
LVtang
Biotechnology Co., Ltd.

About us

Ningbo Lvtang Biotechnology Co., Ltd. was founded in September 2018. It is a company specializing in the R&D, production and sales of in vitro diagnostic products, belonging to the field of high-end medical equipment and devices.

Currently, its main products are POCT instant diagnostic reagents, which are mainly used in the detection of infectious diseases (including COVID-19 detection products), drugs of abuse, fertility, tumor marker and cardiac marker detection, among which infectious disease and drugs of abuse detection are the two core product series of the company.

R&D Future Direction

In addition to POCT instant diagnostic reagent, according to the R&D field and direction, the company continues to invest in the R&D of biological raw material platform, molecular diagnostic platform, liquid biochip platform and in vitro diagnostic instrument platform, and formulates the strategy of synchronous development of each technology platform, so as to promote the development of the company through integrated R&D mode.

Our Certifications

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices.

Manufacturer: NINGBO LVTANG BIOTECHNOLOGY CO., LTD.
Address: NO.9 DONGPU ROAD, CHENGDONG INDUSTRIAL AREA, DAUX TOWN, XIANGSHAN COUNTY, NINGBO CITY, ZHEJIANG PROVINCE, CHINA, 315706

European Representative: Lotus NL B.V.
Contact person: Peter **E-mail:** peter@lotusnl.com
Address: Koningin Julianaplein 10, 1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)
- SARS-CoV-2 Antigen Detection Kit (Saliva)
- SARS-CoV-2 Neutralization Antiboby Detection Kit (Colloidal Gold Method)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed: *Isa Yuan*
12, Aug, 2021

Place: Ningbo, China

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

NINGBO LVTANG BIOTECHNOLOGY CO., LTD.

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
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Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20215151

Bijlagen
-

Uw aanvraag
30 juli 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 12 augustus 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 30 juli 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam NINGBO LVTANG BIOTECHNOLOGY CO.,LTD. met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

SARS-CoV-2 Antigen Detection Kit(Colloidal Gold Method)
SARS-CoV-2 Antigen Detection Kit(Saliva)
SARS-CoV-2 Neutralization Antibody Detection Kit(Colloidal Gold Method)
(geen merknaam) (NL-CA002-2021-61642)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Product Introduction

1 Test/Box

This product is used for qualitative detection of SARS-CoV-2 antigen in saliva samples.

The SARS-CoV-2 belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the SARS-CoV-2 are the main source of infection.

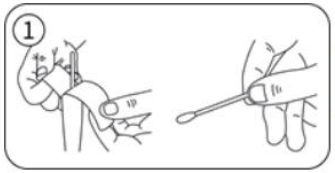
IVD

Product Introduction

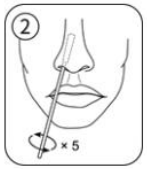
Box gauge

- Fast results in 10–20 minutes
- Easy to get the results
- Simple operation, no equipment required
- High accuracy

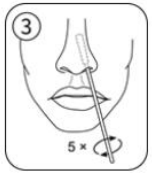
Testing Procedure --Nasal Swab



•Peel to open the package of sampling swab.
•Do not touch the swab tip.

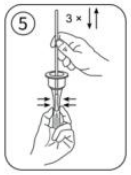


• Gently insert the swab tip 2-3cm into one cnasal cavity.
• Gently rotate the swab 5 rounds for 20 seconds to collectsecretion in the nose.
• Do not force the swab, so as not to injure the nose.



• Repeat the same steps in the other nostril.

• Unscrewing extraction tube
• Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 10s.



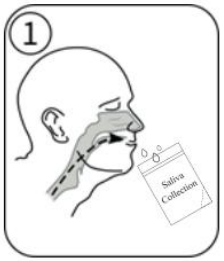
•Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
•Screw the dripper onto the tube
•Press the nozzie cap tightly onto the tube.

•Apply 2-3 drops of extracted specimen to the specimen hole of the test card.

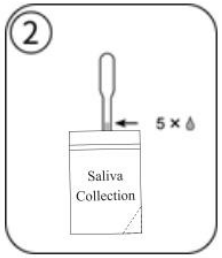
• Read the results within 10-15 minutes. Strong positive results can be reported within 10 minutes,however, negative results must be reported after 20 minutes, and the results after 30 minutes are no longer valid.

