JOINSTAR

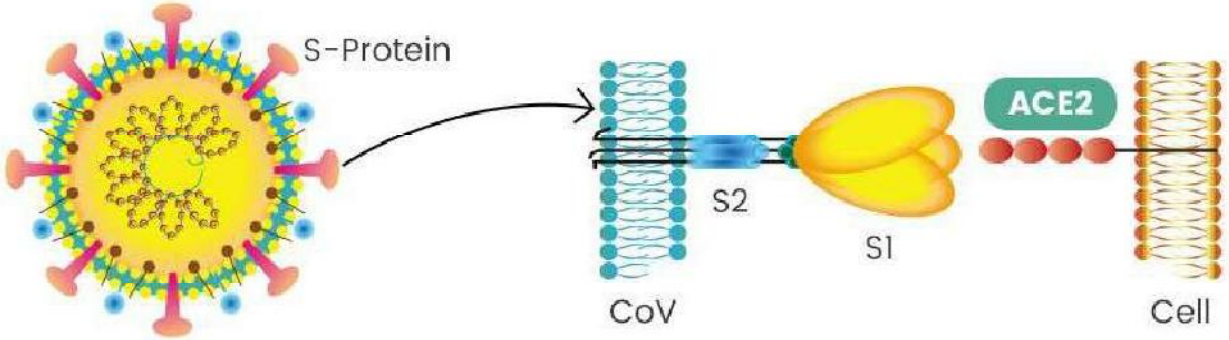
JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.

COVID-19 ANTIGEN RAPID TEST (Latex)

hg-klinikbedarf.de

INTRODUCTION

- The novel coronaviruses 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.
- The novel coronavirus invades human cells by the specific binding of its spike glycoprotein (ligand) to the ACE2 receptor located on human cellular membrane. In this test the ACE2 receptor has been substituted for antibody to establish a novel ligand-receptor chromatography test kit for rapid detection of the novel coronavirus.



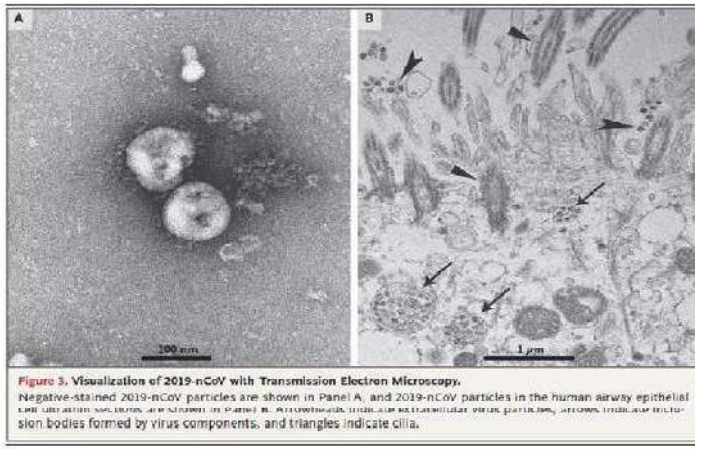
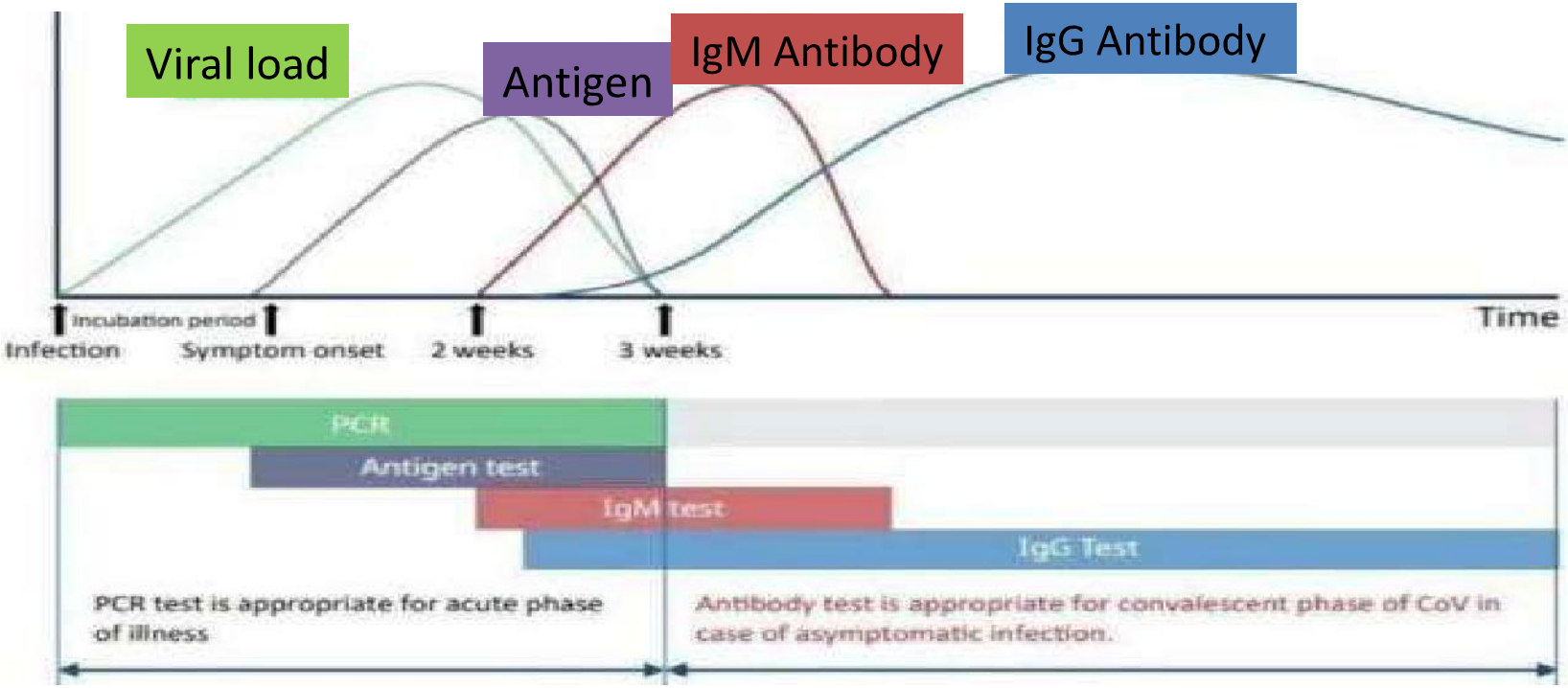


