

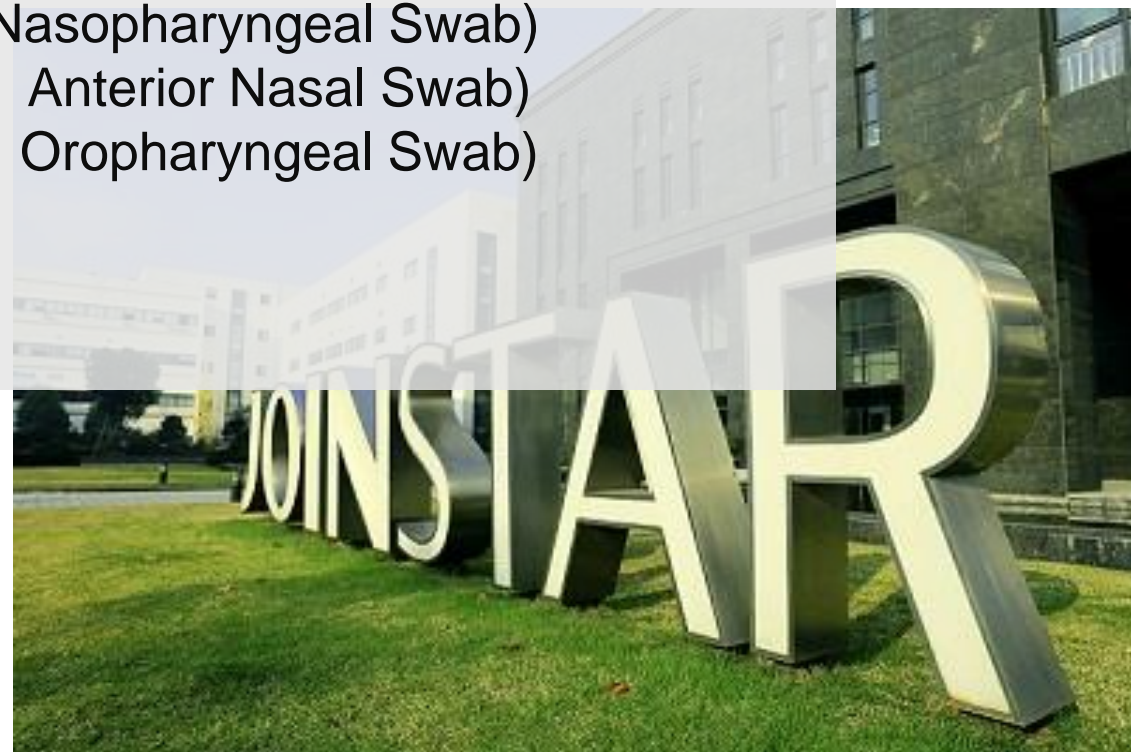
COVID-19 ANTIGEN RAPID TEST (Colloidal Gold)

P/N: FGCOVG300 (Sample type: Nasopharyngeal Swab)

P/N: FGCOVG1300 (Sample type: Anterior Nasal Swab)

P/N: FGCOVG1600 (Sample type: Oropharyngeal Swab)

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.



CONTACT:

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Web: <http://en.joinstar.cn>

 @JoinstarBioTech

 @JoinstarBioTech

 www.linkedin.com/company/joinstar

COVID-19 ANTIGEN RAPID TEST (Colloidal Gold)

P/N: FGCOVG300 (Sample type: Nasopharyngeal Swab)



- **Sample type:** Nasopharyngeal Swab
- **High sensitivity & specificity.** Can be used for early screening. Facilitates patient treatment decisions quickly;
- **Suitable for multiple scenarios:** medical institution testing; screening before resumption of work and school, continuous monitoring, etc.
- **One-step method,** easy to operate, reducing missed or false inspections caused by operator errors;
- **All necessary reagent provided & No equipment required;**
- **Time saving procedures,** results are available in 10 minutes;
- **Storage temperature:** 2~30 °C . No cold-chain transportation needed;
- **Specification:** 25 tests/box, 1 test/box;
- **Diverse cooperation modes:** OEM/ODM accepted.

