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

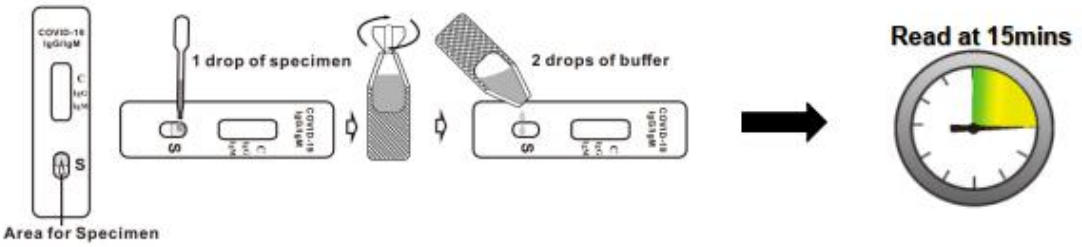
CLUNGENE® COVID-19 IgG/IgM Rapid Test

Safety lancet

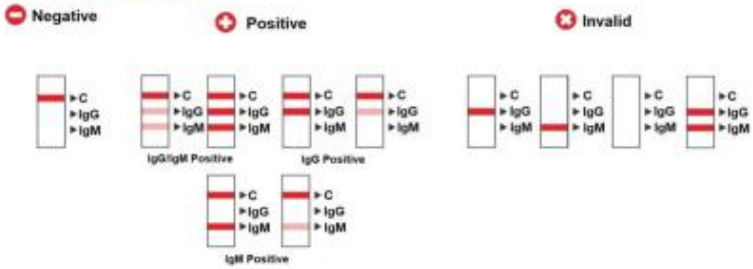
Buffer

Cat. No.	ICOV4212-100496
Product Name	CLUNGENE® COVID-19 IgG/IgM Rapid Test
Specimen	Whole blood/Serum/Plasma
Sample Volume	10μl
Results read time	15mins
Operation Temperature	15-30℃
Storage	4-30℃
Shelf life	24months
Package	25Tests+25Droppers+25safety lancets+25alcohol pads+25individual buffer+1Package insert/box,1250pcs/CTN; Carton size:64*34*55cm,G.W.:16.8kgs

Test Procedure



Results Interpretation



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

BUSINESS LICENSE-ENGLISH VERSION

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

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

MEDICAL DEVICE PRODUCTION LICENSE

THE PEOPLE'S REPUBLIC OF CHINA

LICENSE FOR PRODUCER OF MEDICAL DEVICE

No. ZSYJXSCX 20130164

Enterprise: Hangzhou Clongene Biotech Co., Ltd.

Legal Representative: Zheng Shujian

Registered Address: No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China

Person in Charge of Enterprise: Zheng Shunjian

Production Address: No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China

Production Scope: 6840 vitro diagnostic reagents of Class II and III***

Issued By Zhejiang Food and Drug Administration (Seal)

Valid until: 9, Jan. 2025

Date: 10, Jan. 2020

Printed and issued under the supervision of State Food and Drug Administration

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

CERTIFICATE-ISO13485:2016

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design/development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test of Fertility, Drug of Abuse, Infectious Diseases, Tumour Markers and Cardiac Markers

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-04-16
Certificate Registration No.:	SX 60137252 0001
An audit was performed. Report No.:	15073650 006
This Certificate is valid until:	2020-11-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-04-16

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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

EC Declaration of Conformity

EC Declaration of Conformity

Name and address of the manufacturer: **Hangzhou Clongene Biotech Co., Ltd.**
No.1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
China

We declare under our sole responsibility that

the medical device: **COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)-ICOV4212**

of class: **Other**
according to aticle 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 98/79/EC Annex III**

Name and address of the Authorised Representative: **Shanghai International Holding Corporation GmbH (Europe)**
Eiffestrasse 80
20537 Hamburg
Germany

CE

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Hangzhou, Mar.04.2020
Place, date

Shujian Zheng, Legal representative
Name and function

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

Australia TGA

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	333341
ARTG Start date	5/04/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The COVID-19 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies(IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma

Manufacturer Details	Address	Certificate number(s)
Hangzhou Clongene Biotech Co Ltd	No 1 Yichuang Road Yuhang Sub district Yuhang District, Hangzhou, 311121 China	DV-2020-MC-04126-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Severe acute respiratory syndrome-associated coronavirus IVDs

This entry: contains System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
COVID-19 IgG/IgM Rapid Test Cassette	Point of care testing

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

US FDA

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

BRAZIL ANVISA

Apresentação/Modelo
25 x 1 cassete de teste; 1 frasco x 4mL de tampão; 25 x 1 pipeta

Tipo de Arquivo	Arquivos	Expediente, data e hora de inclusão
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	INSTRUCAO-DE-USO - 1 de 1.DOC	1233019/20-1 - 13/05/2020 - 07:45

