
TIGSUN
®

BEIJING TIGSUN DIAGNOSTICS CO.LTD

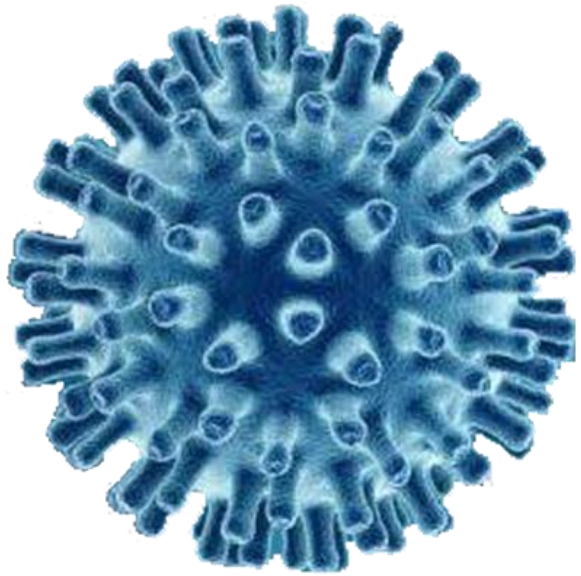
ABOUT OUR COMPANY

- Tigsun Diagnostics Co.,Ltd (Tigsun) was established in 2004 in Beijing, China. Tigsun specializes in in vitro diagnostic (IVD) products, with a full capacity of R&D, manufacturing and distribution channel for IVD products. Tigsun is one of the largest CLIA kits suppliers in China. Our main customers are hospitals, clinics, medical centers, laboratories, and research institutions. Our products are actively used in near 2,000 hospitals in China, distributed over all 34 provinces in China.

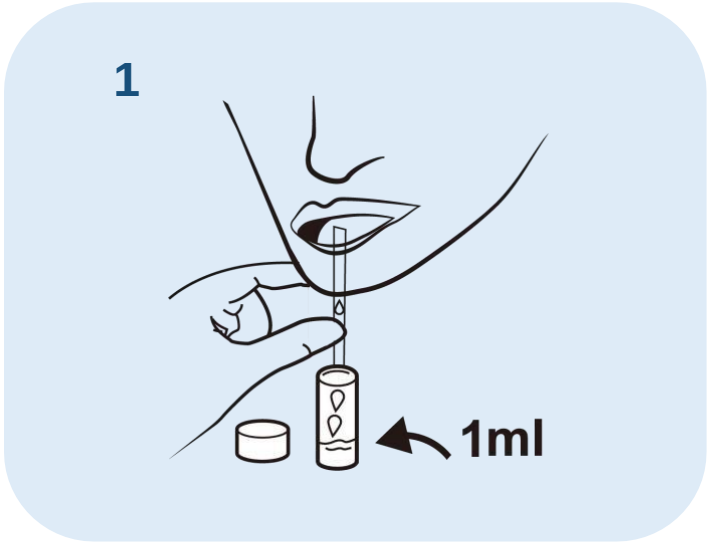
- Tigsun possess one of the largest number of State Food and Drug administration (SFDA)-registered CLIA products in China. 96 IVD products from Tigsun have been certified from the SFDA in China. We dedicate ourselves to providing customers with high-quality products and services.
- The GMP quality control and management system run by Tigsun is based on the ISO13485 and ISO9001 standards, which provides a reliable guarantee to good quality and stability of products.

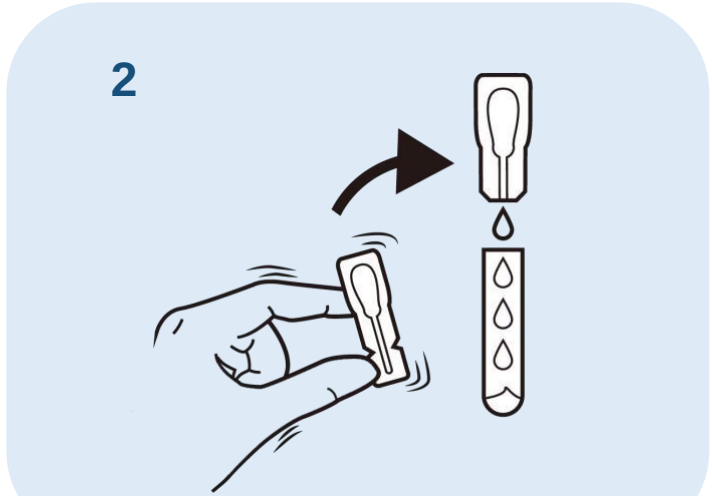
TIGSUN COVID-19 SALIVA ANTIGEN RAPID

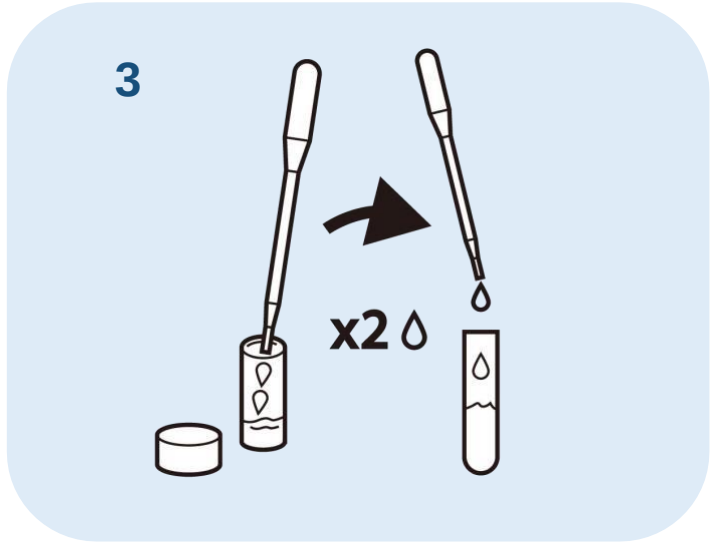
- Tigsun COVID-19 Saliva Antigen Rapid Test is a lateral flow immunochromatographic assay intended for the rapid and qualitative detection of antigen from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human saliva samples from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.
- Results are for the identification of SARS-CoV-2 antigen. The antigen is generally detectable in upper respiratory samples during the acute phase of infection.
- The test is intended for self-use in adults. The application in adolescents and children should be carried out under the supervision of adults.



