JOYSBIO®

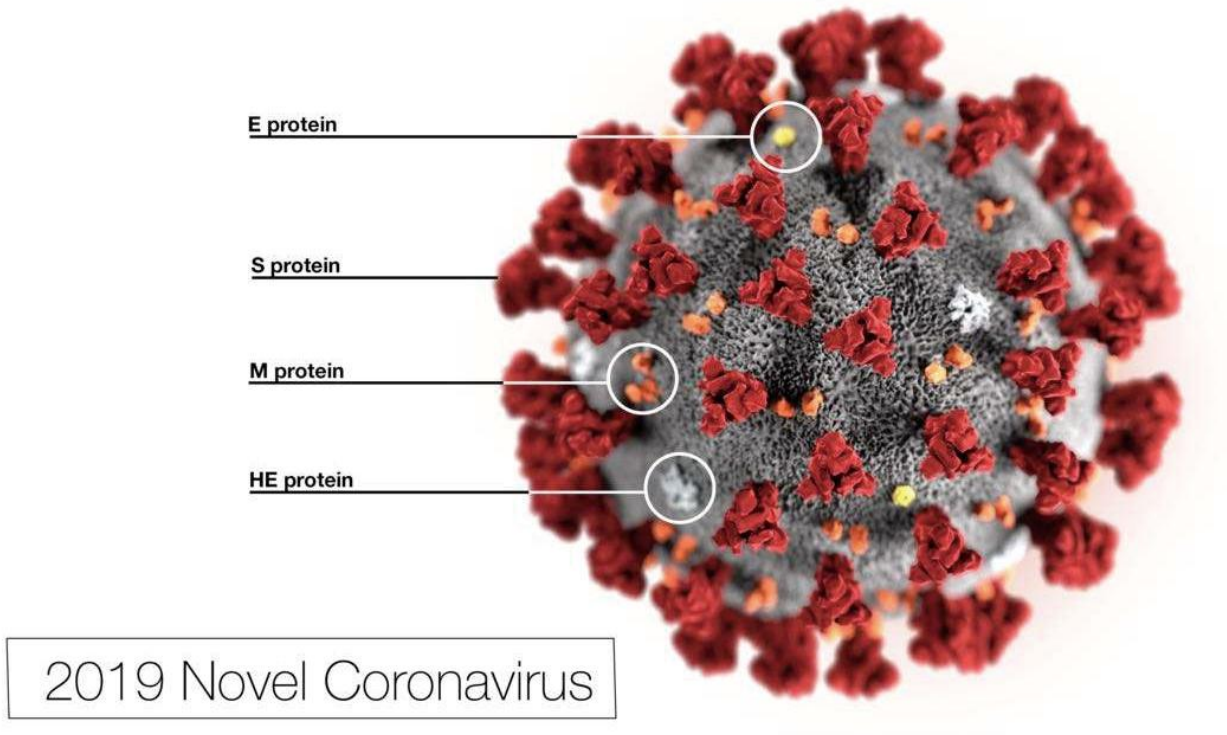
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

SARS-CoV-2 Antigen

PREFACE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease 2019 (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N).

The antigen is generally detectable in upper respiratory samples during the acute phase of infection.



SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

INTRODUCTION

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

INTENDED USE

For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PRODUCT PHOTOS

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PACKAGE SIZE (BOX)

Product package size:

Length:195mm

Width:165mm

Height:68mm

Weight:308g

Include:20 Test Kit，20 pcs/box

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

PACKAGE SIZE (CARTON)

Product package size:

Length:410mm
Width:510mm
Height:610mm
Weight:17.4kg

Include:50 box，1000 PCS（product& carton）

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

TEST PRINCIPLE

The Kit use immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19.

