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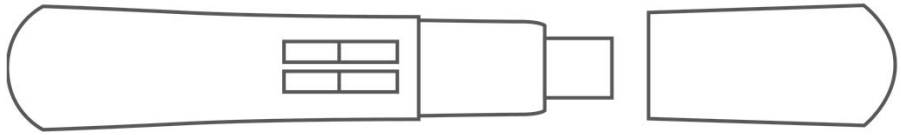
DER **CORONA TEST** LOLLY

DAS ORIGINAL



Keine Tränen. Kein Drama.

Der COVID-19-TEST in wenigen Minuten

- Kinderleicht zum Selbsttesten.
- BfArM gelistet unter Test-ID AT153/20.

CE

Bundesinstitut
für Arzneimittel
und Medizinprodukte

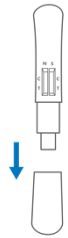
Olly Lolly

In der Liste des Bundesinstituts für Arzneimittel und Medizinprodukte, der Antigentests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 WHO Listung – für Diagnostische SARS-CoV-2 Tests.
Ein-Schritt-Covid-19 Antigentest
Testergebnis innerhalb von 15 Minuten
Lagertemperatur 2-30°C
Kein Rachen und Nasenabstrich nötig
12 Monate Haltbarkeit

Klinische Performance
Sensivität: 89,2%
Spezifizität: 100% Zertifikate

Verpackungseinheit 20 Test-Kits pro Box

Die Anwendung*

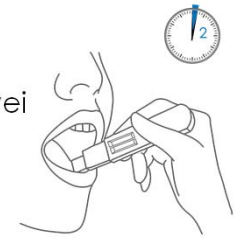


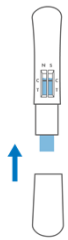
SCHRITT 1:

Tief aus dem Rachen räuspern und mit Speichel im Mund sammeln. Öffnen Sie den Aluminiumfolienbeutel und nehmen Sie das Test Kit heraus und entfernen Sie die Kappe.

SCHRITT 2:

Legen Sie den Testkassetten-Absorptionsstab für zwei Minuten unter die Zunge. Das Kit nimmt so Speichelflüssigkeit auf. Der Schnelltest wird nur bei genügend Speichel aktiviert.



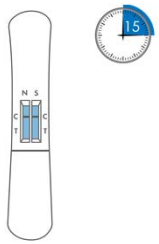


SCHRITT 3:

Halten Sie das Test Kit aufrecht und lassen Sie die Speichelflüssigkeit nach oben wandern, bis sie Linie C erreicht oder überschreitet. Setzen Sie dann den Deckel wieder auf und legen Sie die Testkassette auf den Tisch.

SCHRITT 4:

Deuten Sie das Testergebnis nach 15 Minuten gemäß dem Testergebnis Diagramm.



* OLLY-LOLLY ist ein einfach anzuwendendes Medizinprodukt. Weiterführende Hinweise entnehmen Sie bitte der Gebrauchsanweisung.

Deutung der Testergebnisse

Positiv:

Es erscheinen zwei Linien im Bereich N und/oder S. Eine schwarze Linie befindet sich in der Kontrollregion (C), eine weitere hellgraue/ schwarze Linie befindet sich in der Testregion (T). Ein positives Ergebnis bedeutet, dass in der Speichelprobe SARS-CoV-2 N/S-Antigene vorhanden sind. Der Farbton im Bereich der Testlinie (T) kann variieren, sollte aber immer als positiv angesehen werden, sobald eine schwache Linie vorhanden ist.
Bei einem positiven Test begeben Sie sich umgehend in Isolation und wenden Sie sich an Ihr zuständiges Gesundheitsamt.

Negativ:

Eine schwarze Linie befindet sich in der Kontrollregion (C), aber in der Testregion (T) erscheint keine Linie. Dieses negative Ergebnis bedeutet, dass in der Speichelprobe keine SARS-CoV-2 N/S-Antigene vorhanden sind oder die Konzentration zu niedrig ist.