QUICK REFERENCE







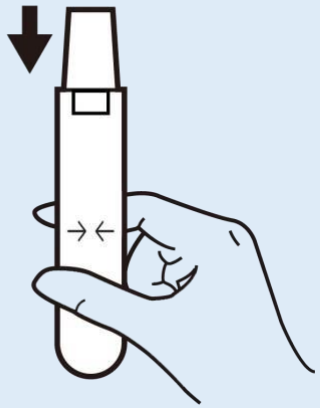
1.Use a straw to split at least
1 ml C L E A R saliva in to a reagent tubes.
specimen collection device.

2.Fill all liquid buffers into
tube with the treatment reagent.

3.Use the dropper to transfer 2
drops of saliva into the reagent

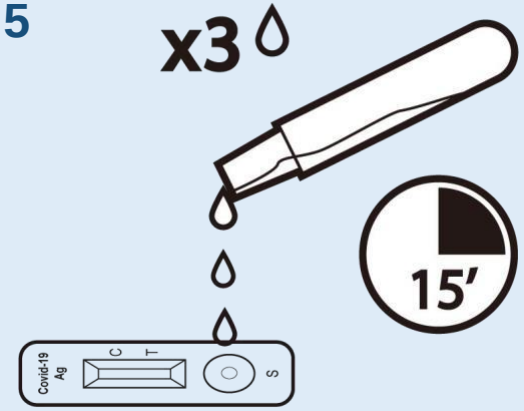
QUICK REFERENCE

4



4.Close the tube with the cap,
The average mix saliva and reagent by pressing repeatedly on the walls of the tube.
reaction time is about 3 minutes.

5



5. Keeping the test tube with dropper cap close,Transfer 3 drops into the appropriate well on the tester and wait up to 15minutes for the Result.

Content:

1 × Individual sealed pouch; each contains 1 test cassette

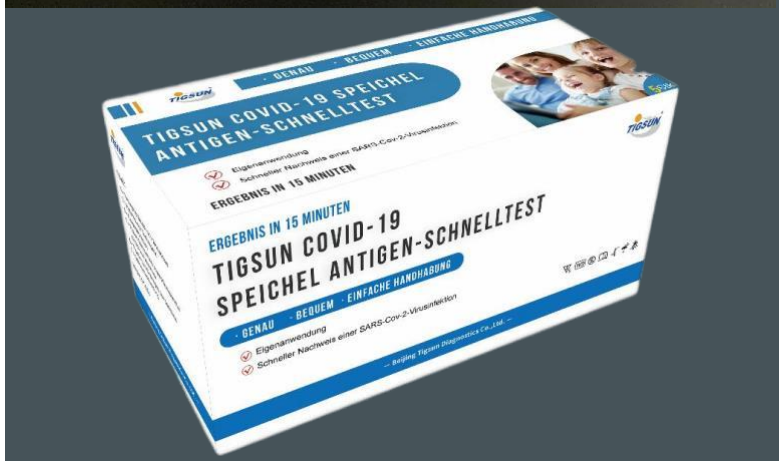
1 × Treatment Reagent

1 × Reagent Tube and Cap

1 × Specimen Collection Devices

1 × Dropper

1 × Instructions for use

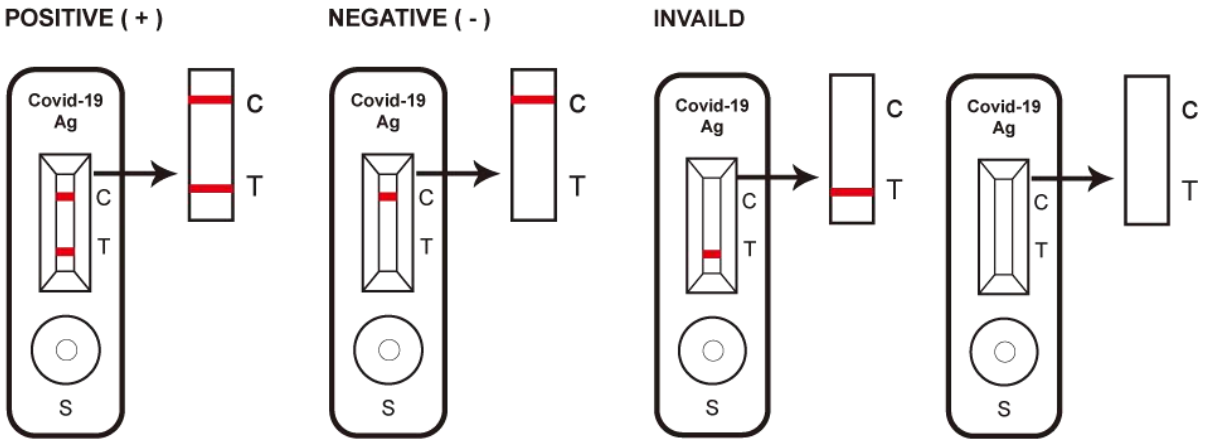


Content:

- 5 × Individual sealed pouch; each contains 5 tests cassette
- 5 × Treatment Reagent
- 5 × Reagent Tube and Cap
- 5 × Specimen Collection Devices
- 5 × Dropper
- 5 × Instructions for use

Content:

- 25 × Individual sealed pouch; each contains 25 tests cassette
- 25 × Treatment Reagent
- 25 × Reagent Tube and Cap
- 25 × Specimen Collection Devices
- 25 × Dropper
- 25 × Instructions for use



- 30 seconds hands-on time
- 15 minutes for visual results
- No instrument needed

RESULT INTERPRETATION

Fact Sheet

Tigsun COVID-19 Saliva Antigen Rapid Test

· Result within 15-20 mins · Sample Type: CLEAR Saliva · No instrument needed · Specificity 98.76%

Principle

CE IVD

Tigsun COVID-19 Saliva Antigen Rapid Test employs immunochromatography technology to detect the SARS-CoV-2 antigen in human saliva specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip.The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane.

KEY INFORMATIONS

- Inexpensive,cost-efficiency
- Simple to use, no instrument needed
- Non-invasive,fast,results in 15 minnutes
- Accurate and reliable compared to molecular methods.

