
LUNGENE®
RAPID TEST
COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)
Contains: 25 Test Cassettes
25 Droppers
1 Package Insert
1 Buffer
LUNGENE®
RAPID TEST
COVID-19
IgG/IgM
ID:
C
IgG
IgM
S


Alcohol Pad
70% Isopropyl Alcohol
For Disinfection Use
ID:
C
IgM
IgG
S

THE PEOPLE'S REPUBLIC OF CHINA

BUSINESS LICENSE of CORPORATION

Registration No.: 330105000070713

Name of Enterprise: Hangzhou Clongene Biotech Co., Ltd

Legal Representative: Shujian Zheng

Address: 4 Building, 20# Longquan Road, Cangqian Sub-district, Yuhang District, Hangzhou City

Registration Capital: 5,100,000RMB

Paid-up Capital: 5,100,000RMB

Enterprise Type: Limited liability company

Business Scope: Production and sales of non-medical use of biological raw materials(antigens and antibodies); Production of Class 2 and 3, 6840 in vitro diagnostic reagents(Producer License of of Medical Device which is valid until February 10, 2014); sales of subsidiary agricultural products(Excluding the products requiring pre-authorization as per the laws and regulations) and instruments and consultation, and technical service of biological products; Import and export of commodities(excluding business prohibited by the laws and regulations; by license if required); any other legal businesses not requiring authorization.*** By license if required.

Date of Establishment: June 9, 2004

Term of Validity: From June 9, 2004 to June 8, 2014

Note: Please apply for annual verification between March and June each year and visit www.hzaic.gov.cn for instruction.

Registered at Yuhang Branch, Hangzhou Municipal Administration for Industrial and Commerce

Date: December, 2011

杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.
Tel: +86-571-88262120
Fax: +86-571-88261752
Web: www.clongene.com
Email: marketing@clongene.com

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 article 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**

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

Hangzhou, 03/03/2020
Place, date

Shujian Zheng, Legal representative
Name and function

EC Declaration of Conformity
Revision 5.0

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

地址：北京市西城区月坛北小街4号5号楼1429

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

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

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

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: 913301107620252127

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

地址：北京市西城区月坛北小街4号5号楼1429

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
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 and Infectious Diseases, In-vitro Diagnostic Rapid Test of Tumour 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:	2018-02-06
Certificate Registration No.:	SX 60126181 0001
An audit was performed. Report No.:	15073650 005
This Certificate is valid until:	2020-11-12

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-02-06

X. Ren

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

July 30, 2018

Jesse Xia, Manager
LSI International
504 E Diamond Ave, Suite I
Gaithersburg, MD 20877 US

Re: CR180448
CLIA Parent(s): k181790
Applicant: Hangzhou Clongene Biotech Co.,Ltd.
Device: CLUNGENE Multi-Drug Test Dip Card, CLUNGENE Multi-Drug Test Easy Cup
Dated: June 25, 2018
Received: July 5, 2018
CLIA Effective Date: July 30, 2018

Categorization Notification (Waived)

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte(s): (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported in FDA's CLIA Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm . This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. FDA reserves the right to re-evaluate and re-categorize this test based upon additional information received.

If you have any questions regarding this complexity categorization, please contact Helen Yousefi at helen.yousefi@fda.hhs.gov.

Sincerely yours,

Donald St.Pierre
Acting Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Parent Number : k181790

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Easy Cup
Analyte : Buprenorphine
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Dip Card
Analyte : Buprenorphine
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Dip Card
Analyte : Methylenedioxymethamphetamine (MDMA)
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Easy Cup
Analyte : Methylenedioxymethamphetamine (MDMA)
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Dip Card
Analyte : Phencyclidine (PCP)
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Easy Cup
Analyte : Phencyclidine (PCP)
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Dip Card
Analyte : Tricyclic antidepressants
Complexity : WAIVED

Test System : Hangzhou Clongene Biotech Co.,Ltd. CLUNGENE Multi-Drug Test Easy Cup
Analyte : Tricyclic antidepressants
Complexity : WAIVED

空 运
By Air

NO.2020370734

CNAS 中国认可 检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 诊断试纸；诊断试剂

Sample Name: Diagnostic kit; Diagnostic Reagent

委托单位： 杭州隆基生物技术有限公司

生产单位： 杭州隆基生物技术有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods　　NO. 2020370734

样品名称 Sample Name	中文 Chinese	诊断试纸：诊断试剂
	英文 English	Diagnostic kit; Diagnostic Reagent
委托单位 Consignor		杭州隆基生物技术有限公司
生产单位 Manufacturer		杭州隆基生物技术有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		无色透明液体和白色试剂条，稍有气味 Colorless transparent liquid and white reagent strips, Weak odor
IDENTIFICATION CONCLUSION 鉴定结论		1. 危险性识别(Hazards identification) 无。 None. 2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR) 根据特殊规定A122，可按非限制性货物条件办理。 The substance is not subject to IATA DGR according to special provision A122. 3. 包装要求(Packaging requirements) 无。 None. 检验日期: Inspection Date: 2019-12-22　签发日期: Issue Date: 2019-12-22　生效日期: Effective Date: 2020-01-01
备注 Comment		无。 None.

批准 Approver:　　审核 Checker:　　主检 Appraiser:

医疗器械生产许可证

许可证编号：浙食药监械生产许 20130164 号

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

法定代表人：郑曙剑

生产范围：第二、三类 6840 体外诊断试剂***

企业负责人：郑曙剑

住　　所：杭州市余杭区余杭街道义创路 1 号

发证部门：浙江省食品药品监督管理局

有效期限：至　2020　年5　月31　日　　发证日期：　2017　年 2　月22　日

国家食品药品监督管理总局制

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020370734

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:576173-

报告结束

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

CE

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.

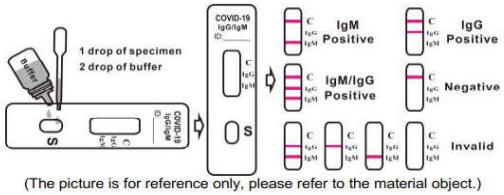
[SPECIMEN]

- 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	
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

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

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

EC REP Authorized representative in the European Community

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