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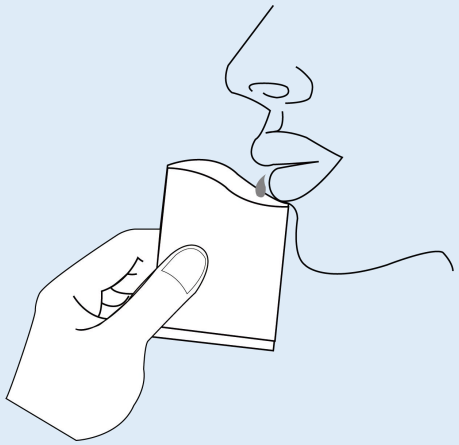
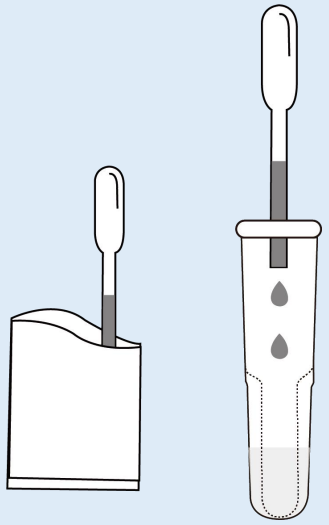
TEST METHOD

1



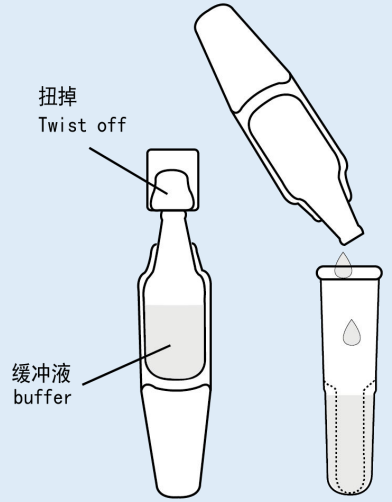
1. Before collecting oral fluid relax your cheeks and gently massage cheeks with fingers for 15-30 seconds, Gently spit oral fluid into the collection bag.

2



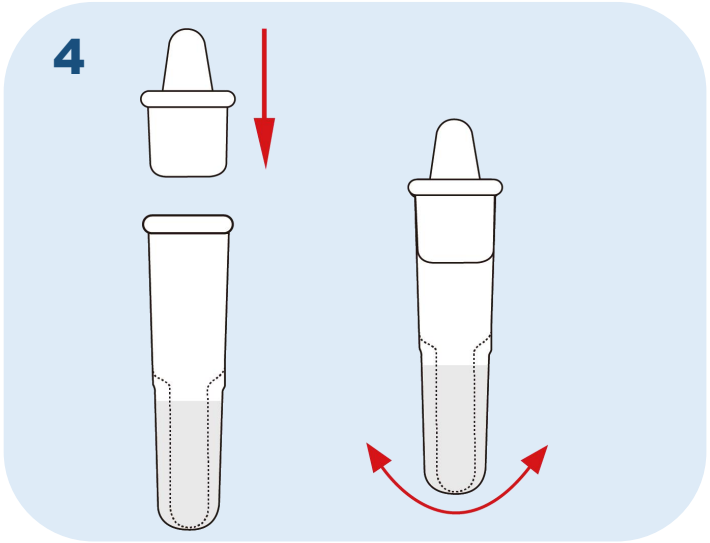
2. Hold the dropper vertically and **draw oral fluid from** collection bag and transfer 3 drops of oral fluid into the buffer bottle.

