

HYCISUN[®]



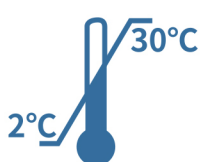
Anbio Biotech

COVID-19 Antigen Schnelltest (Kolloidales Gold) Schnelltest (Spucktest) für die Eigenanwendung

REF A6061213



IVD



Test zur Eigenanwendung - Befristete Sonderzulassung zur Eigenanwendung nach §11 MPG in Deutschland (BfArM GZ: 5640-S-058/21)

HYGISUN[®]

EAN: 4260676530614



1 PCS/box

500 Box/ctn

6000 PCS/pallet

Contents tests**Kit****COVID-19 Antigen Test Card****1 test****Extraction Solution****1 ml / tube****Saliva collection device****1****Instruction for Use****1****Plastic Dropper****1**

Anbio (Xiamen) Biotechnology Co., Ltd.

REF A6061213

HYCISUN[®]



Anbio Biotech

COVID-19 Antigen Schnelltest (Kolloidales Gold)

Schnelltest (Spucktest) für die Eigenanwendung

Rapid COVID-19 Antigen Test (Colloidal Gold)

Saliva test for personal use

Packungsinhalt: **1** TEST
Package: **1** TEST



Anbio (Xiamen) Biotechnology Co., Ltd.
No.2016, Wengqiao West Road, Xinyang
Street, Haicang District, Xiamen, Fujian,
China



Leibes NL B.V.
Koningin Julianaplein 10, 1e Verd, 2555AA,
The Hague, Netherlands



Sunbeam International GmbH
Schumannstr. 12, 52146, Würselen, Germany

Packungsinhalt: **1** TEST
Package: **1** TEST



Verwendungszweck:

Das Kit dient zum qualitativen Nachweis von SARS-CoV-2-Antigenen im menschlichen Speichel in vitro.

Hauptkomponenten:

Testkassette verpackt im Folienbeutel, Einweg-Pipette, Speichelsammelgefäß mit 1 ml Extraktionslösung, Trichter, Bedienungsanleitung.

Qualitätsstandard: IVDD 98/79 / EC

ANTIGEN SCHNELLTEST (SPEICHELTEST)

- ALLE NOTWENDIGEN REAGENZIEN ENTHALTEN
- HOHE SENSIBILITÄT UND SPEZIFITÄT

WICHTIGE HINWEISE

- SIE SOLLTEN MINDESTENS 30 MINUTEN VORHER NICHTS ESSEN, RAUCHEN, KAUGUMMI KAUEN ODER ALKOHOLISCHE GETRÄNKE ZU SICH NEHMEN.
- SPÜLEN SIE IHREN MUND MIT WASSER AUS UND WARTEN SIE 10 MINUTEN.

TIPP: MASSIEREN SIE IHRE WANGEN UND REIBEN SIE IHRE ZUNGE AM GAUMEN, UM DIE SPEICHELSEKRETION ZU STIMULIEREN.

IVD

In Vitro Diagnostik Test

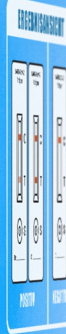


Gebrauchsanweisung beachten.



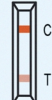
Nicht zur Wiederverwendung.

Test zur Eigenanwendung - Befristete Sonderzulassung zur Eigenanwendung
nach §11 MPG in Deutschland (BfArM GZ: 5640-S-058/21)



ERGEBNISANSICHT

SARS-CoV-2
Antigen



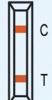
C

T



ID: _____

SARS-CoV-2
Antigen



C

T



ID: _____

POSITIV

SARS-CoV-2
Antigen



C

T



ID: _____

NEGATIV

LOT 2021026139

 20210222

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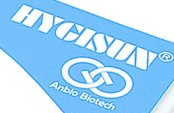
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COVID-19 Antigen Schnelltest
(Kolloidales Gold)
Schnelltest (Spucktest) für die Eigenanwendung

Rapid COVID-19 Antigen Test
(Colloidal Gold)
Saliva test for personal use



Anbio (Xiamen) Biotechnology Co., Ltd.
REF A6061213

COVID-19 Antigen Schnelltest
(Kolloidales Gold)
Schnelltest (Spucktest) für die Eigenanwendung



Rapid COVID-19 Antigen Test
(Colloidal Gold)
Saliva test for personal use

Packungsinhalt:
Package: **1 TEST**

Lot: A6061213
Exp. Date: 12/21



Anbio (Xiamen) Biotechnology Co., Ltd.
Address: Xiamen, China
Tel: +86 592 888 8888
Fax: +86 592 888 8888
Email: info@anbio.com
Website: www.anbio.com

Anblo (Xiamen) Biotechnology Co.,Ltd

Package: 1 Test

Rapid COVID-19 Antigen Test
(Colloidal Gold)

LOT 2021016132

 20210112

 20230111

IVD

 2°C / 30°C







Authorization Letter

Subject : Letter of Authorization

We, Anbio (Xiamen) Biotechnology Co.,Ltd. with detail address at No.2016,Wengjiao West Road,Xinyang Street, Haicang District, Xiamen,Fujian,P.R.China 361026, manufacturer hereby authorize Sunbeam International GmbH, Schumanstr.12, 521 46 Wurselen, Germany, as our authorized distributor to distribute, market our below products in Germany.

NO.	Product name	CE number
1	Rapid COVID-19 Antigen Test (Colloidal Gold)	NL-CA002-2020-53206
2	Neutralizing Antibody of SARS-CoV-2 Test (Immuochromatographic Assay)	NL-CA002-2020-54641
3	Rapid Neutralizing Antibody of SARS-CoV-2 Test (Colloidal Gold)	NL-CA002-2020-54641
4	Immuofluorescence Analyzer	NL-CA002-2020-50112

This letter of Authorization is valid from the date of issue for a period of two years.

Thank you

Yours faithfully,

Authorized Signature

Full Name: Wang Daming

Designation: CEO

Date: Oct29, 2020



Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Listung und ggfs. auch Streichung von der Liste zugrundeliegenden Kriterien finden Sie auf unserer [Webseite zu Antigentests auf SARS-CoV-2](#).

Q

Suchen: Alle Textspalten

Los

Aktionen

Zurücksetzen

☒

Hersteller Land gleich CN

X

Test-ID	Hersteller			Deutsche/r Vertreter	Europäischer Bevollmächtigter						Sensitivität		Spezifität		Gebrauchs-anweisung
	Name ↑	Stadt	Land	Name	Name	Stadt	Land	Handelsname des Tests	Testort *	Artikelnummer	%	95%iges Vertrauensintervall	%	95%iges Vertrauensintervall	
AT168-01	Bioscience Co., Ltd.	Heilong	CN	Procellence GmbH & Co. KG	Mediwin/Gesche Safety Services GmbH	Hannover	DE	ACCE-TEST SARS-CoV-2 IgG/Concent	POC (ohne Gerät)	AB1-001-0001	98,7%	98,30 - 99,00	99,20	97,80 - 99,60	Link öffnen
AT168-02	ACCE-Bioscience (Hangzhou) Co., Ltd.	Guangzhou	CN		Mediwin-Gesche	Münster	DE	SARS-CoV-2 Antigen Schnelltest	POC (ohne Gerät)	LSG-L-1000	97,4%	93,8 - 98,9	99,90	97,7 - 99,9	Link öffnen
AT168-03	ACCE-Bioscience (Hangzhou) Co., Ltd.	Hangzhou	CN	GesundheitSSG-F. Bergner K.	Mediwin GmbH	Hannover	DE	Flowflex SARS-CoV-2 Antigen Schnelltest	POC (ohne Gerät)		97,4%	93,8 - 98,9	99,90	97,7 - 99,9	Link öffnen
AT168-04	Shuang Diagnostics Co., Ltd.	Shenzhen	CN		Mediwin/Gesche GmbH	Münster	DE	SARS-CoV-2 Antigen Testkit (Immuno-Chromatography)	POC (ohne Gerät)		97,3%	93,80 - 99,43	99,90	98,80 - 99,90	Link öffnen
AT168-05	Shuang Diagnostics (Shanghai) Co., Ltd.	Shanghai	CN	Stadel Pharm GmbH & Co. KG	Lotus NL B.V.	The Hague	NL	EasyVirus COVID-19 Antigen (Solventless)	POC (ohne Gerät)		96,7%	74 - 99	97,30	95 - 98	Link öffnen
AT147/20	Anbio (Xiamen) Biotechnology Co., Ltd.	Xiamen	CN	Bold Sales GmbH	Lotus NL B.V.	Gravenhage	NL	Rapid COVID-19 Antigen Test (Colloidal Gold)	POC (ohne Gerät)		96,36	87,47 - 99,56	100,00	96,19 - 100	Link öffnen
AT168-06	Anbio (Xiamen) Biotechnology Co., Ltd.	Heilong	CN	Anbio Consulting & Trading (Beijing)	Lotus Lebensmittel GmbH	Witten	DE	anbio rapid test kit - antigen test (Colloidal Gold)	POC (ohne Gerät)		96,7%	94,3 - 98,1	99,30	96,1 - 99,7	Link öffnen
AT168-07	Anbio (Xiamen) Biotechnology Co., Ltd.	Heilong	CN	Fa. DRIVOPOL International GmbH	Lotus Lebensmittel GmbH	Witten	DE	COVID-19 (Rapid CoV-2) Antigen testkit (Colloidal Gold)			96,7%	94,3 - 98,1	99,30	96,1 - 99,7	Link öffnen
AT168-08	Anbio (Xiamen) Biotechnology Co., Ltd.	Heilong	CN	Dr. Osh HealthCare GmbH	Lotus Lebensmittel GmbH	Witten	DE	COVID-19 antigen Test	POC (ohne Gerät)	Antigen Blue	96,7%	94,3 - 98,1	99,30	96,1 - 99,7	Link öffnen
AT168-09	Anbio (Xiamen) Biotechnology Co., Ltd.	Heilong	CN	Guangzhou Anbio	Lotus Lebensmittel GmbH	Witten	DE	COVID-19 (Rapid CoV-2) Antigen Test Kit (Colloidal Gold)	POC (ohne Gerät)		96,7%	94,3 - 98,1	99,30	96,1 - 99,7	Link öffnen
AT168-10	Anbio (Xiamen) Biotechnology Co., Ltd.	Anbio	CN	Elbion GmbH	Lotus Lebensmittel GmbH	Witten	DE	Dengyue	POC (ohne Gerät)		96,4%	95,80 - 99,20	99,80	98,40 - 99,90	Link öffnen
AT168-11	Anbio (Xiamen) Biotechnology Co., Ltd.	Hangzhou	CN	SDS BioAsia GmbH	UNIMED B.V.	BAKHORHEDONP	NL	COVID-19 Antigen Rapid test Device	POC (ohne Gerät)	COVID-19	96,0%	73,8 - 98,3	99,00	97,7 - 99,9	Link öffnen
AT168-12	Anbio (Xiamen) Biotechnology Co., Ltd.	Langfang City	CN	Shenzhen Anbio	MT Promed Consulting	St. Ingbert	DE	Rapid Testkit SARS-CoV-2 Antigen Rapid Testkit (Colloidal Gold Immuno-Chromatography)	POC (ohne Gerät)	COVID-19 (Rapid) / COVID-19 (Rapid)	97,80	94,7 - 98,3	99,30	97,4 - 99,9	Link öffnen

03.02.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

Ziel

Vergleich verschiedener Antigenschnelltests mit identischem Probenmaterial

Material

Pools von naso- und oropharyngealen Abstrichen.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer CT Werte, die 1:10 in negativen Proben in PBS verdünnt wurden. Die CT Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmassliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein CT Wert von 25 etwa 106 RNA Kopien / mL. Es wurden jeweils 18 Proben mit CT<25, 23 Proben mit CT zwischen 25 und 30 und 9 Proben mit CT>30 analysiert. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50µL des Pools mit den vom Test bereitgestellten Komponenten z.B. Tupfer, analysiert. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit demselben Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

Diejenigen POCT, die bislang in die vergleichende Evaluierung eingegangen sind und hier als dem derzeitigen Stand der Technik entsprechend bewertet wurden, sind in der folgenden Tabelle aufgeführt. Weitere Tests, die als nicht dem Stand der Technik entsprechend bewertet wurden, wurden aus der Liste des BfArM entfernt. Die Untersuchungen werden kontinuierlich fortgeführt, die Tabelle entsprechend ergänzt.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und viele weitere Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:

E-Mail: sarscov2ivd@pei.de

Stand 03.02.2021

Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend“ bewertet wurden

Testname	Hersteller (Vertrieb)
Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd (Medicovid-AG; technomed GmbH; Löwe Medizintechnik)
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
Gensure™ COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd

Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics Inc.
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co.,Ltd.



Feb 05, 2021

To whom it may concern,

We, Anbio(Xiamen) Biotechnology Co.,Ltd recently has launched our new version COVID19 Antigen test by nasal swab, throat swab, saliva 3 specimens which could greatly improve the specificity of the test by saliva specimen.

In addition, we hereby declare that our COVID19 Antigen test is effective to mutant strain in British and South Africa. Please see below details.

