お取扱注意 | 日本語版

JOINSTAR

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.

COVID -19 ANTIGEN RAPID TEST (Latex)

COVID-19 抗原検査キット(ラテックス法)

株式会社MOSTA 大阪本店

〒550-0013 大阪府大阪市西区新町1丁目7番5号 四ツ橋GTCビル3F

Tel. 06-7777-4242 (代) Fax. 06-7777-4241

JOINSTAR JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

特長 Features

特許出願番号（米国：T13520.PROV）

Patent Application No. (USA): T13520.PROV

「JOINSTATR COVID 19 ANTIGEN RAPID TEST」は、完全なる輸出資格を持っております。唾液（口腔咽頭）、喀痰（かくたん）や便で、非侵襲的（身体に負担を与えないを意味する）な早期検出・診断ができるので安心です。

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

- 国際的にも革新的であり、病原体Sタンパク質の直接検出ができます。ウイルス変異の影響を受けない高感度特異度の検査ですので、早期スクリーニングに利用できます。

  Internationally innovative, direct detection of pathogen S protein, not affected by virus mutation, high sensitivity specificity, and can be used for early screening;

- 便利で非侵襲的な検体調査ができるタイプです。唾液（口腔咽頭）/喀痰/便にて、本格的な検疫前に自宅で自己検査に使用可能（セルフメディケーション）。仕事・学校の再開前の子供・年配者の経過監視のための非侵襲的なスクリーニング検査に適しています。

  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;

- 容易なワンステップ方法です。オペレーターによって引き起こされるエラーや見逃し、または、不正確な点検を減らすことができます。

  One-step method, easy to operate, reducing missed or false inspections caused by operator errors;

- 装置などは必要ありません。結果は、10～15分で速い検出が可能です。

  No equipment required, fast detection, results are available in 10-15 minutes;

- 保管温度は2~30℃となります。冷却状態でのチェーン輸送は必要ありません。

  Storage temperature: 2~30℃. No cold chain-transportation needed;

- 仕様は、25テスト/箱、および1テスト/箱となります。※次頁 多様な協力モード・OEM/ODM

  Specification 25 tests/box; 1 test/box; Diverse cooperation modes; OEM/ODM accepted.

※日本語訳は英文の内容を解釈した文章となります。あらかじめご理解ください。

JOINSTAR JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

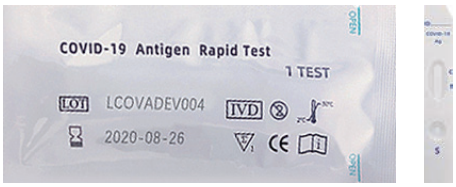
仕様 Specification

25Tests/Box

1000Tests/CTN (40*60*37CM 15/17KG)

FLCOVA200

テストカセット × 25



サンプル抽出チューブ × 25

スポイト（ドロッパー） × 25

使い捨て紙カップ × 25

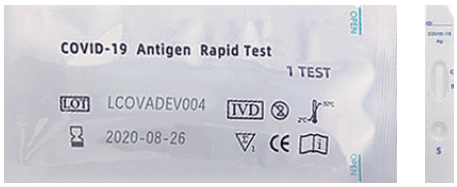
添付文書 × 1

1Tests/Box

350Tests/CTN(40*60*37CM 6/7KG)

