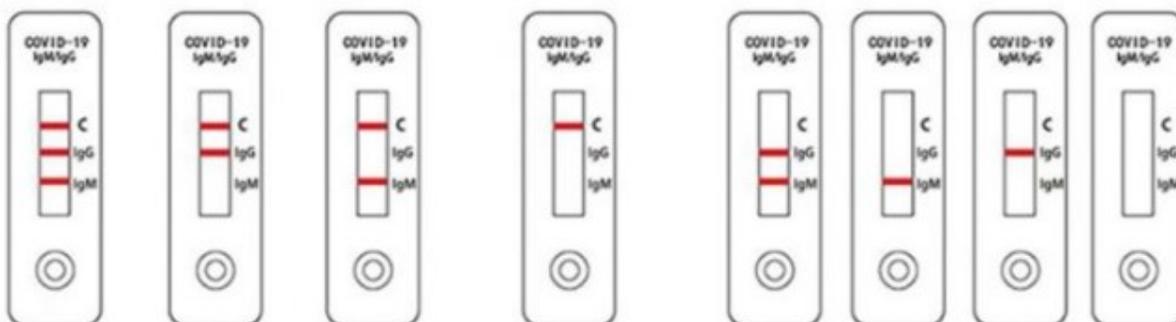
Resultado

TEST RÁPIDO PARA DETECCIÓN DE COVID - 19 / SEROLÓGICA

INTERPRECIÓN DE LOS RESULTADOS:

- Una línea roja aparecerá en el **área C** de la ventana de lectura para mostrar que la prueba esté trabajando de manera apropiada. Esta línea es la **línea de control**.
- Una línea roja que podría aparecer en la ventana de lectura es la línea de prueba de IgG.
- Una línea roja que podría aparecer en la ventana de lectura es la línea de prueba de IgM.

Por favor, consulte la siguiente ilustración:



IgG e IgM POSITIVO: * La presencia de la línea de Control y la línea de prueba IgG e IgM dentro de la ventana de lectura indica un resultado positivo tanto para IgG como para IgM.

IgG POSITIVO: * La presencia de ambas líneas: la línea de Control y la línea de prueba IgG dentro de la ventana de lectura indica un resultado positivo para IgG.

IgM POSITIVO: * La presencia de ambas líneas: la línea de Control y la línea de prueba IgM dentro de la ventana de lectura indica un resultado positivo para IgM.

(*) NOTA: La intensidad del color en las regiones de la línea de prueba de IgG e IgM puede variar, dependiendo de la concentración de anticuerpos COVID-19 presentes en el espécimen. Por lo tanto, cada línea visible en el área IgG e IgM deberá considerarse positiva.

NEGATIVO:

La presencia solo de la línea de Control y la ausencia visibles de las líneas de prueba IgG e IgM dentro de la ventana de lectura indica un resultado negativo.

NO VÁLIDO:

La ausencia de la línea de Control en la ventana de lectura indica un resultado no valido. Si esto ocurre, se recomienda leer nuevamente las Instrucciones de Uso y volver a probar el espécimen con un nuevo dispositivo de prueba.

CERTIFICACIÓN

CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex II and NOT self-test)

Manufacturer: Biotech (Hangzhou) Co., Ud.

Address: Building 2/203 No.18 Haishu Rd Cangqian Sub-district, Yuhang District Hangzhou, Zhejiang China 311121

EC Representative: Wellkang Ud
Suite B 29 Harley Street, London W1G 9QR UK

We, the manufacturer, declare under our sole responsibility that

the medical	Product Name	Covid-19 IgM Rapid Test Kit (Whole Blood/serum/plasma)
device(s)	Type/model, identification of product allowing traceability (where applicable)	Cassette(NC0-4012)
of Category	Common/Others IVD	

(Devices of NOT Annex II and NOT self-test)

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards national standards or other normative documents	EN 18023640:2015	EN ISO 18113-1:2011
	EN 13612:2002	ISO 18113-2: 2009
	EN 13641:2002	EN 1041-2008
	EN ISO 14971:2012	EN 18015223-1:2016
	ISO 13485:2016	

Conformity assessment procedure ~~Module A (EC Declaration of Conformity) (Annex III, except point 6)~~

Notified Body (name & number) NOT applicable

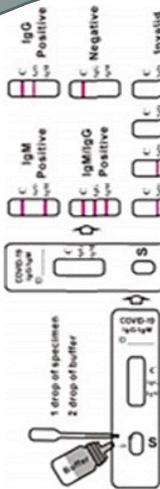
Certificate & number

Signed on: 6 March, 2020 **Place:** Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer): _____ *2020.3.6*

Name of authorized signatory: Kebin Qiu
Position held in the company: Qe Manager
Seal/Stamp: _____

FICHA INSTRUCTIVA TEST RÁPIDO COVID - 19



(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 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, discontinuing 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] IgG/IgM Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the antibody in the blood correlates 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	
CLUNGENE®	67	1	68
	10	89	99
	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%.

- 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 dry pad which contains colloidal gold coupled with Novel coronavirus recombinant antigen.

The quantity of tests was printed on the labeling.

Materials Provided

- *Test cassette
- Buffer
- *Package insert
- *Specimen collection container
- *Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at the temperature (4-30°C or 40-86°F). 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]

- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Store specimens at 2-8°C (36-46°F) if not tested immediately. Store specimens at 2-8°C up to 7 days. The specimens should be frozen at -20°C (-4°F) 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°C or 59-86°F) prior to testing.
- Remove the test cassette from the sealed pouch.
 - 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.
 - Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.

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

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] 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]

FICHA INSTRUCTIVA TEST RÁPIDO COVID - 19

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
CLUNGENE®	Positive	75	75
	Negative	2	2
Total		77	77

Cross-Reactivity and Interference

- 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.
- 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	+	-

- 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	+	-
Benzoyfecgonine	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

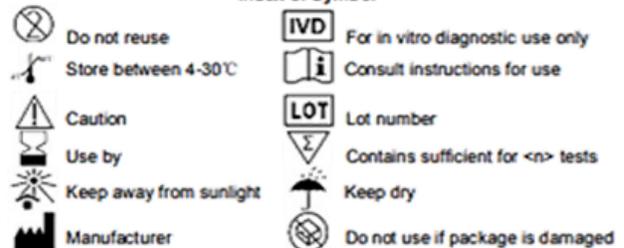
agreement was 100 %.



Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,
311121 Hangzhou, China

EC REP Shanghai International Holding Corp.GmbH (Europe)
Eiffelstrasse 80, D-20537 Hamburg, Germany

Index of Symbol



EC REP Authorized representative in the European Community

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