Figure 3. Visualization of 2019-nCoV with Transmission Electron Microscopy.
Negative-stained 2019-nCoV particles are shown in Panel A, and 2019-nCoV particles in the human airway epithelial
sion bodies formed by virus components, and triangles indicate cilia.

SARS-CoV-2 INFECTION TIME WINDOW



Test method	PCR	IgM / IgG antibody rapid test	Antigen rapid test (latex)
Environmental requirements	High requirements for laboratory environment	Low environmental requirements, not necessarily performed in the laboratory	Low environmental requirements, not necessarily performed in the laboratory
Operational requirements	Professional testing personnel, need equipment	The operation is simple and no instrument is needed	The operation is simple and no instrument is needed
Sample type	Nasopharynx swab, high sampling requirements, pain	Blood samples, invasive sampling	Oropharyngeal saliva, sputum and feces of the posterior oropharynx
Performance	Gold standard of diagnosis;	Auxiliary diagnosis; Good sensitivity and specificity	Auxiliary diagnosis; Higher sensitivity, 100% specificity
Detection time	2-3 Hours	15 minutes	10-15 minutes
Cost	higher	Economics	Economics
Applicability	Applicable to all periods	Weeks after symptom onset	Early detection and mass screening of suspected population or animals

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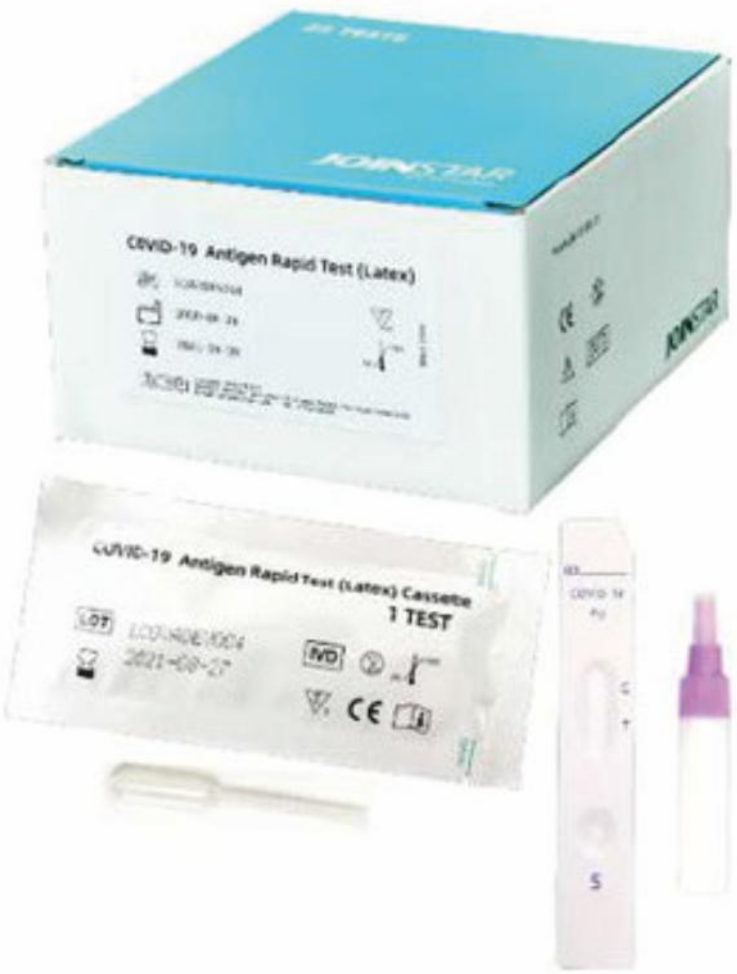
Features

COVID-19 ANTIGEN RAPID TEST (Latex)



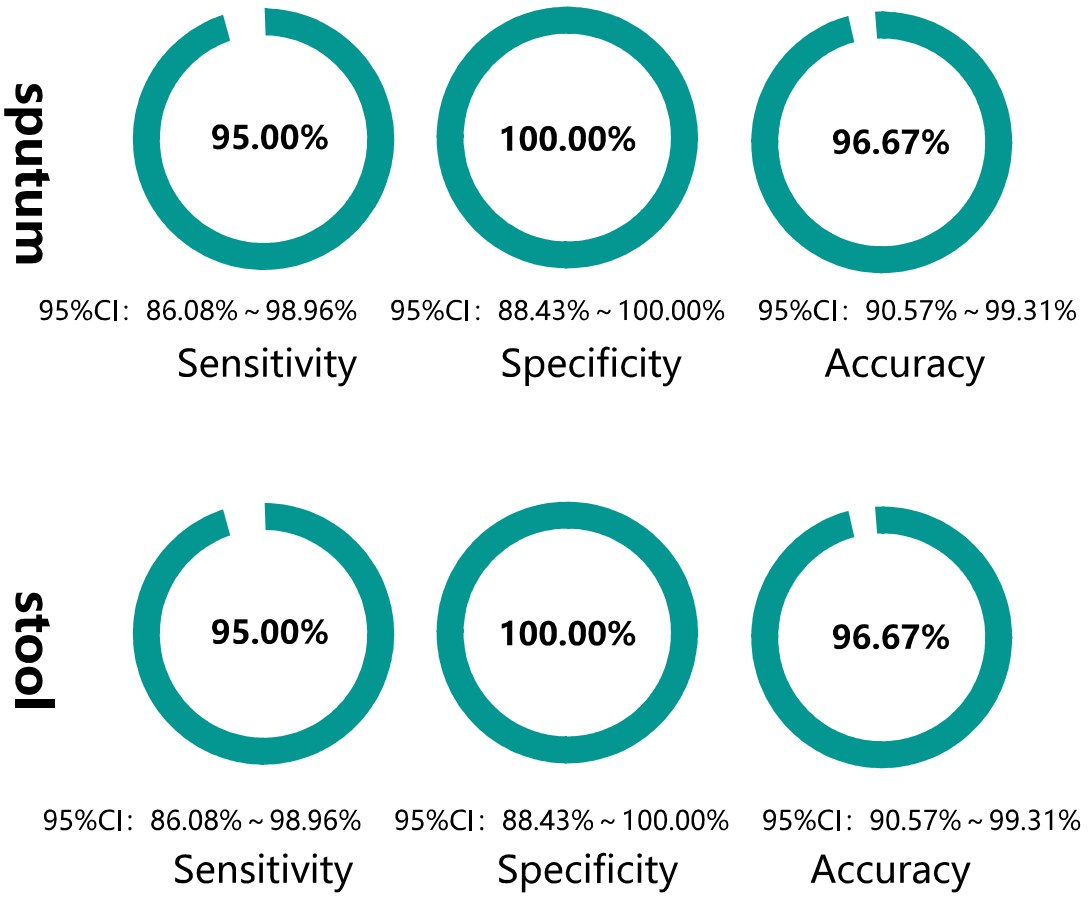
Patent Application No. (USA) : T13520.PROV