FLCOVA100

テストカセット × 1



サンプル抽出チューブ × 1

スポイト（ドロッパー） × 1

使い捨て紙カップ × 1

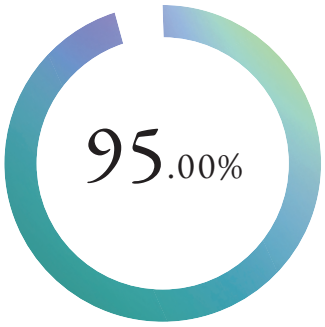
添付文書 × 1

JOINSTAR JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

性能特性 Performance Characteristics

日本国内 ／ 1870症例分の結果

唾液 Sputum

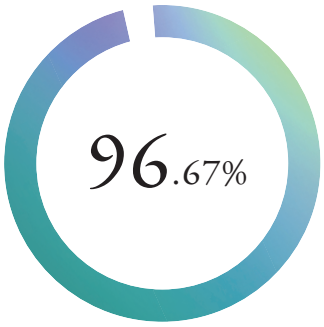


95%CI
86.08%~ 98.96%

感度 Sensitivity

95%CI
88.43% ~ 100.00%

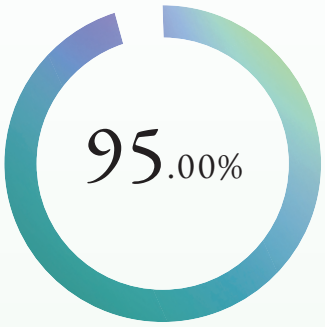
特異性 Specificity



95%CI
90.57% ~ 99.31%

正確さ Accuracy

便 Stool

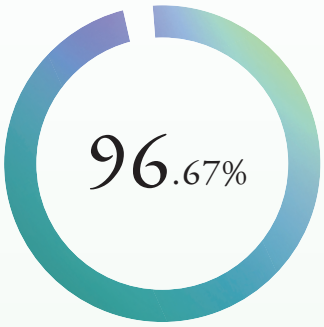


95%CI
86.08%~ 98.96%

感度 Sensitivity

95%CI
88.43% ~ 100.00%

特異性 Specificity



95%CI
90.57% ~ 99.31%

正確さ Accuracy

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

証明書 Certificate

ISO13485

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

TÜV SÜD Product Service

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICADO ◆ CERTIFICAT

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

CE Registration

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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

Datum: 8 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 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

JOINSTAR JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

証明書 Certificate

CE Declaration of Conformity

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.

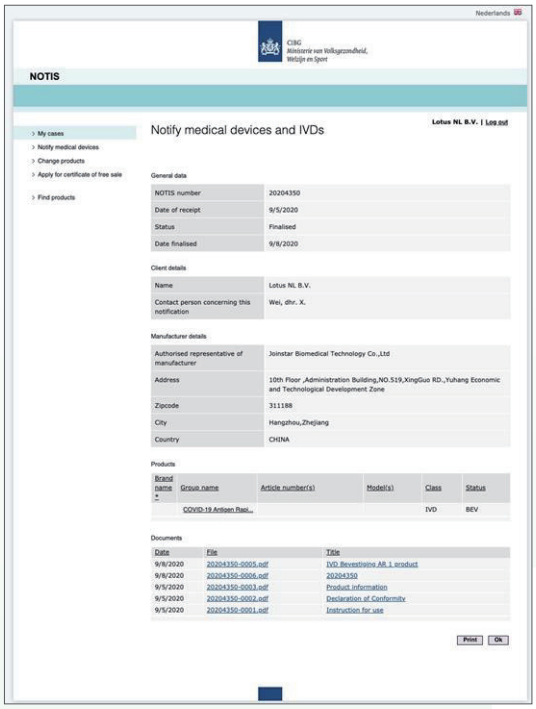
Date Signed: 2020.09.02

Xuyi ZHOU
General Manager
Joinstar Biomedical Technology Co.,Ltd

Joinstar Biomedical Technology Co.,Ltd.

Version:0.0

CE Notify medical devices and IVDs



NOTIS

Notify medical devices and IVDs

Lotus NL B.V. | Log out

- My cases
- Notify medical devices
- Change products
- Apply for certificate of free sale
- Find products

General data

NOTIS number	20204350
Date of receipt	9/5/2020
Status	Finalised
Date finalised	9/8/2020

Client details

Name	Lotus NL B.V.
Contact person concerning this notification	Wei, dhr. X.