Nome Técnico	CORONAVÍRUS
Registro	80102512481
Processo	25351.324783/2020-17
Fabricante Legal	• FABRICANTE: HANGZHOU CLONGENE BIOTECH CO., LTD - CHINA, REPÚBLICA POPULAR
Classificação de Risco	III - Classe III: produtos de alto risco ao indivíduo e ou médio risco à saúde pública
Vencimento do Registro	14/05/2021

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

CERTIFICATES-ISO9001:2015

ZJQC

中 经 认 证

No：04419Q11975R0M

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the quality management system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 913301107620252127

REG.、AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

GB/T 19001-2016/ISO 9001:2015 standard

The certificate is valid for the following scope:

DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS (WITHIN THE SCOPE OF ADMINISTRATIVE LICENSE)
(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Oct 17th,2019 Expiry Date:Oct 17th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Oct 17th,2019

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

WeChat Query

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C044-M

地址：北京市西城区月坛北小街4号5号楼1429

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

CERTIFICATES-ISO45001:2018

ZJQC

中 经 认 证

No：04419S21047R0M

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the occupational health and safety management system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 91330110762025212 7

REG./AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

ISO 45001： 2018 standard

The certificate is valid for the following scope:

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT ACTIVITIES OF DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS

(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Oct 17th,2019 Expiry Date:Oct 17th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Oct 17th,2019

WeChat Query

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

CNAS 中国认可 管理体系 MANAGEMENT SYSTEM CNAS C044-M

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

CERTIFICATES-ISO14001:2015

ZJQC

中 经 认 证

No：04419E11187R0M

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the environmental system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 913301107620252127

REG./AUDIT ADD: NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU CITY, ZHEJIANG

is in conformity with

GB/T 24001-2016/ISO 14001:2015 standard

The certificate is valid for the following scope:

ENVIRONMENTAL MANAGEMENT ACTIVITIES OF DEVELOPMENT, MANUFACTURE AND SERVICE OF IN-VITRO DIAGNOSTIC REAGENTS

(This certificate and certification symbols will not be applicable when multi-site is out of the registration scope.)

Issue Date:Nov 11th,2019 Expiry Date:Nov 11th,2022

Beijing Zhongjing Quality Certification Co., Ltd. General Manager:

Date: Nov 11th,2019

To verify validity of the certificate:
1. Please scan two-dimensional code on the left
2. Access the website www.zjqc.com
3. Access the website of CNCA www.cnca.gov.cn
4. The Certificate is valid ONLY if the organization pass the surveillance audit

WeChat Query

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C044-M

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

Certificate of Analyses

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

CERTIFICATE OF ANALYSES

COVID-19 IgG/IgM Rapid Test Cassette
Batch Number : 2020050022

Description: Testing Cassette
Appearance: Well sealed in foil pouch

TEST	Specification	Result
Physical Inspection		
Appearance	The surface of reagent is flat and clean, no damage, all the materials are assembled well, and no missing component.	Conforms
Width of the membrane	≥ 2.5mm	3.0
Liquid migration rate	≥ 10mm/min	15
Sensitivity		
COVID-19 IgG positive Control	IgG Positive (+);IgM Negative (-)	IgG +;IgM -
COVID-19 IgM positive Control	IgM Positive (+);IgG Negative (-)	IgM +;IgG-
Specificity		
Negative sample	IgG Negative (-);IgM Negative (-);	IgG -;IgM -

This product was tested and approved in accordance with Quality Control testing performance criteria.

Quality Control Approval:

Xingqiao Pang

Date Tested: May.11, 2020
EXP. Date: 2022-04

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

Instruction for Use

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 immunoassay designed for the qualitative detection of IgG and IgM antibodies to the SARS-CoV-2 virus in whole blood, serum or plasma specimens from individuals suspected of COVID-19 infection by their healthcare provider.

The COVID-19 IgG/IgM Rapid Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. It is suggested to use as a supplementary test indicator for suspected cases with negative nucleic acid test of novel coronavirus or used in conjunction with nucleic acid test in suspected cases. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

The test is intended to be used at clinical laboratories or by healthcare workers at the point-of-care, not for home use. The test should not be used for screening of donated blood.

[SUMMARY]

Coronavirus disease 2019 (COVID-19) is caused by a coronavirus. Coronaviruses are a large family of viruses which may cause illness in animals or humans. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (named SARS-CoV-2).

The virus that causes COVID-19 is mainly transmitted through droplets generated when an infected person coughs, sneezes, or speaks. It is currently thought that an infected person can go up to 14 days before noticing any symptoms. According to WHO, the incubation period is, on average, five to six days. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. There have been reports of persons who were infected by individuals who had only shown slight or non-specific symptoms of disease. In some patients, the virus can lead to severe illness, including difficult breathing, and to pneumonia. Deaths have mainly occurred among patients who were elderly and/or had prior underlying chronic illnesses.