Ungültig:

Es erscheint keine Kontrolllinie. Die wahrscheinlichsten Gründe für das Ausbleiben der Kontrolllinie sind unzureichendes Probenvolumen, falsches Verfahren oder technische Fehler. Überprüfen Sie das Verfahren und wiederholen Sie den Test mit einem neuen Test Kit. Sollte das Problem weiterhin bestehen, stellen Sie die Verwendung der Charge sofort ein
und wenden sich an Ihren lokalen Händler.

Beschreibung

Speichel SARS-Cov-2 (2019-nCoV)
Antigen-Kombi-Testkit (Nanocarbon Assay）
Katalognummer NBMLRS-XG-S1
Speichel SARS-Cov-2(2019-nCoV)
Antigen-Kombi-Testkit（Nanocarbon Assay) ist ein Ein-Schritt-Immuntest für den qualitativen Nachweis von N/ S-Antigen in Speichelproben.

Bei dem vorliegenden SARS-COV-2 Antigen Schnelltest handelt es sich um ein Medizinprodukt das für den Eigengebrauch geeignet ist. Der Hersteller hat gegenüber der Aufsichtsbehörde im Rahmen einer Bestätigung erklärt, dass bei Eigenanwendung des Antigen Schnelltests das erforderliche Sicherheits- und Leistungsniveau und eine ausreichende Funktionalität gewährleistet sind.
Das Bundesamt für Sicherheit im Gesundheitswesen führt eine öffentliche Liste über diese Erklärungen welche unter https://www.basg.gv.at/fuer-unternehmen/ medizinprodukte/covid-19 abgerufen werden kann.
Das Produkt sollte bei 2℃ - 30℃ an einem trockenen Ort gelagert und vor Licht geschützt werden; es hat ein Verfallsdatum von 12 Monaten ab dem Herstellungsdatum und darf nicht eingefroren werden.
Das Produkt sollte innerhalb einer Stunde nach dem Zerreißen des Alufolienbeutels verwendet werden; wenn der Alufolienbeutel in einer Umgebung mit hoher Luftfeuchtigkeit zerrissen wird.
Wenn der Alufolienbeutel in einer Umgebung mit hoher Luftfeuchtigkeit zerrissen wird, sollte er sofort verwendet werden. Verwenden Sie das Produkt nicht nach Ablauf des Verfallsdatums.

Das Testgerät liefert nur ein vorläufiges analytisches Ergebnis. Um ein bestätigtes Ergebnis zu erhalten, muss eine sekundäre Analysemethode verwendet werden.

Bitte beachten Sie die weiterführenden Hinweise auf dem Beipackzettel des Herstellers.
Stand: Januar 2021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Combined Test Kit (Nanocarbon Assay)
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CE ISO9001
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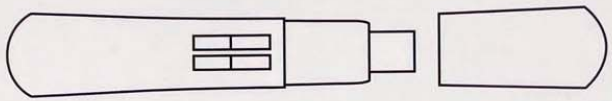

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GEBRAUCHSANWEISUNG
PRODUKTNAME
Ningbo Saliva SARS-COV-2 (2019-nCoV) Antigen Combined Test Kit (Nanocarbon Assay)
VERPACKUNGSEINHEIT
20 Test Kits / Box
VERWENDUNGSZWECK
Ningbo Saliva SARS-COV-2 (2019-nCoV) Antigen Combined Test Kit (Nanocarbon Assay) ist ein Antigen
Schnelltest für den qualitativen Nachweis von N/S-Antigen in Speichelproben. Dieses für den professionellen Gebrauch
bestimmte Produkt dient der Erzielung eines visuellen, qualitativen Ergebnisses. Dieser Test liefert ein vorläufiges, ana-
lytisches Testergebnis. Für ein bestätigtes analytisches Testergebnis muss eine spezifischere Methode, bevorzugterweise
ein PCR-Test, verwendet werden.
VERFAHRENSPRINZIP
Die Ein-Schritt-SARS-CoV-2 N/ S-Antigen-Testvorrichtung ist ein chromatografischer Schnellimmunoassay, der auf
dem Prinzip der Sandwich-Antikörper- und Antigenbindung basiert. Während des Tests bindet das SARS-CoV-2 N/
S-Antigen, wenn die Virusantigene in der Speichelprobe vorhanden sind, an die Antikörperkonjugate und bildet einen
Komplex. Und wandert durch die Kapillare nach oben. Der Komplex wird dann von dem immobilisierten Antikörper
eingefangen, der im Bereich der Testlinie auf der NC-Membran aufgebracht ist. Eine sichtbare schwarze Linie wird in
der Testlinienregion erscheinen. Die schwarze Linie bildet sich nicht in der Testlinienregion, wenn kein Virusantigen in der
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COVID-19
Antigen
Saliva
N S
C C
T T