3

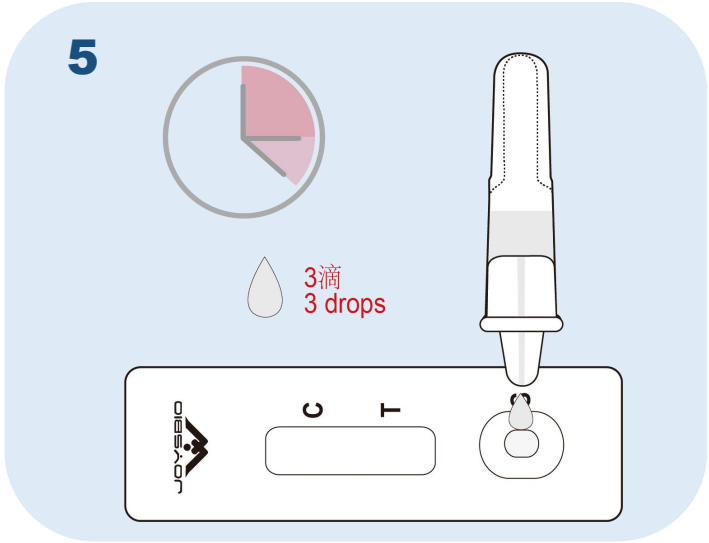


3. Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction Tube.

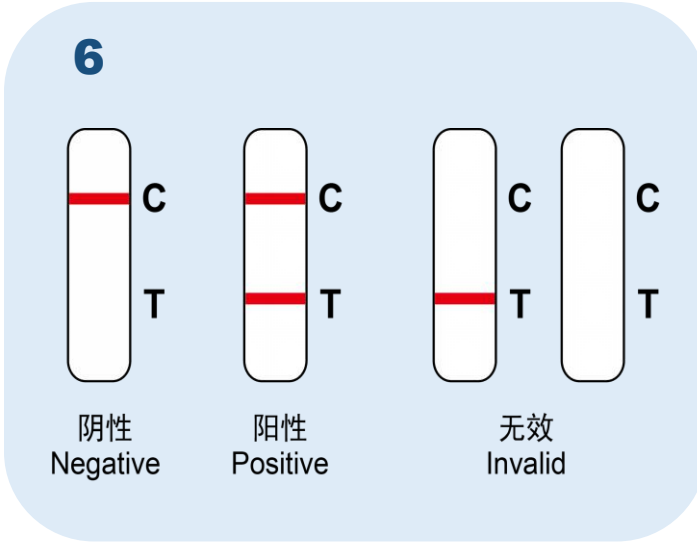
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)



4. Tighten the cap of the buffer bottle. Gently shake the buffer bottle for **10 seconds.**



5. Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface. Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well. Read the test results between 15 and 20 minutes.



6.POSITIVE: Two lines appear. One colored line should be in the control line region (C), a colored line appears in test line (T) region. NEGATIVE: Only one colored control line appear. INVALID: Control line fails to appear.

Consistency analysis of test results

There were 772 nasal swab specimens were collected to evaluate the clinical performance of the SARS-CoV-2 Antigen Rapid Test Kit Specimen Stability Study. The nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 5 days of onset) who were suspected of COVID-19 and no duplicate samples were selected. Nasal swabs were collected following the dual nares method and handled as described in the package insert of the collection device.

A total of 154 samples were tested positive by SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). There were 2 samples in which the SARS-CoV-2 Antigen Rapid Test Kit ware positive and the Real-time fluorescent RT-PCR kit for detecting 2019-nCoV produced by BGI BIOTECHNOLOGY (WUHAN) ware negative, and 6 samples in which the SARS-CoV-2 Antigen Rapid Test Kit ware negative and the Real-time fluorescent RT-PCR kit for detecting 2019-nCoV produced by BGI BIOTECHNOLOGY (WUHAN) was positive.

There were 610 samples with negative test results in experimental reagent and 612 samples with negative test results in reference reagent. Hence, the sensitivity and specificity were 96.25% and 99.67% respectively.

The Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 produced by BGI BGI Genomics Co. Ltd was used as a comparator test. This is an FDA approved for EUA use product.

