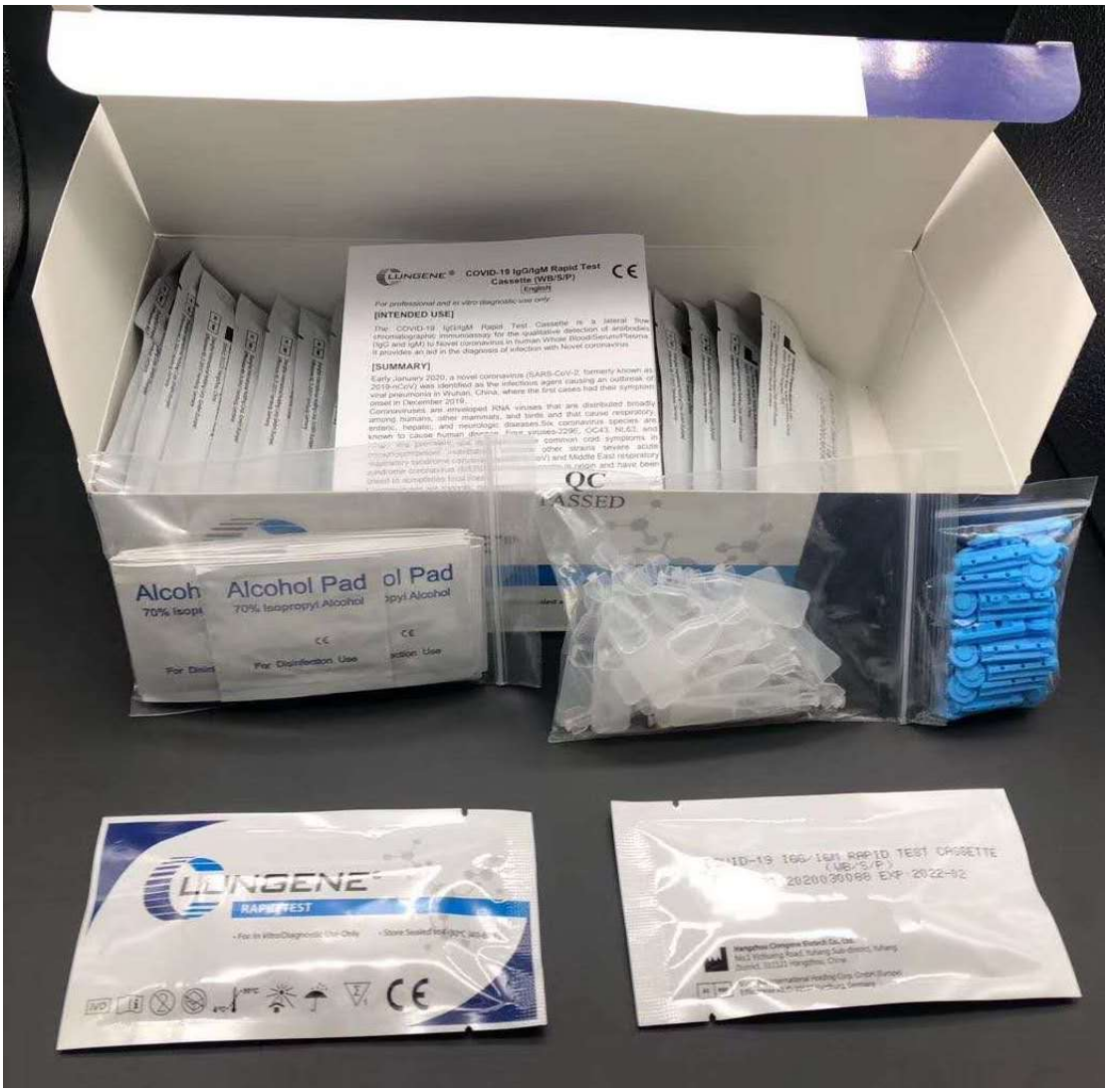

LUNGENE®
RAPID TEST
COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)
Contains:25 Test Cassettes
1 Package Insert
25 Droppers
1 Buffer
LUNGENE®
RAPID TEST
- For in Vitro Diagnostic Use Only
COVID-19
IgG/IgM
ID:
C
IgG
IgM
S


LUNGENE®
COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)
English
For professional and in vitro diagnostic use only
[INTENDED USE]
[SUMMARY]
QC PASSED
Alcohol Pad
70% Isopropyl Alcohol
For Disinfection Use
LUNGENE
RAPID TEST

U.S. FOOD & DRUG ADMINISTRATION

July 30, 2018

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

Re: CR180448
[redacted] Easy Cup
[redacted] 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

U.S. Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
www.fda.gov

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.

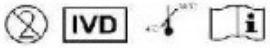
Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	20μg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200μg/ml	+	-
Lipids	20mg/ml	+	-

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	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
EC REP Authorized representative in the European Community	

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

Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

To whom it may concern

Ihre Zeichen	Unsere Zeichen	Datum
YourRef.	Our Ref. 02PBJ267	Date: March 9, 2020

Declaration of Notification

The undersigned, JIN, Liang, General Manager of Shanghai International Holding Corporation GmbH (Europe), hereby declares that:

[redacted]

China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD product (for professional use only):

COVID-19 IgG/IgM Rapid Test

The notification to the German Competent Authorities has been carried out on March 9, 2020 by Shanghai International Holding Corporation GmbH (Europe), the appointed Authorized Representative of Hangzhou Clongene Biotech Co., Ltd.

JIN, Liang
General Manager
Shanghai International Holding Corporation GmbH (Europe)
Authorized Representative

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80 20537 Hamburg

Tel.:(49) 40 2513175
Fax.:(49) 40 255726
Mail:
shholding@hotmail.com

Amtsgericht Hamburg
HRB 56 583
Geschäftshührer:
Liang Jin

Finanzamt Hamburg
Steuer-Nr.22/795/00590
Ust-ID-Nr.DE166892350

Bankverbindungen
SEB AG Hamburg
BLZ 200 101 11
Konto:1343865200

EC Declaration of Conformity

Name and address of the manufacturer:

[redacted] Co., Ltd

[redacted]

Yuhang
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

[redacted]

Hangzhou, Mar.04.2020

Place, date

[redacted]sentative

Name and function