IVD V 1.0

REF NBMLRS-XG-S1
Hergestellt in PRC

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DER CORONA TEST LOLLY

GEBRAUCHSANWEISUNG

PRODUKTNAME
Ningbo Saliva SARS-COV-2 (2019-nCoV) Antigen Combined Test Kit (Nanocarbon Assay)

VERPACKUNGSEINHEIT
20 Test Kits / Box

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IVD REF NBMLRS-XG-51 Hergestellt in PRC CE V 1.0

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GEBRAUCHSANWEISUNG

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Beautiful Life
解码生命 精准医疗

EC Declaration of Conformity

Manufacturer:
Name: Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.
Address: Room 305, Building 4, NO.7 Chuangye Avenue, Free Trade West Zone, Ningbo, China

European Representative:
Name : Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Product Name: Saliva SARS-Cov-2 (2019-nCoV) Antigen Combined Test Kit （Nanocarbon Assay）

Cat: NBMLRS-XG-S1

Model: Cassette
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned product meets the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Directives

General Applicable Directives:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:
EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

Signature:
Name: Xiaoli Tian
Positiion: General Manager
Place: Ningbo
Date of Issue: 8th July, 2020

Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.
Website: www.nbmlrs.com
Email: ceo@shmlrs.cn
Tel: +86 574 86818897

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M.P. Meijer - Michiels

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203531

Bijlagen
-

Uw aanvraag
14 juli 2020

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

Datum: 21 juli 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 14 juli 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Ningbo Beautiful Life Medical Biotechnology Development 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:

Saliva SARS-Cov-2(2019-nCoV)Antigen Combined Test Kit(Nanocarbon Assay)
(geen merknaam) (NL-CA002-2020-52639)

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

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

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

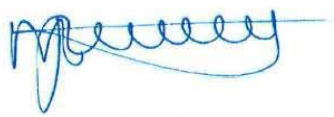
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert 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

Diagnostic Performance Accuracy

Clinical Performance:

Tue study enrolled 200 subjects in a single center study with collection ofsaliva sample. Tue performance ofthe RapideX Saliva™ One Step COVID-19 Antigen Test was established with 180 direct saliva sample prospectively collected and enrolled from individual symptomatic patients within 5 days ofonset and 20 asymptomatic patients who were suspected of COVID- 19. Tue perforrnance of the RapideX Saliva™ One Step COVID-19 Antigen Test was compared to results ofa nasopharyngeal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection ofCOVID-19.

The study enrolled 180 subjects in a single center randomized blinded study with collection of nasal swabs and a saliva sample. Tue performance ofRapideX Saliva™ One Step COVID-19 Antigen Test was established with 180 Saliva samples collected from individual symptomatic patients (within 5 days ofonset) who were suspected of COVID-19. Performance ofthe RapideX Saliva™ One Step COVID-19 Antigen Test (on Saliva specimens), was compared to the authorized Thermo Fisher Scienti:fic TaqPath RT-PCR COVID-19 combo kit by testing nasopharyngeal samples. Nasopharyngeal swabs and saliva were collected from patients in the Pioneer Research Solutions Inc, Houston, TX. Saliva was collected in sterile urine cups without addition ofany preservatives. Nasoph.aryngeal swab was collected in 3 mL viral transport media. These NP and saliva specimens were tested in parallel with the EUA-authorized TaqPath COVID-19 combo kit (on NP specimens) and the RapideX Saliva™ One Step COVID-19 Antigen Test (on saliva specimens). For RT-PCR testing (on NP specimens), the EUA-authorized Thermo Fisher Scientific TaqPath RT-PCR COVID-19 combo kit, and Applied Biosystems™ QuantStudio I"M 12K Flex Real-Time PCR System instrument were utilized. The Thermo Fisher Scientific TaqPath COVID19 combo kit combines RNA extraction using the MagMax Viral/Pathogen Nucleic Acid Isolation Kit with a multiplex RT-PCR diagnostic assay targeting 3 regions ofthe SARS-CoV-2 genome. 'For antigen testing (on saliva specimens), the RapideX Saliva™ One Step COVID-19 Antigen Test was directly used according to product Test when evaluating positive percent agreement (PPA). Tbe 50 TaqPath negative NP specimens were used as the comparator for the RapideX Saliva™ One Step COVID-19 Antig;nrf Test when evaluating negative percent agreement (NPA). Tue results from tbis paired study are described below:

RapideX Saliva™ One Step COVID-19 Antigen Test Performance within 5 days of symptom onset against the Reference RT-PCRAssay (N=180).

Diagnostic PerformanceAccuracy Clinical Performance

RapideX Saliva™ One Step COVID-19 Antigen Test	Reference RT-PCR Assay		
	Positive	Negative	Total
Positive	116	0	**116**
Negative	14	50	**64**
Total	130	50	**180**
Positive Agreement(Sensitivity): 116/130		**89.2%(95%CI:82.6%-94.0%)**	
Negative Agreement{Specificity): 50/50		**100%(95%CI:92.9%-100%)**	

Saliva SARS-Cov-2 (2019-nCo V)

Antigen Combined Test Kit（Nanocarbon Assay）

LOD Test

1.Purpose

Saliva SARS-Cov-2 (2019-nCoV) Antigen Combined Test Kit（Nanocarbon Assay）is tested by inactivated virus supernatant to evaluate the detection limit of the product.

2.Sample

Inactivated Virus

3.Reagent

The reagent uses the kit prepared by Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.

4.Plan

Take the inactivated virus supernatant for detection, S1: $2.0x10^5 TCID_{50}$/ml. Perform 8 serial dilutions of the virus stock solution (S1-S8). The dilution concentration is as follows:

S2: $2.0x10^4 TCID_{50}$/ml

S3: $0.5x10^3$ $TCID_{50}$/ml

S4: $0.25x10^3$ $TCID_{50}$/ml

S5: $1.25x10^2 TCID_{50}$/ml

S6: $0.625x10^2 TCID_{50}$/ml

S7: $0.3125x10^2$ $TCID_{50}$/ml

S8: $0.156x10^2$ $TCID_{50}$/ml

5.Procedure

Take each dilution in S1-S8 to test 20 strips, and use the virus level with a positive detection rate of 90% to 95% as the detection limit to obtain the value of LOD.

6.Results

Number	Dilution concentration $TCID_{50}$/ml	Result	Detection Rate
S1	$2.0x10^5$	Positive (20/20)	100%
S2	$2.0x10^4$	Positive (20/20)	100%
S3	$0.5x10^3$	Positive (20/20)	100%
S4	$0.25x10^3$	Positive（20/20)	100%
S5	$1.25x10^2$	Positive (19/20)	95%
S6	$0.625x10^2$	Positive (17/20)	85%
S7	$0.3125x10^2$	Negative (5/20)	25%
S8	$0.156x10^2$	Negative (0/20)	0%

7.Conclusion

In the end, S5 has a 95% detection rate, so the detection limit of the Saliva SARS-Cov-2 (2019-nCoV) Antigen Combined Test Kit（Nanocarbon Assay） is LOD=$1.25x10^2TCID_{50}$/ml.

Zertifikate

Certificate of Registration

nqa.

This is to certify that the Quality Management System of

SHANGHAI VENTURE BIO-TECH CO., LTD.

Unified Social Credit Code： 913101046311103535

Operation Address : Room 313, 203, 216, 217, Building 2, No.2715 Longwu Road, Xuhui District, Shanghai, China

Registered Address : Room 313, Building 2, No.2715 Longwu Road, Xuhui District, Shanghai, China

applicable to

The R&D, Production and Sales of Drugs In-vitro Diagnostic Reagent(Details for Annex), Human Chorionicgonadotrophin(HCG)Test Paper(Colloidal Gold)(Within the Scope of License Qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number 39552