JOINSTATR COVID-19 ANTIGEN RAPID TEST has complete export qualifications; non-invasive; saliva (oropharyngeal), sputum and stool can be detected, early diagnosis reassures your mind

- **Internationally innovative,** direct detection of pathogen S protein, not affected by virus mutation, high sensitivity & specificity, and can be used for early screening;
- **Convenient and non-invasive sampling**. Specimen type: oropharyngeal saliva/sputum/stool, which can be used for home self-inspection during the quarantine, and screening before resumption of work and school; Non-invasive testing is particularly suitable for continuous monitoring of children and the elderly;
- **One-step method**, easy to operate, reducing missed or false inspections caused by operator errors;
- **No equipment required**, fast detection, results are available in 10-15 minutes;
- **Storage temperature: 2~30℃**. No cold-chain transportation needed;
- **Specification:** 25 tests/box, 1 test/box; **Diverse cooperation modes**: OEM/ODM accepted.

Specification	P/N	Component	
25tests/box 1000tests/CTN (40*60*37CM 15/17KG)	FLCOVA200	Test cassette*25 Sample extraction tube*25	Paper cup*25 Dropper*25 Package insert*1
1test/box 400tests/CTN (40*60*37CM 6/7KG)	FLCOVA100	Test cassette*1 Sample extraction tube*1	Paper cup*1 Dropper*1 Package insert*1

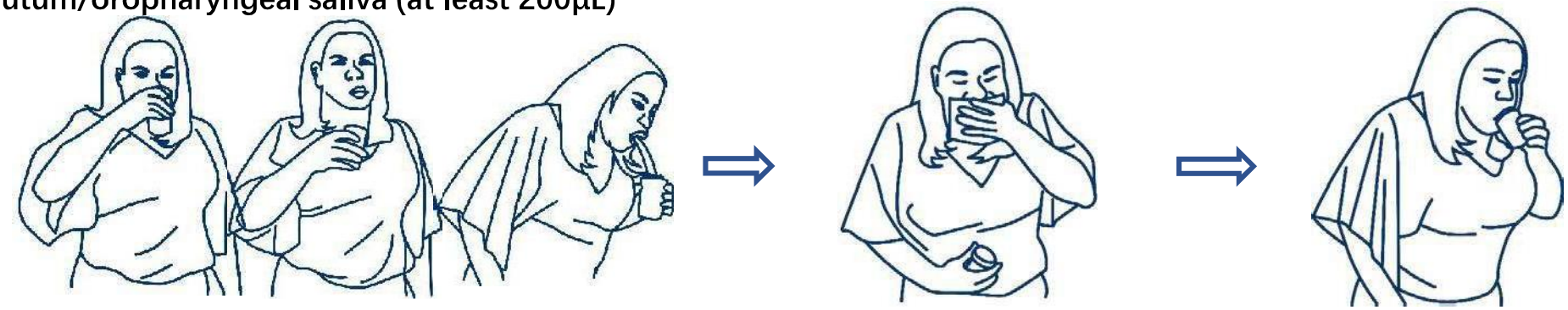
Performance Characteristics



Testing Procedure

Please read the instructions carefully and allow the test device and specimens to equilibrate to temperature (15℃-30℃) prior to testing.