When the SARS-CoV-2 virus infects an organism, RNA, the genetic material of the virus, is the first marker that can be detected. The viral load profile of SARS-CoV-2 is similar to that of influenze, which peaks at around the time of symptom onset, and then begin to decline. With the development of the disease course after infection, the human immune system will produce antibodies, among which IgM is the early antibody produced by the body after infection, indicating the acute phase of infection. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. IgG indicates the convalescent phase of infection or a history of past infection. However, both IgM and IgG have a window period from virus infection to antibody production, IgM almost appear after the onset of disease several days, so their detection often lags behind nucleic acid detection and is less sensitive than nucleic acid detection. In cases where nucleic acid amplification tests are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples (in the acute and convalescent phase) could support diagnosis.

[PRINCIPLE]

The COVID-19 IgG/IgM Rapid Test Cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloid gold (SARS-CoV-2 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 antibodies to SARS-CoV-2, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a anti-SARS-CoV-2 IgM positive test result. IgG antibodies to SARS-CoV-2 if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a anti-SARS-CoV-2 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 SARS-CoV-2 virus recombinant antigen.

The quantity of tests was printed on the labeling.

Materials Provided

- Test cassette
- Buffer (PBS, ProClin300)
- Alcohol pad
- Dropper
- Lancet
- Package insert

Materials Required But Not Provided

- 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.

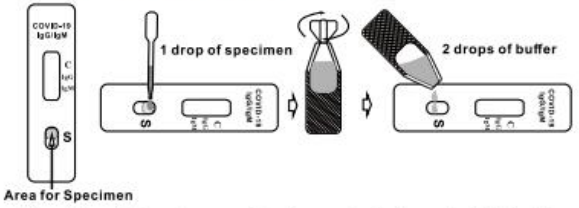
[SPECIMEN]

- The test can be used to test whole blood (venipuncture blood and capillary finger prick blood) /serum /plasma (EDTA, heparin, citrate) 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 serum/ plasma/ anticoagulated venipuncture whole blood specimens at 2-8℃ for up to 3 days. The serum/plasma specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Fresh fingerstick blood specimens should be collected and tested immediately.
- 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]

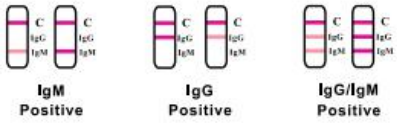
Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop (approximately 10μl) of specimen into the front of the specimen well (S) making sure that there are no air bubbles. For better precision, transfer specimen by a pipette capable of delivering 10μl of volume. See the illustration below.
3. Then, add 2 drops (approximately 70μl) of buffer immediately into the specimen well (S).
4. Start the timer.
5. Wait for colored lines to appear. Interpret the test results at 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.

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

Instruction for Use

The appearance of IgG test line indicates the presence of IgG antibodies to SARS-CoV-2 virus. The appearance of IgM test line indicates the presence of IgM antibodies to SARS-CoV-2 virus. And if both IgG and IgM line appear, it indicates that the presence of both IgG and IgM antibodies to SARS-CoV-2 virus. Regardless of how dark or light the line may appear.

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.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

[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.
- Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- If symptoms persist and the result from the COVID-19 IgG/IgM Rapid Test Cassette is negative, it is recommended to re-sample the patient a few days later or test with an alternative test device.
- A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.
- Proper sample collection is critical, and failure to follow the procedure may give inaccurate results. Improper sample collection, improper sample storage or repeated freezing and thawing of samples can lead to inaccurate results.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Summary data of COVID-19 IgG/IgM Rapid Test as below:

Regarding the IgM test, testing was performed on 167 clinical specimens from individuals suspected of COVID-19 infection compared to RT-PCR.

COVID-19 IgM:

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	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
CLUNGENE®	Positive	75	75
	Negative	2	2
Total		77	77

The results yielding a sensitivity of 97.40%.

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	+	-

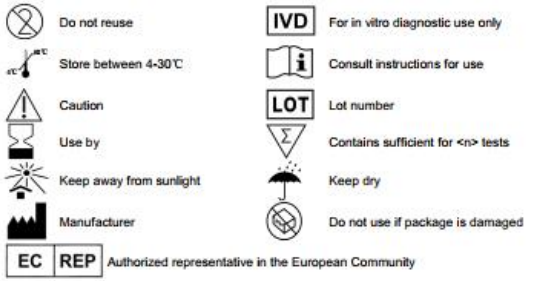
Reproducibility

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 %.

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)
Eiffestrasse 80, D-20537 Hamburg, Germany

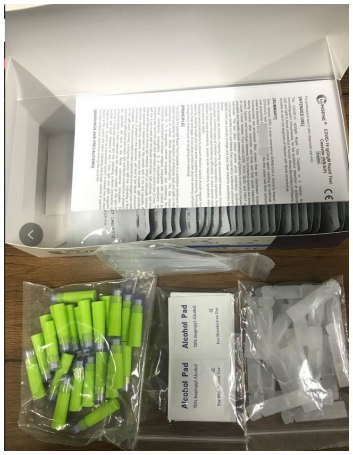
Index of Symbol



Version No.: 2.0
Effective Date: April 16, 2020

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

Packing Details:



ICOV4212-100496:
25Tests+25Droppers+25safety lancets+25alcohol pads+25individual buffer+1Package insert/box,
1250pcs/CTN; Carton size:64*34*55cm,G.W.:16.8kgs