COVID-19 ANTIGEN RAPID TEST(Colloidal Gold)

P/N: FGCOVG1300 (Sample type: Anterior Nasal Swab)

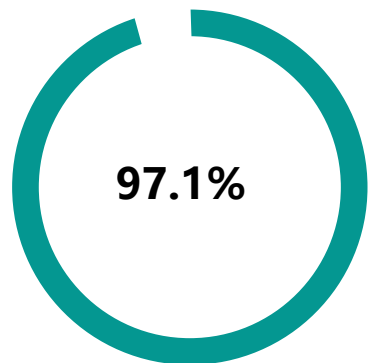
P/N: FGCOVG1600 (Sample type: Oropharyngeal Swab)

- **Sample type:** Anterior Nasal Swab&Oropharyngeal swab
- **Non-invasive, painless sample collection**
- **High sensitivity & specificity.** Can be used for early screening. Facilitates patient treatment decisions quickly;
- **Suitable for multiple scenarios:** medical institution testing; screening before resumption of work and school, continuous monitoring, etc.
- **One-step method,** easy to operate, reducing missed or false inspections caused by operator errors;
- **All necessary reagent provided & No equipment required;**
- **Time saving procedures,** results are available in 15 minutes;
- **Storage temperature:** 2~30 °C . No cold-chain transportation needed;
- **Specification:** 25 tests/box, 1 test/box;
- Diverse cooperation modes: OEM/ODM accepted.

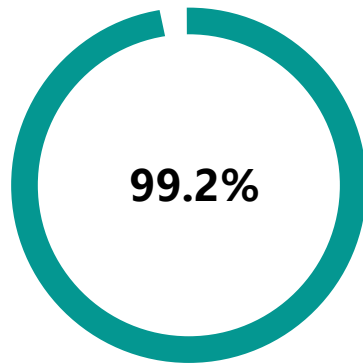


Performance Characteristics

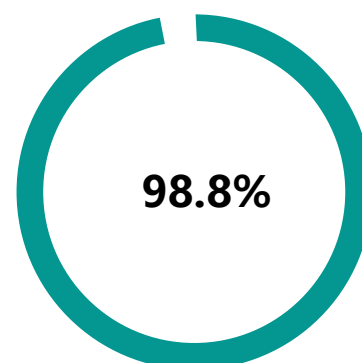
Sample type: Nasopharyngeal Swab



95% CI: 91.64%~99.39%
Sensitivity

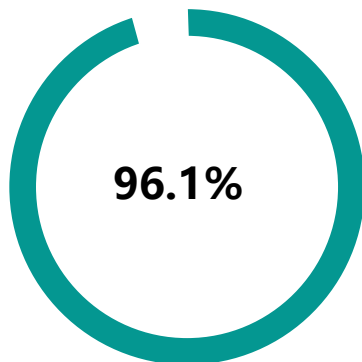


95% CI: 97.96%-99.78%
Specificity

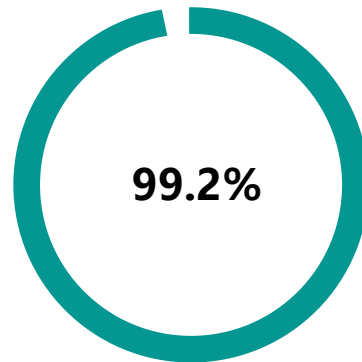


95%CI: 97.62%-99.53%
Accuracy

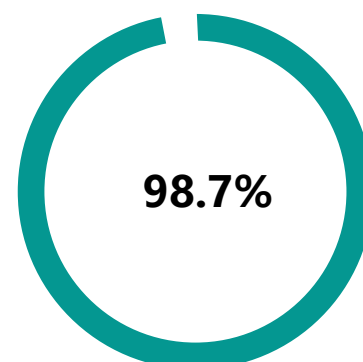
Sample type: Anterior Nasal Swab&Oropharyngeal swab