Manufacturer details

Authorised representative of manufacturer	Joinstar Biomedical Technology Co.,Ltd
Address	10th Floor ,Administration Building,NO.519,XingGuo RD.,Yuhang Economic and Technological Development Zone
Zipcode	311188
City	Hangzhou,Zhejiang
Country	CHINA

Products

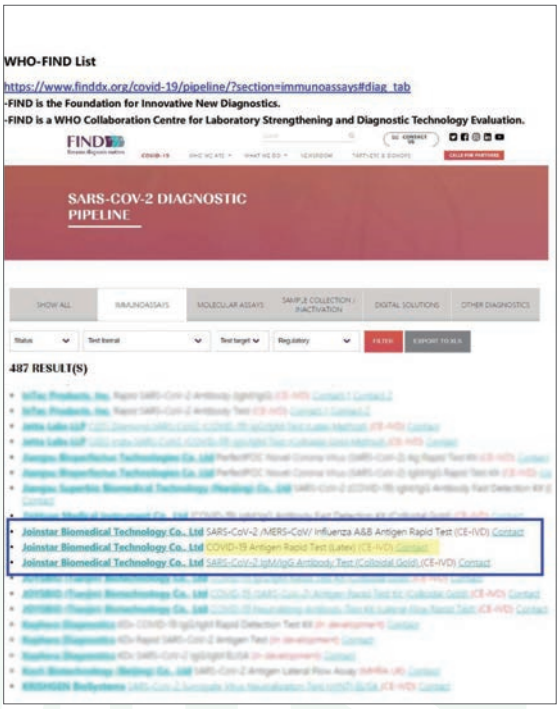
Brand name	Group name	Article number(s)	Model(s)	Class	Status
	COVID-19 Antigen Rapi...			IVD	BEV

Documents

Date	File	Title
9/8/2020	20204350-0005.pdf	IVD Bevestigine AR 1 product
9/8/2020	20204350-0006.pdf	20204350
9/5/2020	20204350-0003.pdf	Product information
9/5/2020	20204350-0002.pdf	Declaration of Conformity
9/5/2020	20204350-0001.pdf	Instruction for use

Print Ok

WHO-FIND List



WHO-FIND List

https://www.finddx.org/covid-19/pipeline/?section=immunoassays#diag_tab

-FIND is the Foundation for Innovative New Diagnostics.

-FIND is a WHO Collaboration Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

FIND

SARS-COV-2 DIAGNOSTIC PIPELINE

SHOW ALL | IMMUNOASSAYS | MOLECULAR ASSAYS | SAMPLE COLLECTION / INACTIVATION | DIGITAL SOLUTIONS | OTHER DIAGNOSTICS

Status | Test format | Test target | Regulatory | FILTER | EXPORT TO XLS

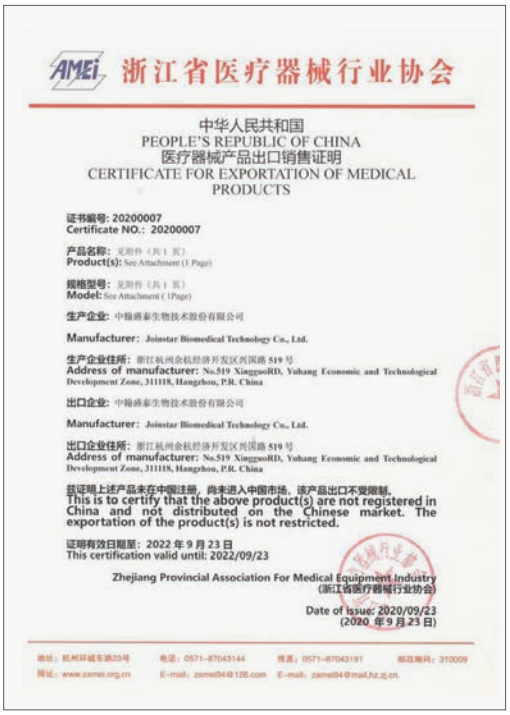
487 RESULT(S)