1. The British and South Africa mutant, commonly known as the B.1.1.7 subtype, has been named VOC-202012/01 novel coronavirus. The most important mutations in this strain relative to the common strain are three mutations in the RBD region K417N, E484K, and N501Y. These three mutations make it easier for the virus to bind to the ACE2 receptor in the human body, making it easier for the virus to spread.

2. Why our product is still effective: a. What we detected is mainly the N protein of novel coronavirus, which is relatively conservative, and this British & South Africa mutant strain is mainly the gene encoding RBD protein; b. The mutant region of the British & South Africa mutant strain is not within our detection range, so our detection reagent was still effective in detecting the antigen of the mutant strain, but it also means that our reagent could not distinguish the mutant strain from the common strain;

3. Simulated data:

3.1. Detection of recombinant full-length RBD protein of mutant strains:

Detection of recombinant full-length RBD protein of mutant strains of
K417N,E484K,N501Y Mutated RBD Protein

mutated recombinant protein	common strain	Sensitivity of national reference
800pg/mL:G4	800pg/mL:G4	S1:G4 (6800TCID50)
400pg/mL:G3	400pg/mL:G3	S2:G4 (3400TCID50)
200pg/mL:G2	200pg/mL:G2	S3:G3 (1700TCID50)
100pg/mL:G1	100pg/mL:G1	S4:G2 (850TCID50)
50pg/mL:G0	50pg/mL:G0	S5:G0 (425TCID50)

Note: color darker than G0 can be judged positive

3.2. Detection of animal model samples: detection of S protein in Clara cells of respiratory tract infected in mouse model:

concentration (pg/mL)	1600	800	400	200	100	50
results	G5	G4	G3	G2	G0	G0

Your sincerely

JieLi Zhang

R&D Director

Anbio Biotechnology





DECLARATION OF CONFORMITY

According Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III.

Manufacturer: Anbio (Xiamen) Biotechnology Co.,Ltd.

Address: No.2016, Wengjiao West Road, Xinyang Street, Haicang District, 361026 Xiamen, Fujian, China.

European Representative: Lotus NL B.V.

Contact person: Peter **E-mail:** peter@lotusnl.com

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

In Vitro Diagnostic Directive:

- **Rapid COVID-19 Antigen Test (Colloidal Gold)**

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD 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

We, the manufacturer, herewith 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.

Signed on: 04/09/2020

Place: Xiamen, China

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

Anbio (Xiamen) Biotechnology Co., Ltd.





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

Datum: 1 september 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 28 augustus 2020 ontvang ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Anbio (Xiamen) 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 Test Kit(Real-time PCR),
Rapid COVID-19 Antigen Test (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-53206)**

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel 10, eerste lid van Richtlijn 98/79/EG).

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

M.P. Meijer - Michiels

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:

CIBG-20204220

Bijlagen

-

Uw aanvraag

28 augustus 2020

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

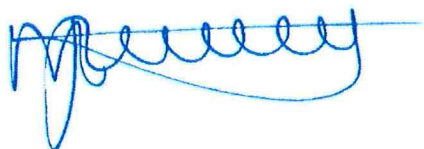
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Anbio (Xiamen) Biotechnology Co.,Ltd. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het 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



Bestätigung

Sehr geehrte Damen und Herren,

Wir, Anbio (Xiamen) Biotechnology Co. Ltd. No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian, China bestätigen hiermit dass der Test analytisch identisch mit dem antragsgegenständigen Test ist.

Mit freundlichen Grüßen,

Daming Wang

CEO von Anbio Xiamen Biotechnology Co. Ltd

Xiamen, 07 Mar 2021



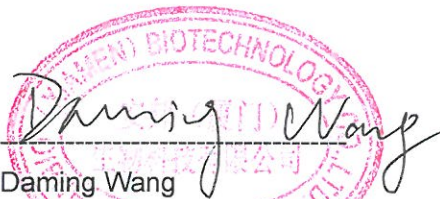
Anbio (Xiamen) Biotechnology Co.,Ltd.

Bestätigung vom PEI evaluierte Test

Sehr geehrte Damen und Herren,

Wir, Anbio (Xiamen) Biotechnology Co. Ltd. No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian, China bestätigen hiermit, dass der vom Paul-Ehrlich-Institut evaluierte Test analytisch identisch mit dem antragsgegenständigen Test ist.

Mit freundlichen Grüßen,



Daming Wang

CEO von Anbio Xiamen Biotechnology Co. Ltd

Xiamen, 07-Mar-2021

BUREAU VERITAS
Certification



Anbio (Xiamen) Biotechnology Co., Ltd

No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen City,
P.R. China

Certified site:

NO.2016, WENGJIAO WEST ROAD, XINYANG STREET, HAICANG DISTRICT, XIAMEN CITY,
P.R. CHINA

*Bureau Veritas Italia S.p.A. certifies that the Management System of the
above organisation has been audited and found to be in accordance
with the requirements of the management system standards detailed below*

EN ISO 13485:2016

Scope of certification

Design and manufacture of fluorescence-based immunoassay reagent and devices, as an aid in clinical assessment of cardiovascular, gastric, inflammation, diabetic and infectious diseases detection, as well as hormone, vitamin testing. Design and manufacture of IVD reagents as an aid in clinical assessment of blood type testing.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date: **22/06/2020**

Expiry date of previous cycle: **n.a.**

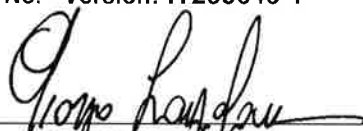
Certification / Recertification Audit date: **17/05/2020**

Certification / Recertification cycle start date: **22/06/2020**

Subject to the continued satisfactory operation of the organization's
Management System, this certificate expires on: **21/06/2023**

Certificate No. - Version: **IT298645-1**

Revision date: **22/06/2020**


GIORGIO LANZAFAME - Local Technical Manager

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia



SGQ N° 009A

Member of the Assosiasi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Further clarifications regarding the scope of this certificate and the applicability of the
management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it



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中国食品药品检定研究院

检验报告



报告编号: RZ202009287

检品名称: 新型冠状病毒COVID-19抗原检测试剂盒(胶体金法)

生产单位/产地: 安邦(厦门)生物科技有限公司

检验目的: 注册检验(国产体外诊断试剂/首次注册/质量标准复核)

检验依据: 产品技术要求



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中国食品药品检定研究院检验报告

报告编号: RZ202009287

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检品名称	新型冠状病毒COVID-19抗原检测试剂盒(胶体金法)	检品编号	RZ2804202014368
生产单位/产地	安邦(厦门)生物科技有限公司	批号	2020036133
供样单位	福建省药品监督管理局	规格	/
检验目的	注册检验(国产体外诊断试剂/首次注册/质量标准复核)	剂型/型号	/
检验项目	全检	包装规格	20人份/盒
收样日期	2020年12月15日	有效期至/失效日期	2022年3月24日
检品数量	6盒	签封数量	/
检验依据	产品技术要求		

检验项目	标准规定	检验结果
2.1理化性质		
2.1.1外观	试剂盒外观应完整, 无破损, 组分齐全; 标签内容完整, 正确, 字迹清晰; 提取液为无色透明溶液	符合规定
2.1.2宽度	膜条宽度应不小于2.5mm	3.1mm
2.1.3移行速度	液体移行速度应不低于10mm/min	34mm/min
2.2阳性参考品符合率	检测国家阳性参考品, 应均为阳性	P1~P8均为阳性, 阳性符合率为8/8
2.3阴性参考品符合率	检测国家阴性参考品, 应均为阴性	N1~N20均为阴性, 阴性符合率为20/20
2.4重复性	检测国家重复性参考品, R1和R2的10次检测结果应均为阳性, 且显色度均一无差别	符合规定
	R1	10次检测结果均为阳性, 且显色度均一无差别
	R2	10次检测结果均为阳性, 且显色度均一无差别

接下页

中国食品药品检定研究院检验报告

报告编号： RZ202009287

共2页，第2页

接上页					
检验项目		标准规定		检验结果	
2.5最低检测限		检测国家最低检测限参考品，S1～S4应均为阳性，S5、S6不作要求		S1～S4为阳性，S5、S6为阴性	
以下空白					
备注：申请人：安邦（厦门）生物科技有限公司。1. 检验用参考品为新型冠状病毒抗原检测试剂国家参考品，批号370095-202001，由中国食品药品检定研究院提供。2. 阴性参考品直接使用原液进行检测，其余参考品使用新型冠状病毒COVID-19抗原检测试剂盒提取液进行稀释，上样量为70 μL。					
检验结论		本品按产品技术要求检验，结果符合规定。			
授权签字人				签发日期	2020年12月31日



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National Institutes for Food and Drug Control

Test report

Report NO.: RZ202009287

Name of the test product: Rapid COVID-19 Antigen Test (Colloidal Gold)

Manufacture: Anbio (Xiamen) Biotechnology Co., Ltd.

Testing purpose: Registration inspection (IVD/first registration/Quality standard review)

Criteria for examination: Technical Requirements

National Institutes for Food and Drug Control

Testing Report

Report Number: RZ202009287

Product Name	Rapid COVID-19 Antigen Test (Colloidal Gold)	Inspection item No	RZ2804202014368
Manufacture	Anbio (Xiamen) Biotechnology Co., Ltd.	Lot Number	2020036133
Sample supplier	Fujian Medical Product administration	Specification	/
Testing popuse	Registration inspection (IVD/first registration/Quality standard review)	Dosage form/Model	/
Testing Item	All	Package specification	20tests/kit
Datereceived	December 15,2021	Valid until/Limitation date	March 24,2022
Product quantity	6 kits	Number of signings	/
Criteria for examination	Technical Requirements		
Testing Item	Standard and	Result	
2.1 Physico-chemical properties			
2.1.1 Appearance	The appearance is complete without damage, and the components are complete; the label content is complete, correct and clear; the Sample Diluent is colorless and transparent liquid	Pass	
2.1.2 Width	The width of Membrane strip shall not less than 2.5mm	3.1mm	
2.1.3 Liquid velocity	The liquid velocity shall not less than 10mm/min	34mm/min	
2.2 Coincidence rate of positive reference	Testing with national positive reference,should all be positive.	P1~P8 Positive Positive coincidence rate is 8/8.	
2.3 Coincidence rate of negative reference	Testing with national positive reference,should all be negative.	N1~N20 Negative Negative coincidence rate is 20/20	
2.4 Repeatability	Testing national repeatability reference,the result of 10 times of R1 and R2 should be positive , and the color should be uniform and no difference.	Compliance	
	R1	The result of 10 times is positive,and	

		the color should be uniform and no difference.	
	R2	and the color should be uniform and no difference.	
2.5 limits of detection	National Limits of detection reference ,S1~S4 should be all positive,S5、 S6 no requirement.	S1~S4 positive, S5、 S6 is negative	
Ramarks:Applicant: Anbio (Xiamen) Biotechnology Co., Ltd.. 1 The reference is national reference for SARS-CoV-2 Antigen test. Batch number is 370095-202001,supplied by National Institutes for Food and Drug Control. 2 The negative reference is stock solution, the other reference is diluted by the extract solution within the Rapid COVID-19 Antigen Test, the volume is70μl.			
Conclusion	According to the technical requirement, the result is compliance with the requirement.		
Signature of authorizer		Date of issue	Dec 31,2020

IEC 62366

Medical devices

Application of usability engineering to medical devices

Report Reference No. : 62366-A6061203-1

Date of issue..... : February,16,2021

Product Name..... **Rapid COVID-19 Antigen Test(Colloidal Gold)**

Version V 2.0

Manufacturer Anbio (Xiamen) Biotechnology Co.,Ltd.

ANBIO (XIAMEN) BIOTECHNOLOGY CO.,LTD.

Add: No.2016, Wengjiao West Road, Xinyang Street, Haicang District,Xiamen, Fujian , China.