PRODUCT SHOW

* THIS INFORMATION IS VERY IMPORTANT, PLEASE READ IT CAREFULLY.

Target Customers

Tigsun COVID-19 Saliva Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests using rapid lateral flow tests.

For in vitro diagnostic use only.
For professional use only.

What is inside the box?

Material Provided

· 25 Individual sealed pouches, each contains 1 test cassette
· Treatment Reagent (25 pcs)
· Reagent Tube and Caps (25 pcs)
· Specimen Collection Devices (25 pcs)
· Dropper (25 pcs)
· Instructions for use

Material Required but not Provided

· Timers
· Personal protective equipment, such as protective gloves, medical masks, goggles, and lab coats
· Appropriate biohazard waste containers and disinfectants

TIGSUN®

Company Name : Beijing Tigsun Diagnostics Co., Ltd.

Add：No. 16 Guba Road, District #1, Chengguan Street, Fangshan District, Beijing, 102400, P.R.China.

E-mail : world.sales@tigsun.com

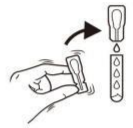
Tigsun COVID-19 Saliva Antigen Rapid Test

Instructions

CE IVD

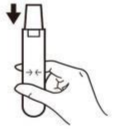
1. Use a straw to split at least 1ml **CLEAR** saliva into a specimen collection device.

2. Fill all liquid buffers into reagent tubes.

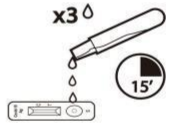


3. Use the dropper to transfer **2 drops** of saliva into the reagent tube with the treatment reagent.

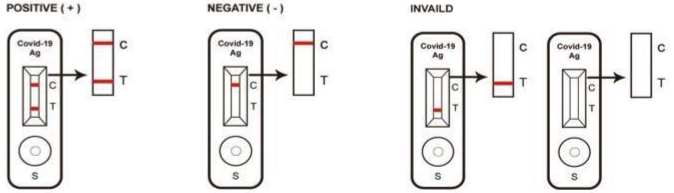
4. Close the tube with the cap,mix saliva and reagent by pressing repeatedly on the walls of the tube.



5. Keeping the test tube with dropper cap closed, transfer **3 drops** into the appropriate well on the tester and wait up to 15 minutes for the result. The average reaction time is about 3 minutes.



Result Interpretation



1.Positive Result:

Both control line (C) and test line (T) appear.

2.Negative Result:

Only control line (C) appears

3.Invalid Result:

Discard the test if no control line (C) or only test line (T) is visible. Repeat the test with a new cassette.

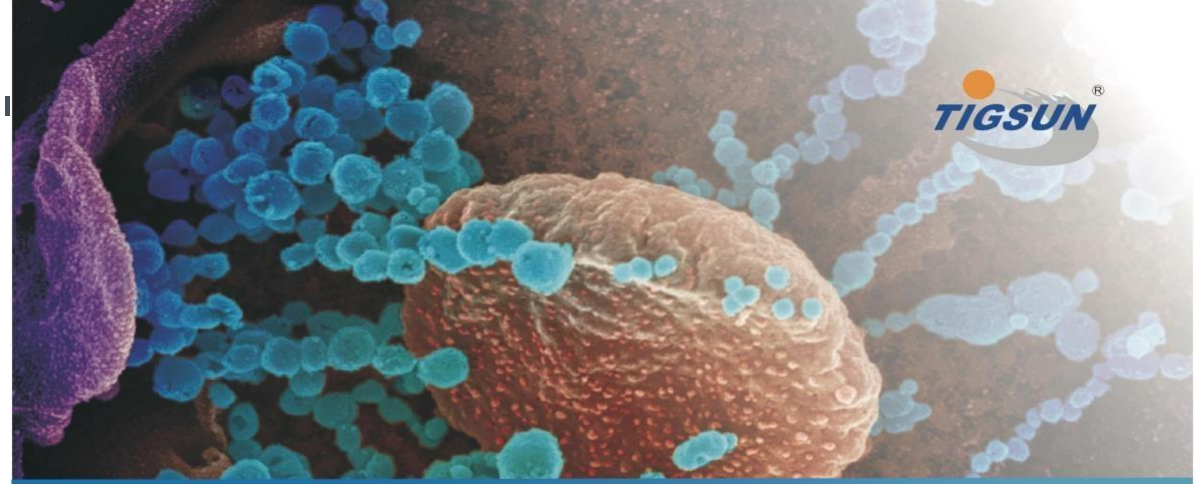
V1210508

Tel : +86-10-89350910 400-0666-093

Fax : +86-10-89350980

Website : www.tigsun.com/en

TIGSUN®



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Tigsun COVID-19 Saliva Antigen Rapid Test

(Saliva Sample by lateral Flow Method)

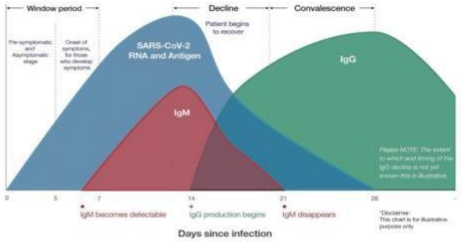
Advantages

- Inexpensive, cost-efficiency
- Simple to use, no instrument needed
- Non-invasive, fast, result in 15 minutes
- Accurate and reliable compared to molecular methods
- WHO FIND List /CCCMHPIE/CE approved

Fast /Convenient /Accurate /Reliable

Principle

Tigsun COVID-19 Saliva Antigen Rapid Test employs immunochromatography technology to detect the SARS-CoV-2 antigen in human saliva specimens. Offering lab-quality results at the point of care with reliable performance in 15 minutes.