95% CI:(90.26%-98.92%)
Sensitivity



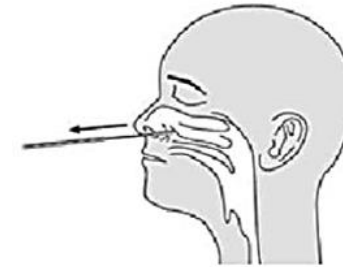
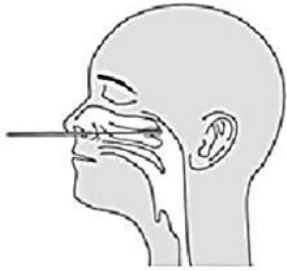
95%CI: (97.96%-99.78%)
Specificity



95%CI: 97.40%-99.42%
Accuracy

Nasopharyngeal Swab Sample collection

P/N: FGCOVG300 (Sample type: NasopharyngealSwab)



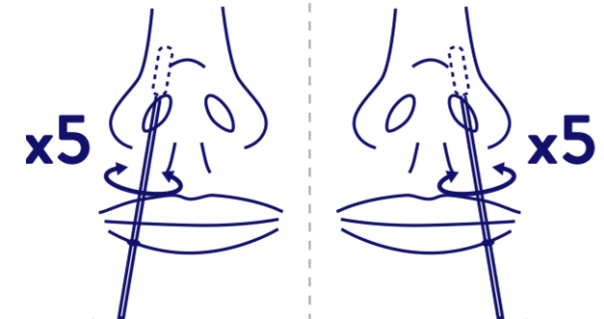
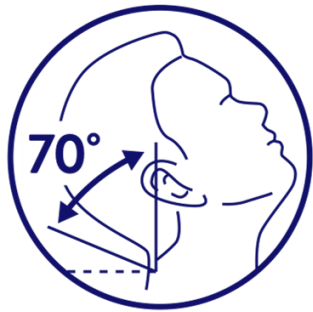
1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection

2. Swab over the surface of the posterior nasopharynx. Rotate the swab 3~4 times

3. Withdraw the swab from the nasal cavity

Anterior Nasal Swab Sample collection

P/N: FGCOVG1300 (Sample type: Anterior Nasal Swab)



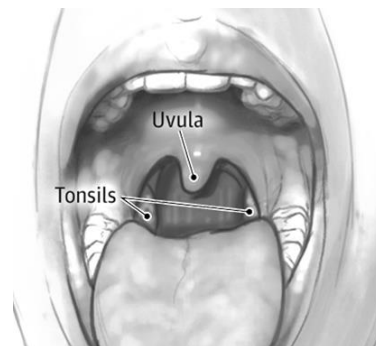
1. Tilt the patient' s head back 70 degrees.

2. While gently rotating the swab insert swab about 2~2.5 cm into nostril

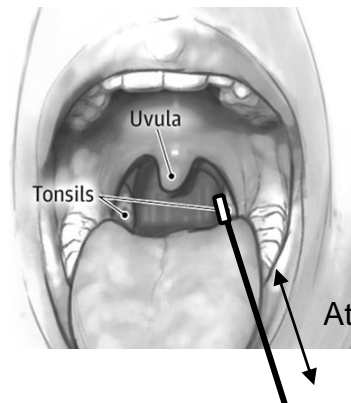
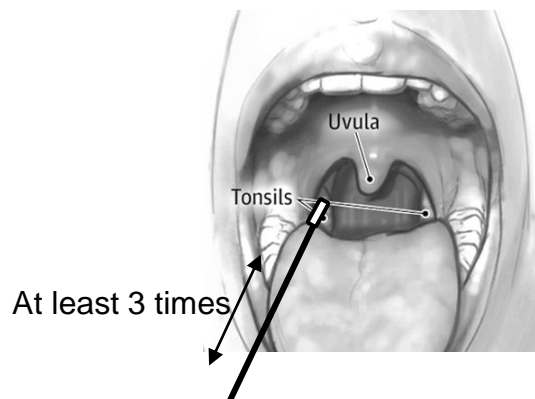
3. Rotate the swab five times against the nasal wall then slowly remove from the nostril. Using the same swab repeat the collection procedure with the second nostril.