Tel : 86-592-6312399 Email : info@anbio.com www.anbio.com

EN 62366-1:2015 Usability Engineering Checklist			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		
4.1	General Requirements		
4.1.1	Usability Engineering Process		
	Has the manufacturer established, documented and maintained a usability engineering process to provide Safety for the patient, user and others related to usability for the product?	Instruction For Use QA/QC Process Control File	Compliance
	Does the Process address user interactions with the medical device according to the accompanying document including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	Instruction For Use	Compliance
4.1.2	Risk control as it relates to user interface design		
	Shall the manufacturer use options (e.g. inherent safety by design, protective measures in the medical device itself or in the manufacturing process, information for safety) to reduce use-related risk?	Risk Management Report	Compliance
4.1.3	Information for Safety as it relates to usability		
	The information for safety is used as a risk control measure, Manufacturer subject the information to the usability engineering process to determine that the information (e.g., is perceivable by, is understandable to, supports correct use of the medical device by etc.) in the UE file and Accompanying documents.	Risk Management Report Instruction For Use	Compliance
	Conscious disregard of such information for safety by the user is considered to be an intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer (i.e. abnormal use).	Risk Management Report	Compliance
4.2	Usability Engineering File		
	The results of the usability engineering process are recorded in the usability engineering file	List of Content of CE Technical Files QA/QC Process Control File	Compliance
	The records and other documents that make up the usability engineering file form part of other documents and files (e.g., a manufacturer's product design file or risk management file),	List of Content of CE Technical Files QA/QC Process Control File	Compliance
4.3	Tailoring of the usability engineering effort		

	The level of effort and the choice of methods and tools used to perform the usability engineering process may vary based on: a) the size and complexity of the user interface ; b) the severity of the HARM associated with the use of the medical device ; c) the extent or complexity of the use specification ; d) the presence of user interface of unknown provenance ; e) the extent of the modification to an existing medical device user interface that had been subjected to the usability engineering process .	Risk Management Report	Compliance
5	USABILITY ENGINEERING PROCESS		
5.1	Prepare use specification		
	The manufacturer shall prepare a use specification, include:	Instruction For Use	Compliance
	– intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented);		
	– intended patient population (e.g., age, weight, health, condition);		
	– intended part of the body or type of tissue applied to or interacted with;		
	– intended user profile		
	– intended conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); and		
	– operating principle(s)		
5.2	Identify user interface characteristics related to safety and potential use errors		
	The manufacturer shall identify user interface characteristics that could be related to safety as part of a risk analysis performed. This identification shall include consideration of the primary operating functions that are provided in applicable particular medical device safety standards.	List of Content of CE Technical Files Risk Management Report	Compliance
	Based on the identified user interface characteristics and use specification, the manufacturer shall identify the use errors that could occur and are related to the user interface.		
	The results of this identification of characteristics related to safety shall be stored in the usability engineering file.		
5.3	Identify known or foreseeable hazards and hazardous situations		
	The manufacturer shall identify known or foreseeable hazards and hazardous situations, which could affect patients, users or others, related to use of the medical device. This identification shall be conducted as part of a risk analysis performed according to ISO 14971:2007, 4.3 and the first paragraph of ISO 14971:2007, 4.4.	Risk Management Report Instruction For Use	Compliance

	During the identification of hazards and hazardous situations , the following shall be considered: – use specification , including user profile – information on hazards and hazardous situations known for existing user interfaces of medical devices of a similar type, if available; and – identified user errors		
	Results of this identification characteristics related to safety recorded in the usability engineering file		
5.4	Identify and describe hazard – related use scenarios		
	The manufacturer shall identify and describe the reasonably foreseeable hazard – related use scenarios associated with the identified hazards and hazardous situations. The description of each identified hazard – related use scenarios shall include all tasks and their sequences as well as the severity of the associated HARM	Risk Management Report Instruction For Use	Compliance
5.5	Select the hazard – related use scenarios for summative evaluation		
	The manufacturer shall select the hazard – related use scenarios to be included in the summative evaluation.	Instruction For Use List of Content of CE Technical Files	Compliance
	The manufacturer shall select either: – all hazard – related use scenarios; or – the subset of the hazard – related use scenarios based on the severity of the potential HARM that could be caused by use error (e.g. for which medical intervention would be needed).		
	The choice of the scheme used to select the hazard – related use scenarios may additionally depend on other circumstances specific to the medical device and the manufacturer.		
	A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the usability engineering file.		
5.6	Establish user interface specification		
	The manufacturer shall establish and maintain a user interface specification.	Instruction For Use List of Content of CE Technical Files Risk Management Report	Compliance
	The user interface specification shall consider: – the user specification – the known or foreseeable use errors associated with the medical device; and – the hazard – related use scenarios		
	The user interface specification shall include: – testable technical requirements relevant to the user interface, including the requirements for those parts of the user interface associated with the selected risk control measures; – an indication as to whether accompanying documentation is required; and – an indication as to whether medical device -specific training is required.		
	The user interface specification shall be stored in the usability engineering file. The user interface specification may be integrated into other specifications.		
5.7	Establish user interface evaluation plan		
5.7.1	General		
	The manufacturer shall establish and maintain a user interface evaluation plan for the user interface specification.	Instruction For Use	Compliance

	The user interface evaluation plan shall a) document the objective and identify the method of any planned formative evaluations and summative evaluations;	List of Content of CE Technical Files Risk Management Report Test Reports	
	b) if usability tests are employed, – document the involvement of the representative intended users and user profiles to which they belong. Multiple user profiles may be combined into a user group for the purposes of a usability test; – document the test environment and other conditions of use, based on the use specification; – specify whether accompanying documentation is provided during the test; – specify whether medical device -specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.		
	user interface evaluation methods may be quantitative or qualitative. user interface evaluation may be performed in a variety of locations, such as, in a laboratory setting, in a simulated use environment or in the actual use environment.		
	The user interface evaluation plan may be integrated into other plans.		
	The user interface evaluation plan shall be stored in the usability engineering file.		
5.7.2	Formative evaluation planning		
	The user interface evaluation plan for formative evaluation shall address: a) the evaluation methods being used; b) which part of the user interface is being evaluated; and c) when in the usability engineering process to perform each of the user interface evaluations.	List of Content of CE Technical Files Test Reports Clinic Evaluation Report	Compliance
5.7.3	Summative evaluation planning		
	For each selected hazard-related use scenario, the user interface evaluation plan for Summative evaluation shall specify: a) the evaluation method being used and a rationale that the method produces objective evidence.	List of Content of CE Technical Files Test Reports Clinic Evaluation Report	Compliance
	b) which part of the user interface is being evaluated;		
	c) where applicable, the criteria for determining whether the information for safety is perceivable, understandable and supports correct use of the medical device.		
	d) the availability of the accompanying documentation and provision of training during the Summative evaluation; and		
	e) for a usability test, – the test environment and conditions of use and a rationale for how they are adequately representative of the actual conditions of use; and – the method of collecting data during the usability test for the subsequent analysis of observed use errors .		
	The Summative evaluation may be performed in a single evaluation or multiple evaluations.		
5.8	Perform user interface design, implementation and formative evaluation		
	The manufacturer shall design and implement the user interface, including the accompanying documentation if needed, and training capability, if needed, as described in the user interface specification	Products do not have this requirement	Non-compliance

	The manufacturer shall utilize, as appropriate, usability engineering methods and techniques, including formative evaluation to accomplish this design and implementation. The results of the utilized formative evaluation shall be stored in the usability engineering file. Where new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this step, the manufacturer shall repeat the steps of Clause 5 as appropriate.		
	If training on the specific medical device is required for the safe use of the medical device by the intended user, the manufacturer shall design and implement a training capability for the expected service life of the medical device by doing at least one of the following: – provide the materials necessary for training; – ensure that the materials necessary for training are available; – make the training available; or – make training available to the responsible organization that enables it to train its users		
	Compliance is checked by inspection of the usability engineering file, including for evidence of the formative evaluation, if performed, and the existence of the training strategy, if required.		
5.9	Perform summative evaluation of the usability of the user interface		
	Upon completion of the design and implementation of the user interface, the manufacturer shall perform a summative evaluation of each hazard-related use scenario selected in 5.5 on the final or production equivalent user interface according to the user interface evaluation plan. For summative evaluation, the manufacturer may use data obtained from the summative evaluations of products with an equivalent user interface together with a technical rationale for how this data is applicable. The results shall be stored in the usability engineering file.		
	The data from the summative evaluation shall be analysed to identify the potential consequences of all use errors that occurred. If the consequences can be linked to a hazardous situation, the root cause of each use error shall be determined. The root causes should be determined based on observations of user performance and subjective comments from the user related to that performance.	Test Reports Clinic Evaluation Report Risk Management Report	Compliance
	If new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this data analysis: – if yes, then the manufacturer shall repeat the activities of Clause 5 as appropriate;		
	if not, the manufacturer shall determine whether further improvement of the user interface design as it relates to safety is necessary and practicable. 1) if yes, then the manufacturer shall re-enter the usability engineering process at 5.6; 2) if not, then the manufacturer shall: i) document why improvement is not practicable; ii) identify the data from the usability engineering process needed to determine the residual risk related to use; and iii) evaluate the residual risk according to ISO 14971:2007, 6.4.		

	If the usability engineering process detailed in this International Standard has been complied with, then the usability of a medical device as it relates to safety is presumed to be acceptable, unless there is objective evidence to the contrary.		
5.10	User interface of unknown provenance		
	Instead of all the requirements of 5.1 through 5.9, UOUP may be evaluated according to Annex C.	Products do not have this requirement	Non-compliance

1 Overview

In general, the determination and application of usability targets in the design process of medical devices improves safety and usability. When the design reaches the usability goal, it is expected that the user should be able to complete its basic operations safely. It is required to apply a good design control process to achieve the usability goal of a good process in medical device design.

2 Basic information of the product

2.1 Product Name: **ANBIO Corona Antigen Saliva Test**

2.2 Package and Specification:

1 test/kit

2.3 Main Components:

Sample type	Materials
Saliva (only)	1. COVID-19 Antigen Test Card 2. Saliva collection device (with 1ml extraction solution) 3. Saliva collection Funnel 4. Instruction for Use 5. Disposable dropper

2.4 Storage Conditions And Shelf Life:

1. Store the Product at 2-30°C, the shelf life is 24 months.

2 Test Card should be used right after opening the pouch.

2.5 Reference standard: BS EN 62366-1:2015 IEC 62366-1:2015 Medical devices-Application of usability engineering to medical devices(IEC 62366:2007) .

2.6 The manufacturer

Anbio (Xiamen) Biotechnology Co.,Ltd.

Address: No.2016,Wengjiao West Road, Xinyang Street, Haicang District, Xiamen,Fujian,China.

Tel:+86-0592-6312399.

3 Inputs to the USABILITY SPECIFICATION

3.1 Specification of The Intended Use/Intended Purpose

3.1.1 Description

The Rapid COVID-19 Antigen Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human saliva from individuals who are suspected of COVID-19 by their healthcare provider

This reagent is based on colloidal gold immunochromatography assay.

During the test, specimen extracts are applied to the Test Cards. If there are SARS-CoV-2 antigen in the extract, the antigen will bind to the SARS-CoV-2 monoclonal antibody. During lateral flow, the complex will move along the nitrocellulose membrane toward the end of the absorbent paper. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line shows a red line; when passing the line C, colloidal gold-labeled goat anti-rabbit IgG is captured by control line (line C, coated with rabbit IgG) shows a red line.

3.1.2 Application Specification

3.1.2.1 Intended Use

The Rapid COVID-19 Antigen Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human saliva from individuals who are suspected of COVID-19 by their healthcare provider

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary for patient management.

3.1.2.2 Patient Population

- a. Age: Over 3 years old.
- b. Weight: Suitable for various weights.
- c. Nationality: Multiple.
- d. Patient state: Emergency and semi-emergency treatment or surgical case screening are required for high-risk COVID-19; Where necessary, screening for low-risk death cases; Screen symptomatic persons in confirmed cluster/outbreak management; Screen close contacts in confirmed cluster/outbreak management; Screen patients with acute respiratory infections.

3.1.2.3 Part Of Body Or Type Of Tissue Applied To Or Interacted With

No direct contact with the patient- saliva.

3.1.2.4 Intended Operator

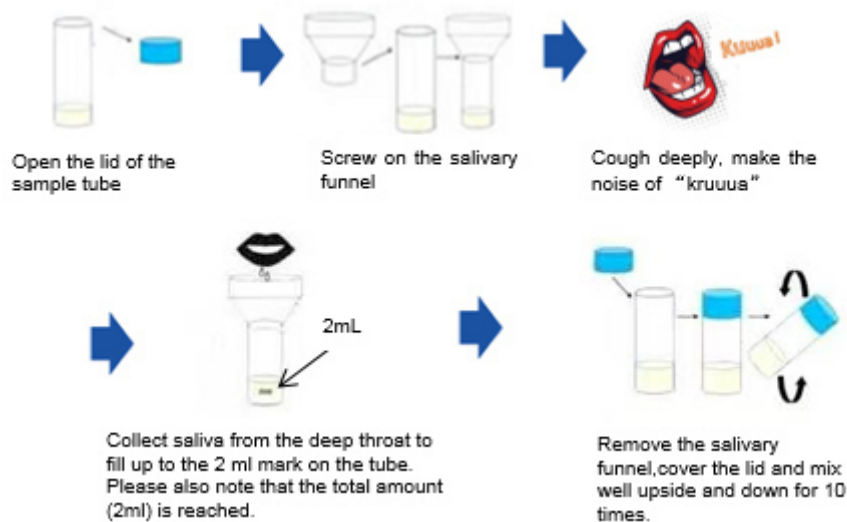
The trained medical or paramedical staff who have received professional medical knowledge, or Non health care person, we can fully understand and understand the content identification and description.

3.1.2.5 Application

- a. Environment: Hospitals and professional medical institutions and laboratories; Closed or semi-closed groups include schools, nursing homes, cruise ships, prisons, workplaces and dormitories, or Non-laboratory sites.
- b. Single-used.
- c. Single patient use.

3.1.2.6 Instructions

- a. Sample Collection Handling



b. Specimen Transport and Storage

Samples should be tested as soon as possible after collection. Saliva specimen can be stored in Extraction Solution for up to 24 hours at room temperature or 2° to 8°C. Do not freeze.

c. Test Method

1). The test should be operated at room temperature (15-30°C) .