Overall Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	154	2	156
negative	6	610	616
Subtotal	160	612	772

Positive Percent Agreement (PPA)= 96.25% (95%CI:92.0%~98.6%)

Negative Percent Agreement (NPA)= 99.67% (95%CI:98.8%~100%)

Accuracy=98.96%

Kappa=0.97＞0.5

Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. All the results showed that SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)meet the needs of clinical test.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

SIGNIFICANCE

RESEARCH BACKGROUND

During the epidemic Situation, many countries have the following problems:

Existing detection methods cannot achieve large-scale rapid screening.

lack of technical expertise and inadequate laboratory capacity, Erroneous Operation can easily lead to missed inspections.

Can't afford high testing costs.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Globally, as of 3:59pm CEST, 17 August 2020, there have been 21,549,706 confirmed cases of COVID-19, including 767,158 deaths, reported to WHO.

SIGNIFICANCE

According to the WHO, during the outbreak of SARS-CoV-2, in areas with confirmed SARS-CoV-2 community-wide transmission; confirmed outbreaks in closed or semi-closed communities; in high-risk groups; among contacts of confirmed cases; SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) as a tool to monitor disease incidence is a particularly effective detection method.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

ADVANTAGE

1.Easy to collect samples， simple operation，without professional equipment.

2.The test results are available in 15 minutes, and the test results are clearly visible.

