21. 11. 2020

Porovnanie vlastností testov od spoločností JOISBIO

Porovnávané testy sú určené ako rýchle antigénové testy na testovanie antigénu COVID-19 založenom na princípe imunochromatografie. Test slúži na kvalitatívnu detekciu antigénu COVID-19 / negat, posit. / t. j. špecifického proteínu vírusu zo vzorky získanej výterom zo slizníc nosohltanu výterovým tampónom. Tento tampón sa vloží do tekutiny čím sa uvoľni vírus zo vzorky . Táto tekutina sa potom nanesie na testovaciu doštičku, ktorú pokrývajú protilátky, ktoré sú schopné naviazať z vírusu proteíny. V prípade pozitivity do 15-30 minút sa na testovacej doštičke objavia dve farebné čiary, ktoré tak Identifikujú vírusovú infekciu COVID-19. V prípade negativity sa na testovacej doštičke objaví len jedna čiara.

Hlavnou výhodou tohto testu je jeho rýchlosť a jednoduchosť použitia, keďže celý test trvá 15 max.30 minút.

Antigénové testy predstavujú rýchlu metódu testovania na akútnu prítomnosť ochorenia Covid – 19, čím spĺňajú požiadavku na testovanie v rámci rýchleho screeningu potrebného k celkovému obrazu o rozšírení nákazy COVID – 19 v populácii.

Senzitivitu záchytu ochorenia COVID – 19 tohto antigénového testu udáva výrobca 97,08% a špecificitu 99,05%. Z pohľadu screeningového testovania je vyššia špecificita výhodou. Test je vhodný pre pacientov s príznakmi ochorenia a tých, ktorí majú nálož vírusu vysokú a sú skutočne infekční. Všetky tri testy sa používajú rovnako, po výtere priloženým vatovým tampónom sa tento vypláchne v priloženej tekutine a následne nakvapká do testovacieho otvoru na kazete.

Senzitivita a špecificita je v priloženej tabuľke:

Test/výrobca	Senzitivita	Špecificita
SARS CoV-2 Antigen Rapid Test Kit / JOISBIO	**97,08%**	**99,05%**

Údaje sú z materiálov k jednotlivým testom, každá spoločnosť ich definuje z vyhodnotenia série meraní.

Všetky tri spoločnosti sú certifikované pre použitie v EU, majú teda značku CE a IVD, ako rýchlotest pre in vitro diagnostiku

S úctou

.....

MUDr. Marčišin Jozef

mikrobiológ

MINISTÉRIO DA SAÚDE

ANVISA - AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICATE OF GOOD MANUFACTURING PRACTICES AND HEALTH PRODUCTS CONTROL

Considering the provisions of Law No. 9,782, of January 26, 1999, Decree No. 3,029, of April 16, 1999 and the publication in the Federal Official Gazette by means of Resolution RE No. 2,900 on 08/10 / 2020 I certify that the company, described below, complies with the current sanitary legislation, regarding the Good Manufacturing Practices for health products required by the Brazilian health authority, being subject to periodic inspections.

Manufacturer: JoysBio (Tianjin) Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, Tianjin - 300457, China

Requesting company: Winning Trading Importação e Exportação Ltda. CNPJ: 13.352.623/0001-75

Operation permit: 8.19.527-2 Expedient: 1766337/20-1

Certificate of Good Manufacturing Practices for Health Products:

Diagnostic products for in vitro use of classes III and IV.

Validity until: 08/10/2022

Document electronically signed by Ronaldo Lucio Ponciano Gomes, General Manager of Sanitary Inspection and Inspection, on 08/10/2020, at 11:45 am, according to official Brasília time, based on art. 6, § 1, of Decree No. 8,539, of October 8, 2015 http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.htm.

The authenticity of this document can be checked on the website https:sei.anvisa.gov.br/autenticidade, informing the verification code 1116771 and the CRC code C6831E26.

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:
R.A.C. Ori

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201797

Bijlagen
-

Uw aanvraag
29 april 2020

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

Datum: 12 mei 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 29 april 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. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-50908)

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, JOYSBIO (Tianjin) Biotechnology 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

Dhr. M.J. van de Velde

SALUD

SECRETARÍA DE SALUD

COFEPRIS MX FDA

The Federal Commission for the Protection against Sanitary Risk

Product Details

Company Name: GRUPO RCC CONSULTORES EMPRESARIALES S. DE R.L. DE C.V.

Adress : Avenida Presidente Masaryk número 191, Polanco, Polanco V sección, Miguel Hidalgo, C.P. 11560, Ciudad de México, México.

Product Name: **COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)**

Product Specifications: 20Tests/box (1Test/bag ×20 Bags)
40 Tests /box (1Test / bag ×40 Bags)

Technical Name: Coronavirus

Registration Number: **203300401 B1302**

Classification : 001

Manufacturer: **JOYSBIO (Tianjin) Biotechnology Co., Ltd.**

Registration Validity Period: 10/08/2025

www.promedical.com.au
sales@promedical.com.au
1300 886 590
5-22 Alexandra Place,
Murarrie, QLD, 4172,
Australia
ABN: 40 625 347 944

Date: 18th March 2020

Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined, pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

Personal Protective Equipment EUA:
On the basis of this determination, the Secretary declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

In Vitro Diagnostic devices EUA's:
CDC has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Promedical COVID-19 Rapid test Kit EUA Reference: **PEUA200057.**

Please quote the above number at the customs or border protection on clearing goods.

Kind Regards

Neran De Silva

CEO, Promedical Equipment Pty Ltd

FAKULTNÍ NEMOCNICE KRÁLOVSKÉ VINOHRADY

Šrobárova 50, 100 31 Praha 10
TELEFON: 267161111
IČO. 00064 173
DIČ: CZ 00064 173
Bankovní spojení.: ČNB
Č. ú. 16334101/0710

VÁŠ DOPIS ZNAČKY/ZE DNE	NAŠE ZNAČKA	VYŘIZUJE/LINKA	V PRAZE DNE
čj. FNKV	/2200	/2200	19.2.2021

Věc.: JOYSBIO SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) REF G10314

Vážený pane,

na základě Vaší žádosti jsme provedli v našem odběrovém místě pro antigenní testování COVID-19 v období od 20.1. do 15.2.2021 dvacet odběrů antigenními testy COVID-19 JOYSBIO SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) REF G10314 u pacientů, u kterých byla před tím diagnostikována infekce COVID-19 standardním antigenním testem a následně potvrzena testem PCR. V rámci tohoto porovnání byla shoda u pozitivních pacientů 90%

S pozdravem

FAKULTNÍ NEMOCNICE
KRÁLOVSKÉ VINOHRADY
Šrobárova 50, 100 34 Praha 10
Ředitelství

Prof. MUDr. Petr Arenberger, DrSc., MBA, FCMA
ředitel FNKV

2.Austria

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

SELBSTVERPFLICHTUNG für das Inverkehrbringen von Schnelltests zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2 gemäß § 323c Abs. 18 der Bundesabgabenordnung, idgF

An das
Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 Wien

Hiermit bestätige ich
Firma: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Name: Mr.Yuan
Anschrift: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China

als Verantwortlicher für das Inverkehrbringen, dass hinsichtlich der nachstehend beschriebenen Schnelltests zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2, die durch den Hersteller für eine Probennahme im anterior nasalen Bereich oder andere ähnlich minimal invasive Probennahmen in Verkehr gebracht und mit einer CE-Kennzeichnung gemäß dem Medizinproduktegesetz oder auf der Grundlage der Richtlinie 98/79/EG ergangenen nationalen Vorschriften anderer Vertragsparteien des Abkommens über den Europäischen Wirtschaftsraum versehen sind, jedoch vom Hersteller bisher nicht zur Eigenanwendung in Verkehr gebracht wurde, ein Sicherheits- und Leistungsniveau erreicht wird, das die Funktionstauglichkeit und die Einsatztauglichkeit für den geplanten Zweck (Eigenanwendung) gewährleistet.

Schnelltest zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2

Nr.	Genaue Bezeichnung des Medizinproduktes	Name und Anschrift des Herstellers gemäß § 2 Abs. 7 österreichisches Medizinproduktegesetz	Name und Anschrift des Bevollmächtigten gemäß § 2 Abs. 8a österreichisches Medizinproduktegesetz
1	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Lotus NL B.V.
2		Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China	Koningin Julianaplein 10, 2595AA 's-Gravenhage

Selbstverpflichtung bezüglich Inverkehrbringen von SARS-CoV-2 Schnelltests

Inverkehrbringer		Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten
Firma	Anschrift			
Inndix GmbH	Josef-Drapela-Strasse 26, A-2231 Strasshof an der Nordbahn	SGTi-flex Covid-19 Ag	Sugentech Inc. 721-26, Jeongjungyeonie-ro, Osong-eup, Heungdeok-gu Cheongju-si, Chungcheongbuk-do, 28161, Korea	MT Promedt Consulting GmbH, Altenhofstr. 80, D- 66386 St. Ingbert, Deutschland
Bridge Commerce GmbH	Lassallestraße 7a/ Unit5/Top1 , 1020 Wien	Joysbio SarS-CoV-2 Antigen Rapid Test Kit	JOYSBIO(Tianjin) Biotechnology Co., Ltd. Address : Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No. 220, Dongting Road, TEDA 300457 Tianjin China	Lotus NL B V. Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
Porod Medizintechnik GmbH	3580 Frauenhofen, Hornerstrasse 24	COVID-19-NG08 Sputum/Rachenabstrich	New Gene (Hangzhou) Bioengineering Co., Ltd. Raum 1606, Etage 16, Gebäude 5, Bin'An-Str 688, Changhe Kommune, Binjiang Viertel, Hangzhou Stadt, Zhejiang Proving, VR China	Porod Medizintechnik GmbH 3580 Frauenhofen Hornerstrasse 24
Porod Medizintechnik GmbH	3580 Frauenhofen, Hornerstrasse 24	COVID-19 NG10 Rachenabstrich	New Gene (Hangzhou) Bioengineering Co., Ltd. Raum 1606, Etage 16, Gebäude 5, Bin'An-Str 688, Changhe Kommune, Binjiang Viertel, Hangzhou Stadt, Zhejiang Proving, VR China	Porod Medizintechnik GmbH 3580 Frauenhofen Hornerstrasse 24
Porod Medizintechnik GmbH	3580 Frauenhofen, Hornerstrasse 24	Corona Antigen Schnelltest Nasenabstrich 0230005	mòLab GmbH. Dietrich-Bonhoeffer-Straße 9, 40764 Langenfeld, Deutschland	

3.France

ansm
Agence nationale de sécurité du médicament et des produits de santé

REPUBLIQUE FRANÇAISE

DIRECTION DES DISPOSITIFS MEDICAUX, DES COSMETIQUES ET DES DISPOSITIFS DE DIAGNOSTIC IN VITRO

Saint-Denis, le 26 juillet 2021

Dossier suivi par **Corine Maillard**
Tél. : +33 (0)1 55 87 31 14
E-mail : corine.maillard@ansm.sante.fr
N/Ref. : OTES

JOYSBIO (Tianjin) Biotechnology
Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220.
Dongting Road.
TEDA 300457
Tianjin
Chine
bd@joysbio.com

Objet : dérogation pour le dispositif médical de diagnostic in vitro dénommé JOYSBIO SARS-COV-2 Antigen Rapid Test Kit (home test)

PJ : Cahier des charges version du 21 juillet 2021

Monsieur,

Vous avez formulé auprès de mes services une demande de dérogation afin de pouvoir mettre sur le marché en tant qu'autotest, le dispositif médical de diagnostic in vitro (DIV) de détection antigénique du virus SARS-CoV-2 visé en objet.