Date: 30 December 2013

Reissue Date: 24 December 2019

Valid Until: 03 September 2021

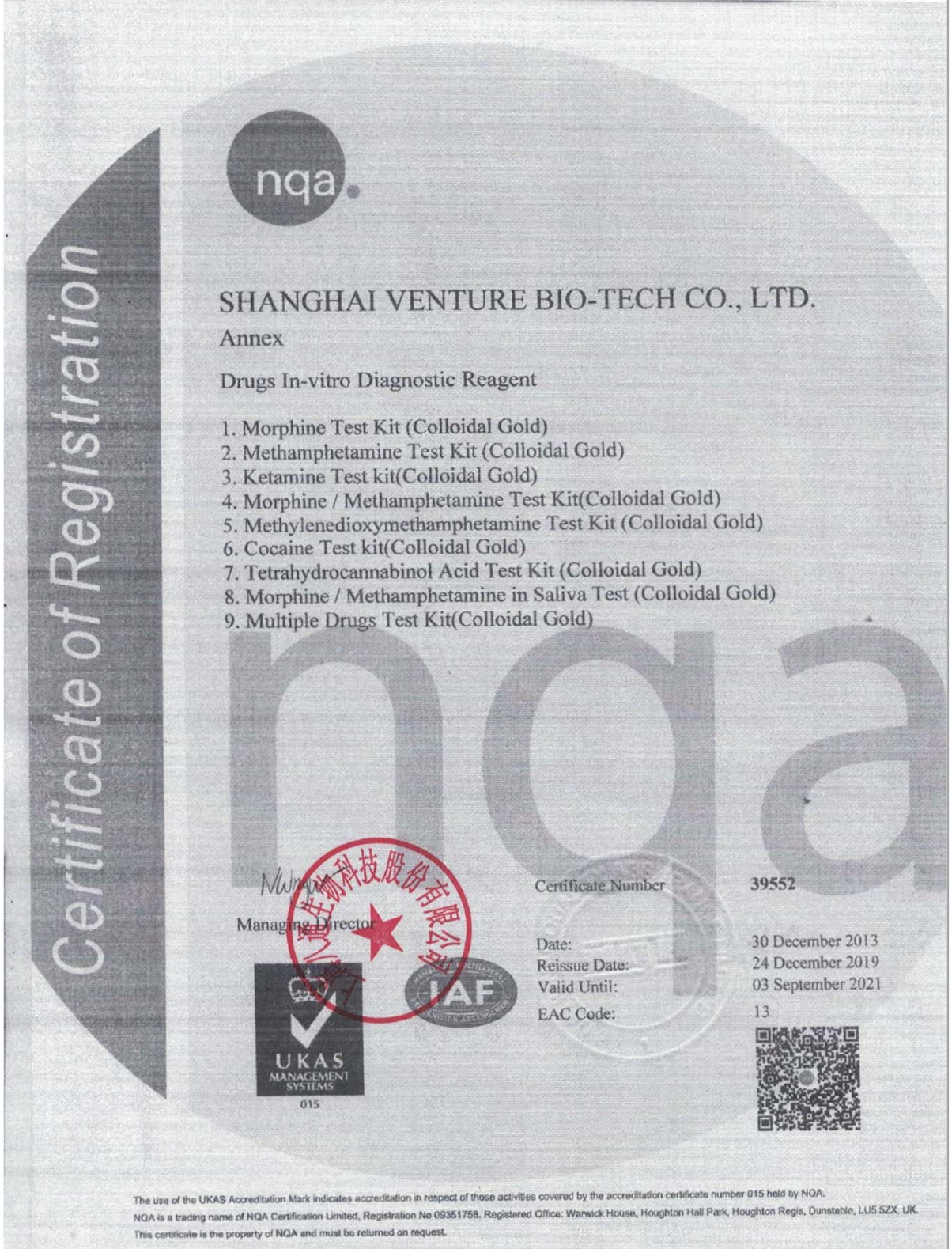
EAC Code: 13

UKAS MANAGEMENT SYSTEMS 015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

Zertifikate



Certificate of Registration

nqa.

SHANGHAI VENTURE BIO-TECH CO., LTD.