- Joinstar Biomedical Technology Co., Ltd SARS-CoV-2 /MERS-CoV/ Influenza A&B Antigen Rapid Test (CE-IVD) Contact
- Joinstar Biomedical Technology Co., Ltd COVID-19 Antigen Rapid Test (Latex) (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.
COVID -19 ANTIGEN RAPID TEST (Latex)

証明書 Certificate

FSC



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 页）
Product(s): See Attachment (1 Page)

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

生产企业: 中翰盛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: 中翰盛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(乳胶法) COVID-19 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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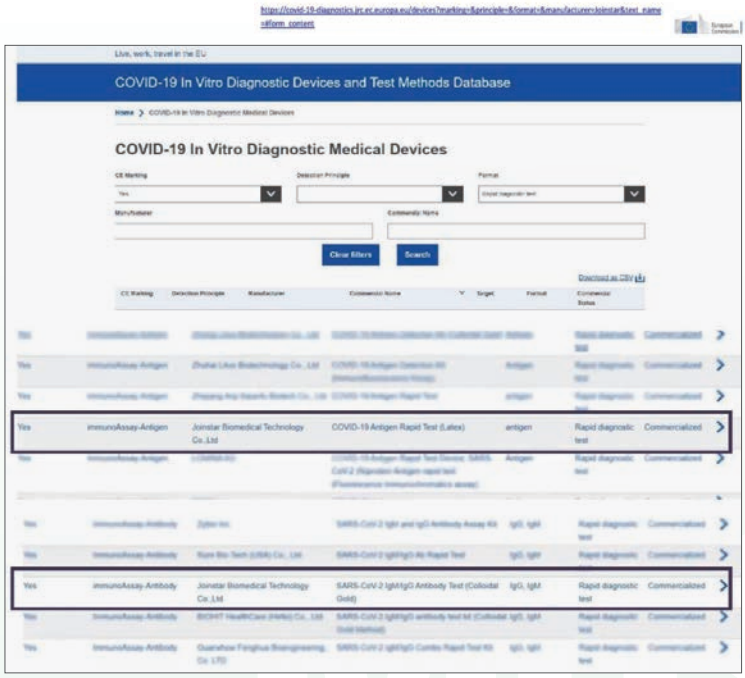
Listed in COVID-19 In VitroDiagnostic Devices and Test Methods Database



COVID-19 In Vitro Diagnostic Devices and Test Methods Database

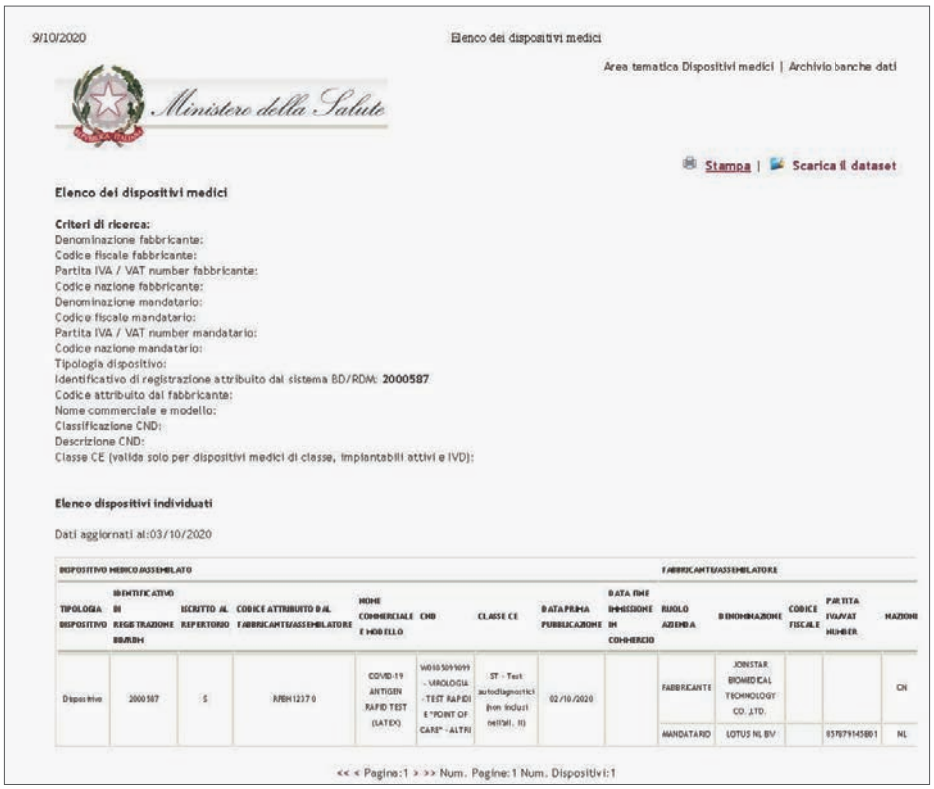
COVID-19 In Vitro Diagnostic Medical Devices

CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status	
Yes	immunoAssay-Antigen	Joinstar Biomedical Technology Co.,Ltd	COVID-19 Antigen Rapid Test (Latex)	antigen	Rapid diagnostic test	Commercialized	
Yes	immunoAssay-Antibody	Joinstar Biomedical Technology Co.,Ltd	SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)	IgG, IgM	Rapid diagnostic test	Commercialized	

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
COVID -19 ANTIGEN RAPID TEST (Latex)

証明書 Certificate

Registration in Italy



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

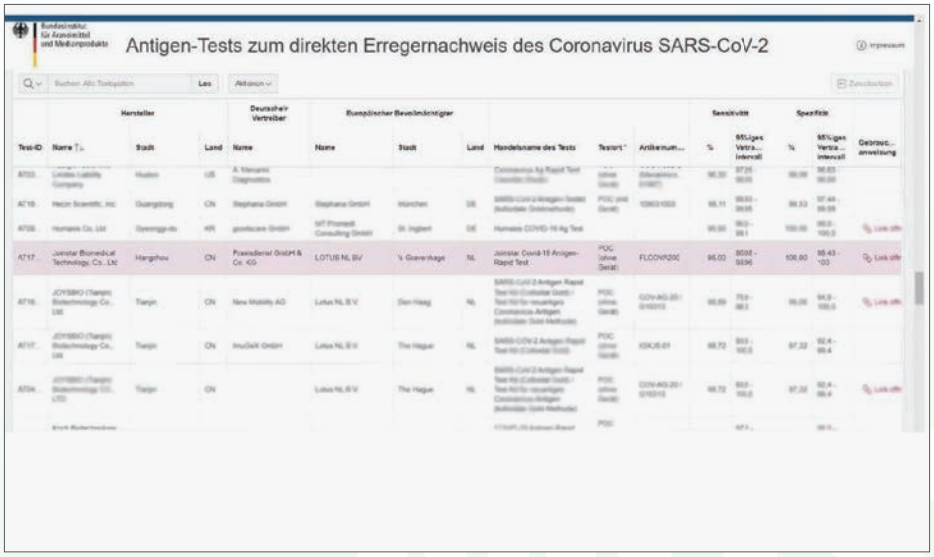
Dati aggiornati al:03/10/2020

DISPOSITIVO MEDICO/ASSEMBLATO										FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2000587	S	RBH12370	COVID-19 ANTIGEN RAPID TEST (LATEX)	W0105091099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	ST - Test autodiagnostici (non inclusi nell'All. II)	02/10/2020		FABBRICANTE	JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD.			CN
									MANDATARIO	LOTUS NL BV		857879145B01	NL

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

Registration in Germany

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



Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

JOINSTAR COVID-19 ANTIGEN RAPID TEST (Latex)
抗原検査キット(ラテックス法)取扱説明書

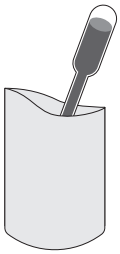
キット内容

説明書　キット本体　チューブ　スポイト　紙カップ

1 ❶ 唾液 ／ ❷ 喀痰 ／ ❸ 便の、いづれかの検体を採取

❶ 唾液

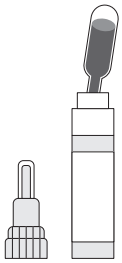
起床後すぐに口の奥から唾液を絞り出すように口内に溜め、付属のカップに吐き出します。