Ce produit n'a pas encore satisfait aux procédures de conformité applicables aux autotests et nécessaires à l'apposition du marquage CE telles que prévues par la directive 98/79/CE du Parlement européen et du Conseil du 27 octobre 1998 relative aux dispositifs médicaux de diagnostic in vitro relative, et dont le respect doit être préalable à la mise sur le marché des dispositifs médicaux de diagnostic in vitro ; il n'est notamment pas couvert, à ce jour, par un certificat CE de conformité délivré par un organisme notifié.

L'article 9 § 12 de la directive 98/79/CE précitée me permet toutefois de vous autoriser, à titre dérogatoire et sous conditions, à mettre sur le marché des dispositifs n'ayant pas fait l'objet de ces procédures de certification, mais dont l'utilisation présente un intérêt pour la protection de la santé.

Dans ce contexte et à cet égard, l'arrêté du 26 mars 2021 modifiant l'arrêté du 10 juillet 2020 prescrivant les mesures d'organisation et de fonctionnement du système de santé nécessaires pour faire face à l'épidémie de covid-19 dans le cadre de l'état d'urgence sanitaire, prévoit notamment qu'une telle dérogation est susceptible d'être accordée pour des autotests qui n'auraient pas complété leur évaluation de conformité permettant l'apposition du marquage CE, d'une part s'ils satisfont aux critères édictés par la Haute autorité de santé (HAS), d'autre part s'ils respectent le cahier des charges publié sur le site internet du Ministère chargé de la santé et de l'Agence nationale de sécurité du médicament et des produits de santé.

4. Slovenia

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA
ZDRAVILA IN MEDICINSKE PRIPOMOČKE
Slovenčeva ulica 22
1000 Ljubljana, Slovenija

Številka: 314-3/2021-15

Datum: 14. 5. 2021

Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Slovenčeva ulica 22, 1000 Ljubljana (v nadaljevanju: JAZMP), na podlagi 25. člena Zakona o medicinskih pripomočkih (Uradni list RS, št. 98/09, v nadaljevanju: ZMedPri) v zvezi z vlogo za odobritev dajanja v uporabo medicinskih pripomočkov, za katere niso bili izvedeni postopki ugotavljanja skladnosti, v izrednih razmerah, predlagatelja Nacionalni inštitut za javno zdravje, Trubarjeva 2, 1000 Ljubljana, Slovenija (v nadaljevanju: predlagatelj), z dne 29. 4. 2021, izdaja naslednjo

ODLOČBO

1. Predlagatelju se odobri dajanje v uporabo medicinskih pripomočkov, testov SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) za vzorčenje v nosu, proizvajalca JOYSBIO (Tianjin) Biotechnology Co., Ltd., Tianjin International Joint Academy of Biotechnology&Medicine 9th floor, No.220, Dongting Road, TEDA, 300457 Tianjin, Kitajska (referenčna številka G10313), za izvajanje samotestiranja v okviru posebnega presejalnega programa za šolstvo, pod pogoji, ki so določeni v izreku te odločbe.

2. Medicinski pripomočki iz prve točke izreka se lahko dajejo v uporabo 6 mesecev od dneva pravnomočnosti te odločbe.

3. Vsaka enota pakiranja mora biti na vidnem mestu označena z napisom: »Izredno odobreno za samotestiranje, za izvajanje posebnega presejalnega programa.«

4. Predlagatelj mora v primeru prepakiranja v manjše enote pakiranja zagotoviti, da je prepakiranje izvedeno v pogojih, ki ne vplivajo na skladnost pripomočkov. Vsaka nova enota mora vsebovati podatke za identifikacijo in pravilno uporabo pripomočka, vključno z nazivom in naslovom proizvajalca in njegovega pooblaščenega predstavnika, označbo iz 3. točke izreka te odločbe, navodili za uporabo in kontaktnimi podatki predlagatelja.

5. Predlagatelj mora zagotoviti, da so pogoji skladiščenja in prevoza takšni, da ne ogrožajo skladnosti pripomočkov.

6. Predlagatelj mora voditi evidenco, ki vsebuje podatek o instituciji, ki so ji bili pripomočki dani v uporabo, količini pripomočkov, seriji oziroma partiji in času dajanja pripomočkov v uporabo.

5. Czech Republic

MINISTERSTVO ZDRAVOTNICTVÍ
Palackého náměstí 375/4, 128 01 Praha 2

Praha 20. dubna 2021
Č. j.: MZDR 16652/2021-2/OLZP

MZDRX01FMGYA

ROZHODNUTÍ

Ministerstvo zdravotnictví (dále jen „Ministerstvo") jako orgán příslušný k rozhodnutí podle ustanovení § 12 odst. 1 písm. h) zákona č. 22/1997 Sb., o technických požadavcích na výrobky a o změně a doplnění některých zákonů, ve znění pozdějších předpisů ve spojení s § 4 odst. 8 nařízení vlády č. 56/2015 Sb., o technických požadavcích na diagnostické zdravotnické prostředky in vitro (dále jen „nařízení vlády"), na základě žádosti společnosti

Pharmedex s.r.o.
se sídlem Lisabonská 799/8, 190 00 Praha 9, IČO: 27151387
(dále jen „žadatel")

rozhodlo v souladu s ustanovením § 67 a násl. zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád") tak, že

povoluje

žadateli uvést na trh a do provozu diagnostický zdravotnický prostředek in vitro **SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)**, jehož výrobcem je JOYSBIO (Tianjin) Biotechnology Co., Ltd., se sídlem Tianjin International Joint Academy of Biotechnology & Medicine, 9th floor No. 220, Dongting road, TEDA 300457 Tchien-tin, Čína, pro použití laickou osobou

a stanovuje

po dobu platnosti tohoto rozhodnutí žadateli následující povinnosti k zajištění ochrany veřejného zdraví:

- zajistit, aby konečný laický uživatel testu byl informován, že toto povolení se nevztahuje na variantu testu, která využívá nazofaryngeálního odběru vzorku
- informovat odběratele o povinnosti v rámci testování zajistit při pozitivitě antigenního testu provedeného laickou osobou bezprostřední informování poskytovatele zdravotních služeb za účelem provedení konfirmačního testu.
- v případě zájmu odběratele zajistit proškolení určené osoby.

6. Sweden

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Beslut

Enheten för Medicinteknik

Datum: 2021-06-23

Dnr: 5.2.3-2021-039511

JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of
Biotechnology& Medicine 9th floor No.220,
Dongting Road, TEDA 300457
Tianjin, P.R. China

Beträffande ansökan om dispens från kraven på procedur för bedömning av överensstämmelse gällande självtest

Beslut

JOYSBIO (Tianjin) Biotechnology Co., Ltd. ansökan om dispens från kraven på procedur för bedömning av överensstämmelse gällande produkten 'SARS-CoV-2 Antigen Rapid Test Kit (självtest)' beviljas.

Dispensen gäller som längst fram till den 31 juli 2021 eller så snart produkten CE-märkts, om så blir fallet dessförinnan.

Dispens beviljas med följande villkor:

- Tillverkaren eller den som företräder tillverkaren ska vid dispensens utgång säkerställa att försäljningen (tillhandahållandet) av produkten till slutanvändaren upphör.
- Tillverkaren eller den som företräder tillverkaren ska upplysa berörda återförsäljare om att produkten har beviljats tillfällig dispens från kraven på procedur för bedömning av överensstämmelse som innefattar anmält organs granskning (extern oberoende organisation) avseende produktens konstruktion samt upplysa om att dispensen endast gäller inom Sverige.
- Tillverkaren eller den som företräder tillverkaren ska säkerställa att produktens medföljande information (bruksanvisning, förpackning) ska vara avsedd för självtestning (användning av lekmän i hemmiljö) och vara avfattad på svenska.
- Tillverkaren eller den som företräder tillverkaren ska säkerställa att medföljande bruksanvisning innehåller rådgivande information om de åtgärder som användaren skall vidta i händelse av ett positivt, negativt eller oklart resultat.
- Tillverkaren eller den som företräder tillverkaren ska i medföljande information (bruksanvisning, förpackning) informera om sannolikheten för ett falskt positivt eller falskt negativt resultat samt övriga begränsningar gällande testets tillförlitlighet som självtest samt vilka konsekvenser begränsningarna medför för den enskilde användaren.
- Tillverkaren eller den som företräder tillverkaren ska utan fördröjning meddela

7. Germany

Impressum Administration

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests auf SARS-CoV-2 zur professionellen Anwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Schnelltests")