I. Sputum/oropharyngeal saliva (at least 200μL)

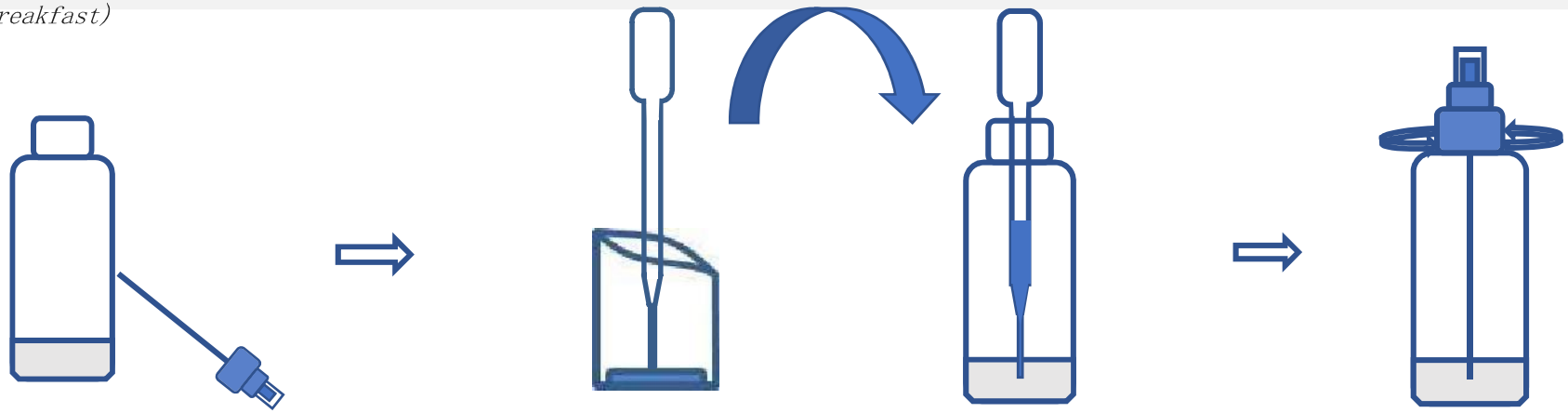


1. Rinse and spit with water. This is important to make sure there won't be mouth bacteria in the sputum collected.

*It is recommended to collect Sputum/oropharyngeal saliva in early-morning (first thing in the morning upon awakening, before teeth brushing, mouth rinsing, and eating breakfast)

2. Cough deeply, Make the noise of "Kruuua" from the throat to clear sputum/oropharyngeal saliva from deep throat.

3. Once the sputum/ oropharyngeal saliva is in your mouth, release it into the container

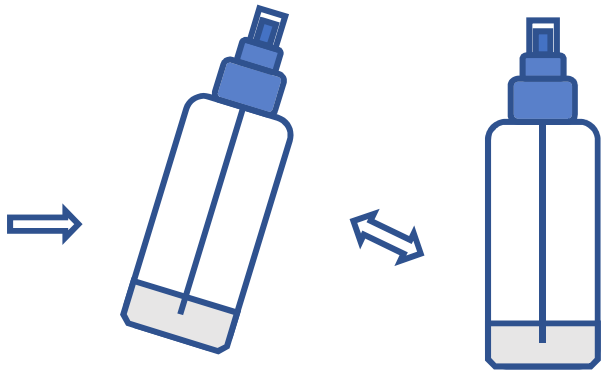


4. Unscrew the Sample Extraction Tube

5. Transfer **200μL** of fresh Sputum/oropharyngeal saliva samples from container into the Sample Extraction Tube.

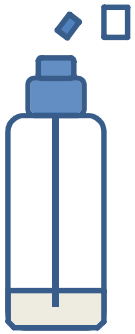
6. Tighten the sample extraction tube

Testing Procedure

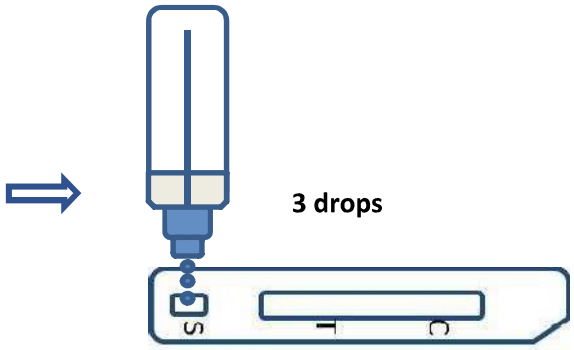


7. Shake and mix completely

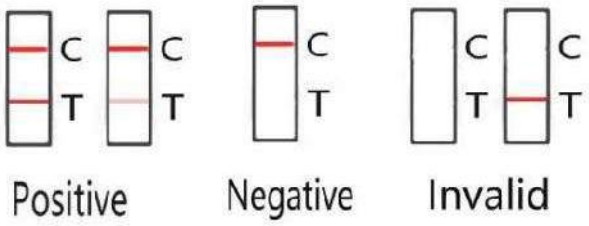
8. Take the test cassette from the packaging bag, place it on a table