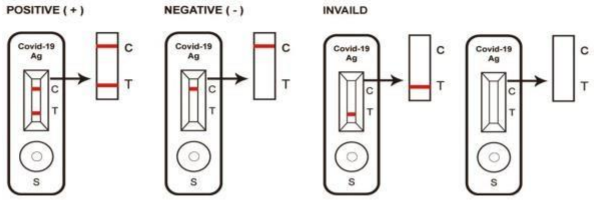


Reference:
Purpose and Options for Testing for SARS-Cov2(the COVID-19 virus):Considerations for World Bank Task Teams Managing COVID-19 Fast Track Facility Operations

Procedure

1. Use a straw to split at least 1ml **CLEAR** saliva into a specimen collection device.
2. Fill all liquid buffers into reagent tubes.
3. Use the dropper to transfer **2 drops** of saliva into the reagent tube with the treatment reagent.
4. Close the tube with the cap, mix saliva and reagent by pressing repeatedly on the walls of the tube.
5. Keeping the test tube with dropper cap closed, transfer **3 drops** into the appropriate well on the tester and wait up to 15 minutes for the result. The average reaction time is about 3 minutes.

Test Result



Product Name	Catalog No.	Packing	Sample Type	Storage	Shelf Life
Tigsun COVID-19 Saliva Antigen Rapid Test	1417	1T	Saliva	2~30℃	24 months

TIGSUN®

V1210508

CE | DOC | ISO-13485 | CHINA EXPORTING WHITE LIST

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/04092020.1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of
Beijing Tigsun Diagnostics Co.,Ltd.
No. 16, Region 1, Guba Road, Chengguan Street, Fangshan District, 102400 Beijing, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2077/2020**

CE

Issued on: 04/09/2020 Valid until: 03/09/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

Declaration of Conformity

Manufacturer:
Beijing Tigsun Diagnostics Co.,Ltd.
No. 16, Region 1, Guba Road, Chengguan Street, Fangshan District, 102400 Beijing, China
Tel : +86-10-89350910 400-0666-093 (Toll Free)
Fax: +86-10-89350980
E-mail: world.sales@tigsun.com Website: www.tigsun.com/en

European Representative:
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel.: +34951214054 E-mail: info@cmcmedicaldevices.com

Product Name:
Tigsun COVID-19 Antigen Rapid Test (FIA)
Tigsun COVID-19 Antigen Rapid Test
Tigsun COVID-19 Saliva Antigen Rapid Test
Model: 1/20/25/40/50/80/100 tests

Classification:
Others/General

Conformity Assessment Route: Annex III (IVDD 98/79/EC)
We herewith declare under sole responsibility that the products mentioned above meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

Standards Applied:

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1: 2016
EN ISO 18113-1:2011	EN ISO 23640:2015	EN ISO 14971:2012
EN 13641:2002	EN ISO 18113-2:2011	EN ISO 17511:2003

Signature: Managing Director

Place, Date of Issue: Beijing, 31 August, 2020

CE TIGSUN

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

TÜV SÜD Product Service

Certificate
No. Q5 074503 0003 Rev. 01

Holder of Certificate: **Bei Jing Tigsun Diagnostics Co., Ltd.**
No.16, Region 1, Guba Road, Chengguan Street
Fangshan
102400 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Bei Jing Tigsun Diagnostics Co., Ltd.
No.16, Region 1, Guba Road, Chengguan Street, Fangshan,
102400 Beijing, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

Certification Mark:

Scope of Certificate: **Design and Development, Production and Sales of Chemiluminescence Immunoassay Test Kits, Colloidal Gold Method Test Kits, Latex Chromatography Test Kits.**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 074503 0003 Rev. 01