2). Add the specimens

Saliva Specimen: Open the lid and absorb a tube of liquid with a disposable dropper. drip 3 drops of extraction solution into the sample well of the Test Card, and start the timer.



3). Read the results at 15~20 minutes.



3.2 Primary Operating Function

3.2.1 Frequently Used Functions

- Tear open the aluminum foil bag.
- Sample collection and storage.
- Keep the kit and sample balance at room temperature.
- Add the samples to the sample well.
- Read the test results between 15 and 20 minutes.
- Instrument cleaning and environmental disinfection.
- Treat as medical waste.

3.2.2 Functions To Safety

- a. Tear open the aluminum foil bag.
- b. Sample collection and storage.
- c. Keep the kit and sample balance at room temperature.
- d. Add the samples to the sample well.
- e. Read the test results between 15 and 20 minutes.
- f. Instrument cleaning and environmental disinfection.
- g. Treat as medical waste.

3.3 Risk Analysis

3.3.1 Intended Use/Intended Purpose

See the 3.1.2.1.

3.3.2 User Profile

See the 3.1.2.4.

3.3.3 Things That Could Go Wrong

Sources: Literature, Device Alerts, Sales, Healthcare Staff, Risk Analysis etc.

a. Use Errors:

- The production of test strip does not meet quality requirements.
- The sample collection process does not meet the requirements.
- Use samples of the wrong type for testing.
- The transportation and storage of the kit and sample do not meet the requirements.
- The operation does not conform to the standard operation.
- The aluminum foil bag is not sealed.

b. Environment: The product is exposed to high humidity and high temperature conditions for a long time.

c. Hygiene:

- Cross-contamination of products to patients.
- Illegal reuse.

3.3.4 Task requirements

- a. Clearly recognisable labels and IFU.
- b. The aluminum foil bag is sealed and it is easy to tear.
- c. The appearance of the test card is complete, clean and free of burrs.
- d. The liquid reagent is clarified and the filling quantity meets the requirements.

3.3.5 The Context Of Use

See the 3.1.2.5.

3.3.6 Information On Hazards Known For Existing Device

See the 3.3.3.

3.3.7 Resulting Hazardous Situations And Harms

- The production of test strip does not meet quality requirements-the test card cannot be used normally and the result is wrong.
- The sample collection process does not meet the requirements-wrong results and judgments.
- Use samples of the wrong type for testing-wrong results and judgments.

-The transportation and storage of the kit and sample do not meet the requirements-the test card cannot be used normally and the result is wrong.

-The operation does not conform to the standard operation-wrong results and judgments.

-The aluminum foil bag is not sealed-the test card cannot be used normally and the result is wrong.

4 Usability specification analysis

4.1 Clearly recognizable labels and IFU

Use Scenarios	Potential error	Consider when designing
Open the kit to use the components and accessories.	1.The description used in the IFU is not clear. 2.The printing content of label is not clear. 3.The location of the sample hole cannot be found, and the detection line is not clearly marked.	1.The text description should be as concise as possible to make it clear and easy to understand. 2.Choose an appropriate method to print the label to make the label print content clear and not easy to wear. 3.The layout of sample holes, test lines and quality control lines is reasonable and clearly marked.

4.2 The aluminum foil bag is sealed and it is easy to tear

Use Scenarios	Potential error	Consider when designing
Open the aluminum foil bag	1.The wrong opening method delays the test time.	1.The tear opening of the bag should be easy to identify and easy to use.

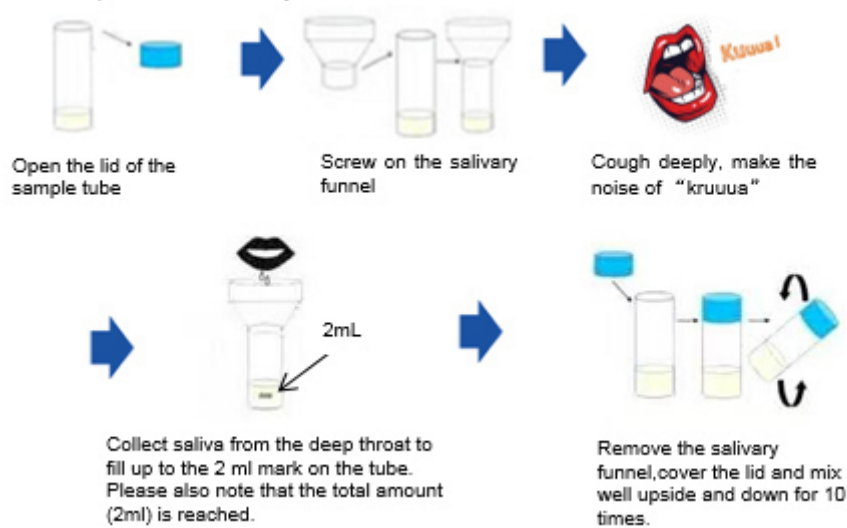
4.3 The appearance of the test card is complete, clean and free of burrs

Use Scenarios	Potential error	Consider when designing
Open the kit to use	1.The unsealed detection cassette causes the side leakage of the sample liquid to contaminate the user and the environment which also leads to the test failure. 2.The cassette is too tight so that the liquid cannot be chromatographically moved to achieve the purpose of detection. 3.The sample hole is too shallow, causing the side leakage of the sample liquid to contaminate the operator and the environment which also leads to the test failure.	1.During the production process, the pressing force is moderate, not too tight or too loose. 2.The inner side of the opening of the sample hole is designed with lines to increase the surface tension of the liquid so that the liquid is not easy to leak.

4.4 Simulate usage scenarios

4.4.1The worst case of the usage scenario is a person who has not received training but can operate independently.

a. Sample Collection Handling



b. Test Method

1). The test should be operated at room temperature (15-30°C) .

2). Add the specimens

Saliva Specimen: Open the lid and absorb a tube of liquid with a disposable dropper. drip 3 drops of extraction solution into the sample well of the Test Card, and start the timer.



3). Read the results at 15~20 minutes.



Result: Non-trained personnel can perform simulation operations according to the instructions, and can complete the operations accurately and without error.

4.4.2 Non health care person and Non-laboratory sites Usability Study Report- Saliva

a. Criteria for Participant

(1) Gender: Male or female.

(2) Age rang:

Age rang	3-12 years	13-24 years	25-64 years	>64 years
Proportion	At least 20%	10-15%	30-35%	At least 35%

(3) Education level:

Education	High school degree	College degree	Graduate degree	Higher than
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level				graduate degree
Proportion	30%-35%	40%-45%	At least 15%	At least 5%

Age range: 3-12 years, Record parents or legal guardians' education level.

(4) Test type

Test type	one participants test another person	Self test	parents or legal guardians test their children
Proportion	At least 50%	At least 30 cases	At least 30 cases

(5) Exclusion

Participants with prior medical or laboratory training should be excluded. Participants who have prior experience with self-collection or self-testing (including glucose testing) should also be excluded.

b. Summary of saliva specimen

1) 150 samples were tested in this clinical trial.

2) All cases with subjects test results consistent with PCR results in this clinical trial, included 53 cases positive, 97 negative.

3) The sensitivity, specificity and total coincidence rate of product testing and the PCR test results are 100%, 100% and 100% respectively.

c. Summary of test type

Among them, there were 80 cases with one participant testing another person, 30 cases with parents or legal guardians testing their children, 40 cases where the user tested himself. All test results using the Anbio Saliva test were consistent with PCR results in this clinical trial.

d. Questionnaire survey analysis

Through the questionnaire survey of the subjects, it is shown that the subjects can successfully complete sample collection, testing, and result evaluation according to the instructions.

5 Usability engineering analysis conclusions

5.1 Whether The Basic Functions And Safety Meet The Requirements

5.1.1 Open the kit: The packaging and labels have met the requirements.

5.1.2 The design of product: The product is easy to operate and the results are acceptable.

5.1.3 The design of product appearance: The product is easy to operate and The appearance design of the product meets user requirements.

5.1.4 Treatment after use of the device: The product is a single-use product and must not be reused. It has been clearly marked on the IFU and labels.

5.1.5 Hygiene: The product is a single-use product and must not be reused. There is no cross-contamination will occur and the packaging should not be used if it is damaged or expired.

5.2 Conclusion

Through the above analysis, the product has provided comprehensive protective measures in design, packaging labels and IFU to prevent unnecessary harm caused by incorrect use.



Clinical Evaluation Report

Product name: Rapid COVID-19 Antigen Test (Colloidal Gold)

Company name: Anbio (Xiamen) Biotechnology Co., Ltd.

Duration of experiment: September 01, 2020 to February 05, 2021

Draft / Date: Xinhui Zheng / February 02, 2021

Reviewed By / Date: Jieli Zhang / February 02, 2021

Approved By / Date: Daming Wang / February 05, 2021

Signature: *Daming Wang*

Sign on: February 05, 2021

Place: Xiamen, China



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1. Objective

Anbio (Xiamen) Biotechnology Co., Ltd. intends to introduce Rapid COVID-19 Antigen Test (Colloidal Gold) into the market. The objective of this study was designed to evaluate the user performance of COVID-19 Antigen Colloidal Gold Test.

The test results of samples from clinical cases were compared with RT-PCR results of cases to verify the clinical performance of the test reagent.

2. Background information for clinical evaluation

The novel coronaviruses belong to the β genus of Coronaviridae. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary, for patient management.

3. Materials and Equipment

- (1) Rapid COVID-19 Antigen Test (Colloidal Gold)
Lot: #2020086131 (A1), #2020086132 (A2), #2020086133 (A3)
Manufacturer: Anbio (Xiamen) Biotechnology Co., Ltd.
- (2) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV
Lot: #S1572054
Manufacturer: BGI Genomics Co, Ltd.
- (3) Real time fluorescence quantitative PCR
Type: ABI 7500
Manufacturer: Applied Biosystems
- (4) Clinical specimens

4. Evaluation Sites

- (1) POC in Guangzhou, China
- (2) POC in Xiamen, China
- (3) POC in Beijing, China



The above POC sites are the designated laboratory for COVID-19 testing, and each POC site is operated by 3 - 5 professionals.

5. Number of clinical specimens

Tab1 Number of clinical specimens

Group	PCR result (nasopharyngeal swab)	Sample type	Number	Collection Day
1	Positive	Saliva	At least 100 cases	2020/9/1 to 2021/2/3
2	Negative	Saliva	At least 100 cases	2020/9/1 to 2021/2/3

6. Criteria for Participant

- (1) Gender: Male or female.
- (2) Age: No restriction, neonates are excluded.
- (3) Days from Symptom Onset

Days from Symptom Onset	0-7 days	> 7 days
Percentage	85%	15%

- (4) Mild patients: Minor respiratory symptoms, no fever and there is no pneumonia in imaging.

Moderate patients: Respiratory symptoms, Fever and pneumonia can be seen on imaging.

Severe patients: Breathless, $RR \geq 30$ times/min, or Finger oxygen saturation $\leq 93\%$ when inhaling air in resting state, or $PaO_2/FiO_2 \leq 300$ mmHg, or Lung imaging showed that the lesions progressed significantly by 50% within 24-48 hours.

Critically ill patients: Respiratory failure occurs and requires mechanical ventilation, or shock, or combined occurrence of other organ failure requires ICU monitoring and treatment.

- (5) Test within 24 hours after sample collection.

7. Clinical specimens' storage

- (1) Applicable clinical specimen's type: nasal swab specimen
- (2) Storage: Samples should be tested as soon as possible after collection. Processed samples (add Extraction Solution) are stable for up to 24 hours at room temperature or 2°C to 8°C and cannot be frozen.
- (3) The specimens must be balanced to room temperature before testing.

8. Operation

8.1 Limit of Detection (LoD)

(1) The LOD for the Rapid COVID-19 Antigen Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 virus. The material was supplied frozen at a concentration of 3.40×10^5 TCID₅₀/mL.

In this study, designed to estimate the LOD of the assay when using a direct saliva, the starting material was spiked into a volume of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices with 3 batches using a 10-fold dilution series of 3 replicates per concentration. At each dilution, 1mL samples were added to Saliva collection device then tested in the assay using the procedure appropriate for patient saliva specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was



further refined with a dilution series of 3 replicates per concentration.

Choose 3 concentrations (negative, LOD, 2 LOD) repeat the test for each concentration 20 times. Calculate the positive rate, the lowest concentration where the positive rate is greater than or equal to 95% is LOD.

This study included the use of three different lots of the Rapid COVID-19 Antigen Test.

(2) Clinical sample verification

Test clinically confirmed population samples to determine the TCID₅₀ of samples. Select 30 samples with concentration between 2.215×10^2 TCID₅₀/mL and 4.24×10^2 TCID₅₀/mL, select 30 samples with concentration between 4.25×10^2 TCID₅₀/mL and 8.5×10^2 TCID₅₀/mL for testing.

8.2 Cross-Reactivity

8.2.1 Cross reactivity sample preparation

(1) Preparation of saliva samples (negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 1).

(2) Preparation of saliva samples (positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentrations are 3 LOD and 1.5 LOD, add interfering substances (according to the final concentration in Table 1).