Los Aktionen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test ID	Handelsname	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall	Gebrauchsanweis
AT236/20	Covid-19 Antigen Schnelltest (Colloidales Gold)	Ja	Joinstar Biomedical Technology Co., Ltd	Hangzhou	CN	Lotus NL B.V.	The Hague	NL	POC (ohne Gerät)	96.10	93.9 - 99.2	99.10	95.3 - 99.5	Link öff...
AT824/21	Joinstar COVID-19 Antigen-Schnelltest Spucktest (Kolloidales Gold)	Nein	Joinstar Biomedical Technology Co.,Ltd	Hangzhou	CN	Lotus NL B.V.	The Hague	NL	POC (ohne Gerät)	96.10	90.26 - 99.92	99.00	97.68 - 99.57	Link öff...
AT359/21	COVID-19 Antigen Schnelltest (Kolloidales Gold)	Nein	JOINSTAR BIOMEDICAL TECHNOLOGY CO.,LTD	Hangzhou	CN	Lotus NL B.V.	The Hague	NL	POC (ohne Gerät)	96.10	90.28 - 98.92	99.20	97.95 - 99.78	Link öff...
AT527/20	COVID-19 Speichel Antigen Rapid Test	Ja	Joysbio Biotechnology Co. Ltd	Tianjin	CN	Lotus NL B.V.	The Hague	NL		98.10	93.9 - 99.4	100.00	98.6 - 100	Link öff...
[illegible]	SARS-CoV-2 Antigen Rapid Test Kit-PRO (Colloidal Gold) / Testkit für neuartiges Coronavirus-Antigen PRO (Kolloidale Gold-Methode)	Ja	JOYSBIO (Tianjin) Biotechnology CO., LTD	Tianjin	CN	Lotus NL B.V.	The Hague	NL	POC (ohne Gerät)	98.13	93.5 - 99.8	99.55	97.5 - 100.0	Link öff...
AT1285/21	KOL Biotechnology COVID-19 Antigen Rapid Test Kit (seit 01.08.2021: LOT NCV11 210901 / Haltbarkeit 31.08.22; LOT NCV11 211115 / Haltbarkeit 14.11.22	Nein	KOL Biotechnology (Beijing) Co., Ltd	Beijing	CN	CARETECHION GmbH	Düsseldorf	DE	POC (ohne Gerät)	98.50	97.20 - 99.60	99.50	98.80 - 100	Link öff...
[illegible]	SARS-CoV-2 Antigen Saliva Rapid Test Kit	Nein	Labnovation Technologies Inc.	Shenzhen Guangdong	CN	MedNet EC-Rep GmbH	Münster	DE	POC (ohne Gerät)	94.29	87.98 - 97.87	99.00	97.46 - 99.73	Link öff...
AT127/20	LABNOVATION SARS-CoV-2 Antigen Schnelltest	Ja	LABNOVATION TECHNOLOGIES, INC.	Guangming District Shenzhen	CN	MedNet EC-Rep GmbH	Münster	DE	POC (ohne Gerät)	98.03	95.03 - 99.46	100.00	99.54 - 100.00	Link öff...
[illegible]	LooK SPOT COVID-19 Test System	Nein	Labac Technology Inc.	Markham	CA	Obelis s.a.	Brussels	BE	POC (mit Gerät)	95.15	88.2 - 99.9	99.55	96.5 - 100	Link öff...
[illegible]	Medicovid SARS-CoV-2 AG Antigen Schnelltest SRBC-HL-1	Nein	LANGJIE Biotechnology Ltd	Xiamen, Fujian	CN	EUNGO EUROPE B.V.	Amsterdam	NL	POC (ohne Gerät)	91.71	80.11 - 94.41	99.69	98.09 - 100	

« ‹ ... 2 3 4 5 6 › » 301 - 400 von 591

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Detalhes do Produto

Nome da Empresa	WINNING TRADING IMPORTACAO E EXPORTACAO LTDA
Produto	Kit Teste Rápido Covid-19 IgG/IgM (Colloidal Gold)
Apresentação/Modelo	Kit com 20 testes
CNPJ	13.352.623/0001-75
Autorização	8.19.527-2

Tipo de Arquivo	Arquivos	Expediente, data e hora de inclusão
ROTULAGEM OU MODELO DE ROTULAGEM	ROTULAGEM.PDF	2659843/20-1 - 11/08/2020 - 07:38
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	Instruções de uso.pdf	2659843/20-1 - 11/08/2020 - 07:38

Nome Técnico	CORONAVÍRUS
Registro	81952720001
Processo	25351.535874/2020-86
Fabricante Legal	• FABRICANTE: JOYSBIO (TIANJIN) BIOTECHNOLOGY CO., LTD. - CHINA, REPÚBLICA POPULAR
Classificação de Risco	III - Classe III: produtos de alto risco ao individuo e ou médio risco à saúde pública
Vencimento do Registro	10/08/2021

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

Clinical Evaluation Report

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

Packing specification: 20 tests/box

Clinical evaluation category: Comparison with Bosphore Novel Coronavirus Detection kit produced by Anatolia Geneworks

Clinical evaluation place: Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALY.

Start date: October 5, 2020

End date: November 5, 2020

Laboratory (seal):

Application company (seal)：JOYSBIO (Tianjin) Biotechnology Co., Ltd.

Phone：-86-022-65378415

Report date: November 6, 2020

Introduction:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (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. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Detection principle:

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

Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane was coated with anti-nucleocapsid protein antibody and goat anti- chicken IgY antibody.

When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold 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. A color band will show up when antigen-conjugate is deposited at the Test “T” position and the Control “C” position on the device.

Purpose:

Evaluation the clinical performance of the SARS-CoV-2 Antigen Rapid Test Kit for accurately detection of SARS-CoV-2 antigen in human nasal swab.

Testing management:

During the trial, the main investigator is responsible for the coordination and management of the entire clinical trial, and the main participants are responsible for the main trial work. During the clinical trial, the main researcher supervises the quality control of the testing laboratory. Any problems found in the test must be contacted with the main researcher in time and appropriate measures should be taken. The final test results are statistically analyzed by the person in charge of statistics, and the main investigator confirmed and wrote the report.

Methods:

Synchronous blind test and methodological comparison design.

The nasal swab and rino oropharyngeal swab samples were collected by hospital professional medical staff in accordance with the sampling methods of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and Bosphore novel coronavirus detection kit. The nasal swab and rino oropharyngeal swab samples are blindly numbered and grouped by the Centro Diagnostico Delta S.r.l. sito editor. Nasal swab samples are divided into one group, rino oropharyngeal swab samples are divided into another group, and then tested by Centro Diagnostico Delta S.r.l. sito laboratory inspectors.

Discussion and Conclusion

Results:

In this clinical trial, nasal swab specimens were obtained from Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALIA and tested with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and the comparator device Bosphore novel coronavirus detection kit produced by Anatolia Geneworks. Statistical analysis was performed to calculate the positive agreement rate and negative agreement rate.

In this study, a total of 190 nasal swab samples were obtained for clinical performance evaluation by comparing the investigational device, the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), and reference reagent Bosphore novel coronavirus detection kit. The nasal swabs prospectively collected from individual patients who were suspected of COVID-19. No duplicate samples were selected. The sex ratio was distributed among 136 males (71.58%) and 54 females (28.42%). The age of enrolled patients ranged from 6 to 90 years. There were 112 cases with negative SARS-CoV-2 AG, accounting for 58.95% and 78 positive samples, accounting for 41.05%. In October and November 2020, 190 PCR (Bosphore novel coronavirus detection kit) samples from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALIA.

According to the consistency analysis of 190 samples, clinical study results showed that the detection sensitivity was 98.72% and the specificity was 97.32%.

Conclusion:

This clinical trial by comparing the results obtained by testing potential SARS-CoV-2 positive samples with investigational device that the SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold) devices performs as it is claimed in the clinical. The detection sensitivity for the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was 98.72%, and the specificity was 97.32%. The results showed that the investigational device, the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), meets the needs of clinical testing.

Main Content

General design

This test uses a synchronous blind test and methodological comparison design.

In order to eliminate the possible impact of the subjective biases and personal preferences of researchers on the test results during the clinical trial process, this test uses a blind test. That is, the test personnel in this test do not know the specific information of the sample, and the clinical information of the sample may not be released until the end of the test. After the samples were enrolled, the samples were coded by the blind editor authorized by the clinical trial, in which the blind editor was not involved in the test operation of the clinical trial. Testing personnel shall test the coded sample according to the reagent test specification. In the process of test operation, clinical test researchers should strictly follow the requirements of the product specification for test operation and interpretation check, and the results obtained in the test process should be truthfully recorded in the data collection table.

For the detection of SARS-CoV-2 Antigen, the nasal swab and rino oropharyngeal swab samples were collected by hospital professional medical staff in accordance with the sampling methods of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and Bosphore novel coronavirus detection kit. The nasal swab and rino oropharyngeal swab samples are blindly numbered and grouped by the Centro Diagnostico Delta S.r.l. sito editor. Nasal swab samples are divided into one group, rino oropharyngeal swab samples are divided into another group, and then tested by Centro Diagnostico Delta S.r.l. sito laboratory inspectors. Among them, there are 3 Centro Diagnostico Delta S.r.l. sito laboratory inspectors.

Measures to reduce and avoid bias

Subjects were screened strictly according to the blind grouping of the clinical trial protocol to reduce the selection bias.

Prior to the start of the trial, the sponsor trained the lab operators to correctly perform the tests and follow the trial protocol.

Clinical sample related requirements

1) DOs and DON'Ts of Sample Collection

• Do test sample immediately.

• Use only swabs provided with the kit.

2) Sample storage

- Specimen Transport and Storage
- Freshly collected specimens should be processed within 1 hour.
- It is essential that correct specimen collection and preparation methods be followed.

Clinical sample selection

1) Inclusion criteria

Sample inclusion criteria: the sample should be a sample with clearly recorded source, including different age, gender and other factors. The collection and treatment of samples are in accordance with the reagent specification or relevant regulations. Sample information should be complete, including age, sex, sample collection date, clinical diagnosis such as confirmation or exclusion of SARS-CoV-2 infection.

2) Exclusion criteria

- Samples that are unable to complete the test process human factors (sample contamination during operation).
- Samples were contaminated with bacteria or/and nosebleed.
- Samples went through too many freeze-thaw cycles.
- Samples not kept at the requirement conditions.

Quality control

Definition

Quality control is defined as the operation of techniques and activities, such as monitoring, under the quality assurance system to verify that the research quality meets the requirements. Quality control must be applied at every stage of data processing to ensure that all data is trusted and properly located.

1）Study monitoring

During the outbreak, authorized and qualified inspectors will conduct regular remote primary data checks according to the monitoring plan to verify compliance with protocols and regulations and assist investigators.

2） Laboratory quality control

The laboratory of the testing shall establish a unified test index, standard operating procedures and quality control procedures.

3）Quality control of reagent testing process

In each test, the control line shall have red strip (qualified quality control). If the control line does not have red strip (unqualified quality control), the cause shall be found out and retested until the quality control result is qualified, so as to ensure the reliability and stability of the system.

4）Qualification of researchers

The researchers participating in the clinical trial must have the specialty, qualification and ability of the clinical trial, and pass the qualification examination. The personnel requirements should be relatively fixed.

Reagents and instruments for clinical research

The information of reagents for test is shown in Table 1:

Table 1 Reagent Information

	Assessment reagent	Reference reagent
Reagent Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Bosphore Novel Coronavirus (2019-nCov) Detection Kit
Specification	20 tests/box	100 reactions/box
Company	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	Anatolia Geneworks
Lot Number	2020090804	SAG002
Expiration	2022.09.06	2021.12
Preserrvation Condition	2~30℃	< -20℃

Statistical analysis method of clinical trial data

Use SPSS16.0 statistical software or the following formula for statistical analysis.

Table 2 Consistency data analysis

Experimental Reagent Group	Reference Reagent Group		Sum
	Positive	Negative	
Positive	a	b	a+b
Negative	c	d	c+d
Sum	a+c	b+d	a+b+c+d

Sensitivity	a/(a+c)
Specificity	d/(b+d)
Accuracy	ACC/OPA=(a+d)/(a+b+c+d)*100%
Kappa	$\frac{2(ad-bc)}{(a+b)(b+d)+(a+c)(c+d)}$
95%CI	Normal approximation

Clinical Trial Results and Analysis

Overall distribution of samples

In this test, a total of 190 cases of nasal swab specimens were enrolled in the consistency comparison test of experimental reagent and reference reagent, and 0 cases of repeated samples were excluded for statistical analysis, including 112 negative samples (58.95%), 78 positive samples (41.05%).