Report No.: BJ20021401
Valid from: 2021-01-11
Valid until: 2024-01-10

Date, 2021-01-07 Christoph Dicks

CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

30 | 中国医药保健品进出口商会 服务产业链 | 助力国际化

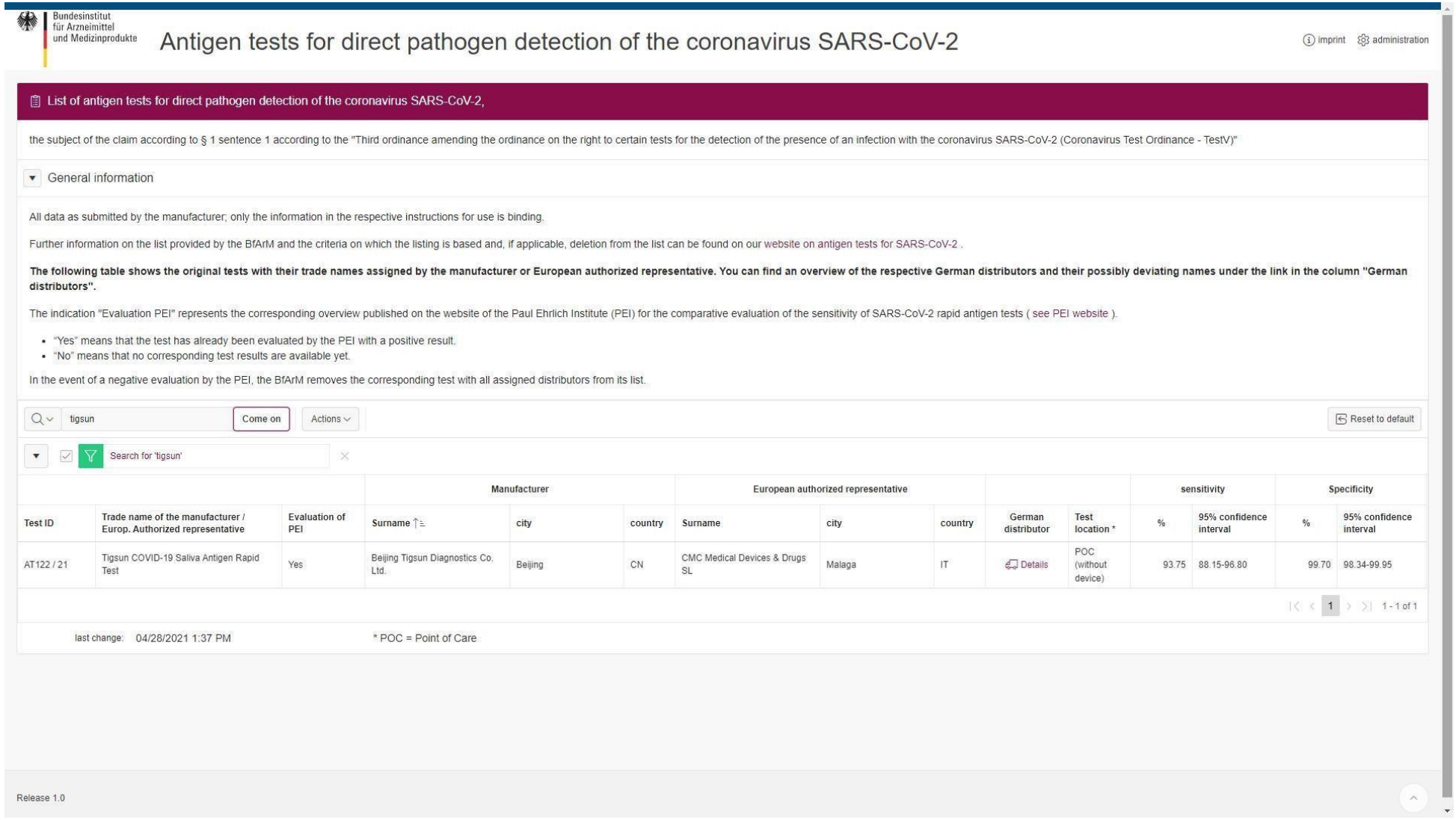
首页 关于商会 新闻中心 行业服务 权威发布

所闻中心 > 通知公告

动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年05月15日 中国医药保健品进出口商会

取得国外标准认证或注册的医疗物资生产企业清单			
Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries 动态更新：2020年5月15日 下载			
序号	生产企业	统一社会信用代码	国外注册认证情况
178	北京泰格科信生物科技有限公司 Beijing Tigsun Diagnostics Co., Ltd.	91110108766297223C	欧盟CE



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen tests for direct pathogen detection of the coronavirus SARS-CoV-2

imprint administration

List of antigen tests for direct pathogen detection of the coronavirus SARS-CoV-2,

the subject of the claim according to § 1 sentence 1 according to the "Third ordinance amending the ordinance on the right to certain tests for the detection of the presence of an infection with the coronavirus SARS-CoV-2 (Coronavirus Test Ordinance - TestV)"

General information

All data as submitted by the manufacturer; only the information in the respective instructions for use is binding.

Further information on the list provided by the BfArM and the criteria on which the listing is based and, if applicable, deletion from the list can be found on our website on antigen tests for SARS-CoV-2 .

The following table shows the original tests with their trade names assigned by the manufacturer or European authorized representative. You can find an overview of the respective German distributors and their possibly deviating names under the link in the column "German distributors".

The indication "Evaluation PEI" represents the corresponding overview published on the website of the Paul Ehrlich Institute (PEI) for the comparative evaluation of the sensitivity of SARS-CoV-2 rapid antigen tests (see PEI website).

- "Yes" means that the test has already been evaluated by the PEI with a positive result.
- "No" means that no corresponding test results are available yet.

In the event of a negative evaluation by the PEI, the BfArM removes the corresponding test with all assigned distributors from its list.

tigsun | Come on | Actions | Reset to default

Search for 'tigsun'

			Manufacturer			European authorized representative					sensitivity		Specificity	
Test ID	Trade name of the manufacturer / Europ. Authorized representative	Evaluation of PEI	Surname	city	country	Surname	city	country	German distributor	Test location *	%	95% confidence interval	%	95% confidence interval
AT122 / 21	Tigsun COVID-19 Saliva Antigen Rapid Test	Yes	Beijing Tigsun Diagnostics Co. Ltd.	Beijing	CN	CMC Medical Devices & Drugs SL	Malaga	IT	Details	POC (without device)	93.75	88.15-96.80	99.70	98.34-99.95

1 - 1 of 1

last change: 04/28/2021 1:37 PM

* POC = Point of Care

Release 1.0

GERMANY BFARM

ITALY - MINISTERO

Ministero della Salute

Thematic area Medical devices | Database archive

Press | Download the dataset

List of medical devices

Search criteria:
Manufacturer name: **tigsun**
Manufacturer tax code:
VAT number / manufacturer VAT number:
Manufacturer country code:
Representative name:
Tax code of attorney:
VAT number / representative VAT number:
Representative country code:
Device type:
Registration ID assigned by the BD / RDM system:
Code assigned by the manufacturer:
Trade name and model:
CND classification:
CND Description:
CE class (valid only for medical class, active implantable and IVD devices):

List of detected devices

Data updated on: 25/04/2021

MEDICAL DEVICE / ASSEMBLED									MANUFACTURER / ASSEMBLER				
DEVICE TYPE	BD / RDM REGISTRATION ID	ENROLLED IN THE REPERTOIRE	CODE ASSIGNED BY THE MANUFACTURER / ASSEMBLER	TRADE NAME AND MODEL	CND	CE CLASS	DATE OF FIRST PUBLICATION	END OF RELEASE ON THE MARKET	COMPANY ROLE	NAME	FISCAL CODE	VAT NUMBER / VAT NUMBER	NATION
Device	2045079	No.	TG 1417	TIGSUN COVID-19 SALIVA ANTIGEN RAPID TEST	W0105040619 - CORONAVIRUS	IVD - Another type of IVD	16/12/2020		MANUFACTURER	BEIJING TIGSUN DIAGNOSTICS CO. LTD			CN
									AGENT	CMC MEDICAL DEVICES & DRUGS SL		B93316149	ES
Device	2059704	No.	TG-1417	TIGSUN COVID-19 SALIVA ANTIGEN RAPID TEST	W0105040519 - CORONAVIRUS - NAS REAGENTS	IVD - Another type of IVD	29/01/2021		MANUFACTURER	BEIJING TIGSUN DIAGNOSTICS CO. LTD			CN
									AGENT	TOMED SRL	12315290010	12315290010	IT
Device	2041767	No.	1415	COVID-19 ANTIGEN RAPID TEST (FIA)	W0105099099 - VIROLOGY - QUICK TESTS AND "POINT OF CARE" - OTHERS	IVD - Another type of IVD	08/12/2020		MANUFACTURER	BEIJING TIGSUN DIAGNOSTICS CO., LTD			CN
									AGENT	DIAGNOSTIC PROJECT LIMITED LIABILITY COMPANY	09561321002	09561321002	IT