8.2.2 Test clinical specimens with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold)

according to the Instruction for Use. Each sample was tested 3 times per batch. Record the results respectively. Positive signals are recorded as "+" and negative signals are recorded as "-".

8.2.3 Check if there were "-" for C line, which indicates invalid test results. If any invalid test were observed, the invalid results should be abandoned, and the specimen should be tested again. If the second test of the specimen were still invalid, the specimen should be abandoned from the experiment.

8.2.4 Check if there was "+" for T line, which indicates a positive result. Otherwise it is a negative result. Count and record the number of positive result(s) (Np) and negative result(s) (Nn).

8.2.5 Calculate the ratio of negative results versus total tests (Nn%) with formula $Nn\% = Nn/(Np+Nn) \times 100\%$; Calculate the ratio of positive results versus total tests (Np%) with formula $Np\% = Np/(Np+Nn) \times 100\%$.

8.2.6 Information about Cross Reactivity of potential reactants

Tab1 List of cross reactivity species

S.N.	Potential cross-reactant	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10^6 pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10^6 pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6 pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6 pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6 pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6 pfu/mL
7	Influenza B Victoria	B-Victoria	10^6 pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10^6 pfu/mL

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9	Respiratory syncytial virus type B	RSV-B	10 ⁶ pfu/mL
10	Enterovirus A	CV-A10	10 ⁶ pfu/mL
11	Enterovirus B	Echovirus 6	10 ⁶ pfu/mL
12	Enterovirus C	CV-A21	10 ⁶ pfu/mL
13	Enterovirus D	EV-D68	10 ⁶ pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10 ⁶ pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10 ⁶ pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10 ⁶ pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10 ⁶ pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10 ⁶ pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10 ⁶ pfu/mL
20	Adenovirus type 1	HAdV-1 VR-1	10 ⁶ pfu/mL
21	Adenovirus type 2	HAdV-2 VR-846	10 ⁶ pfu/mL
22	Adenovirus type 3	HAdV-3	10 ⁶ pfu/mL
23	Adenovirus type 4	HAdV-4 VR-1572	10 ⁶ pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10 ⁶ pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10 ⁶ pfu/mL
26	Adenovirus type 55	HAdV-55	10 ⁶ pfu/mL
27	Human metapneumovirus	HMPV	10 ⁶ pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10 ⁶ pfu/mL
29	Measles virus	MV VR-24	10 ⁶ pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10 ⁶ pfu/mL
31	Rotavirus	RV VR-2018	10 ⁶ pfu/mL
32	Norovirus	NOR	10 ⁶ pfu/mL
33	Mumps virus	MuV VR-106	10 ⁶ pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10 ⁶ pfu/mL



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35	Legionella	33152	10 ⁷ cfu/mL
36	Bordetella pertussis	BAA-589	10 ⁷ cfu/mL
37	Haemophilus influenzae	Hib	10 ⁷ cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10 ⁷ cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10 ⁷ cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10 ⁷ cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10 ⁷ cfu/mL
42	Mycobacterium tuberculosis	25177	10 ⁷ cfu/mL
43	Mycoplasma pneumoniae	39505	10 ⁷ cfu/mL
44	Chlamydia pneumoniae	VR-2282	10 ⁷ cfu/mL
45	Aspergillus fumigatus	AF293	10 ⁷ cfu/mL
46	Candida albicans	SC5314	10 ⁷ cfu/mL
47	Candida glabrata	ATCC 2001	10 ⁷ cfu/mL
48	Cryptococcus neoformans	H99	10 ⁷ cfu/mL
49	Cryptococcus gutii	R265	10 ⁷ cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10 ⁷ cfu/mL
51	Coronavirus229E	VR-740	10 ⁶ pfu/mL
52	CoronavirusOC43	VR-1558	10 ⁶ pfu/mL
53	CoronavirusNL63	COV-NL63	10 ⁶ pfu/mL
54	Coronavirus HKU1	COV-HKU1	10 ⁶ pfu/mL
55	Coronavirus MERS	MERS	10 ⁸ TU/mL
56	Coronavirus SARS	SARS	10 ⁸ TU/mL
57	Pooled human nasal wash	/	10 ⁷ cfu/mL

8.3 Interference Substances Study

8.3.1 Interference sample preparation

(1) Preparation of saliva samples (negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 2).

(2) Preparation of saliva samples (positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentration is 3 LOD, add interfering substances (according to the final concentration in Table 2).

8.3.2 Test the interference samples with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold) according to the Instruction for Use. Each sample was tested 5 times per batch. Record the results respectively. Positive signals are recorded as “+” and negative signals are recorded as “-”.



8.3.3 Check if there were “-” for C line, which indicates invalid test results (Ri). Count the total number of Ri.

8.3.4 Check if there were “+” for T line while testing negative samples. Any “+” should be regarded as false positive (Fp). Count the total number of Fp. Check if there were “-” for T line while testing positive samples. Any “-” should be regarded as false negative (Fn). Count the total number of Fn.

8.4 Clinical Trials

(1) Specimens collection and information record

The main researchers of the clinical institutions designate special personnel to select the eligible cases according to the enrollment criteria, and collect the clinical information of the enrolled specimens, including: age, gender, clinical symptoms, clinical classification (mild or moderate), sample collection time and other information. The specimens are numbered according to the sequence before and after grouping, i.e. Specimens number.

(2) Specimens blinding

The main researchers of the clinical institution designated the person to randomly number the specimens in the group with the random number generating tool, record the random number of the specimens and the corresponding specimens number, and the person arranged the specimens according to the sequence of the random number, and handed them to the test operator for testing according to this sequence, noting that the person and the test operator cannot be the same person.

(3) Testing

The test operator shall test the specimens and operate according to the instructions. RT-PCR test is used for in-vitro qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in nasopharyngeal swab, oropharyngeal swab, sputum, and alveolar lavage fluid samples.

(4) Unblinding

At the end of the test, according to the corresponding relationship between random number and specimens' number, record the test results.

(5) Result determination

The test results should be statistically analyzed with clinical diagnosis to evaluate the clinical application performance of the product.

9. Control method

(1) Before the start of clinical research, the enterprise shall train the researchers to make them familiar with and master the operation method and technical performance of the product, to minimize the test error.

(2) Researchers should strictly follow the product's operation specifications and related requirements for testing to ensure that the testing error can be minimized.

(3) The supervisors shall check the relevant activities and documents of the clinical trial, whether the trial is conducted in accordance with the test scheme, standard operating procedures and relevant regulations, and whether the test data is recorded in a timely, clear, accurate and complete manner.

10. Data management

(1) Traceability of data, filling, and transfer of case report form

Ensure the traceability of clinical trial data. According to the original observation records of the subjects, the researchers recorded the data in the case report form in a timely, complete, accurate



and clear manner. The supervisor shall monitor whether the trial is carried out in accordance with the plan, confirm that the case report form is filled in correctly and completely, and is consistent with the original data. In case of any mistake or omission, the researcher shall be required to correct it in time. The original record shall be kept clear and visible during modification, and the correction shall be signed and dated by the researcher.

(2) Data entry and modification

To ensure the accuracy of data, two data entry personnel are responsible for independent entry and proofreading. During the data analysis, for the questions in the case report form, the researcher should answer and return them as soon as possible, and the statistician should modify, confirm, and input them according to the researcher's answers.

(3) Lock of database

At the end of the test, after data entry, the researcher and the sponsor check the data, and lock the data after confirming that the data set is correct, and then lock the data for statistical analysis.

11. Results and Statistical Analysis

11.1 Results for Limit of Detection (LoD)

(1) LOD of human saliva specimen matrix

Tab2 Results of 10-fold dilution series

	TCID ₅₀	A1			A2			A3		
1	3.40x10 ⁵ /mL	+	+	+	+	+	+	+	+	+
2	3.40x10 ⁴ /mL	+	+	+	+	+	+	+	+	+
3	3.40x10 ³ /mL	+	+	+	+	+	+	+	+	+
4	3.40x10 ² /mL	-	+	-	-	-	-	-	+	-
5	3.40x10 ¹ /mL	-	-	-	-	-	-	-	-	-
6	3.40/mL	-	-	-	-	-	-	-	-	-

Tab3 Results of fold dilution series

	TCID ₅₀	A1			A2			A3		
1	3.40x10 ³ /mL	+	+	+	+	+	+	+	+	+
2	1.70x10 ³ /mL	+	+	+	+	+	+	+	+	+
3	8.5x10 ² /mL	+	+	+	+	+	+	+	+	+
4	4.25x10 ² /mL	+	+	+	+	+	+	+	+	+
5	3.40x10 ² /mL	-	-	+	-	+	-	-	-	-
6	2.125x10 ² /mL	-	-	-	-	-	-	-	-	-

Tab4 Repeat test results for LOD

	8.5x10 ² TCID ₅₀ /mL			4.25x10 ² TCID ₅₀ /mL			3.40x10 ² TCID ₅₀ /mL		
	A1	A2	A3	A1	A2	A3	A1	A2	A3
1	+	+	+	+	+	+	-	-	-
2	+	+	+	+	+	+	-	-	-
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-
6	+	+	+	+	+	+	-	-	-
7	+	+	+	+	-	+	-	-	-
8	+	+	+	+	+	-	-	-	-



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9	+	+	+	+	+	+	-	-	-
10	+	+	+	+	+	+	+	-	-
11	+	+	+	+	+	+	-	+	-
12	+	+	+	+	+	+	-	-	-
13	+	+	+	+	+	+	-	-	-
14	+	+	+	+	+	+	-	-	-
15	+	+	+	+	+	+	-	-	-
16	+	+	+	+	+	+	+	-	-
17	+	+	+	+	+	+	-	-	-
18	+	+	+	+	+	+	-	-	-
19	+	+	+	+	+	+	-	-	-
20	+	+	+	+	+	+	-	-	-
Positive rate	100% (60/60)			96.7% (58/60)			5% (3/60)		

(2) Clinical sample verification

Tab5 Saliva specimen (2.215×10^2 TCID₅₀/mL~ 4.24×10^2 TCID₅₀/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	-	-	-	16	-	-	-
2	-	-	-	17	-	-	-
3	-	-	-	18	-	-	-
4	-	-	-	19	-	-	-
5	-	-	-	20	-	-	-
6	-	-	-	21	-	-	-
7	-	-	-	22	-	-	-
8	-	-	-	23	-	-	-
9	-	-	-	24	-	-	-
10	-	-	-	25	-	-	-
11	-	-	-	26	-	-	-
12	-	-	-	27	-	-	-
13	-	-	-	28	-	-	-
14	-	-	-	29	-	-	-
15	-	-	-	30	-	-	-

Tab6 Saliva specimen (4.25×10^2 TCID₅₀/mL~ 8.5×10^2 TCID₅₀/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	+	+	+	16	+	+	+
2	+	+	+	17	+	+	+
3	+	+	+	18	+	+	+
4	+	+	+	19	+	+	+
5	+	+	+	20	+	+	+
6	+	+	+	21	+	+	+
7	+	+	+	22	+	+	+
8	+	+	+	23	+	+	+
9	+	+	+	24	+	+	+



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10	+	+	+	25	+	+	+
11	+	+	+	26	+	+	+
12	+	+	+	27	+	+	+
13	+	+	+	28	+	+	+
14	+	+	+	29	+	+	+
15	+	+	+	30	+	+	+

11.2 Results for Cross Reactivity Study

Tab7 Test results of saliva specimens with common respiratory infections

S.N.	A1			A2			A3		
1	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-



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35	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-
55	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-

Tab8 Test Results of Nn% (saliva)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	0	9	100%
Seasonal H1N1 influenza virus	9	0	9	100%
H3N2 influenza virus	9	0	9	100%
H5N1 avian influenza virus	9	0	9	100%
H7N9 avian influenza virus	9	0	9	100%
Influenza B Yamagata	9	0	9	100%
Influenza B Victoria	9	0	9	100%
Respiratory syncytial virus type A	9	0	9	100%
Respiratory syncytial virus type B	9	0	9	100%
Enterovirus A	9	0	9	100%
Enterovirus B	9	0	9	100%
Enterovirus C	9	0	9	100%
Enterovirus D	9	0	9	100%
Parainfluenza virus type 1	9	0	9	100%
Parainfluenza virus type 2	9	0	9	100%