9. Cut off the protrusion of the collection tube



10. Add 3 drops of the sample into the sample hole vertically

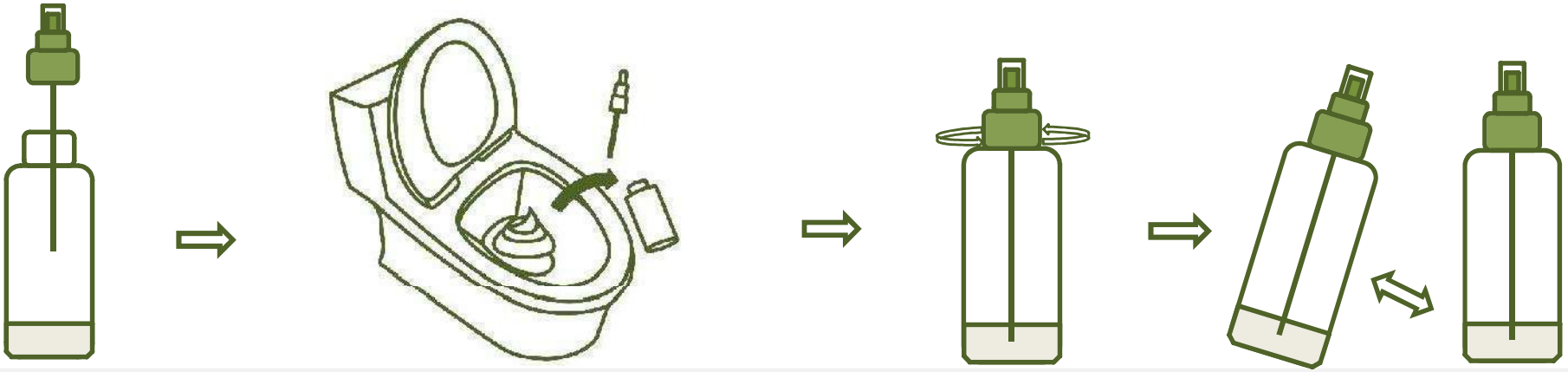


11. Read the result after 15 minutes.
If left unread for 20 minutes or more, the results are invalid, and a repeat test is recommended.

Testing Procedure

Please read the instructions carefully and allow the test device and specimens to equilibrate to temperature (15℃-30℃) prior to testing.

II. Stool Sample (at least 30mg)

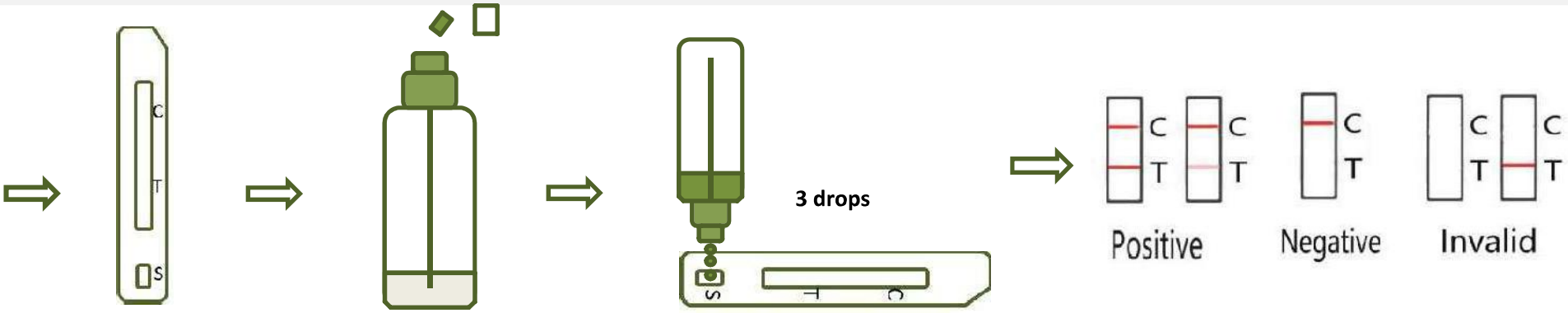


1. Unscrew the Sample Extraction Tube

2. Use the sampling rod to pick up about 30mg fresh stool samples (Cover the end of the sampling rod)

3. Tighten the sample extraction tube

4. Shake and mix completely



5. Take the test cassette from the packaging bag, place it on a table

6. Cut off the protrusion of the collection tube

7. Add 3 drops of the sample into the sample hole vertically

8. Read the result after 15 minutes.
If left unread for 20 minutes or more, the results are invalid, and a repeat test is recommended.