Oropharyngeal Swab Sample collection

P/N: FGCOVG1600 (Sample type: Sample type: Oropharyngeal Swab)



1. Tilt the patient's head slightly and make "ahhh" sounds, exposing the pharyngeal tonsils on both sides



2. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for **at least 3 times**

Test Procedure

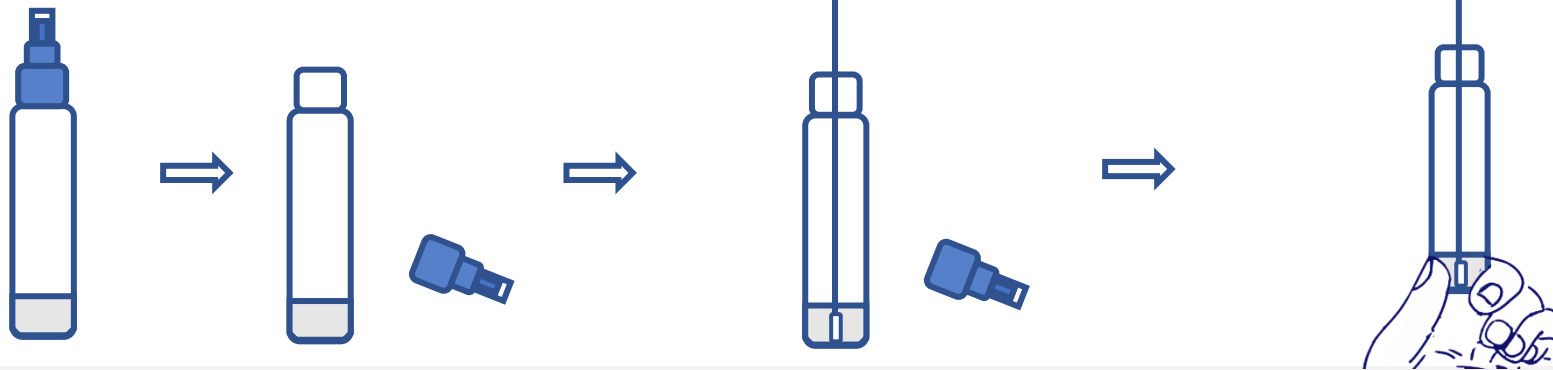
for COVID-19 Antigen Rapid Test (Colloidal Gold)

P/N: FGCOVG300 (Sample type: Nasopharyngeal Swab)

P/N: FGCOVG1300 (Sample type: Anterior Nasal Swab)

P/N: FGCOVG1600 (Sample type: Oropharyngeal Swab)

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



1. Open the cap of the extraction tube

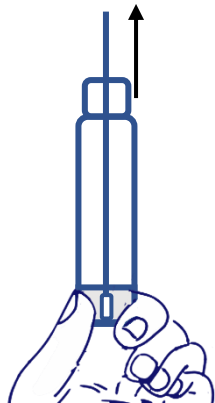
2. put the anterior nasal swab with the sample into the extraction tube and rotate it 10 times

3. Squeeze the wall of the extraction tube by hand

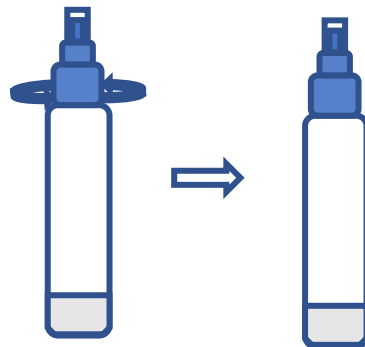
Test Procedure

for COVID-19 Antigen Rapid Test (Colloidal Gold)