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Parainfluenza virus type 3	9	0	9	100%
Rhinovirus A	9	0	9	100%
Rhinovirus B	9	0	9	100%
Rhinovirus C	9	0	9	100%
Adenovirus type 1	9	0	9	100%
Adenovirus type 2	9	0	9	100%
Adenovirus type 3	9	0	9	100%
Adenovirus type 4	9	0	9	100%
Adenovirus type 5	9	0	9	100%
Adenovirus type 7	9	0	9	100%
Adenovirus type 55	9	0	9	100%
Human metapneumovirus	9	0	9	100%
Epstein-Barr virus	9	0	9	100%
Measles virus	9	0	9	100%
Human cytomegalovirus	9	0	9	100%
Rotavirus	9	0	9	100%
Norovirus	9	0	9	100%
Mumps virus	9	0	9	100%
Varicella-zoster virus	9	0	9	100%
Legionella	9	0	9	100%
Bordetella pertussis	9	0	9	100%
Haemophilus influenzae	9	0	9	100%
Staphylococcus aureus	9	0	9	100%
Streptococcus pneumoniae	9	0	9	100%
Streptococcus pyogenes	9	0	9	100%
Klebsiella pneumoniae	9	0	9	100%
Mycobacterium tuberculosis	9	0	9	100%
Mycoplasma pneumoniae	9	0	9	100%
Chlamydia pneumoniae	9	0	9	100%
Aspergillus fumigatus	9	0	9	100%
Candida albicans	9	0	9	100%
Candida glabrata	9	0	9	100%
Cryptococcus neoformans	9	0	9	100%
Cryptococcus gutii	9	0	9	100%
Pneumocystis jirovecii (PJP)	9	0	9	100%
Coronavirus229E	9	0	9	100%
CoronavirusOC43	9	0	9	100%
CoronavirusNL63	9	0	9	100%
Coronavirus HKU1	9	0	9	100%
Coronavirus MERS	9	0	9	100%
Coronavirus SARS	9	0	9	100%
Pooled human nasal wash	9	0	9	100%

Tab9 Test results of saliva specimens (1.5 LOD)



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S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+



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43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab10 Test Results of Np% (1.5 LOD)

Cross reactant	Total tests	Positive results	Negative results	Np%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%



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Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

Tab11 Test results of saliva specimens (3 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+



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8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+



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51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab12 Test Results of Np% (3 LOD)

Cross reactant	Total tests	Positive results	Negative results	Np%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%



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Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

11.3 Results for Interference Substances Study

Tab13 Results of testing interference saliva samples(negative)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	-	-	+	+	-	-	-	-	-	+	-	-	-	-	-
		4%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Mucin	1%(v/v)	+	+	+	-	+	+	+	+	-	-	+	+	+	+	+
		0.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.25%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	Ricola (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Sucrets (Dyclonin)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Sucrets (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Chloraseptic (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Chloraseptic (Benzocaine)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Naso GEL (NeilMed)	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	Afrin (Oxymetazoline)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Nasal Gel (Oxymetazoline)	10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	Zicam	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	Homeopathic (Alkalol)	1:10	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	Fisherman's Friend	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	Sore Throat Phenol Spray	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	Tobramycin	4µg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2µg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1µg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	Mupirocin	10mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	Fluticasone Propionate	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Tab14 Results of testing interference saliva samples (positive)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	+	-	+	+	+	-	-	-	+	+	+	-	-	+	+
		4%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	Mucin	1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.25%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3	Ricola (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4	Sucrets (Dyclonin)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	Sucrets (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6	Chloraseptic (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Chloraseptic (Benzocaine)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8	Naso GEL (NeilMed)	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	Afrin (Oxymetazoline)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
12	Nasal Gel (Oxymetazoline)	10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
13	Zicam	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+



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		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Homeopathic (Alkalol)	1:10	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:15	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:20	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
15	Fisherman's Friend	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
16	Sore Throat Phenol Spray	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
17	Tobramycin	4µg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2µg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1µg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
18	Mupirocin	10mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
19	Fluticasone Propionate	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Tab15 Results summary of interference experiment

Substances	Concentration	Ri	Fp	Fn
Whole Blood	10%(v/v)	0	20%	40%
	4%(v/v)	0	0	0
	1%(v/v)	0	0	0
Mucin	1%(v/v)	0	80%	0
	0.5%(v/v)	0	0	0
	0.25%(v/v)	0	0	0
Ricola (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Dyclonin)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic	1.5mg/mL	0	0	0



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(Benzocaine)	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Naso GEL (NeilMed)	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
CVS Nasal Drops (Phenylephrine)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Afrin (Oxymetazoline)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
CVS Nasal Spray (Cromolyn)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Nasal Gel (Oxymetazoline)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
Zicam	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Homeopathic (Alkalol)	1:10	0	0	0
	1:15	0	0	0
	1:20	0	0	0
Fisherman's Friend	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sore Throat Phenol Spray	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Tobramycin	4µg/mL	0	0	0
	2µg/mL	0	0	0
	1µg/mL	0	0	0
Mupirocin	10mg/mL	0	0	0
	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
Fluticasone Propionate	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0



11.4 Results for Clinical Trials

11.4.1 Results analysis table

Tab16 Analysis table of clinical specimens' results (Saliva)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	524(a)	0(b)	524(a+b)
Antigen Test (Colloidal	Negative	26(c)	123(d)	149(c+d)
Gold) result	Total	550(a+c)	123(b+d)	673(a+b+c+d)

11.4.2 Coincidence rate and 95% confidence interval

Tab17 Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	95.27%	93.15%~96.89%
Clinical specificity	100%	97.05%~100%
Total coincidence rate	96.14%	94.39%~97.46%

11.4.3 Statistical Analysis

Kappa value (K) calculation

$K = 0.8805 > 0.75$ indicates that the high consistency of two methods and equivalence of two such systems.

11.4.4 Separate analysis

(1) Clinical classification

Tab18 Analysis table of different Clinical classification

	Mild	Moderate	Severe	Critically ill
PCR result	437	76	25	12
Product result	418	69	25	12
PPA	95.65%	90.79%	100%	100%

(2) Clinical classification

Tab19 Analysis table of different days from symptom onset

	0-7 days	>7 days
PCR result	486	64
Product result	465	59
PPA	95.68%(95% CI:93.47%~97.31%)	92.19%(95% CI:82.70%~97.42%)

Simultaneous PCR and antigen testing were performed on 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The sensitivity of antigen detection is 95.68% (95% CI: 93.47%~97.31%).

11.4.5 Determination of diagnostic sensitivity (0-7 days after the onset of symptoms)

	Statistics
Sample number	Antigen-positive:465, Antigen-negative:21
Ct value average(PCR-positive)	34.68
Ct value average(antigen-positive / PCR-positive)	34.53
Ct value average(antigen-negative / PCR-positive)	37.54



Ct value average(Detection rate> 90%)	34.21
---------------------------------------	-------

12. Conclusion

12.1 Limit of Detection (LoD)

	Estimated LOD/Cut off	No. Positive/Total	% Positive
saliva specimen	4.25 x10 ² TCID ₅₀ /mL	58/60	96.7%

The LOD/Cut-off value of the Rapid COVID-19 Antigen Test (Colloidal Gold) is 4.25 x10² TCID₅₀/mL.

12.2 Cross-Reactivity

None of the viral and microbial pathogens tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold).

Tab20 Non-interfering Viruses / Microbials

S.N.	Viruses / Microbials	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10 ⁶ pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10 ⁶ pfu/mL
3	H3N2 influenza virus	A-H3N2	10 ⁶ pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10 ⁶ pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10 ⁶ pfu/mL
6	Influenza B Yamagata	B-Yamagata	10 ⁶ pfu/mL
7	Influenza B Victoria	B-Victoria	10 ⁶ pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10 ⁶ pfu/mL
9	Respiratory syncytial virus type B	RSV-B	10 ⁶ pfu/mL
10	Enterovirus A	CV-A10	10 ⁶ pfu/mL
11	Enterovirus B	Echovirus 6	10 ⁶ pfu/mL
12	Enterovirus C	CV-A21	10 ⁶ pfu/mL
13	Enterovirus D	EV-D68	10 ⁶ pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10 ⁶ pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10 ⁶ pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10 ⁶ pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10 ⁶ pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10 ⁶ pfu/mL

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19	Rhinovirus C	HRV-16 VR-283	10 ⁶ pfu/mL
20	Adenovirus type 1	HadV-1 VR-1	10 ⁶ pfu/mL
21	Adenovirus type 2	HadV-2 VR-846	10 ⁶ pfu/mL
22	Adenovirus type 3	HadV-3	10 ⁶ pfu/mL
23	Adenovirus type 4	HadV-4 VR-1572	10 ⁶ pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10 ⁶ pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10 ⁶ pfu/mL
26	Adenovirus type 55	HAdV-55	10 ⁶ pfu/mL
27	Human metapneumovirus	HMPV	10 ⁶ pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10 ⁶ pfu/mL
29	Measles virus	MV VR-24	10 ⁶ pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10 ⁶ pfu/mL
31	Rotavirus	RV VR-2018	10 ⁶ pfu/mL
32	Norovirus	NOR	10 ⁶ pfu/mL
33	Mumps virus	MuV VR-106	10 ⁶ pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10 ⁶ pfu/mL
35	Legionella	33152	10 ⁷ cfu/mL
36	Bordetella pertussis	BAA-589	10 ⁷ cfu/mL
37	Haemophilus influenzae	Hib	10 ⁷ cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10 ⁷ cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10 ⁷ cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10 ⁷ cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10 ⁷ cfu/mL
42	Mycobacterium tuberculosis	25177	10 ⁷ cfu/mL
43	Mycoplasma pneumoniae	39505	10 ⁷ cfu/mL
44	Chlamydia pneumoniae	VR-2282	10 ⁷ cfu/mL
45	Aspergillus fumigatus	AF293	10 ⁷ cfu/mL
46	Candida albicans	SC5314	10 ⁷ cfu/mL



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47	Candida glabrata	ATCC 2001	10 ⁷ cfu/mL
48	Cryptococcus neoformans	H99	10 ⁷ cfu/mL
49	Cryptococcus gutii	R265	10 ⁷ cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10 ⁷ cfu/mL
51	Coronavirus229E	VR-740	10 ⁶ pfu/mL
52	CoronavirusOC43	VR-1558	10 ⁶ pfu/mL
53	CoronavirusNL63	COV-NL63	10 ⁶ pfu/mL
54	Coronavirus HKU1	COV-HKU1	10 ⁶ pfu/mL
55	Coronavirus MERS	MERS	10 ⁸ TU/mL
56	Coronavirus SARS	SARS	10 ⁸ TU/mL
57	Pooled human nasal wash	/	10 ⁷ cfu/mL

12.3 Interference Substances Study

None of the substances tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold).

Tab21 Non-interfering Substances

S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration
1	Whole Blood	4%(v/v)	11	CVS Nasal Spray (Cromolyn)	15%(v/v)
2	Mucin	0.5%(v/v)	12	Nasal Gel (Oxymetazoline)	10%(v/v)
3	Ricola (Menthol)	1.5mg/mL	13	Zicam	5%(v/v)
4	Sucrets (Dyclonin)	1.5mg/mL	14	Homeopathic (Alkalol)	1:10
5	Sucrets (Menthol)	1.5mg/mL	15	Fisherman's Friend	1.5mg/mL
6	Chloraseptic (Menthol)	1.5mg/mL	16	Sore Throat Phenol Spray	15%(v/v)
7	Chloraseptic (Benzocaine)	1.5mg/mL	17	Tobramycin	4µg/mL
8	Naso GEL (NeilMed)	5%(v/v)	18	Mupirocin	10mg/mL
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	19	Fluticasone Propionate	5%(v/v)
10	Afrin (Oxymetazoline)	15%(v/v)	20	Tamiflu (Oseltamivir Phosphate)	5mg/mL



12.4 Clinical Trials

(1) In summary, 572 samples were tested in this clinical trial, Among them, there were 562 cases with product test results consistent with RT-PCR result in this clinical trial, included 221 cases were positive, 341 cases were negative.

(2) There were overall 10 cases of product test results inconsistent with RT-PCR result in this clinical trial due to the difference in methodologies used.

Tab22 Inconsistent results

No.	Sampling day	Age	Sex (F/M)	Days from Symptom Onset	Clinical classification	Saliva result	PCR result			
							Ct value (RdRP)	Ct value (N gene)	Ct value (E gene)	result
3	2020/9/1	67	F	2	Moderate	-	36	37	39	+
19	2020/9/11	42	F	9	Mild	-	38	38	36	+
42	2020/10/1	51	F	4	Mild	-	36	/	38	+
50	2020/10/1	60	M	4	Mild	-	37	41	/	+
51	2020/10/1	47	F	2	Mild	-	39	/	37	+
80	2020/10/9	27	F	6	Mild	-	37	37	36	+
89	2020/10/9	37	M	2	Mild	-	38	39	/	+
90	2020/10/9	71	M	2	Mild	-	39	/	/	+
99	2020/10/9	62	M	4	Moderate	-	39	38	38	+
115	2020/10/16	59	F	1	Mild	-	34	35	36	+
122	2020/11/2	42	F	3	Mild	-	37	/	38	+
124	2020/11/2	64	M	8	Moderate	-	40	36	38	+
135	2020/11/2	31	M	1	Moderate	-	37	40	38	+
143	2020/11/13	18	F	4	Mild	-	35	35	38	+
146	2020/11/13	31	M	6	Moderate	-	35	35	/	+
165	2020/11/16	64	M	8	Mild	-	35	37	37	+
166	2020/11/16	33	F	2	Moderate	-	36	38	37	+
171	2020/11/16	50	F	1	Moderate	-	39	/	/	+
182	2020/11/21	54	F	5	Mild	-	37	38	40	+
203	2020/11/25	56	F	10	Mild	-	39	41	40	+
215	2020/11/30	31	M	3	Mild	-	37	39	38	+
269	2020/12/05	17	F	2	Mild	-	39	41	39	+
281	2020/12/05	11	F	2	Mild	-	39	/	40	+
334	2020/12/10	77	F	2	Mild	-	39	38	41	+
395	2020/12/13	71	F	14	Mild	-	39	39	38	+
522	2021/01/07	23	M	1	Mild	-	40	41	/	+

(3) The sensitivity, specificity and total coincidence rate of product testing and RT-PCR result are 95.27%,100% and 96.14%, respectively. The sensitivity is more than 95%, the specificity is more than 99%.