• Unscrewing extraction tube
• Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 10s.

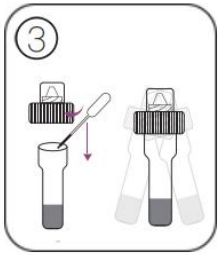
Testing Procedure--Saliva



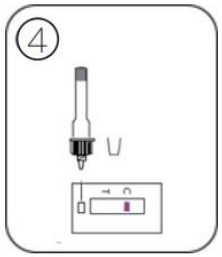
• Clear your throat, Make a [Kuuua] sound in the throat to clear saliva from the throat into the Saliva Collection Bag.



• Use a dropper to draw the sample to about half the height of the dropper

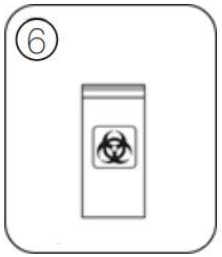


• Unscrewing extraction tube
• Add 5 drops(about 200μl) of the sample in a sample extraction tube.
• Screw the dripper onto the tube and and turn up side down and mix well.



• Apply 2-3 drops of extracted specimen to the specimen hole of the test card.

• Read the results within 10-15 minutes. Strong positive results can be reported within 10 minutes, however, negative results must be reported after 20 minutes, and the results after 30 minutes are no longer valid.

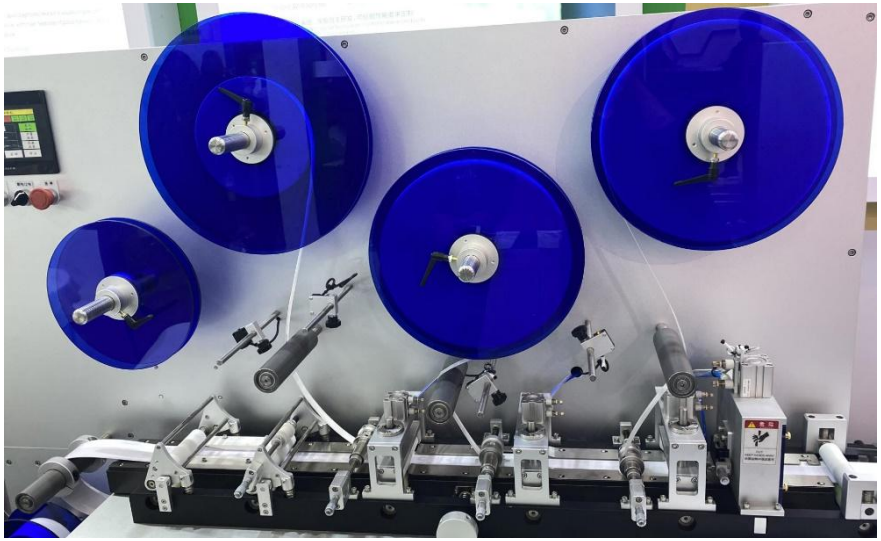


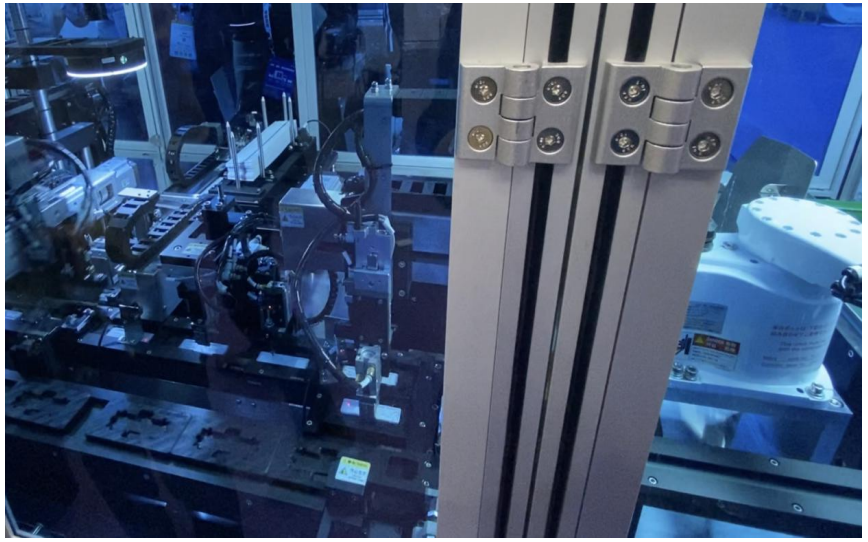
• Put all the components into the specimen bag to prevent pollution to the environment.