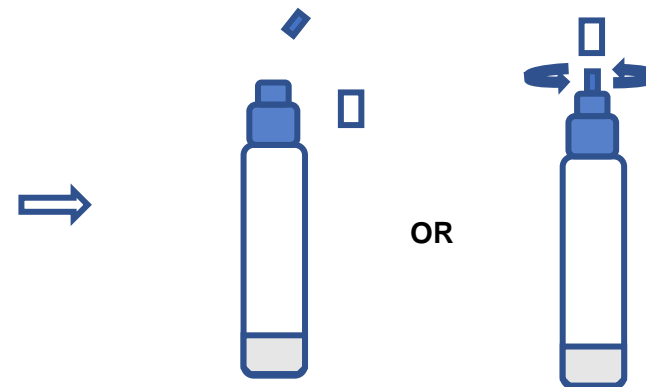
Please read the instructions carefully and allow the test device and specimens to equilibrate to temperature (15°C-30°C) prior to testing.



4. Take out the swab

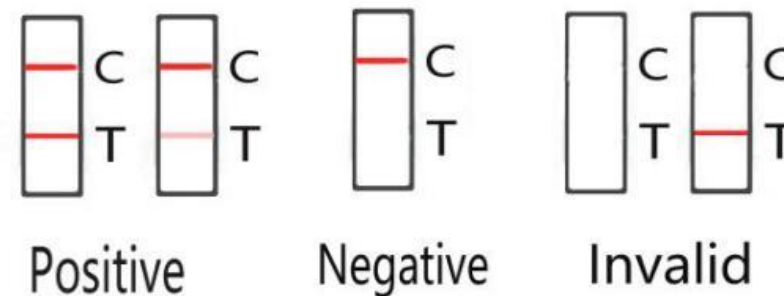
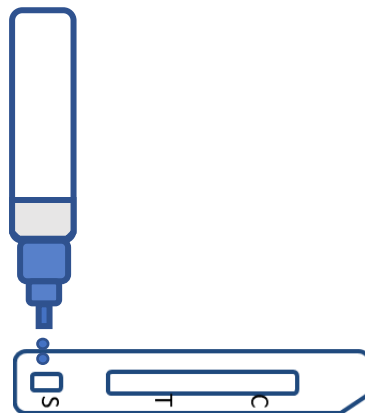