Table 3 Proportion and number distribution of clinical trials

Sample	nasal swab specimens	
	Negative	Positive
Number of cases	112	78
Ratio	58.95%	41.05%
Number of total cases Positive	190	

Sex and age distribution of samples

A total of 190 nasal swab specimens were enrolled in the consistency comparison test of experimental reagent and reference reagent, including 136 males and 54 females.

The specific distribution of samples is shown in the following table:

Table 4 Sex and age distribution

Index	Sample type	Nasal swab specimens
Number of samples	Total	190
Sex	Male（N,%）	136 (71.58%)
	Female（N,%）	54 (28.42%)
Age（y）	X±SD	41.17±16.71
	Min-Max	6~90

Consistency analysis of test results

1) Consistency comparison of experimental reagent and reference reagent

Clinical sample stratification statistics

- **Overall Clinical Study**

In this study, 190 nasal swab specimens were obtained in the clinical performance study to compare SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) (evaluating device for antigen testing) and the Bosphore novel coronavirus detection kit (Anatolia Geneworks). The clinical performance data of the SARS-CoV-2 test results were analyzed, and 77 samples were tested positive by the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). There were 3 samples in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was positive and the Anatolia Geneworks device was negative. There was 1 sample in which the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) was negative and the reference reagent was positive. There were 109 samples with negative test results in experimental reagent and 112 samples with negative test results in reference reagent. Hence, the sensitivity and specificity were 98.72% and 97.32% respectively.

Table 5 Overall Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	77	3	80
negative	1	109	110
Subtotal	78	112	190

Positive Percent Agreement (PPA)= 77/78(98.72%) （95%CI: 93.0%~100.0%）

Negative Percent Agreement (NPA)= 109/112 (97.32%)（95%CI:92.4%~99.4%）

Accuracy=(77+109)/190×100%=97.89%

Kappa=2×（77×109-3×1）/(80 ×112+78 ×110)=0.96＞0.5

2) Test Reliability

- The collection and preservation methods of all test samples are reliable.
- The operators have received special training throughout the test process to ensure the reliability of the test results.
- When conducting clinical trials, the tests shall be conducted in strict accordance with the requirements of laboratory quality control and clinical trial program in clinical hospitals. The results were analyzed by experienced researchers to ensure the reliability of clinical trials.

3) Discussion and Conclusion

In this test, a total of 190 nasal swab specimens samples were enrolled for the consistency comparison of experimental reagent and reference reagent, and no duplicate samples were selected. The sex ratio was distributed among 136 males (71.58%) and 54 females (28.42%). The age of enrolled patients ranged from 6 to 90 years. There were 112 cases with negative SARS-CoV-2 AG, accounting for 58.95% and 78 positive samples, accounting for 41.05%. In October and November 2020, 190 PCR (Bosphore Novel Coronavirus Detection kit) samples from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALIA.

According to the consistency analysis of 190 samples, clinical study results showed that the detection sensitivity was 98.72% and the specificity was 97.32%.

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) Clinical Evaluation Report

Basic information of positive and negative samples of SARS-CoV-2, 190 cases verified by PCR (Bosphore Novel Coronavirus Detection kit) were collected in October and November 2020 from the Centro Diagnostico Delta S.r.l. sito in Piazza San Giuseppe Moscati,8-82030 Apollosa (Benevento) ITALY.

Basic information on positive samples of SARS-CoV-2

NO.	Sample ID	Gender	Age	Physiological state	Experimental reagent Assessment test results					PCR test results				
					Sample type	Collection date	Test date	test line appearan	Determination	Sample type	Collection date	Test date	Determination	CT
1	100800172	M	55	Fever > 37 ℃; Headache	nasal swab	2020/10/5	2020/10/5	< 5 min	Positive	Rino oropharyngeal swab	2020/10/5	2020/10/5	Positive	(N 19; E 21; RdRP 22)
2	100800173	M	51		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 19; E 19; RdRP 20)
3	100800174	M	50		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 21; E 21; RdRP 22)
4	100800176	F	48		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 21; E 20; RdRP 20)
5	100800180	M	24		nasal swab	2020/10/8	2020/10/8	< 5 min	Positive	Rino oropharyngeal swab	2020/10/8	2020/10/8	Positive	(N 20; E 19; RdRP 19)
6	101300042	F	44	Headache	nasal swab	2020/10/13	2020/10/13	< 8 min	Positive	Rino oropharyngeal swab	2020/10/13	2020/10/13	Positive	(N 33; E 28; RdRP 29)
7	101400211	M	87		nasal swab	2020/10/14	2020/10/14	/	Negative	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 42; E 30; RdRP 29)
8	101400267	F	60		nasal swab	2020/10/14	2020/10/14	< 5 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 20; E 21; RdRP 22)
9	101400269	M	64		nasal swab	2020/10/14	2020/10/14	< 8 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 22; E 22; RdRP 23)
10	101400398	M	20		nasal swab	2020/10/14	2020/10/14	< 5 min	Positive	Rino oropharyngeal swab	2020/10/14	2020/10/14	Positive	(N 19; E 19; RdRP 18)
11	102607178	M	57		nasal swab	2020/10/26	2020/10/26	< 5 min	Positive	Rino oropharyngeal swab	2020/10/26	2020/10/26	Positive	(N 20; E 21; RdRP 21)
12	102607263	F	24		nasal swab	2020/10/26	2020/10/26	< 5 min	Positive	Rino oropharyngeal swab	2020/10/26	2020/10/26	Positive	(N 21; E 21; RdRP 22)
13	102607262	F	32		nasal swab	2020/10/26	2020/10/26	< 8 min	Positive	Rino oropharyngeal	2020/10/26	2020/10/26	Positive	(N 31; E 27; RdRP 26)

										swab				
14	102900007	M	64		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 24; RdRP 25)
15	102900008	M	30		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 29; E 28; RdRP 29)
16	102900012	F	31		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 19; E 19; RdRP 18)
17	102900013	M	31		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 19; E 20; RdRP 20)
18	102900022	M	50		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 26; E 29; RdRP 27)
19	102900023	F	50		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 21; RdRP 22)
20	102900030	M	33		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 18; E 20; RdRP 19)
21	102900045	M	44		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 30; E 29; RdRP 29)
22	102900047	M	51		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 30; E 30; RdRP 33)
23	102900066	M	26		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 20; RdRP 20)
24	102900078	F	25		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 19; E 18; RdRP 20)
25	102900081	F	42		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 21; RdRP 22)
26	102900082	M	52		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 20; RdRP 20)
27	102900104	M	81		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 21; RdRP 22)
28	102900117	F	26		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/29	Positive	(N 21; E 21; RdRP 22)
29	102907866	M	56		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/30	Positive	(N 28; E 27; RdRP 27)
30	102900134	F	25		nasal swab	2020/10/29	2020/10/29	< 8 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/30	Positive	(N 34; E 30; RdRP 31)

31	102907891	M	35		nasal swab	2020/10/29	2020/10/29	< 5 min	Positive	Rino oropharyngeal swab	2020/10/29	2020/10/31	Positive	(N 22; E 21; RdRP 21)
32	103000014	F	36		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 21; RdRP 21)
33	103000086	F	64		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 23; E 24; RdRP 24)
34	103000087	M	70		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 20; RdRP 20)
35	103000035	M	15		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 20; E 19; RdRP 19)
36	103000094	M	52		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 19; E 19; RdRP 19)
37	103000066	M	38		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 15; E 15; RdRP 15)
38	103000115	F	74		nasal swab	2020/10/30	2020/10/30	< 10 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 27; E 26; RdRP 26)
39	103000072	F	52		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 18; E 18; RdRP 18)
40	103000081	M	20		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 24; E 30; RdRP N/A)
41	103000124	M	27		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 20; E 19; RdRP 20)
42	103000137	F	35		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 21; RdRP 21)
43	1030000210	M	68		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 21; E 20; RdRP 21)
44	103000177	M	31		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 23; E 22; RdRP 23)
45	103000172	M	40		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 31; E N/A; RdRP N/A)
46	103000220	F	42		nasal swab	2020/10/30	2020/10/30	< 5 min	Positive	Rino oropharyngeal swab	2020/10/30	2020/10/30	Positive	(N 22; E 21; RdRP 21)
47	103000343	M	20		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 22; E 21; RdRP 21)
48	103000338	M	52		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal	2020/10/31	2020/11/2	Positive	(N 20; E 21; RdRP 20)

										swab				
49	103100016	M	57		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 18; E 18; RdRP 17)
50	103000316	M	57		nasal swab	2020/10/30	2020/10/31	< 8 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 24; E N/A; RdRP N/A)
51	103100005	M	55		nasal swab	2020/10/30	2020/10/31	< 8 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 24; E 25; RdRP 27)
52	103100008	F	22		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 21; E 22; RdRP 21)
53	103000311	M	90		nasal swab	2020/10/30	2020/10/31	< 5 min	Positive	Rino oropharyngeal swab	2020/10/31	2020/11/2	Positive	(N 23; E 24; RdRP 28)
54	110200121	F	25		nasal swab	2020/11/2	2020/11/2		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/3	Positive	(N 23; E 23; RdRP 22)
55	110200070	F	42		nasal swab	2020/11/2	2020/11/2		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/3	Positive	(N 24; E 24; RdRP 23)
56	110200099	F	63		nasal swab	2020/11/2	2020/11/2		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/3	Positive	(N 25; E 26; RdRP 25)
57	110200095	M	64		nasal swab	2020/11/2	2020/11/2		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/3	Positive	(N 21; E 18; RdRP 17)
58	110300071	F	57		nasal swab	2020/11/3	2020/11/3		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/4	Positive	(N 17; E 18; RdRP 40)
59	110300076	F	56		nasal swab	2020/11/3	2020/11/3		Positive	Rino oropharyngeal swab	2020/11/3	2020/11/4	Positive	(N 25; E 27; RdRP 26)
60	110400027	M	64		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 19; E 19; RdRP 19)
61	110400039	M	68		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 18; E 19; RdRP 17)
62	110400040	F	49		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 22; E 25; RdRP 23)
63	110400044	F	70		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 23; E 22; RdRP 21)
64	110400006	M	17		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 23; E 24; RdRP 22)
65	110400023	M	50		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 26; E 26; RdRP 25)

66	110400043	M	29		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 23; E 24; RdRP 23)
67	110400076	M	56		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 19; E 19; RdRP 19)
68	110400089	M	58		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 20; E 20; RdRP 19)
69	110400086	M	46		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 20; E 19; RdRP 18)
70	110400088	F	51		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/4	2020/11/4	Positive	(N 19; E 20; RdRP 18)
71	110400143	M	62		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 24; E 26; RdRP 24)
72	110400184	M	53		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 20; E 22; RdRP 21)
73	110400205	F	55		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 24; E 26; RdRP 24)
74	110400180	F	26		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 34; E N/A; RdRP N/A)
75	110400181	M	58		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 19; E 19; RdRP 18)
76	110400188	M	68		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 25; E 29; RdRP 26)
77	110400144	M	24		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 32; E N/A; RdRP N/A)
78	110400142	M	28		nasal swab	2020/11/4	2020/11/4		Positive	Rino oropharyngeal swab	2020/11/5	2020/11/5	Positive	(N 31; E N/A; RdRP N/A)

