CLONGENE BIOTECH

LUNGENE

TEST RÁPIDO

IgG/IgM Cassette

COVID-19

TEST **RÁPIDO**

IgG/IgM Cassette

COVID-19

El Test Rápido tipo cassette de COVID-19 IgG/IgM es un inmuno-ensayo de flujo lateral diseñado para la detección cualitativa de anticuerpos de Inmunoglobina M e Inmunoglobina G contra el virus SARS-CoV-2, detectable en la sangre, plasma y suero sanguíneo, en individuos sospechosos de infección por COVID-19.

TKK4500052

Materiales provistos en el kit:

- Prueba tipo cassette
- Reactivo (Solución salina tamponado con fosfato (PBS), ProClin300)
- Toallita con alcohol
- Gotero
- Lanceta
- Prospecto

TEST **RÁPIDO**

IgG/IgM Cassette

COVID-19

¿CÓMO FUNCIONA EL TEST RÁPIDO?

TKK4500052

1.- PREPARACIÓN DE LA ZONA

Limpie la zona con la toallita que viene en el kit y proceda a insertar la lanceta en la yema del dedo.

2.- TOMA DE LA MUESTRA

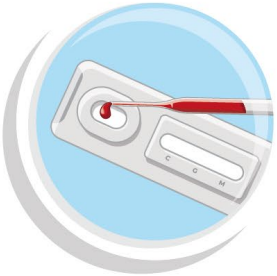
Recolecte la muestra de sangre obtenida por punción venosa con el gotero.

TEST RÁPIDO

IgG/IgM Cassette

COVID-19

TKK4500052

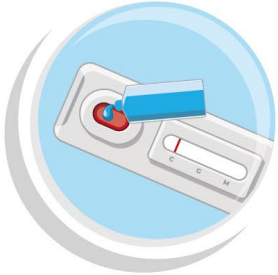


3.- ENTREGA DE MUESTRA

Agregue la sangre recolectada desde el gotero al pocillo de muestra del cassette de prueba.

4.- ADICIONAR REACTIVO Y ESPERE RESULTADO

Agregue las gotas del reactivo en el pocillo de muestra del castette.



Con la ayuda de un temporizador esperar 15 minutos como mínimo y no dejar pasar 20 minutos como máximo.

TEST **RÁPIDO**

IgG/IgM Cassette

COVID-19

INTERPRETACIÓN DE RESULTADOS

TKK4500052

IgM
Positivo

IgG
Positivo

IgG/IgM
Positivo

Negativo

Inválido

TEST **RÁPIDO**

IgG/IgM Cassette

COVID-19

CERTIFICADOS

TKK4500052

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60098616 0001

Report No.: 15073650 001

Manufacturer: Hangzhou Clongene Biotech Co., Ltd.
Building 4, No.20 Longquan Road
Cangqian Sub-district, Yuhang District
311121 Hangzhou
China

Products:
- HCG Pregnancy Rapid Tests
- LH Ovulation Rapid Tests

Replaces Approval, Registration No.: HL 60084119 0501

Expiry Date: 2019-11-12

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2016-01-30

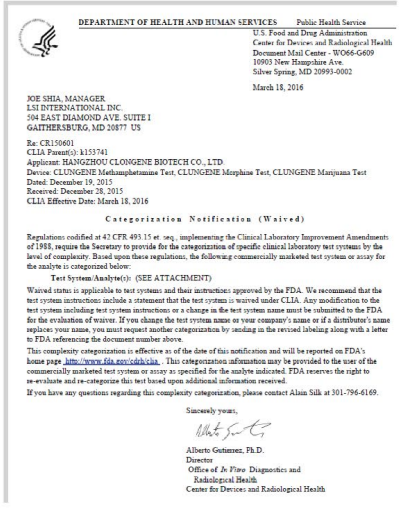
Date: 2016-01-30

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

March 18, 2016

JOE SHIA, MANAGER
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG, MD 20877 US

Re: CR150601
CLIA Parent(s): k153741
Applicant: HANGZHOU CLONGENE BIOTECH CO., LTD
Device: CLUNGENE Methamphetamine Test, CLUNGENE Morphine Test, CLUNGENE Marijuana Test
Dated: December 19, 2015
Received: December 28, 2015
CLIA Effective Date: March 18, 2016

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)

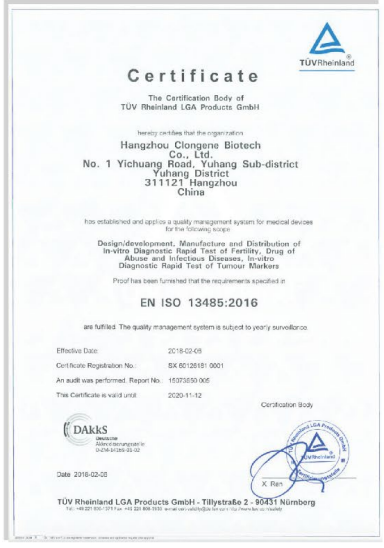
Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name 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 on FDA's home page, http://www.fda.gov/cdrh/clia. 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 Alain Silk at 301-796-6169.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health



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: 2018-02-08
Certificate-Registration No.: ISK 60126181 0001
An audit was performed, Report No.: 15073650 005
This Certificate is valid until: 2020-11-12

Certification Body

DAkkS

X. Ren

Date: 2018-02-08

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TEST **RÁPIDO**

IgG/IgM Cassette

COVID-19

CERTIFICADOS

TKK4500052

甲经认证

No: 04419Q11975R0M

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the quality management system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 91330110762025212 7

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

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

甲经认证

No: 04419S21647R0M

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

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

甲经认证

No: 04419E11187R0M

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

Certificate

This is to certify the environmental system of

HANGZHOU CLONGENE BIOTECH CO., LTD.

CREDIBILITY CODE: 91330110762025212 7

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

WeChat Query

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