(4) $K = 0.8805 > 0.75$ indicates that the high consistency of two methods and equivalence of two such systems.

(5) 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The



sensitivity of antigen detection is 95.68%(95% CI:93.47%~97.31%).

(6) 486 patients with new coronavirus infections whose symptoms appeared within 0-7 days. The Ct value average (PCR-positive) is 34.68; the Ct value average (antigen-positive / PCR-positive) is 34.53; the Ct value average (antigen-negative / PCR-positive) is 37.54; Diagnostic sensitivity: The Cut-off value (Ct value average) of this reagent is 34.21 (Detection rate> 90%).

(7) The specificity rate of antigen testing and RT-PCR result are 100% for 123 Non-infected.

Test zur Eigenanwendung - Befristete Sonderzulassung zur Eigenanwendung nach §11 MPG in Deutschland (BfArM GZ: 5640-S-058/21)**COVID-19 Antigen Schnelltest (Kolloidales Gold) Schnelltest (Spucktest) für die Eigenanwendung**

Zur Anwendung bei Personen zwischen 18 und 75 Jahren.

Bei Kindern und Jugendlichen unter 18 Jahren, sowie bei Personen über 75 Jahren nur unter Aufsicht einer zur Anwendung berechtigten Person.

VERWENDUNGSZWECK

Der „HYGISUN® COVID-19 Antigen Schnelltest (Kolloidales Gold) Schnelltest (Spucktest) für die Eigenanwendung“ ist ein immunologischer Lateral-Flow-Test zur qualitativen Bestimmung von SARS-CoV-2-Nukleokapsid-Antigenen in Speichelproben des Menschen und für die Eigenanwendung geeignet. Der Test liefert ein schnelles Ergebnis über das mögliche Vorliegen einer COVID-19 Infektion bei der untersuchten Person. Für die Testdurchführung ist keine invasive Probenentnahme notwendig.

Der Antigentest kann bei Einhaltung der Gebrauchsanweisung einen wichtigen Beitrag zur **Pandemiebekämpfung** leisten, da der Antigentest in der akuten Phase der Infektion, wenn die Viruslast groß ist, der Patient aber oft noch symptomfrei ist, bereits reagiert. Bei korrekter Durchführung des Tests sowie der anschließenden Bestätigung positiver Testergebnisse durch einen PCR-Test, kann ein schnelles eigenverantwortliches Ergreifen von Maßnahmen zu einer Verbesserung des Infektionsschutzes und zu einer **Verlangsamung der Ausbreitung von SARS-CoV-2** führen.

Das Testen entbindet nicht von der Einhaltung der AHA+L-Regel (Abstand, Hygiene, Alltagsmasken, Lüften).

Positives Testergebnis: Ein positives Ergebnis liefert den Hinweis auf eine SARS-CoV-2 Infektion. Bitte begeben Sie sich in Quarantäne, halten Sie die örtlichen Richtlinien zur Selbstisolation ein und kontaktieren Sie umgehend einen Arzt oder das örtliche Gesundheitsamt. Ein PCR-Bestätigungstest ist notwendig!

Negatives Testergebnis: Ein negatives Ergebnis schließt eine Infektion mit SARS-CoV-2 nicht aus. Ein negatives Testergebnis ist nur eine Momentaufnahme. Im Verdachtsfall wiederholen Sie den Test nach 1-2 Tagen, da das Coronavirus nicht in allen Phasen einer Infektion genau nachgewiesen werden kann. Ein negatives Ergebnis entbindet nicht von der Einhaltung der AHA+L-Regel.

Ungültiges Testergebnis: Ein ungültiges Ergebnis ist eventuell hervorgerufen durch fehlerhafte Testdurchführung. Wiederholen Sie daher bitte den Test. Bei weiterhin ungültigen Testergebnissen ist ein Arzt oder ein COVID-19 Testzentrum zu kontaktieren.

ZUSAMMENFASSUNG

SARS-CoV-2 (severe acute respiratory syndrome coronavirus type 2) ist ein neues Beta-Coronavirus, das Anfang 2020 als Auslöser der COVID-19 Erkrankung identifiziert wurde. Coronaviren sind unter Säugetieren und Vögeln weit verbreitet. Sie verursachen beim Menschen vorwiegend milde Erkältungskrankheiten, können aber mitunter schwere Atemwegserkrankungen hervorrufen. Zu den häufigsten Symptomen zählen Husten, Fieber, Schnupfen und Beeinträchtigung des Geruchs- und/oder Geschmackssinns. Der Hauptübertragungsweg für SARS-CoV-2 ist die respiratorische Aufnahme virushaltiger Partikel, die beim Atmen, Husten, Sprechen, Singen und Niesen entstehen. Die Übertragung erfolgt von bereits infizierten Personen mit Symptomen aber auch symptomfreien infizierten Personen. Basierend auf aktuellen epidemiologischen Untersuchungen beträgt die mittlere Inkubationszeit 5-6 Tage, sie kann jedoch auch bis zu 14 Tage dauern.

VERPACKUNGSEINHEITEN

Einzelpackung (1 Test / Packung).

TESTPRINZIP

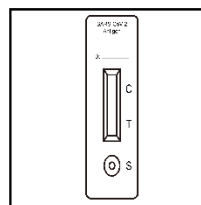
Der Test dient dem Nachweis des SARS-CoV-2-Nukleokapsid-Antigens. Dieses Antigen ist in der Regel während der akuten Phase der Infektion im Speichel nachweisbar. Die COVID-19 Antigen Rapid Test Kassette (Saliva) ist ein immunologischer Lateral-Flow-Test, der auf dem Prinzip der Doppelantikörper-Sandwich-Technik basiert. Der mit farbigen Mikropartikeln konjugierte monoklonale SARS-CoV-2-Nukleokapsid-Protein-Antikörper wird als Detektor verwendet und auf das Konjugationspad gesprüht. Während des Tests interagiert das SARS-CoV-2-Antigen in der Probe mit dem SARS-CoV-2-Antikörper, der mit Farbmikropartikeln konjugiert ist, wodurch ein Antigen-Antikörper-markierter Komplex entsteht. Dieser Komplex wandert aufgrund der Kapillarkraft auf der Membran bis zur Testlinie, wo er vom vorbeschichteten monoklonalen SARS-CoV-2-Nukleokapsid-Protein-Antikörper eingefangen wird. Eine farbige Testlinie (T) wird im Ergebnisfenster sichtbar, wenn SARS-CoV-2-Antigene in der Probe vorhanden sind. Das Fehlen der T-Linie deutet auf ein negatives Ergebnis hin. Die Kontrolllinie (C) dient zur Verfahrenskontrolle und sollte immer angezeigt werden, wenn das Testverfahren ordnungsgemäß durchgeführt wurde.

WARNUNGEN UND VORSICHTSMAßNAHMEN

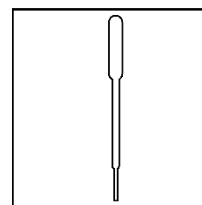
- ◆ Nur zur In-vitro-Diagnostik.
- ◆ Nur für die einmalige Anwendung geeignet.
- ◆ Negative Ergebnisse schließen eine SARS-CoV-2-Infektion nicht aus. Ein negatives Testergebnis ist nur eine Momentaufnahme. Personen, die negativ getestet wurden und weiterhin COVID-ähnliche Symptome aufweisen, sollten sich an Ihren Arzt/Hausarzt wenden.
- ◆ **ENTSORGUNG**
Das Testkit kann mit dem normalen Hausmüll unter Beachtung der geltenden örtlichen Vorschriften entsorgt werden.
- ◆ Verwenden Sie dieses Produkt nicht nach dem Verfallsdatum, welches Sie auf der Außenverpackung finden.
- ◆ Lesen Sie bitte alle Informationen in dieser Packungsbeilage, bevor Sie den Test durchführen.
- ◆ Die Testkassette sollte bis zur Verwendung im versiegelten Beutel aufbewahrt werden.

ZUSAMMENSETZUNG**Einzelpackung**

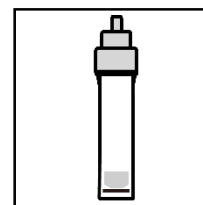
- ◆ 1 Testkassette verpackt im Folienbeutel
- ◆ 1 Einweg-Pipette
- ◆ 1 Speichelsammelgefäß mit 1ml Extraktionslösung
- ◆ 1 Trichter (zum Sammeln des Speichels)
- ◆ 1 Bedienungsanleitung



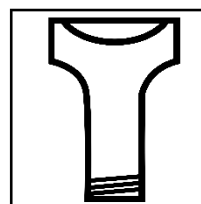
Testkassette verpackt im Folienbeutel



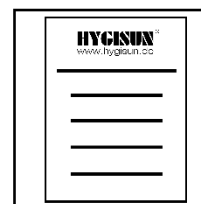
Einweg-Pipette



Speichelsammelgefäß mit 1ml Extraktionslösung



Trichter (zum Sammeln des Speichels)



Bedienungsanleitung

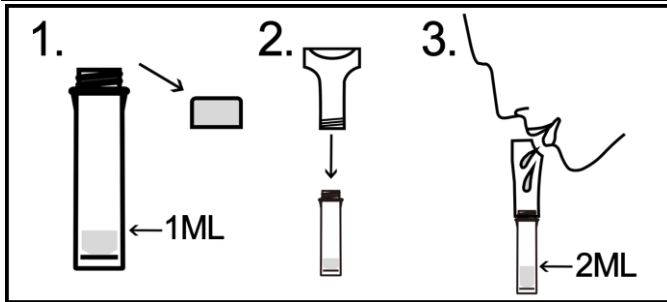
PROBENENTNAHME UND VORBEREITUNG

1. Der COVID-19 Antigen-Schnelltest wird mit einer Speichelprobe durchgeführt.
2. Achtung: Nehmen Sie bitte 30 Minuten vor der Probenentnahme keine Lebensmittel oder Getränke zu sich und vermeiden Sie in diesem Zeitfenster auch Kaugummis und Tabak zu konsumieren, da dies das Testergebnis beeinflussen kann.
3. Machen Sie sich vorab mit dem Inhalt des Testkits vertraut. Alle Materialien sollten Raumtemperatur (15-30°C) aufweisen. Bitte lesen Sie die Gebrauchsanweisung vor Testbeginn genau durch. Sollten Sie Fragen haben, wenden Sie sich an den Hersteller.
4. Stellen Sie eine Uhr bereit.
5. Bitte waschen Sie vor der Probenentnahme Ihre Hände. Vermeiden Sie überflüssigen Hautkontakt mit dem Inneren und dem Rand des Trichters und der weiteren Materialien um Verunreinigungen vorzubeugen.
6. Öffnen Sie die Verpackung des Tests und legen Sie alle Bestandteile des Tests bereit.

Speichel Probenentnahme:

- ◆ Nehmen Sie bitte 30 Minuten vor der Probenentnahme keine Lebensmittel oder Getränke zu sich und vermeiden Sie in diesem Zeitfenster auch Kaugummis und Tabak zu konsumieren, da dies das Testergebnis beeinflussen kann.
- ◆ Sie benötigen den Trichter sowie das Sammelröhrchen für die Probenentnahme.
- 1. Stecken Sie den Trichter in das Sammelröhrchen (Siehe Abbildung.)
- 2. Räuspert Sie sich und lösen Sie den Speichel aus dem Rachen.
- 3. Halten Sie im Anschluss den Trichter nahe an die Lippen und lassen Sie den Speichel über den Trichter in das Sammelröhrchen fließen.

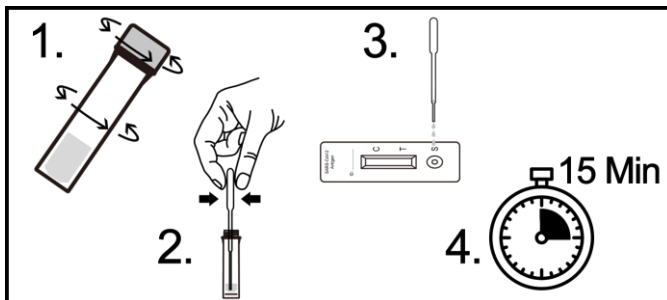
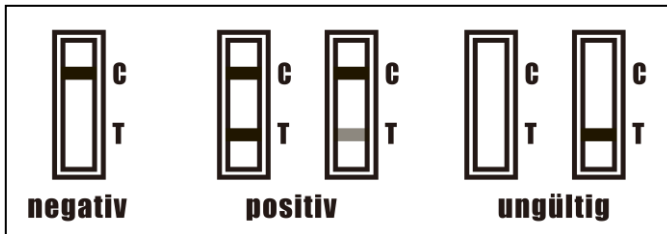
Der Skalenstrich auf dem Sammelröhrchen gibt Ihnen vor, wie viel Speichel für die Probe benötigt wird (entspricht ca. 1 ML).

