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

TÜVRheinland®
Precisely Right.

2020-11-03

To Whom It May Concern

This is to confirm that a Re-certification Audit for ISO 13485, Surveillance Audit for IVDD was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body (CE0197) as follows:

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

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, In-vitro Diagnostic Rapid Test of Cardiac Markers**

Standards: **EN ISO 13485:2016**

Date: 2020-04-09~10 remote, 2020-08-17~19 on-site
Report No.: 15073650

The result of on-site audit is positive. It is recommended that the TÜV Rheinland LGA Products GmbH Notified Body (CE0197) approval should be remained valid.

The corrective action proposed by the company are acceptable, therefore the auditors will recommend that TÜV Rheinland LGA Products GmbH Notified Body (CE0197) Certificate for a Quality Assurance System should be issued in soon.

Terry Zhang

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Confirmation letters do not permit the use of a test mark and are no equivalent substitute to a certificate.

TÜV Rheinland
(Shanghai) Co., Ltd.

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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 Antigen Rapid Test**

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**

Standards Applied:

EN ISO 13485:2016	**EN ISO 15223-1:2016**
EN ISO 23640:2015	**EN 13612:2002/AC:2002**
EN 13975:2003	**EN ISO 14971:2012**
EN ISO 18113-1:2011	**EN ISO 18113-2:2011**
EN 62366-1:2015	

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

Hangzhou, July, 15, 2020
Place, date

Shujian Zheng, Legal representative
Name and function

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

COVID-19 Antigen Rapid Test Cassette

English

For professional use only.
For in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 Antigen Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab and oropharyngeal swab during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.

The COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

[SUMMARY]

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[PRINCIPLE]

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated with color micro-particles is used as detector and sprayed on conjugation pad. During the test, SARS-CoV-2 antigen in the specimen interacts with SARS-CoV-2 antibody conjugated with color microparticles making antigen-antibody labeled complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody. A colored test line (T) would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. Absence of the T line suggests a negative result. The control line (C) is used for procedural control, and should always appear if the test procedure is performed properly.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use this product as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status of COVID-19.
- 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]

Materials Provided

- 25 Test Cassettes: each cassette with desiccant in individual foil pouch
- 25 Extraction Reagent: ampoule containing 0.3 mL of extraction reagent
- 25 Sterilized Swabs: single use swab for specimen collection
- 25 Extraction Tubes
- 25 Dropper Tips
- 1 Work Station
- 1 Package Insert

Materials Required but not Provided

- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at 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.

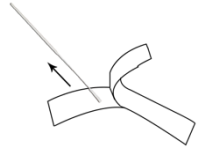
[SPECIMEN]

Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to obtain accurate test results.

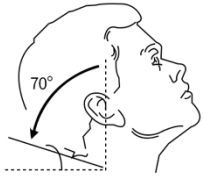
Acceptable specimen type for testing is a direct swab specimen or a swab in viral transport media (VTM) without denaturing agents.

Prepare the extraction tube according to the Test Procedure and use the sterile swab provided in the kit for specimen collection.

Nasopharyngeal Swab Specimen Collection

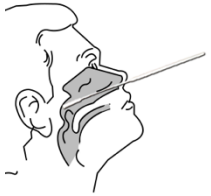


1. Remove the swab from the package.

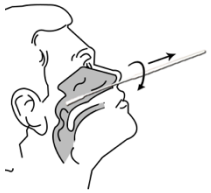


2. Tilt patient's head back about 70°.

3. Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

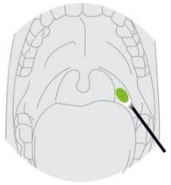


4. Slowly remove swab while rotating it.



Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Oropharyngeal Swab Specimen Collection



Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

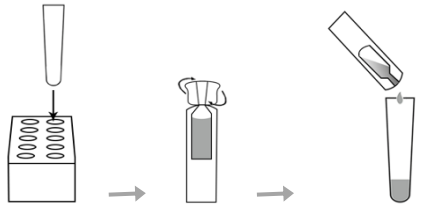
Specimen Transport and Storage

Do not return the swab to the original swab packaging. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8℃ for no more than 24 hours; Store at -70℃ for a long time, but avoid repeated freeze-thaw cycles.

[TEST PROCEDURE]

Note: Allow the test devices, reagents and specimens to equilibrate to room temperature (15-30℃ or 59-86℉) prior to testing.

- Put an extraction tube on the work station.
- Unscrew the lid of an extraction reagent. Add all of the extraction reagent into an extraction tube.
- Sampling refer to section 'Specimen Collection'.



Direct Swab Test Procedure

1. Insert the swab specimen into the extraction tube which contains extraction reagent. Roll the swab at least 5 times while pressing the head against the bottom and side of the extraction tube. **Leave the swab in the extraction tube for one minute.**
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. The extracted solution will be used as test sample.
3. Cover the extraction tube with a dropper tip tightly.