3.Convenient transportation and low price, higher accuracy.

4.Suitable for large-scale rapid screening.

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

REGISTERED

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

REGISTERED

EU CE Certification

Emergency Use Authorization

WHO-Emergency Use Listing

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

CE CERTIFICATE

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:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M.P. Meijer - Michiels
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204011

Bijlagen
-

Uw aanvraag
13 augustus 2020

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

Datum: 18 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 13 augustus 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam JOYSBIO (Tianjin) Biotechnology Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),Immunochromatography analyzer
(geen merknaam) (NL-CA002-2020-53008)

Tuberculosis Antibody Test Kit (Colloidal Gold) ,Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),Treponema Pallidum Antibody Test Kit (Colloidal Gold),Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53009)

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

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen 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).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, JOYSBIO (Tianjin) Biotechnology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

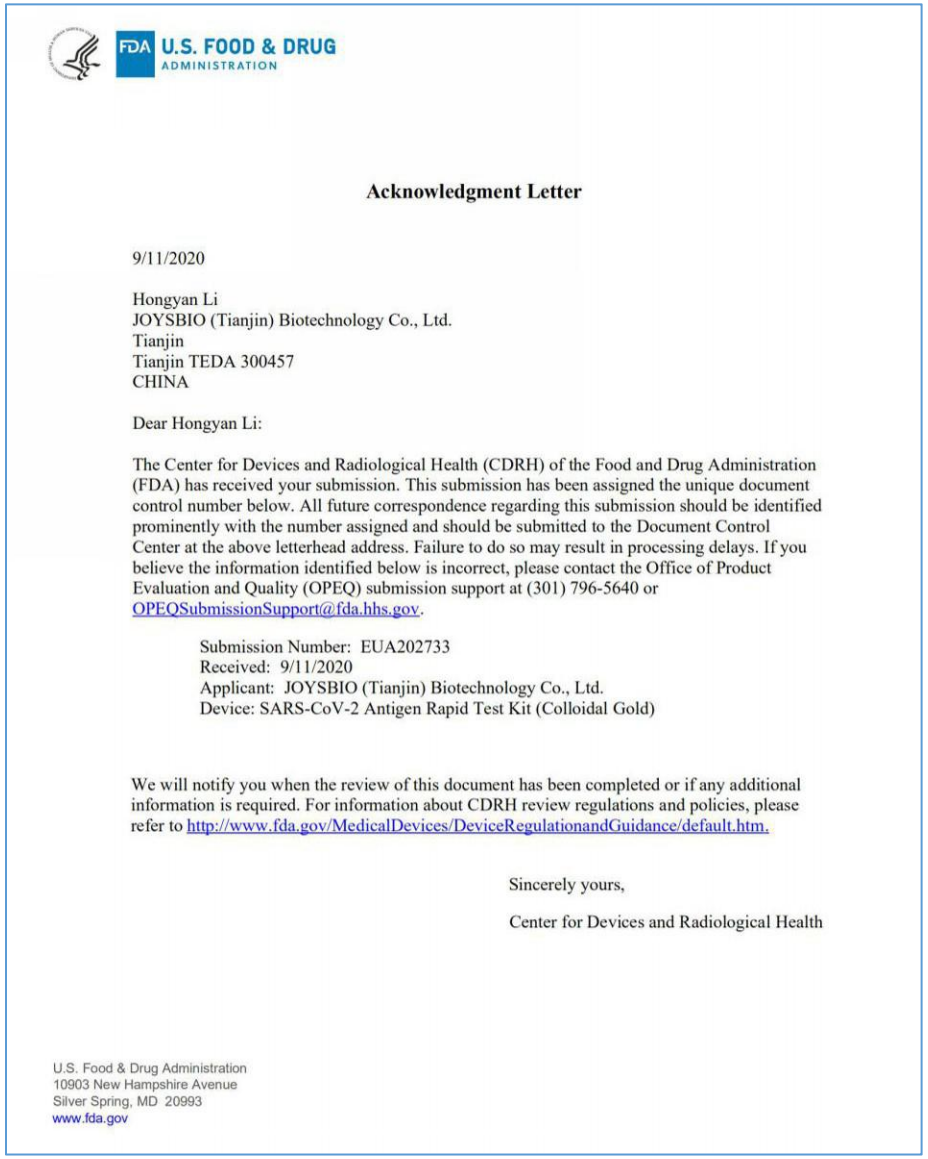
De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