<< < Page: 1 > >> Num. Pages: 1 Num. Devices: 3

30/12/2020 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: **TIGSUN**
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:
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):

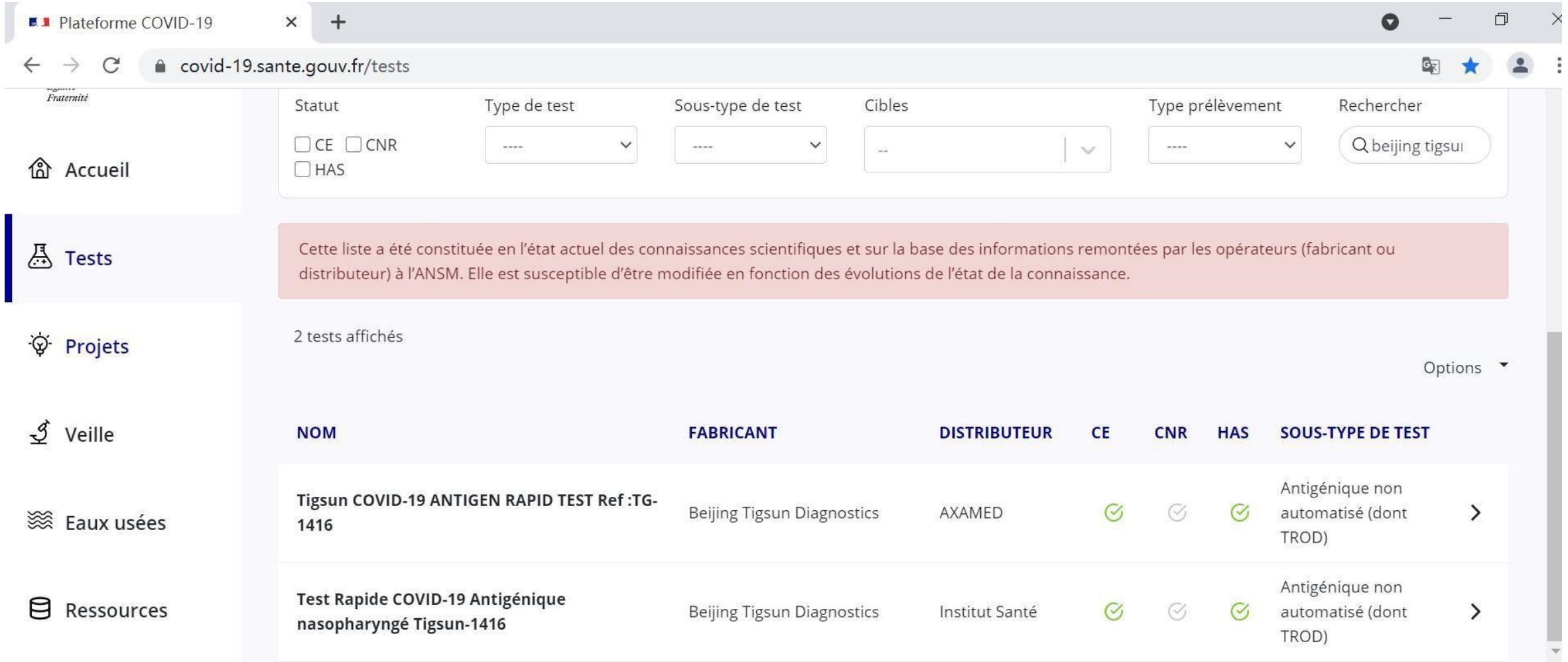
Elenco dispositivi individuati

Dati aggiornati al:27/12/2020

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
Dispositivo	2045079	N	TG 1417	TIGSUN COVID-19 SALIVA ANTIGEN RAPID TEST	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	16/12/2020		FABBRICANTE	BEIJING TIGSUN DIAGNOSTICS CO. LTD		
									MANDATARIO	CMC MEDICAL DEVICES & DRUGS S.L.		B93316149
Dispositivo	2041767	N	1415	COVID-19 ANTIGEN RAPID TEST (FIA)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	08/12/2020		FABBRICANTE	BEIJING TIGSUN DIAGNOSTICS CO.,LTD		
									MANDATARIO	DIAGNOSTIC PROJECT SOCIETA' A RESPONSABILITA LIMITATA	09561321002	09561321002
Dispositivo	2041909	N	FIC-S1	DRY IMMUNOFLUORESCENCE ANALYZER	W0299 - STRUMENTAZIONE IVD - ALTRI	IVD - Altro tipo di IVD	08/12/2020		FABBRICANTE	BEIJING TIGSUN DIAGNOSTICS CO.,LTD		
									MANDATARIO	DIAGNOSTIC PROJECT SOCIETA' A RESPONSABILITA LIMITATA	09561321002	09561321002

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:3

FRANCE - MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ



CROATIA - HALMED CONFIRMATION

REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
Ksaverska c.4, 10000 ZAGREB, CROATIA
Tel.: ++ 385 1 4884 100, Fax: ++385 1 4884 110
e-mail: lialmed@halmied.hr
www.halmed.hr

Class: 530-09/21-14/369
Order No: 381-13-07/199-21-02

Zagreb, 20 May 2021.

KORMEDIX d.o.o.
Hrvatska,
Zagreb,
Sirolina 8

SUBJECT: Obavijest o stavljanju u market medicovani produktu **Tigsun brzi test za COVID-19 na sallu / Tigsun COVID-19 Saliva Antigen Rapid Test**, for the rapid and qualitative detection of SAR.S-CoV-2 antigen from saliva swabs, manufactured by Beijing Tigsun Diagnostics Co., Ltd., Kina, Beijing, No. 16, Region 1, Guba Road, Chengguan Street, Fangshan District, in the In Vitro - Others risk class

-tries a primitive, gives up

In view of your concerns regarding the use of the medical product Tigsun Rapid Saliva Test for COVID-19 / Tigsun COVID-19 Saliva Antigen Rapid Test, for the rapid and qualitative detection of SARS-CoV-2 antigen from saliva samples, manufactured by Beijing Tigsun Diagnostics Co., Ltd., Kina, Beijing, No. 16, Region 1, Guba Road, Chengguan Street, Fangshan District, risk class In vitro - other, for circulation in the Republic of Korea! Hrvatskoj, delivered under Article 42. Zakona o medicinskim proizvodima ("Narodne novine", broj 76/13.) and Article 42. Pravilnika o bitnim zahtjevima, razvrstavanju, upisu proizvodaca u ocevidnik proizvodaca, upisu medicinskih produkta u ocevidnik medicinskih produkta te ocjenjivanju sukladnosti medicinskih produkta ("Narodne novine", issue 84/13. and 126/19.), we confirm that the Agency for Medicinal Products and Health Products has closed the subject matter of the present notification as of 15.3.2021. godine.