**Lagerung der Proben**

Frisch entnommene Proben sollten so bald wie möglich, jedoch spätestens eine Stunde nach der Probenentnahme verarbeitet werden.

Testverfahren

- Entsorgen Sie bitte den Trichter. Verschließen Sie das Sammelröhrchen mit dem anhängen- den Verschluss. Anschließend schütteln Sie das Sammelröhrchen mindestens 10x kräftig, um den Speichel und das Extraktionsreagenz zu mischen.
- Entfernen Sie vorsichtig den Deckel und entnehmen Sie mit der Einweg-Pipette die Speichelprobe.
- Nehmen Sie die Testkassette aus der Verpackung, legen Sie sie auf die vorab gesäuberte und ebene Fläche. Geben Sie bitte mit der Einweg-Pipette drei Tropfen Ihrer Speichelprobe in die Vertiefung (S) der Kassette.
- Stoppuhr oder Timer starten und Testergebnis nach **15 Minuten** ablesen.

**INTERPRETATION DER ERGEBNISSE**

Positiv: Es erscheinen zwei Linien. Eine farbige Linie erscheint im Kontrollbereich (C) und eine weitere farbige Linie erscheint im Testbereich (T), diese kann je nach Menge der SARS-CoV-2 in der Probe hinsichtlich der Intensität und Sichtbarkeit variieren.

Negativ: Eine farbige Linie erscheint im Kontrollbereich (C), jedoch keine Linie im Testbereich (T).

Ungültig: Es erscheint entweder keine Linie oder lediglich eine Linie im Testbereich (T). Unzureichendes Probenvolumen oder falsche Verfahrenstechniken sind die wahrscheinlichsten Gründe für das Versagen der Kontrolllinie. Überprüfen Sie das Verfahren und wiederholen Sie alle Schritte mit einem neuen Test.

QUALITÄTSKONTROLLE

Eine Verfahrenskontrolle ist im Test enthalten. Eine farbige Linie im Kontrollbereich (C) gilt als interne Verfahrenskontrolle. Sie bestätigt ein ausreichendes Probenvolumen, die vollständige Durchdringung der Membran mit der Probe sowie eine korrekte Verfahrenstechnik.

EINSCHRÄNKUNGEN

- Der COVID-19 Antigen-Schnelltest ist nur für Speichelproben anwendbar. Die Verwendung von anderen Proben wie Blut, Serum, Plasma oder Nasenabstrichen wurde nicht getestet und sollten daher mit diesem Test nicht verwendet werden.
- Das Produkt ist auf einen qualitativen Nachweis beschränkt. Die Intensität der Testlinie steht nicht zwingend im Einklang mit der Konzentration des Antigens in der Probe. Es ist keine Konzentrationsangabe möglich.
- Wenn Ihre Probe positiv getestet wurde, nehmen Sie bitte Kontakt mit einer Gesundheitsinstitution auf. Ein Bestätigungstest ist notwendig! Zur Reduzierung des Übertragungsrisiko ist die schnelle Isolierung nach einem positiven Testergebnis notwendig, sowie die Identifikation und die frühzeitige Quarantäne enger Kontaktpersonen. Durch die Kontaktaufnahme mit dem Arzt/der Gesundheitsinstitution erfolgt dann auch der Eingang in das Meldesystem, bei bestätigtem Testergebnis. Ohne

vorherige Konsultation eines Arztes kann keine medizinisch wichtige Entscheidungen getroffen werden.

- Ein negatives Testergebnis ist nur eine Momentaufnahme und schließt die Möglichkeit einer SARS-CoV-2-Infektion zu keiner Zeit aus. Negative Ergebnisse können z. B. dann vorliegen, wenn die Viruslast gering ist, wie unter anderem in der frühen Inkubationsphase oder ab der zweiten Woche nach Symptombeginn. Ein falsch-negatives Testergebnis kann aber auch auftreten, wenn die Probe unsachgemäß entnommen wurde, die Virusmenge unter der Nachweisgrenze des Tests liegt oder das Virus eine/mehrere geringfügige Aminosäuremutation(en) in der Zielepitopregion unterzogen hat, die von den im Test verwendeten monoklonalen Antikörpern erkannt werden.

Bitte beachten Sie weiterhin die Hygieneregeln und wiederholen Sie den Test bei Bedarf.

- Bei wiederholt negativem Testergebnis und Vorhandensein von klinischen Symptomen
- oder Kontakt mit dem Virus, bzw. infizierten Personen muss eine zusätzliche Nachuntersuchung mit anderen klinischen Methoden erfolgen, um eine Infektion auszuschließen.
- Das Testergebnis kann nicht als alleinige Grundlage für Entscheidungen zum Patientenmanagement verwendet werden. Ein Arzt muss die Ergebnisse in Kombination mit der Anamnese, den körperlichen Befunden und anderen diagnostischen Verfahren des Patienten bewerten.

Anmerkung: Nicht ausreichende Probenmenge, fehlerhafter Testablauf oder ein abgelaufener Test sind die häufigsten Ursachen für ungültige Ergebnisse

LEISTUNGSMERKMALE**Klinische Leistung**

Die klinische Leistung der COVID-19 Antigen Schnelltest (Kolloidales Gold) wurde in prospektiven Studien mit Proben ermittelt, die von 609 einzelnen symptomatischen Patienten (innerhalb von 7 Tagen nach Krankheitsbeginn) und asymptomatische Patienten mit Verdacht auf COVID-19 gesammelt wurden. Die zusammengefassten Daten des COVID-19 Antigen Schnelltest (Kolloidales Gold) Schnelltest (Spucktest) für die Eigenanwendung lauten wie folgt: Die RT-PCR Zyklus-Schwelle (Ct) ist der relevante Signalwert. Ein niedrigerer Ct-Wert weist auf eine höhere Viruslast hin. Die Sensitivität wurde für die unterschiedlichen Ct-Wertebereiche berechnet (Ct-Wert ≤ 35 und Ct-Wert ≤ 40).

COVID-19 Antigen		RT-PCR (Ct-Wert ≤ 35)		Gesamtergebnis
		Positiv	Negativ	
HYGISUN®	Positiv	279	0	279
	Negativ	3	123	126
Gesamtergebnis		282	125	405

PPA (Ct ≤ 35): 98,94% (279/282), (95% CI: 96,92%~99,78%) NPA: 100,00% (123/123), (95%CI: 97,05%~100,00%)

COVID-19 Antigen		RT-PCR (Ct-Wert ≤ 40)		Gesamtergebnis
		Positiv	Negativ	
HYGISUN®	Positiv	465	0	465
	Negativ	21	123	144
Gesamtergebnis		486	123	609

PPA (Ct ≤ 40): 95,68% (465/486), (95% CI: 93,47%~97,31%) NPA: 100,00% (123/123), (95%CI: 97,05%~100,00%)

Nachweisgrenze (Analytische Sensitivität)

Die Nachweisgrenze für den COVID-19-Antigen-Schnelltest (kolloidales Gold) lag bei $4,25 \times 10^2$ TCID₅₀/mL. Die Nachweisgrenze wurde mit limitierenden Verdünnungen des hitzeinaktivierten SARS-CoV-2-Antigens ermittelt.

Kreuzreaktivität (Analytische Spezifität)

Der Rapid Test SARS-CoV-2 Ag wurde mit Proben getestet, die die folgenden Erreger in den angegebenen Konzentrationen enthielten. Die Ergebnisse zeigten keine Kreuzreaktivität.

Potenzieller Kreuzreaktant	Getestete Konzentration Tested
H1N1(2009)	10^6 pfu/mL
Saisonales H1N1-Influenzavirus	10^6 pfu/mL
H3N2-Influenzavirus	10^6 pfu/mL
Aviären Influenza-H5N1-Virus	10^6 pfu/mL
Aviären Influenza-H7N9-Virus	10^6 pfu/mL
Influenza-B-Yamagata	10^6 pfu/mL
Influenza-B-Victoria	10^6 pfu/mL
Respiratorisches Synzytialvirus Typ A	10^6 pfu/mL
Respiratorisches Synzytialvirus Typ B	10^6 pfu/mL
Enterovirus A	10^6 pfu/mL
Enterovirus B	10^6 pfu/mL

Enterovirus C	10 ⁶ pfu/mL
Enterovirus D	10 ⁶ pfu/mL
Parainfluenza-Virus Typ 1	10 ⁶ pfu/mL
Parainfluenza-Virus Typ 2	10 ⁶ pfu/mL
Parainfluenza-Virus Typ 3	10 ⁶ pfu/mL
Rhinovirus A	10 ⁶ pfu/mL
Rhinovirus B	10 ⁶ pfu/mL
Rhinovirus C	10 ⁶ pfu/mL
Adenovirus Typ 1	10 ⁶ pfu/mL
Adenovirus Typ 2	10 ⁶ pfu/mL
Adenovirus Typ 3	10 ⁶ pfu/mL
Adenovirus Typ 4	10 ⁶ pfu/mL
Adenovirus Typ 5	10 ⁶ pfu/mL
Adenovirus Typ 7	10 ⁶ pfu/mL
Adenovirus Typ 55	10 ⁶ pfu/mL
Menschliches Metapneumovirus	10 ⁶ pfu/mL
Epstein-Barr-Virus	10 ⁶ pfu/mL
Masern-Virus	10 ⁶ pfu/mL
Menschliches Zytomegalie-Virus	10 ⁶ pfu/mL
Rotavirus	10 ⁶ pfu/mL
Norovirus	10 ⁶ pfu/mL
Mumps-Virus	10 ⁶ pfu/mL
Varizella-Zoster-Virus	10 ⁶ pfu/mL
Legionellen	10 ⁷ cfu/mL
Bordetella pertussis	10 ⁷ cfu/mL
Haemophilus influenzae	10 ⁷ cfu/mL
Staphylococcus aureus	10 ⁷ cfu/mL
Streptococcus pneumoniae	10 ⁷ cfu/mL
Streptococcus pyogenes	10 ⁷ cfu/mL
Klebsiella pneumoniae	10 ⁷ cfu/mL
Mycobacterium tuberculosis	10 ⁷ cfu/mL
Mycoplasma pneumoniae	10 ⁷ cfu/mL
Chlamydia pneumoniae	10 ⁷ cfu/mL
Aspergillus fumigatus	10 ⁷ cfu/mL
Candida albicans	10 ⁷ cfu/mL
Candida glabrata	10 ⁷ cfu/mL
Cryptococcus neoformans	10 ⁷ cfu/mL
Cryptococcus gutii	10 ⁷ cfu/mL
Pneumocystis jirovecii (PJP)	10 ⁷ cfu/mL
Coronavirus 229E	10 ⁶ pfu/mL
Coronavirus OC43	10 ⁶ pfu/mL
Coronavirus NL63	10 ⁶ pfu/mL
Coronavirus HKU1	10 ⁶ pfu/mL
Coronavirus MERS	10 ⁸ TU/mL
Coronavirus SARS	10 ⁸ TU/mL
Gepoolte menschliche Nasenspülung	10 ⁷ cfu/mL

Mupirocin	10mg/mL
Fluticason-Propionat	5%(v/v)
Tamiflu (Oseltamivirphosphat)	5mg/mL

VERPACKUNG VERWENDETEN SYMBOLE

	In-vitro-Diagnostikum, nicht schlucken		Nur einmal verwenden
	Verwendbar bis		Vor dem Verwenden Gebrauchsanleitung beachten
	Achtung, bitte Anweisungen im Anhang beachten		Hersteller
	Temperaturgrenze		Chargennummer
	Zugelassener Vertreter der Europäischen Union		Produkt trocken lagern
	Vor Sonneneinstrahlung schützen		Nicht verwenden, wenn die Verpackung beschädigt ist
	Herstellungsdatum		Biologische Risiken

Anleitung Version

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REF: A6061213

【Hersteller】

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www.hygisun.de


Interferenz

Die folgenden Substanzen zeigten keine Interferenzen:

Substanzname	Konzentration
Vollblut	4%(v/v)
Mucin	0.5%(v/v)
Ricola (Menthol)	1.5mg/mL
Sucrets (Dyclonin)	1.5mg/mL
Sucrets (Menthol)	1.5mg/mL
Chloraseptikum (Menthol)	1.5mg/mL
Chloraseptikum (Benzocain)	1.5mg/mL
Naso GEL (NeilMed)	5%(v/v)
CVS Nasentropfen (Phenylephrin)	15%(v/v)
Afrin (Oxymetazolin)	15%(v/v)
CVS Nasenspray (Cromolyn)	15%(v/v)
Nasengel (Oxymetazolin)	10%(v/v)
Zicam	5%(v/v)
Homöopathie (Alkalol)	1:10
Fisherman's Friend	1.5mg/mL
Phenol-Spray gegen Halsschmerzen	15%(v/v)
Tobramycin	4µg/mL