Basic information on negative samples of SARS-CoV-2 AG

NO.	Sample ID	Gender	Age	Physiological state	Experimental reagent Assessment test results					PCR test results				
					Sample type	Collection date	Test date	test line appearan	Determination	Sample type	Collection date	Test date	Determination	CT
1	100800171	F	22		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A
2	100800179	F	59		nasal swab	2020/10/8	2020/10/8	< 12 min	Positive	rino oropharyngeal	2020/10/8	2020/10/8	Negative	N/A

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										swab				
3	100800175	M	54		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A
4	100800178	F	51		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A
5	100800080	F	31		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A
6	100800080	F	31		nasal swab	2020/10/8	2020/10/8		Negative	rino oropharyngeal swab	2020/10/8	2020/10/8	Negative	N/A
7	101200189	M	87		nasal swab	2020/10/12	2020/10/12		Negative	rino oropharyngeal swab	2020/10/12	2020/10/12	Negative	N/A
8	101200192	M	45		nasal swab	2020/10/12	2020/10/12		Negative	rino oropharyngeal swab	2020/10/12	2020/10/12	Negative	N/A
9	101200194	F	41		nasal swab	2020/10/12	2020/10/12		Negative	rino oropharyngeal swab	2020/10/12	2020/10/12	Negative	N/A
10	101200195	F	70		nasal swab	2020/10/12	2020/10/12		Negative	rino oropharyngeal swab	2020/10/12	2020/10/12	Negative	N/A
11	101400215	F	83		nasal swab	2020/10/14	2020/10/14		Negative	rino oropharyngeal swab	2020/10/14	2020/10/14	Negative	N/A
12	101400213	M	51		nasal swab	2020/10/14	2020/10/14		Negative	rino oropharyngeal swab	2020/10/14	2020/10/14	Negative	N/A
13	101400271	M	30		nasal swab	2020/10/14	2020/10/14		Negative	rino oropharyngeal swab	2020/10/14	2020/10/14	Negative	N/A
14	101400265	F	31		nasal swab	2020/10/14	2020/10/14		Negative	rino oropharyngeal swab	2020/10/14	2020/10/14	Negative	N/A
15	100900322	F	24		nasal swab	2020/10/14	2020/10/14		Negative	rino oropharyngeal swab	2020/10/14	2020/10/14	Negative	N/A
16	101500288	M	38		nasal swab	2020/10/15	2020/10/15		Negative	rino oropharyngeal swab	2020/10/15	2020/10/15	Negative	N/A
17	103000079	M	79		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
18	103000022	F	42		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
19	103000113	M	28		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A

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20	103000078	F	76		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
21	103000069	M	69		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
22	103000112	F	26		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
23	103000027	M	41		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
24	103000001	M	22		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
25	103000002	M	36		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
26	103000021	F	15		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
27	103000114	F	49		nasal swab	2020/10/30	2020/10/30	< 8 min	Positive	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
28	1030000420	F	31		nasal swab	2020/10/29	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
29	1030000423	M	58		nasal swab	2020/10/29	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
30	103000139	M	39		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
31	103000119	M	31		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
32	103000132	M	6		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
33	103000133	F	50		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
34	103000193	M	19		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
35	103000277	M	48		nasal swab	2020/10/30	2020/10/30		-	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
36	103000274	F	29		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal swab	2020/10/30	2020/10/30	Negative	N/A
37	103000276	F	63		nasal swab	2020/10/30	2020/10/30		Negative	rino oropharyngeal	2020/10/15		Negative	N/A

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										swab				
38	103000339	F	24		nasal swab	2020/10/30	2020/10/31	< 8 min	Positive	rino oropharyngeal swab	2020/10/31	2020/11/2	Negative	N/A
39	110200001	M	59		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
40	110200002	F	56		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
41	110200004	M	30		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
42	110200028	F	34		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
43	110200051	F	49		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
44	110200062	M	25		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
45	110200043	M	49		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
46	110200045	M	47		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
47	110200044	F	45		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/2	2020/11/2	Negative	N/A
48	110200101	M	38		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/3	2020/11/3	Negative	N/A
49	110200100	F	33		nasal swab	2020/11/2	2020/11/2		Negative	rino oropharyngeal swab	2020/11/3	2020/11/3	Negative	N/A
50	110300066	F	24		nasal swab	2020/11/3	2020/11/3		Negative	rino oropharyngeal swab	2020/11/3	2020/11/3	Negative	N/A
51	110300005	M	28		nasal swab	2020/11/3	2020/11/3		Negative	rino oropharyngeal swab	2020/11/3	2020/11/3	Negative	N/A
52	110300065	M	25		nasal swab	2020/11/3	2020/11/3		Negative	rino oropharyngeal swab	2020/11/3	2020/11/3	Negative	N/A
53	110300082	M	30		nasal swab	2020/11/3	2020/11/3		Negative	rino oropharyngeal swab	2020/11/3	2020/11/4	Negative	N/A
54	110400036	M	28		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/4	2020/11/4	Negative	N/A

55	110400016	M	33		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/4	2020/11/4	Negative	N/A
56	110400058	M	69		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/4	2020/11/4	Negative	N/A
57	110500084	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
58	110500037	M	28		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
59	110500090	M	42		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
60	110500137	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
61	110500094	M	38		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
62	110500131	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
63	110500023	M	24		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
64	110500093	M	40		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
65	110500019	M	50		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
66	110500117	M	29		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
67	110500108	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
68	110500091	M	31		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
69	110500097	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
70	110500127	M	65		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
71	110500110	M	28		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
72	110500095	M	51		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal	2020/11/5	2020/11/5	Negative	N/A

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										swab				
73	110500122	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
74	110500038	M	39		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
75	110500107	M	19		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
76	110500105	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
77	110500103	M	29		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
78	110500136	M	21		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
79	110500018	M	47		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
80	110500132	M	32		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
81	110500112	M	40		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
82	110500133	M	34		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
83	110500120	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
84	110500114	M	26		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
85	110500096	M	47		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
86	110500109	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
87	110500086	M	39		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
88	110500135	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
89	110500088	M	29		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A

90	110500116	M	30		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
91	110500099	M	17		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
92	110500130	M	38		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
93	110500113	M	32		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
94	110500100	M	18		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
95	110500119	M	24		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
96	110500118	M	24		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
97	110500159	M	35		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
98	110500087	M	43		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
99	110500104	M	19		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
100	110500017	M	45		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
101	110500092	M	56		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
102	110500085	M	47		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
103	110500106	M	19		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
104	110500022	M	45		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
105	110500115	M	33		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
106	110500129	M	33		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
107	110500021	M	27		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal	2020/11/5	2020/11/5	Negative	N/A

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										swab				
108	110500024	M	48		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
109	110500121	M	24		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
110	110500134	M	43		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
111	110500102	M	34		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A
112	110500111	M	31		nasal swab	2020/11/4	2020/11/4		Negative	rino oropharyngeal swab	2020/11/5	2020/11/5	Negative	N/A

FIND Evaluation of Joysbio (Tianjin) Biotechnology Co., Ltd. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) External Report

Version 1.0, 11 February 2021

Copyright and use of the report

Evaluation process – private sector engagement

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. It works closely with the private and public sectors and receives funding from donors and some of its industry partners. It has internal fire walls, policies and processes to protect it against any undue influence in its work or the publication of its findings.

More information on our policy and guidelines for working with private sector partners can be found here: https://www.finddx.org/policies/

For the COVID-19 response, FIND has commissioned independent evaluations of in vitro diagnostics following an Expression of Interest (EOI) process available on FIND's website by which all test submissions were scored according to their regulatory status and time to market; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

Document history

Document version	Date	Comment
1.0	11 February 2021	Initial version

1 Product info

Manufacturer name	Joysbio (Tianjin) Biotechnology Co., Ltd.
Test name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
Product code(s)	COV-AG-20/G10313
Pack size(s)	20 tests / kit – version used
Contents of kit	Test device, desiccant, buffer, extraction tube, specimen sampling swabs
Equipment and consumables required, but not provided	Positive and negative control swab (optional) PPE, Timer, Biohazard container
Product storage (temp. range)	2-30°C
Shelf-life (months)	24 months
Manufacturing site (country)	China

2 Study details

Study design:	Prospective diagnostic evaluation studies across multiple, independent sites to determine the accuracy of COVID-19 antigen RDTs, using consecutive enrolment. Interim analyses are performed at 25% and 50% enrolment, and the evaluation is stopped if tests do not meet 95% specificity. Presence of symptoms, date of symptom onset and hospitalization status is collected for all enrolled participants.
Index assays:	Novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens.
Reference method:	Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management
Limit of detection:	Verification of analytical sensitivity, i.e. Limit of detection, was performed at the Liverpool School of Tropical Medicine in which standardized serial dilutions of cultured viral isolate were prepared. Proprietary swab provided in the kit was soaked in viral dilution series. Dilutions were tested in triplicate and the LOD was defined as the last dilution where all repeats were interpreted as positive.
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by Joysbio SARS-CoV-2 Antigen Rapid Test among all positives by the reference method and reported as a percentage. Specificity was calculated as the proportion of true negative specimens, identified as negative by Joysbio SARS-CoV-2 Antigen Rapid Test

	among all negatives by the reference method, and reported as a percentage. The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson's score method.
Ease of use	A System usability survey and ease of use questionnaire assessing the quality of the test, test preparation, ease of test execution, procedure time, ease of result interpretation, storage conditions and perceived settings of use was completed by operators and a final score out of 100 was calculated.