5. Cover the cap of the extraction tube, set aside.



OR

6. Cut off the protrusion of the collection tube **OR** unscrew the little transparent cap



Positive

Negative

Invalid

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

8. Add 2 drops of the sample into the sample hole vertically

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

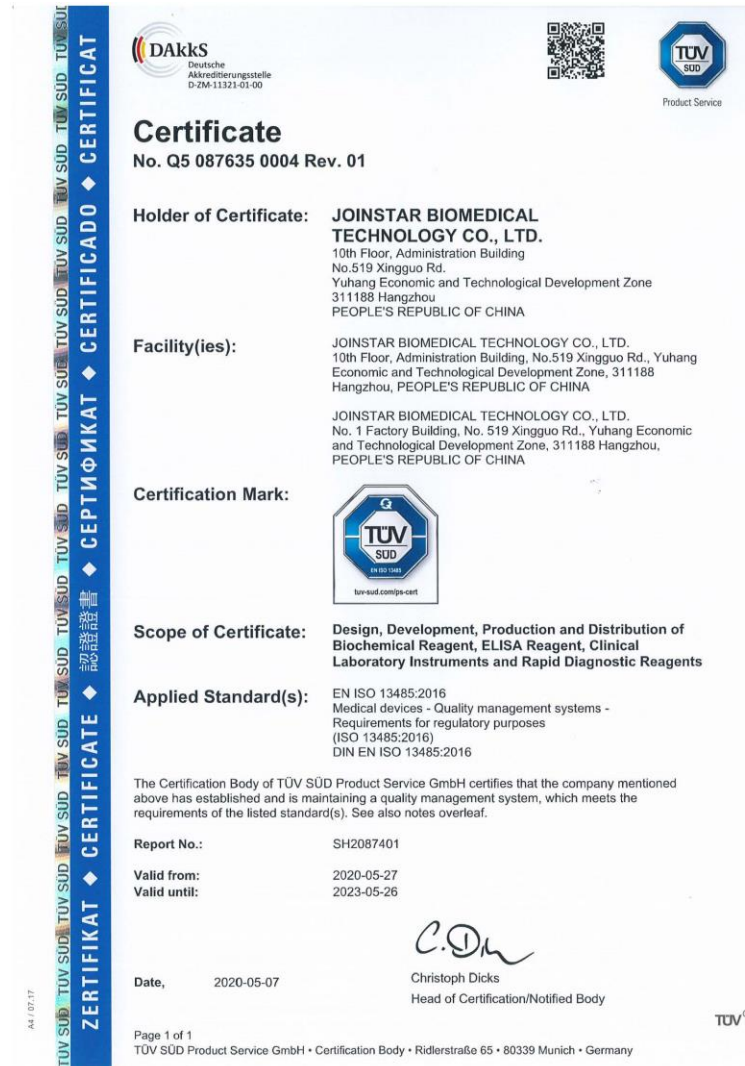
CERTIFICATE



Business license



Medical device production license



ISO13485

CERTIFICATE



CIBG
Ministerie van Volksgezondheid,
Wetzijn 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

Datum: 16 oktober 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 14 oktober 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 (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53843)

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 10, eerste lid van Richtlijn 98/79/EG).

Farmatec
Recepkadres:
Huisdieren
Rijnstraat 50
7515 XP Den Haag
T 070 340 6161
<http://huisdieren.farmatec.nl>

Inlichtingen bij:
M. Schmitz - Korte
wachtische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204977

Bijlagen
Uw aanvraag
14 oktober 2020

Correspondentie omtrent
nichten aan het retouradres met
vermelding van de datum en
het kenmerk van deze brief.

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 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 vigilantiestelsel.

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

Pagina 1 van 2

Pagina 2 van

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 (Colloidal Gold)

1Test/Kit, 20Tests/Kit, 25Tests/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:

2020.11.02

Zhong Wang
Management Representative
Joinstar Biomedical Technology Co., Ltd.

Joinstar Biomedical Technology Co., Ltd.

Version: 0.0

CE Declaration of Conformity

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

WHO-FIND List

Registration in Italy

- [Jingpo Microing Biomedical Technology Co., Ltd](#) Novel coronavirus 2019-nCoV nucleic acid detection kit (RT-PCR method) [\(PRK\)](#)
- [Jingpo Micro Biom Biotechnology Co., Ltd](#) Fluorescent RAA Detection for 2019-nCoV [\(PRK\)](#) [Contact](#)
- [Jingpo Biomedical Biotechnology \(Nanjing\) Co., Ltd](#) SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) [\(PRK\)](#) [Contact](#)
- [Jingpo Yifu Medical Apparatus](#) Detection Kit for Novel Coronavirus 2019-nCoV RNA (RT-PCR) Fluorescence Probing [\(PRK\)](#) [Contact](#)
- [Jinhuan Medical Instrument Co., Ltd](#) (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) [\(CE-IVD\)](#) [Contact](#)
- [JIN Winlays](#) PreTest Covid-19 RT-qPCR kit [\(Singapore HSA - CE-IVD\)](#) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) COVID-19 Antigen Test (Latex) (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) COVID-19 Antigen Rapid Test (Colloidal Gold) (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) (CE-IVD) [Contact](#)
- [Joinstar Biomedical Technology Co., Ltd](#) SARS-CoV-2/MERS-CoV/ Influenza A&B Antigen Rapid Test (CE-IVD) [Contact](#)
- [JQIEMIG \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 (SARS-CoV-2) Antigen Rapid Test Kit (Colloidal Gold) [\(CE-IVD\)](#) [Contact](#)
- [JQIEMIG \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 (SARS-CoV-2) IgM/IgG Rapid Test Kit (Colloidal Gold) [\(CE-IVD\)](#) [Contact](#)
- [JQIEMIG \(Tianjin\) Biotechnology Co., Ltd](#) COVID-19 IgM/IgG Antibody Test Kit (Latex) [\(CE-IVD\)](#) [Contact](#)
- [Kephene Diagnostics](#) KID-Rapid SARS-CoV-2 Antigen Test [\(in development\)](#) [Contact](#)
- [Kephene Diagnostics](#) KID-COVID-19 IgM/IgG Rapid Detection Test Kit [\(in development\)](#) [Contact](#)
- [Kephene Diagnostics](#) KID-SARS-CoV-2 IgM/IgG ELISA [\(in development\)](#) [Contact](#)
- [KIT Medical Co., Ltd](#) RND-COVID-19 Detection Kit and RND-COVID-19 Triple Detection Kit [\(CE-IVD\)](#) [Contact](#)
- [Kitch Biotechnology \(Nanjing\) Co., Ltd](#) SARS-CoV-2 Antigen/ Latex/Flow Assay [\(SARHA-UK\)](#) [Contact](#)