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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 6151

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
H.P. Meijer - Michiels

medische_hulpmiddelen@minvws.nl

Ons kenmerk
CIBG-20204350

Bijlagen

Uw aanvraag
5 september 2020

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

Datum: 9 september 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 5 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Joinstar Biomedical Technology 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:

COVID-19 Antigen Rapid Test (Latex)
(geen merknaam) (NL-CA002-2020-53351)

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).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Joinstar Biomedical Technology Co., Ltd de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiele 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

CE Registration

CE

DECLARATION OF CONFORMITY

Manufacturer: Joinstar Biomedical Technology Co.,Ltd.

Address: 10th Floor, Administration Building, NO.519, XingGuo RD., Yuhang Economic and Technological Development Zone,Hangzhou, Zhejiang,China,311188

EC Representative's Name: Lotus NL B.V

EC Representative's Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague,Netherlands.

Declares, that the product

Product Name and Model:

COVID-19 Antigen Rapid Test (Latex)
1 Test/Kit, 25 Tests/Kit

as described above are in conformity with the requirements as defined in IVDD98/79/EC Annex III.

Additional information:

Conformity assessment route: Directive 98/79/EC, Annex III
Classification: List Others

I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: 2020.09.02

Xuyi ZHOU
General Manager
Joinstar Biomedical Technology Co.,Ltd.

Joinstar Biomedical Technology Co.,Ltd.

Version.0.0

CE Declaration of Conformity

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 087635 0004 Rev. 01

Holder of Certificate: **JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.**
10th Floor, Administration Building
No.519 Xingguo Rd.
Yuhang Economic and Technological Development Zone
311188 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
10th Floor, Administration Building, No.519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
No. 1 Factory Building, No. 519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Biochemical Reagent, ELISA Reagent, Clinical Laboratory Instruments and Rapid Diagnostic Reagents**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH2087401

Valid from: 2020-05-27
Valid until: 2023-05-26

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ISO13485

CERTIFICATE

浙江省医疗器械行业协会

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 20200007
Certificate NO.: 20200007

产品名称: 见附件（共 1 项）
Product(s): See Attachment (1 Page)

规格型号: 见附件（共 1 项）
Model: See Attachment (1 Page)

生产企业: 中翰源泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

生产企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

出口企业: 中翰源泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

出口企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

兹证明上述产品未在中国注册，尚未进入中国市场，该产品出口不受限制。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至: 2022 年 9 月 23 日
This certification valid until: 2022/09/23

Zhejiang Provincial Association For Medical Equipment Industry
(浙江省医疗器械行业协会)

Date of issue: 2020/09/23
(2020 年 9 月 23 日)

附件
ATTACHMENT

证书编号:20200007 （共 1 页 第 1 页）
Certificate No.:20200007 (Page 1 of 1 Page)

序号 SN	产品名称 Product(s)	规格型号 Model
1	新冠病毒抗原检测试剂盒(胶体金法) 2019-nCoV Antigen Rapid Test (Latex)	25 人份/盒,FLCOVA200, FLCOVA200 25TESTS/KIT,FLCOVA200, FLCOVA200 1 人份/盒,FLCOVA100, FLCOVA100 1TESTS/KIT,FLCOVA100, FLCOVA100
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9/10/2020 Elenco dei dispositivi medici

Area tematica Dispositivi medici | Archivio banche dati

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: 2000587
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:03/10/2020

DISPOSITIVO MEDICO ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DI DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA IMMISSIONE IN COMMERCIO	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2000587	S	RISH12270	COVID-19 ANTIGEN RAPID TEST (LATEX)	W0103099099 - UROLOGIA - TEST RAPIDI E POINT OF CARE - ALTRI	SS - Test autodiagnostici (non relativi agli HLA)	02/10/2020		FABBRICANTE	JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD.			CN
									MANDATARIO	LOTUS NI BV		857879145801	NL

<< < Pagina 1 > >> Num. Pagine: 1 Num. Dispositivi: 1

FSC

Registration in Italy