3 Evaluation details

Country of collaborator	**Switzerland**
Location of clinical site(s) (city, town)	University Hospital of Geneva
Health care level of site(s)	Community Testing Clinic
Study period (date to date)	4-13 January 2021
Study cohort inclusion/exclusion	Adults in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care. Provided informed consent
Sample type, antigen test	Anterior Nares (AN, Nasal) swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc) (n=216) Xpert Xpress SARS-CoV-2 (Cepheid) (n=1) TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument) (n=48)
Sample type, PCR test	Nasopharyngeal swab

4 Results

4.1 Study Cohort

Country	**Switzerland**
Total N (valid PCR results)	265

Age [mean (min-max), N]	36.3 (16-80), 265
Gender [%F, (n/N)]	47.5%, (265/265)
Symptoms present[1] [%Yes, (n/N)]	88.6%, (39/44)
Hospitalized (n, % Yes)	Not available
Days from symptom onset[1] [median (Q1-Q3); N]	2 (1-3.5); 31
Days < 0-3 (n, %)	23, 74%
Days 4-7 (n, %)	8, 26%
Days 8+ (n, %)	0, 0%
Positivity [%, (n/N)]	17%, (44/265)
PCR Ct [median (Q1-Q3); N]	26.6 (22.3-30); 44
Ct > 33 (n, %)	6, 14%
Ct > 30 (n, %)	10, 23%
Ct > 25 (n, %)	21, 48%

[1]*Note: data on symptom onset only available for individuals who tested PCR positive.*

4.2 Estimation of clinical performance

Country	**Switzerland**
Clinical Sensitivity (95% CI), N	70.5% (55.8, 81.8), 44
Sensitivity days ≤7, N	74.2% (56.8, 86.3), 31
Sensitivity Ct ≤ 33, N	78.9% (63.7, 88.9), 38
Sensitivity Ct ≤ 25, N	91.3% (73.2, 97.6), 23
Clinical Specificity (95% CI), N	99.1% (96.8, 99.8), 221
Invalid rate (%, n/N)	0%, 0/265

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**1.0 x 10^2 pfu/ml** ~ 1.42 x 10^2 $TCID_{50}$/ml	**1.0 x 10^2** pfu/ml	**2.18 x10^5 copies/ml** applied to test	1.6 x 10^2 $TCID_{50}$/ml ~ 1.12 x 10^2 **pfu/ml**

Note: viral dilution was applied directly to the test cassette, not to the provided swab.

4.3 Ease of use

Joysbio	[TBC] out of 100	TBC operators, Switzerland

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Ministrstvo za zdravje Republike Slovenije
Štefanova 5
1000 Ljubljana

Številka: 6000/051/2021
Datum: 26.4.2021

POROČILO O VERIFIKACIJI HITREGA ANTIGENSKEGA TESTA PROIZVAJALCA JOYSBIO (TIANJIN) BIOTECHNOLOGY Co., LTD.

Uvod

Po navodilu Ministrstva za zdravje Republike Slovenije (v nadaljevanju MZ) z dne, 2. 4. 2021 smo v Nacionalnem laboratoriju za zdravje, okolje in hrano pristopili k verifikaciji testa SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) proizvajalca Joysbio (Tianjin) Biotechnology Co., Ltd. Test je MZ nabavilo v okviru enotnega postopka javnega naročanja na nivoju Evropske unije. Ker test temelji na analizi brisa odvzetega iz sprednjega dela nosu, je bil sprožen postopek za ugotavljanje primernosti testa za namen samotestiranja določenih skupin prebivalcev Slovenije na okužbo z virusom SARS-CoV-2.

Temelj mikrobiološke diagnostike bolezni COVID-19 je dokazovanje ribonukleinske kisline virusa SARS-CoV-2 z metodo RT-PCR po ekstrakciji nukleinske kisline in reverzni transkripciji (v nadaljevanju PCR), ki se uporablja kot »zlati standard« pri oceni drugih metod. Zaradi različnih, zlasti logističnih razlogov, uporaba PCR ni vedno možna.

Hitri antigenski testi za dokazovanje antigenov SARS-CoV-2 (v nadaljevanju HAT) so dopolnilo PCR. So cenejši, čas izvedbe je krajši (do 30 minut), lahko ga izvaja osebje brez predhodne temeljite laboratorijske izobrazbe, praviloma se izvajajo ob preiskovancu. Izkušnje nekaterih držav kažejo, da je teste mogoče uporabiti tudi na način, ko preiskovanec sam sebi odvzame vzorec, sam izvede test in odčita rezultat. S primerno frekvenco testiranja je do določene mere mogoče nadomesti manjšo občutljivost detekcije povzročitelja, ki nastane zaradi uporabe hitrega antigenskega testa namesto RT-PCR metode, odvzema brisa sprednjega dela nosu namesto brisa nosnožrelnega prostora, samoodvzema vzorca namesto odvzema s strani usposobljene osebe in izvedbe hitrega antigenskega testa s strani laika namesto s strani usposobljenega zdravstvenega delavca.

Nacionalni laboratorij za zdravje, okolje in hrano (v nadaljevanju NLZOH) je v skladu z navodilom MZ nemudoma pristopil k izdelavi verifikacijskega protokola in vloge za oceno etične sprejemljivosti. Dne 12. 4. 2021 smo Komisiji Republike Slovenije za medicinsko etiko oddali vlogo za pridobitev soglasja Komisije k protokolu verifikacije. Komisija ga je prejela in na dopisni seji obravnavala 13. 4. 2021. Ocenila ga je kot etično

sprejemljivega. Na podlagi dopisa št. 0120-177/2021-7 z dne 13. 4. 2021 smo v NLZOH pristopili k izvajanju verifikacije po protokolu.

Opredelitev problema

Hitri antigenski test, ki je bil izbran s postopkom javnega naročanja na nivoju EU, ima CE in IVD oznako. Da je test pridobil CE oznako, je bila po navedbah proizvajalca opravljena klinična validacija s strani Centro Diagnostico Delta S.r.l., Apollosa (Benevento), Italija, kjer je bil kot testni vzorec uporabljen bris nosnožrelnega prostora, in neodvisna verifikacija s strani University Hospital of Geneva v Švici, kjer je bil kot vzorec uporabljen bris prednjega dela nosu.

Proizvajalec tako navaja 98,13 % občutljivost in 99,22 % specifičnost testa, s čimer je test glede analitskih sposobnosti zadostil razpisnim pogojem v postopku javnega naročanja, nacionalnim priporočilom za uporabo HAT (> 95 % občutljivost in >98 % specifičnost po podatkih v navodilu proizvajalca) in priporočilom Svetovne zdravstvene organizacije (> 80 % občutljivost in > 97 % specifičnost).

Hitri antigenski test, ki je predmet verifikacije, sodi v skupino imunokromatografskih testov, ki temeljijo na reakciji protitelesa, ki je vezano na testno polje, in za virus specifičnega antigena, ki se nahaja v vzorcu. Reakcija je sposobna zaznati le toliko virusnih sestavin/kopij, kot jih je vzorcu. Običajno je potrebnih več kot milijon kopij virusa, da bo HAT pozitiven.

PCR metoda pa omogoča, da se v reakciji iskana tarča pomnoži. Skozi cca 40 ciklov pomnoževanja se v vsakem ciklu število kopij tarče podvoji, kar omogoča, da lahko pozitivno reakcijo daje že 100 kopij virusa. Koncentracijo virusa v vzorcu lahko približno ocenimo s pomočjo Ct vrednostji pozitivnega vzorca. Ct vrednost je številka cikla, pri katerem se tarča pomnoži do te mere, da je merjeni signal presegel prag, ki loči negativno od pozitivne reakcije. Ct vrednosti med različnimi PCR testi niso povsem primerljive zaradi številnih tehničnih razlogov. Kljub temu približna korelacija obstaja: nižja kot je Ct vrednost, večja je koncentracija virusa v vzorcu.

Povsem razumljivo je torej, da HAT bolj uspešno odkriva okužene med tistimi preiskovanci, pri katerih se je virus namnožil do visokih koncentracij in je izračunana občutljivost testa posledično odvisna od strukture populacije preiskovancev.

Namen verifikacije testa Antigen SARS-CoV-2 Test Kit proizvajalca Joysbio (Tianjin) Biotechnology Co., je oceniti učinkovitost hitrega antigenskega testa (HAT) za antero-nasalne brise z namenom samotestiranja oseb na okužbo SARS-CoV-2 v primerjavi z metodo RT-PCR, pri čemer so si preiskovanci bris sprednjega dela nosu odvzeli sami pod nadzorom zdravstvenega delavca.

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Protokol verifikacije

Za izvedbo verifikacije smo v NLZOH sledili protokolu, ki ga priporoča SZO in so rezultati neodvisnih verifikacij, izvedenih po tem protokolu, objavljeni na naslednji povezavi: https://www.finddx.org/covid-19/pipeline/.

Podatki o hitrem antigenskem testu, ki je predmet verifikacije

IME PROIZVAJALCA	Joysbio (Tianjin) Biotechnology Co., Ltd.
IME TESTA	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
KODA PRODUKTA	COV-AG-20/G10313
VELIKOST PAKIRANJA	20 testov
VSEBINA PAKIRANJA	Testne ploščice, pozitivna in negativna kontrola, ekstrakcijska tekočina v plastičnih epruvetkah (cca 300µl), brisi za odvzem vzorca, navodilo proizvajalca v slovenskem jeziku
DODATNI MATERIAL	Brisi za odvzem vzorca iz nosnožrelnega prostora
POGOJI HRANJENJA	2 do 30°C
ROK UPORABNOSTI	24 mesecev
DRŽAVA PROIZVODNJE	Kitajska

Podatki o protokolu verifikacije

VRSTA ŠTUDIJE	Prospektivna, kohortna; poteka na večih neodvisnih mestih vzorčenja, kjer se v študijo preiskovanci vključujejo zaporedno glede na podano soglasje o sodelovanju
NAMEN ŠTUDIJE	Preveriti učinkovitost hitrega antigenskega testa (HAT) za antero-nasalne brise z namenom samotestiranja oseb na okužbo SARS-CoV-2 v primerjavi vzorcem odvzetim iz nosnožrelnega prostora

	analiziranega z RT-PCR
TRAJANJE VERIFIKACIJE	Od 14. 4. 2021 do 26.4. 2021
PODSKUPINE PREISKOVANCEV	1. Brezsimptomni preiskovanci a. Celotna skupina b. Preiskovanci s Ct vrednostjo pod 25 in pod 30 2. Simptomatski preiskovanci a. Razvrstitev v skupine glede na naslednje kriterije: i. Trajanje bolezenskih znakov 0-3 dni, ii. Trajanje bolezenskih znakov 4-7 dni, iii. Trajanje bolezenskih znakov 8 ali več dni, iv. Ct vrednost pod ali enaka 30, v. Ct vrednost pod ali enaka 25 3. Skupina otrok a. Celotna skupina b. Simptomatski
VRSTA ZBRANIH PODATKOV PRI PREISKOVANCIH	Podatki o prisotnosti/odsotnosti in vrsti bolezenskih znakov, podatki o trajanju bolezenskih znakov, o starosti, spolu.
FORMAT VERIFICIRANEGA HAT	Imunokromatografski test, ki poteka po principu lateralnega toka, kot detekcijski reagent je na protitelesa vezano koloidno zlato.
REFERENČNA RT-PCR METODA	Metoda PCR v realnem času po reverzni transkripciji Allplex 2019-nCoV, proizvajalca Seegene Inc., Južna Koreja
MESTA ODVZEMOV VZORCEV	1. Nacionalni laboratorij za zdravje, okolje in hrano, lokacija Maribor 2. Univerzitetni klinični center Ljubljana 3. Univerzitetni klinični center Maribor 4. Vstopna točka Zdravstvenega doma Kranj 5. Vstopna točka Zdravstvenega doma Maribor

Način izračuna

Občutljivost in specifičnost testa izračunamo iz podatkov o številu preiskovancev predstavljenih v vzorčni tabeli.