Annexes: Inventory of the medical product

Ravnatelj:

Prof. dr. sc. Siniša Tomić

To be delivered
1. KORMEDIX d.o.o., Zagreb, Sirolina 8
2. Pismohrana

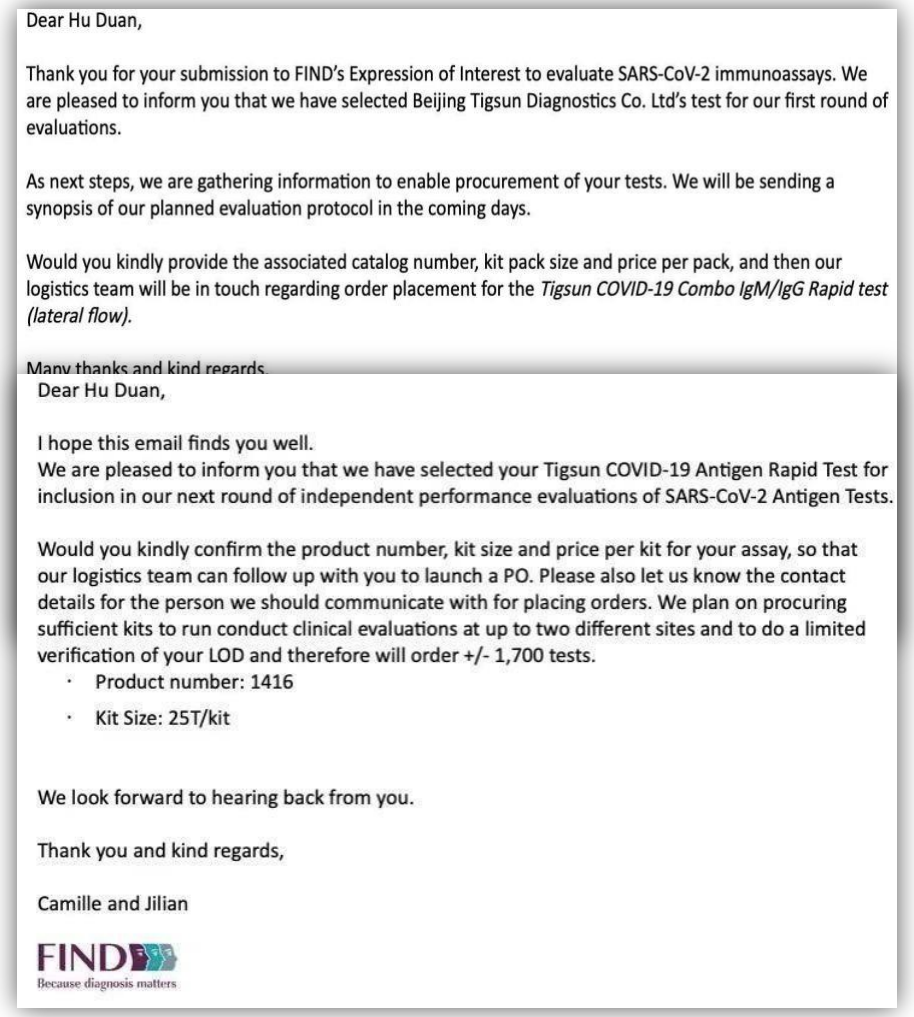
F-01010/1**SU-OP-0029

ENROLLED IN WHO-FIND LIST

- FIND is the Foundation for Innovative New Diagnostics.
- FIND is a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation.

- Beijing Tigsun Diagnostics Co., Ltd Tigsun COVID-19 Antigen Rapid Test (FIA) (CE-IVD) Contact
- Beijing Tigsun Diagnostics Co., Ltd Tigsun Flu A/B, COVID-19 Ag Combo test (CE-IVD) Contact
- Beijing Tigsun Diagnostics Co., Ltd Tigsun Flu A/B, RSV, COVID-19 Ag Combo test (CE-IVD) Contact
- Beijing Tigsun Diagnostics Co., Ltd Tigsun COVID-19 Combo IgM/IgG Rapid Test (Lateral Flow Method)
- Beijing Tigsun Diagnostics Co., Ltd Tigsun COVID-19 Antigen Rapid Test (CE-IVD) Contact
- Beijing Tigsun Diagnostics Co., Ltd Tigsun COVID-19 Antigen Saliva Rapid Test (CE-IVD) Contact

Company	Assay	Target	Country of manufacturer	Interpretation	Regulatory status**
Beijing Tigsun Diagnostics Co., Ltd	Tigsun COVID-19 Combo IgM/IgG Rapid Test (lateral flow)	IgM/IgG	China	Visual	CE-IVD; India



Dear Hu Duan,

Thank you for your submission to FIND's Expression of Interest to evaluate SARS-CoV-2 immunoassays. We are pleased to inform you that we have selected Beijing Tigsun Diagnostics Co. Ltd's test for our first round of evaluations.

As next steps, we are gathering information to enable procurement of your tests. We will be sending a synopsis of our planned evaluation protocol in the coming days.

Would you kindly provide the associated catalog number, kit pack size and price per pack, and then our logistics team will be in touch regarding order placement for the *Tigsun COVID-19 Combo IgM/IgG Rapid test (lateral flow).*

Many thanks and kind regards

Dear Hu Duan,

I hope this email finds you well.
We are pleased to inform you that we have selected your Tigsun COVID-19 Antigen Rapid Test for inclusion in our next round of independent performance evaluations of SARS-CoV-2 Antigen Tests.