FDA-EUA Acknowledgment letter



U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

9/11/2020

Hongyan Li
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin
Tianjin TEDA 300457
CHINA

Dear Hongyan Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202733
Received: 9/11/2020
Applicant: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

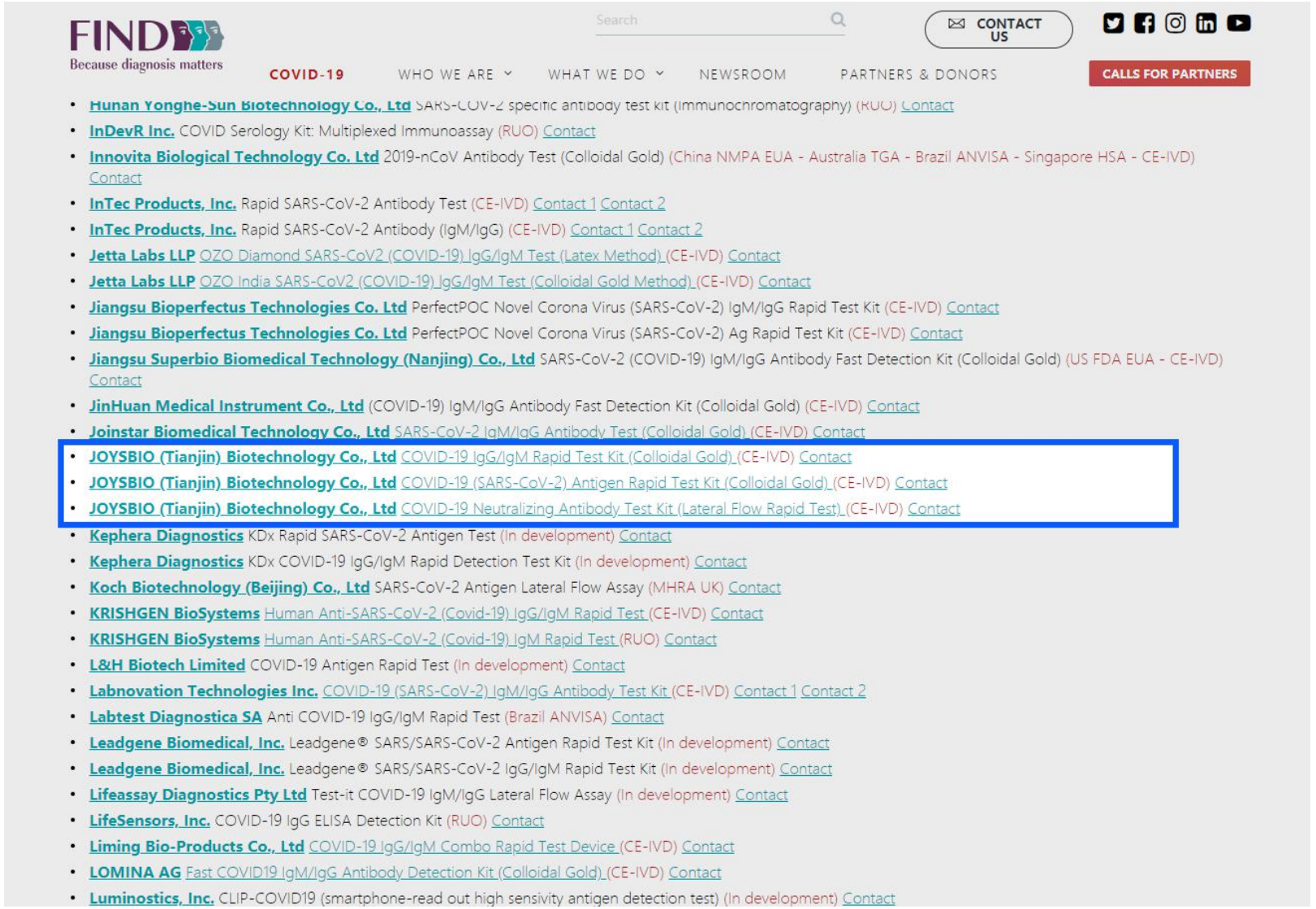
Sincerely yours,

Center for Devices and Radiological Health

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

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Has entered the FIND recommended list