吐き出した、❶または❷の検体を、付属のスポイトで線のところまで採取します。（約200ul）

❷ 喀痰

起床後うがいをし、深く息を吸って強いせきとともに痰を付属のカップに吐き出します。



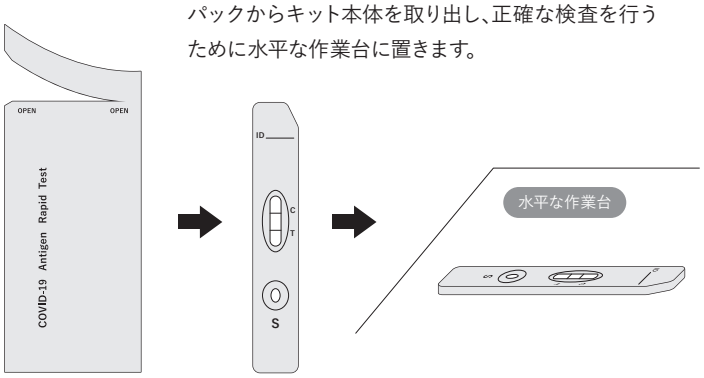
チューブの蓋を開けスポイトで採取した検体（約200ul）を全部入れ、しっかりと蓋を閉めます。

❸ 便

チューブの蓋を開け、蓋に付いているスティックで便を少量（30mg）採取し、スティックをチューブに戻してしっかりと蓋を閉め、チューブを横から押しつぶすように便をチューブの中の緩衝液になじませます。

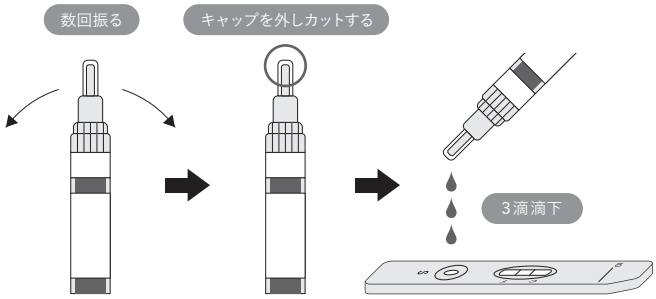
2 キット本体を用意

パックからキット本体を取り出し、正確な検査を行うために水平な作業台に置きます。



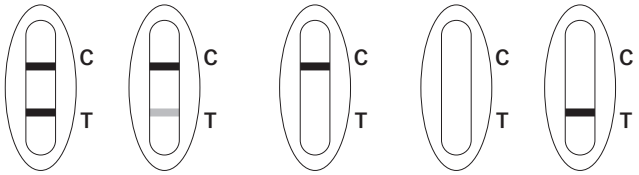
3 検体をキット本体に滴下

チューブを軽く数回振った後、蓋の突起を折って取り、キット本体のサンプル穴(S)に、チューブの検体を3滴滴下します。



4 結果読み取り

15分～20分で下記の結果を読み取ります。
※20分後以降の結果は無効です。



陽性　陰性　無効 / 再検査

製 品 名：COVID-19 ANTIGEN RAPID TEST (Latex)
測定原理：イムノクロマト法（ラテックス凝集法）
使用目的：咽頭または便に存在するSARS-Cov2の特定核タンパク質抗原の検出
判定時間：検体滴下後15~20分
指　　標：精度▶96.67% ・感度▶95% ・特異度▶100%
保存方法：2~30°C以下　直射日光・高温多湿を避ける
有効期限：キット本体の袋に記載

本製品はCE認証を取得しており、世界各国の医療機関等で体外診断用医薬品として使用されていますが、日本国内では研究開発用としての使用に限られますので、検査結果を診断に使用しないでください。判定にはPCR検査との併用が必要です。

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