Občutljivost izražena v odstotkih se izračuna po naslednji formuli: (A/E) x 100.

Občutljivost HAT pove, kolikšen delež s RT-PCR pozitivnih vzorcev je s HAT pozitiven.

Specifičnost izražena v odstotkih se izračuna po naslednji formuli: (D/F) x 100.

Specifičnost HAT pove, kolikšen delež s RT-PCR negativnih vzorcev je s HAT negativen.

Rezultati bodo podani s 95 % intervalom zaupanja.

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	A	B	G
	Negativen	C	D	H
Skupaj		E	F	I

Legenda:

A – pravilno pozitiven rezultat HAT

B – lažno pozitiven rezultat HAT

C – lažno negativen rezultat HAT

D – pravilno negativen rezultat HAT

Rezultati in ugotovitve

V obdobju od 14. 4. 2021 do 26. 4. 2021 smo zbrali in analizirali 986 vzorcev pri 493 preiskovancih. Od tega smo 493 vzorcev nosnožrelnega prostora analizirali z metodo RT-PCR in 493 vzorcev iz sprednjega dela nosu pa s HAT. Med preiskovanci je bilo 348 preiskovancev, ki so navajali bolezenske znake in 145 preiskovancev brez bolezenskih znakov. V raziskavo je bilo vključenih tudi 40 otrok, med njimi jih je 20 kazalo bolezenske znake. Iz raziskave smo 9 simptomatskih preiskovancev izključili zaradi mejnih vrednosti rezultata RT-PCR metode.

V Tabeli 1 prikazujemo skladnost rezultatov med HAT iz brisa sprednjega dela nosu in RT-PCR iz brisa nosnožrelnega prostora pri 348 simptomatskih preiskovancih.

Tabela 1: Skladnost rezultatov med HAT in RT-PCR v skupini simptomatskih preiskovancev

Metoda		**RT-PCR**		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	115	1	116
	Negativen	51	172	223
Skupaj		166	173	339

Občutljivost HAT v celotni skupini simptomatskih preiskovancev je **69,28** % (95 % CI 60,85-77,71 %) in specifičnost **99,42** % (95 % CI 98,28-100 %).

Med 166 simptomatskimi RT-PCR pozitivnimi preiskovanci je 143 takšnih, pri katerih so bile Ct vrednosti pod 30 in 121 takšnih, pri katerih so bile Ct vrednosti pod 25. V skupini 143 preiskovancev je bilo s HAT iz sprednjega dela nosu 113 pozitivnih, kar pomeni **79,02** % občutljivost HAT in v skupini 121 preiskovancev 105 pozitivnih iz brisa sprednjega dela nosu, kar pomeni **86,77** % občutljivost HAT.

Nadalje je bilo med 118 simptomatskimi RT-PCR pozitivnimi preiskovanci, ki so kazali bolezenske znake od 0 do 7 dni in so imeli Ct vrednosti pod 30 in 105 pozitivnih iz brisa sprednjega dela nosu, kar pomeni **88,98** % občutljivost HAT. Med 111 simptomatskimi RT-PCR pozitivnimi preiskovanci, ki so kazali bolezenske znake od 0 do 7 dni in so imeli Ct vrednosti pod 25 pa je bilo 100 pozitivnih iz brisa sprednjega dela nosu, kar pomeni **90,09** % občutljivost HAT.

V Tabeli 2 prikazujemo skladnost rezultatov med HAT iz brisa sprednjega dela nosu in RT-PCR iz brisa nosnožrelnega prostora pri 202 simptomatskih preiskovancih, pri

katerih so se bolezenski znaki pojavili isti dan ali največ tretji dan pred odvzemom vzorcev.

Tabela 2: Skladnost rezultatov med HAT in RT-PCR v skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov od 0 do 3 dni

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	86	0	86
	Negativen	9	107	116
Skupaj		95	107	202

Občutljivost HAT skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov od 0 do 3 dni je **90,53** % (95 % CI 84,34-96,72 %) in specifičnost **100** %.

V Tabeli 3 prikazujemo skladnost rezultatov med HAT iz brisa sprednjega dela nosu in RT-PCR iz brisa nosnožrelnega prostora pri 64 simptomatskih preiskovancih, pri katerih so bolezenski znaki trajali 4 do 7 dni pred odvzemom vzorcev.

Tabela 3: Skladnost rezultatov med HAT in RT-PCR v skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov od 4 do 7 dni

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	21	0	21
	Negativen	8	35	43
Skupaj		29	35	64

Občutljivost HAT skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov od 4 do 7 dni je **72,41** % (95 % CI 53,3 -91,53 %) in specifičnost **100** %.

V Tabeli 4 prikazujemo skladnost rezultatov med HAT iz brisa sprednjega dela nosu in RT-PCR iz brisa nosnožrelnega prostora pri 63 simptomatskih preiskovancih, pri katerih so bolezenski znaki trajali 8 dni in več.

Tabela 4: Skladnost rezultatov med HAT in RT-PCR v skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov 8 dni in več

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	11	1	12
	Negativen	32	19	51
Skupaj		43	20	63

Občutljivost HAT skupini simptomatskih preiskovancev s trajanjem bolezenskih znakov od 8 dni in več je **25,58** % (95 % CI -0,2-51,36 %) in specifičnost **95,00** % (95 % CI 85,2-100 %).

V Tabeli 5 prikazujemo skladnost rezultatov med HAT iz sprednjega dela nosu in RT-PCR iz nosnožrelnega prostora v skupini 145 brezsimptomnih preiskovancev.

Tabela 5: Skladnost rezultatov med HAT in RT-PCR v skupini brezsiptomnih preiskovancev

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	13	0	13
	Negativen	5	127	132
Skupaj		18	127	145

Občutljivost HAT v celotni skupini brezsimptomnih preiskovancev je **72,22** % (95 % CI 47,88-96,57 %) in specifičnost **100** %.

Med 18 RT-PCR pozitivnimi brezsimptomnimi preiskovanci smo pri 15 preiskovancih zabeležili Ct vrednosti pod 30. Pri 12 preiskovancih je bil HAT iz sprednjega dela nosu pozitiven, kar pomeni **80,00** % občutljivost. Pri 12 RT-PCR pozitivnih preiskovancih s Ct vrednostmi pod 25 je bilo 10 pozitivnih iz brisa sprednjega dela nosu, kar pomeni **83,33** % občutljivost HAT.

V Tabeli 6 prikazujemo skladnost rezultatov med HAT iz sprednjega dela nosu in RT-PCR iz nosnožrelnega prostora v celotni skupini 40 otrok.

Tabela 6: Skladnost rezultatov med HAT in RT-PCR v celotni skupini otrok

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	10	0	10
	Negativen	1	29	30
Skupaj		11	29	40

Občutljivost HAT v celotni skupini otrok je **90,91** % (95 % CI 73,09-100 %) in specifičnost **100** %.

V Tabeli 7 prikazujemo skladnost rezultatov med HAT iz sprednjega dela nosu in RT-PCR iz nosnožrelnega prostora v skupini simptomatskih otrok.

Tabela 7: Skladnost rezultatov med HAT in RT-PCR v simptomatski skupini otrok

Metoda		RT-PCR		Skupaj
HAT	Rezultat	Pozitiven	Negativen	
	Pozitiven	8	0	8
	Negativen	1	11	12
Skupaj		9	11	20

Občutljivost HAT v celotni skupini otrok je **88,89** % (95 % 67,09-100 %) in specifičnost **100** %.

Med 20 brezsimptomnimi otroci sta bila RT-PCR pozitivna dva. Pri obeh je bil pozitiven tudi HAT iz sprednjega dela nosu.

Kot je razvidno iz rezultatov je občutljivost pričakovano najvišja v skupini simptomatskih PCR pozitivnih preiskovancev, ki imajo nizke Ct vrednosti.

Meji 25. in 30. cikla smo izbrali skladno s priporočenim protokolom SZO in glede na nekatera stališča, da je malo verjetno, da bi oseba s takšnim PCR rezultatom še izločala infektivne virusne delce.

Zaključki

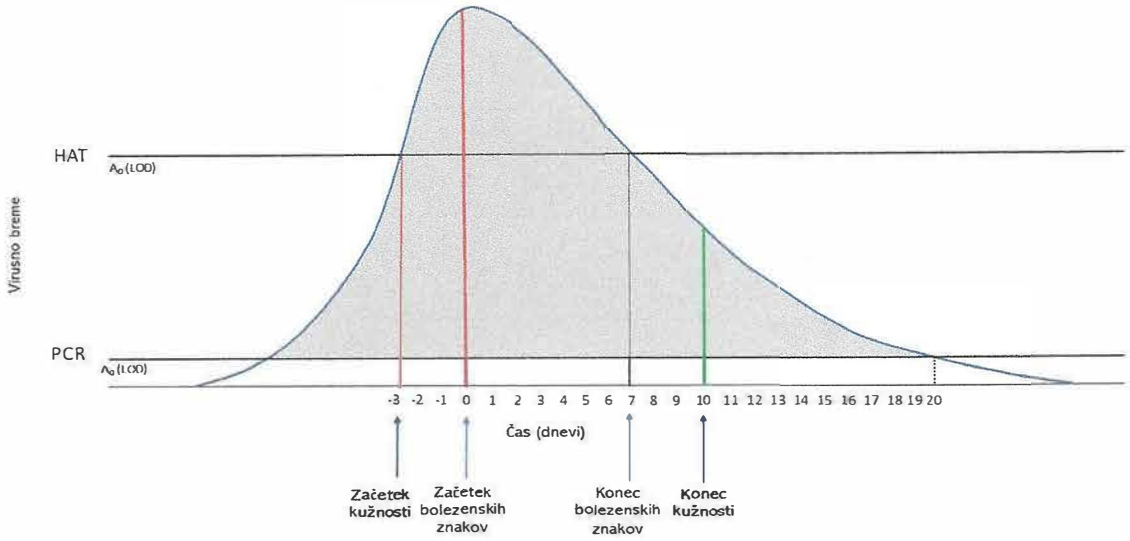
Rezultati verifikacije so pokazali da:

1. Test ne dosega specifikacij proizvajalca glede občutljivosti v nobeni skupini preiskovancev, glede specifičnosti pa v vseh skupinah preiskovancev, vendar je potrebno izrecno poudariti, da navedbe proizvajalca temeljijo na primerjavi rezultatov med RT-PCR iz brisa nosnožrelnega prostora in HAT iz brisa nosno žrelnega prostora in zato rezultati niso neposredno primerljivi.
2. Test zadošča kriterijem nacionalnih smernic za uporabo HAT, ko gre za rezultate neodvisnih verifikacij glede občutljivosti v skupini preiskovancev s Ct vrednostmi do 25, v skupini preiskovancev, ki so kazali bolezenske znake od 0 do 3 dni ter v celotni skupini otrok. Glede specifičnosti odstopa le v skupini simptomatskih, ki so kazali bolezenske znake 8 dni ali več.