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Because diagnosis matters

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CONTACT US

COVID-19 | WHO WE ARE | WHAT WE DO | NEWSROOM | PARTNERS & DONORS | CALLS FOR PARTNERS

- **Hunan Yonghe-Sun Biotechnology Co., Ltd** SARS-CoV-2 specific antibody test kit (immunochromatography) (RUO) Contact
- **InDevR Inc.** COVID Serology Kit: Multiplexed Immunoassay (RUO) Contact
- **Innovita Biological Technology Co. Ltd** 2019-nCoV Antibody Test (Colloidal Gold) (China NMPA EUA - Australia TGA - Brazil ANVISA - Singapore HSA - CE-IVD) Contact
- **InTec Products, Inc.** Rapid SARS-CoV-2 Antibody Test (CE-IVD) Contact 1 Contact 2
- **InTec Products, Inc.** Rapid SARS-CoV-2 Antibody (IgM/IgG) (CE-IVD) Contact 1 Contact 2
- **Jetta Labs LLP** OZO Diamond SARS-CoV2 (COVID-19) IgG/IgM Test (Latex Method) (CE-IVD) Contact
- **Jetta Labs LLP** OZO India SARS-CoV2 (COVID-19) IgG/IgM Test (Colloidal Gold Method) (CE-IVD) Contact
- **Jiangsu Bioperfectus Technologies Co. Ltd** PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit (CE-IVD) Contact
- **Jiangsu Bioperfectus Technologies Co. Ltd** PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (CE-IVD) Contact
- **Jiangsu Superbio Biomedical Technology (Nanjing) Co., Ltd** SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (US FDA EUA - CE-IVD) Contact
- **JinHuan Medical Instrument Co., Ltd** (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) (CE-IVD) Contact
- **Joinstar Biomedical Technology Co., Ltd** SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) (CE-IVD) Contact
- **JOYSBIO (Tianjin) Biotechnology Co., Ltd** COVID-19 Neutralizing Antibody Test Kit (Lateral Flow Rapid Test) (CE-IVD) Contact
- **Kephera Diagnostics** KDx Rapid SARS-CoV-2 Antigen Test (In development) Contact
- **Kephera Diagnostics** KDx COVID-19 IgG/IgM Rapid Detection Test Kit (In development) Contact
- **Koch Biotechnology (Beijing) Co., Ltd** SARS-CoV-2 Antigen Lateral Flow Assay (MHRA UK) Contact
- **KRISHGEN BioSystems** Human Anti-SARS-CoV-2 (Covid-19) IgG/IgM Rapid Test (CE-IVD) Contact
- **KRISHGEN BioSystems** Human Anti-SARS-CoV-2 (Covid-19) IgM Rapid Test (RUO) Contact
- **L&H Biotech Limited** COVID-19 Antigen Rapid Test (In development) Contact
- **Labnovation Technologies Inc.** COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit (CE-IVD) Contact 1 Contact 2
- **Labtest Diagnostica SA** Anti COVID-19 IgG/IgM Rapid Test (Brazil ANVISA) Contact
- **Leadgene Biomedical, Inc.** Leadgene® SARS/SARS-CoV-2 Antigen Rapid Test Kit (In development) Contact
- **Leadgene Biomedical, Inc.** Leadgene® SARS/SARS-CoV-2 IgG/IgM Rapid Test Kit (In development) Contact
- **Lifeassay Diagnostics Pty Ltd** Test-it COVID-19 IgM/IgG Lateral Flow Assay (In development) Contact
- **LifeSensors, Inc.** COVID-19 IgG ELISA Detection Kit (RUO) Contact
- **Liming Bio-Products Co., Ltd** COVID-19 IgG/IgM Combo Rapid Test Device (CE-IVD) Contact
- **LOMINA AG** Fast COVID19 IgM/IgG Antibody Detection Kit (Colloidal Gold) (CE-IVD) Contact
- **Luminostics, Inc.** CLIP-COVID19 (smartphone-read out high sensivity antigen detection test) (In development) Contact

Search Website

https://www.finddx.org/covid-19/pipeline/

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

The Emergency Use Listing

World Health Organization

SARS-CoV-2 Rapid Antigen Tests: progress of the active applications in the emergency use listing assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	QMS Desk Assessment
ESPLINE SARS-CoV-2	231906	Fujirebio, Inc	R	🗁
BIOEASY Diagnostic kit for SARS-CoV-2 Ag (Fluorescence Immunochromatographic Assay)	YRLF04401025, YRLF04401050 and YRLF04401100	Shenzhen Bioeasy Biotechnology Co., Ltd	awaiting submission	awaiting submission
LumiraDx SARS-CoV-2 Ag Test	L0160001nnxxx	LumiraDx UK Ltd	awaiting submission	awaiting submission
SARS-CoV-2 Rapid Antigen Test	9327592190	Roche Diagnostics GmbH	🗁	🗁
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	G10313	JOYSBIO (Tianjin) Biotechnology CO., LTD	🗁	🗁

Progress of the active applications in the emergency use listing assessment pipeline.

JOYSBIO (Tianjin) Biotechnology Co., Ltd.

COMPANY PROFILE

JOYSBIO (Tianjin) Biotechnology Co., Ltd. is a Chinese R&D-based biotechnology company that develops, manufactures, and supplies high-quality medical in-vitro diagnostic (IVD) rapid test kits as well as revolutionary customized solution kits to all parts of the world. Founded by a team of professionals with many years of combined technical,marketing/sales, operational and manufacturing expertise in this industry, we offer high quality but cost-effective rapid test kit.

JOYSBIO (Tianjin) Biotechnology Co., Ltd.