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.

CERTIFICATE

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Stand 04.12.2020

https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=11940645182854

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Suchen: Alle Textspalten

Los

Aktionen ▾

Zurücksetzen

Hersteller		Deutscher Vertrieber		Europäischer Bevollmächtigter				Sensitivität		Spezifität		Gebrauchsanweisung			
Test-ID	Name ↕	Stadt	Land	Name	Name	Stadt	Land	Handelsname des Tests	Testort *	Artikelnum...	%	95%iges Vertrauensintervall	%	95%iges Vertrauensintervall	
AT17	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	Praxisdienst GmbH & Co. KG	LOTUS NL B.V.	The Hague	NL	COVID-19 Antigen Schnelltest (Colloidal Gold)	POC (ohne Gerät)	2121	95,00	88,00 - 99,99	100,00	88,43 - 100	Link öffnen
AT21	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	care impuls Vertriebs GmbH	LOTUS NL B.V.	The Hague	NL	COVID-19 Antigen Schnelltest (Colloidal Gold)	POC (ohne Gerät)	2121	96,10	88,00 - 99,2	98,10	95,3 - 99,5	Link öffnen
AT22	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	care impuls Vertriebs GmbH	LOTUS NL B.V.	The Hague	NL	SARS-CoV-2 Antigen Rapid Test Kit	Labo	COVID-2019-0001	95,88	75,9 - 99,5	98,05	94,8 - 99,9	Link öffnen
AT23	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	care impuls Vertriebs GmbH	LOTUS NL B.V.	The Hague	NL	SARS-CoV-2 Antigen Rapid Test Kit	POC (ohne Gerät)	COVID-2019-0001	95,73	83,0 - 100,0	97,32	94,8 - 100,0	Link öffnen
AT24	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	care impuls Vertriebs GmbH	LOTUS NL B.V.	The Hague	NL	SARS-CoV-2 Antigen Rapid Test Kit	POC (ohne Gerät)	COVID-2019-0001	95,73	83,0 - 100,0	97,32	94,8 - 100,0	Link öffnen

Registration in Germany

Übersicht SARS-CoV-2 Antigenschnelltests
Bewertet mit derzeitigem Stand der Technik entsprechend

Testname	Hersteller (Vertrieb)
Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIO SYNEX COVID-19 Ag BSS	BIO SYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH, unizell Medicare GmbH, Maimed GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co., Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc.
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Prgen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc.
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
Medicovid-AG® SARS-CoV-2 Antigen Schnelltest (REF BT1309)	Xiamen Boson Biotech Co., Ltd
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mo-screen Corona Antigen Test	Molab GmbH

Have passed the performance verification of Paul Ehrlich Institute in Germany

Thanks!

JOINSTAR

公司地址：浙江省杭州市余杭区钱江经济开发区兴国路519号
杭州联络处：浙江省杭州市莫干山路188-200号，之江饭店6号楼2楼

总机号码：0571-89028388
传真号码：0571-89028080

邮箱：poct@joinstar.cn
网址：www.joinstar.cn