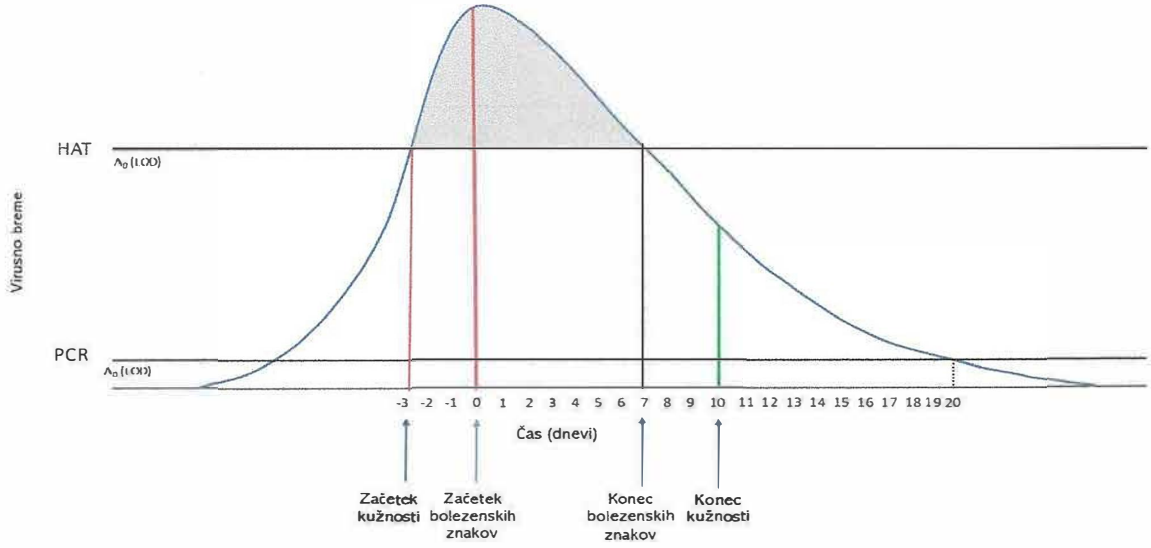
Da test dosega največjo občutljivost in se izračunana vrednost najbolj približa specifikaciji proizvajalca v skupini simptomatskih preiskovancev, pri katerih so Ct vrednosti v PCR nižje, je pričakovan rezultat, saj so to preiskovanci z najvišjim virusnim bremenom.

Za boljšo ponazoritev vloge posameznih testov v odkrivanju okuženih z virusom SARS-CoV-2 prikazujemo grafe od 1 do 3. Poudarjamo, da je prikaz shematski in površine pod krivuljo virusnega bremena le približno odražajo dejanski obseg pozitivnih bodisi s HAT, bodisi z RT-PCR.

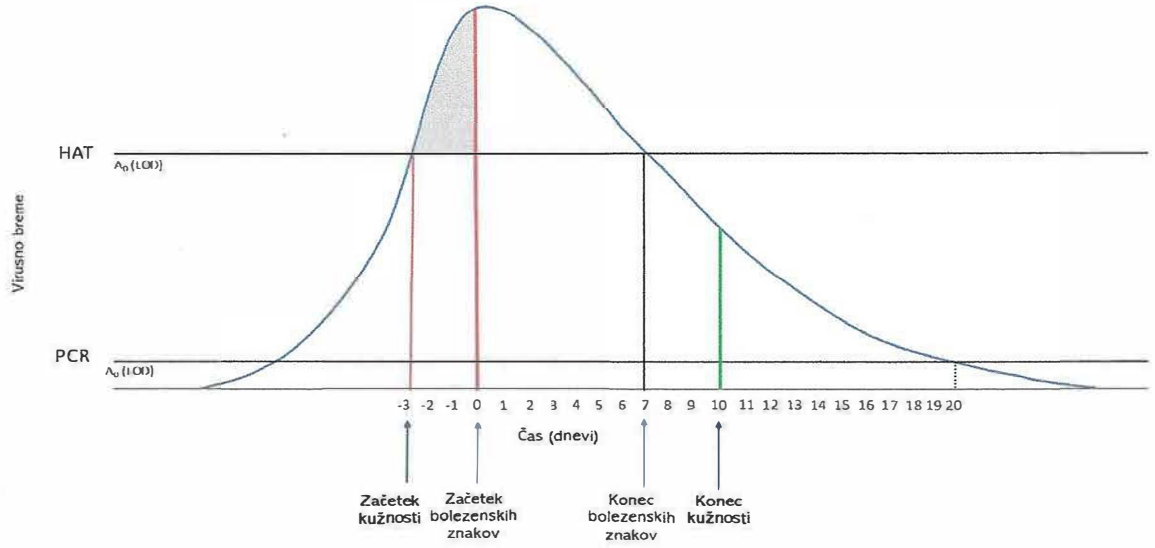
Graf 1: Vzorci (obarvano sivo), ki jih lahko kot pozitivne prepoznamo s pomočjo RT-PCR glede na prag detekcije metode in krivuljo rasti in padanja virusnega bremena



Graf 2: Vzorci (obarvano sivo), ki jih lahko kot pozitivne prepoznamo s pomočjo HAT glede na prag detekcije metode in krivuljo rasti in padanja virusnega bremena



Graf 3: Vzorci (obarvano sivo), ki jih lahko kot pozitivne prepoznamo med brezsimptomnimi s pomočjo HAT glede na prag detekcije metode in krivuljo rasti in padanja virusnega bremena in predstavljajo dodano vrednost samotestiranja



Verifikacija potrjuje, da je pri uporabi HAT je izjemnega pomena, da se preiskovancem pravilno predstavi vrednost negativnega rezultata, ki ne sme povzročiti občutka lažne varnosti. Osnovni namen uporabe HAT je namreč čim hitrejša napotitev oseb z visokim virusnim bremenom v samoizolacijo v populacijah, ki jih ne zmoremo testirati s PCR metodo.

Ugotavljamo, da kljub višjemu pragu detekcije metode in kljub temu, da preiskovanec odvzame vzorec, ki ne velja za zlati standard v diagnostiki, test z več kot 90 % občutljivostjo zazna osebe z visokim virusnim bremenom ob začetku bolezni. Velja tudi, da je visoko virusno breme pri okužbi z virusom SARS-CoV-2 prisotno že najmanj dva dneva pred pojavom bolezenskih znakov. Verifikacija potrjuje, da s samoodvzemom brisa nosu osebo z visokim virusnim bremenom, ki ne kaže bolezenskih znakov, odkrijemo enako učinkovito kot osebo, z visokim virusnim bremenom, ki kaže bolezenske znake. Torej imajo tudi ti testi svoje mesto v diagnostiki SARS-CoV-2.

Viri:

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3. FIND evaluation of SARS-CoV-2 antigen (Ag) detecting tests. Internet: https://www.finddx.org/covid-19-old/sarscov2-eval-antigen
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6. World Health Organisation. Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0. 28 September,2020 Geneva, Switzerland https://www.who.int/publications

Poročilo smo pripravili:

- mag. Tjaša Žohar Čretnik, dr. med., spec.,
- prim. doc. dr. Irena Grmek Košnik, dr. med., spec.,
- Alenka Štorman, dr. med., spec.,
- Mateja Borinc, univ. dipl. biol.,
- asist. dr. Valerija Tkalec, univ. dipl. mikrobiol.

Za delovno skupino:

mag. Tjaša Žohar Čretnik, dr. med., spec. klin. mikrobiol.

Direktorica Nacionalnega laboratorija za zdravje, okolje in hrano

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China**

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-07
Certificate Registration No.:	SX 60143180 0001
An audit was performed. Report No.:	16806278 004
This Certificate is valid until:	2022-10-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-06-05

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Akkreditierungsstelle

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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Doc 1/1, Rev 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60143180 0001
Report No.: 16806278 004

Organization:
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

Scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits used in the Detection of Cancer, Cardiac Markers, Fertility Testing, Pregnancy Testing, Drugs of Abuse, Sexually Transmissible Agents, Infection Diseases including Home Use In-vitro Diagnostic Medical Devices

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜV Rheinland Prüfstelle

Date: 2020-06-07

Jing Zhang

EC Declaration of Conformity

Manufacturer:

Name: JOYSBIO (Tianjin) Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China.

Tel: +86-022-65378415

Email: molly@joysbio.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**Specification**	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
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.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	王森
Signature	王森
Date	2020.08.28
Place	Tianjin, China.
Seal (Manufacturer)	JOYSBIO(Tianjin) Biotechnology Co., Ltd. 正元盛邦(天津)生物科技有限公司 1201160079037

Certificate CN08/31168.01

The management system of

Fapon Biotech Inc.

Business Registration Address: Room 601-604, Unit ABCD, Research and Development Department Building D2, TCL Science Park, NO. 1001, Zhongshanyuan Road, Liuxiandong, Xili, Nanshan Area, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: 4-6F and 8-9F, NO. 1 plant, NO. 5, Hualian Street, Hi-Tech Development, Zone, Songshanhu, Dongguan City, Guangdong Province, P.R. China

Unified Social Credit Code 91440300731124074W

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Development and manufacture of antigens, antibodies and conjugates for in vitro diagnostic industry and research applications

This certificate is valid from 9 July 2020 until 8 July 2023
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 2. Certified since 9 July 2008

Multiple certificates have been issued for this scope
The main certificate is numbered CN08/31168.00

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001-15 01 0118 M3

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

SARTORIUS

Sartorius Stedim Biotech GmbH

August-Spindler-Str. 11
37079 Göttingen
Germany

has established and applies
a Quality Management System for

Development, production, sales and service of products for biotechnology.

An audit was performed, Order No. **707108959**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-05-22** until **2023-05-21**.

Certificate Registration No.: **12 100 59786 TMS**.

Product Compliance Management
Munich, 2020-04-02

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

ZERTIFIKAT

Die Zertifizierungsstelle
der TÜV SÜD Management Service GmbH

bescheinigt, dass das Unternehmen

SARTORIUS

Sartorius Stedim Biotech GmbH

August-Spindler-Str. 11
37079 Göttingen
Deutschland

für den Geltungsbereich

Entwicklung, Produktion, Vertrieb und
Service von Produkten für die Biotechnologie

ein Qualitätsmanagementsystem
eingeführt hat und anwendet.

Durch ein Audit, Auftrags-Nr. **707108959**,
wurde der Nachweis erbracht, dass die Forderungen der

ISO 9001:2015

erfüllt sind.

Dieses Zertifikat ist gültig vom **22.05.2020** bis **21.05.2023**.

Zertifikat-Registrier-Nr.: **12 100 59786 TMS**.

Product Compliance Management
München, 02.04.2020

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019