Would you kindly confirm the product number, kit size and price per kit for your assay, so that our logistics team can follow up with you to launch a PO. Please also let us know the contact details for the person we should communicate with for placing orders. We plan on procuring sufficient kits to run conduct clinical evaluations at up to two different sites and to do a limited verification of your LOD and therefore will order +/- 1,700 tests.

- Product number: 1416
- Kit Size: 25T/kit

We look forward to hearing back from you.

Thank you and kind regards,

Camille and Jilian

FIND
Because diagnosis matters

TIGSUN COVID-19 ANTIGEN SALIVA RAPID TEST

Beijing Tigsun Diagnostics Co., Ltd
http://www.tigsun.com/Content/2020/10-26... world.sales@tigsun.com

EXPORT THIS PAGE IN PDF

REGULATORY STATUS
CE-IVD

TIME TO RESULT
15

ASSAY TARGET
Antigen

TEST FORMAT
Lateral flow assay (strip or cassette)

TECHNOLOGY PRINCIPLE
Antibody-based detection

TARGET ANALYTE
N protein

LABORATORY/POINT-OF-CARE
Point-of-care

SELF-TESTING/SELF-COLLECTION
No

VALIDATED SAMPLE TYPES
Saliva

Manufacturer performance data

SENSITIVITY
92.6%

SPECIFICITY
98.7%

CLINICAL RESEARCH LITERATURE SUPPORT

New Results

Comment on this paper

SARS-CoV-2 proteome microarray for mapping COVID-19 antibody interactions at amino acid resolution

Hongye Wang, Xin Hou, Xian Wu, Te Liang, Xiaomei Zhang, Dan Wang, Fei Teng, Jiayu Dai, Hu Duan, Shubin Guo, Yongzhe Li, Xiaobo Yu

doi: https://doi.org/10.1101/2020.03.26.994756

Proteome-wide analysis of differentially-expressed SARS-CoV-2 antibodies in early COVID-19 infection

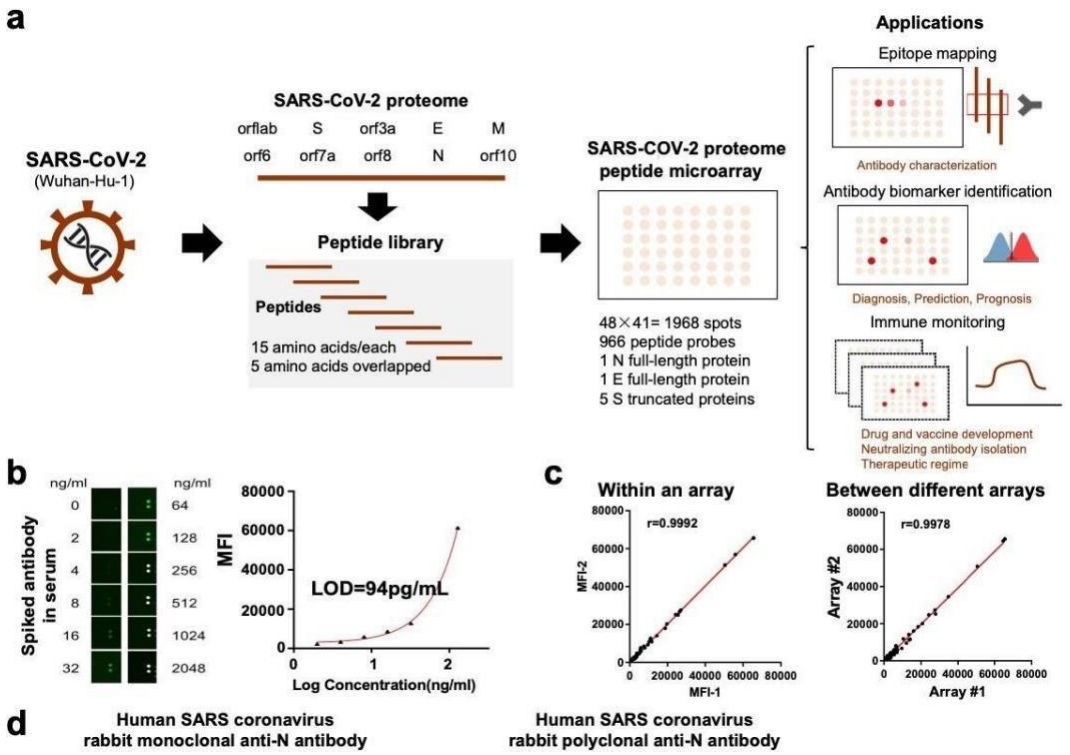
Xiaomei Zhang, Xian Wu, Dan Wang, Minya Lu, Xin Hou, Hongye Wang, Te Liang, Jiayu Dai, Hu Duan, Yingchun Xu, Yongzhe Li, Xiaobo Yu

doi: https://doi.org/10.1101/2020.04.14.20064535

Serum protein profiling reveals a landscape of inflammation and immune signaling in early-stage COVID-19 infection

Xin Hou, Xiaomei Zhang, Xian Wu, Minya Lu, Dan Wang, Meng Xu, Hongye Wang, Jiayu Dai, Hu Duan, Yingchun Xu, Xiaobo Yu, Yongzhe Li

doi: https://doi.org/10.1101/2020.05.08.20095836



- https://www.biorxiv.org/content/10.1101/2020.03.26.994756v1

TIGSUN COVID-19 ANTIGEN-PRODUCT SPECIFICATION

Brand Name	Beijing Tigsun Diagnostics Co., Ltd.
Assay Name	Tigsun COVID-19 Antigen Rapid Test (FIA, Swab, Saliva)
Catalog number	1415, 1416,1417
Packing	25T per Box, 16 Boxes per Carton Box
Weight & Dimension Per Carton Box	Length 550mm*Width365mm*Height290mm Weight: 8kg
Storage	24 months under 2~30°C
Certificate	CE

Unit	25	16	8	0.06
#Tests	**#Boxes**	**#Carton**	**Weight(kg)**	**Volume(m3)**
10,000	400	25	200	1.46
50,000	2,000	125	1,000	7.28
100,000	4,000	250	2,000	14.55
200,000	8,000	500	4,000	29.11
500,000	20,000	1,250	10,000	72.77
1,000,000	40,000	2,500	20,000	145.54

Order need to be based on carton (per 400 tests)