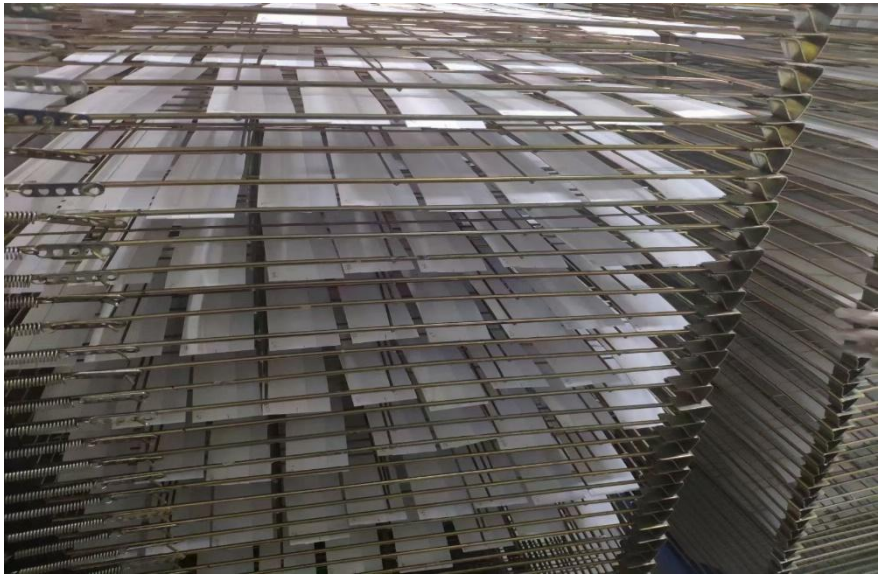
Our Medical Workshop

LVtang
COVID-19 Antigen Rapid Test

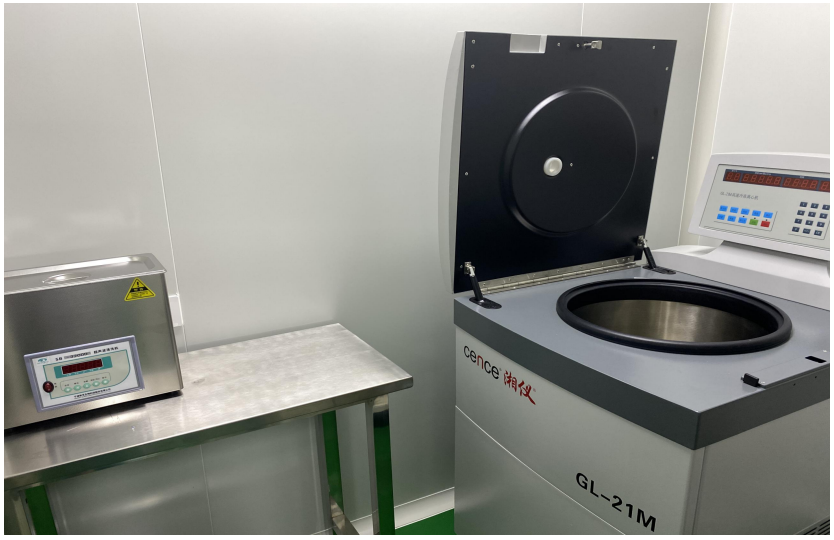
Our Medical Workshop







Our Quality Labs



Our Technology Center

Certification

Malaysia

Japan

Britain

Italy

Germany

Czech Republic

Austria

Netherlands

Finland

Spain

Chile

Brazil

Liverpool team

ISO 13485

Ningbo Lvtang Biotechnology Co., Ltd. has a clean workshop that meets the GMP production standard of medical devices, has passed the ISO13485 system certification of British BSI, and has complete laboratory and production conditions. Relevant in vitro diagnostic reagent products have been registered by the British drug administration (MHRA), obtained EU CE certification, and have been listed in the “white list" of epidemic prevention materials exported by the Ministry of Commerce.

For Your Safety !

LVtang
COVID-19 Antigen Rapid Test

Health & Love