Annex

Drugs In-vitro Diagnostic Reagent

1. Morphine Test Kit (Colloidal Gold)
2. Methamphetamine Test Kit (Colloidal Gold)
3. Ketamine Test kit(Colloidal Gold)
4. Morphine / Methamphetamine Test Kit(Colloidal Gold)
5. Methylenedioxymethamphetamine Test Kit (Colloidal Gold)
6. Cocaine Test kit(Colloidal Gold)
7. Tetrahydrocannabinol Acid Test Kit (Colloidal Gold)
8. Morphine / Methamphetamine in Saliva Test (Colloidal Gold)
9. Multiple Drugs Test Kit(Colloidal Gold)

Managing Director

Certificate Number 39552

Date: 30 December 2013
Reissue Date: 24 December 2019
Valid Until: 03 September 2021
EAC Code: 13

UKAS MANAGEMENT SYSTEMS 015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
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This certificate is the property of NQA and must be returned on request.

Zertifikate

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY/UNDERTAKING

Product identifier

Product name : Saliva SARS-Cov-2(2019-nCoV)Antigen Combined Test Kit (Nanocarbon Assay)

Recommended use of the chemical and restrictions on use

Identified use : For *in vitro* diagnostic use only
(This product is used to qualitatively detect novel Coronavirus antigen in human saliva samples)

2. HAZARDS IDENTIFICATION

Emergency Overview

This product is not considered as hazardous according to China GB standards(GB30000-2013).
Consult a physician. Show this safety data sheet to the doctor in attendance.

GHS-Classification- China standards(GB30000-2013)

This product is not considered as hazardous according to China GB standards(GB30000-2013).

GHS-Labelling- China standards(GB30000-2013)

Hazard pictograms : Not available

Signal word : Not available

Hazard statements : Not applicable

Precautionary statements :

Prevention:

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.

Response:

Zertifikate

Not applicable

Storage:

Not applicable

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Product type : Mixture

Hazardous components

Product component	Chemical name	CAS-No.	Classification (GB 30000.2-29 – 2013)	Concentration
Diagnostic test card	Nitrocellulose membrane	9004-70-0	Expl. 1.1, H201;	-
	PVC board	9002-86-2	Not classified	
	Fiberglass	65997-17-3	Not classified	
	Carbon nanotubes	7440-44-0	Not classified	
	N protein antibody	-	Not classified	
	S protein antibody	-	Not classified	

	Sheep anti mouse IgG antibody	-	Not classified	
Desiccant	Silicon oxide	14808-60-7	Not classified	>90%
	Water	7732-18-5	Not classified	⩽10%

4. FIRST AID MEASURES

General advice : Show this safety data sheet to the doctor in attendance.

If inhaled : Not required under normal conditions of use.
Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : Not required under normal conditions of use.
Wash off with soap and plenty of water.
Consult a physician.

In case of eye contact : Not required under normal conditions of use.
Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
If symptoms persist, call a physician.

If swallowed : Not required under normal conditions of use.
Rinse mouth with water.
If symptoms persist, call a physician.

Notes to physician

Symptoms : None known or anticipated symptoms.

Treatment : Treat symptomatically.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Zertifikate

Unsuitable extinguishing media	:	For this product no limitations of extinguishing agents are given.
Specific hazards during firefighting	:	There is no explosion or fire hazard. Development of hazardous combustion gases or vapors possible in the event of fire.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Further information	:	Prevent fire extinguishing water from contaminating surface water or the ground water system. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	:	Keep sufficient ventilation at working place. Avoid dust formation. Avoid breathing dust, vapor, mist and gas. For personal protection see section 8.
Environmental precautions	:	Prevent product from entering soil, drains and waterways.
Methods for cleaning up	:	Sweep up and shovel. Keep in suitable, closed containers for disposal.
Additional advice	:	Comply with all applicable national and local regulations.

7. HANDLING AND STORAGE

Handling

Advice on safe handling	:	Work under hood or special environment. Provide sufficient ventilation at working place. For personal protection see section 8. Dispose of rinse water in accordance with local and national regulations.
Advice on protection against fire and explosion	:	Normal fire protective measure.

Storage

Requirements for storage areas and containers	:	Keep containers tightly closed in a dry, cool and well-ventilated place.

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Keep locked up or in an area accessible only to qualified or authorized persons.
Store in according to instruction.

Materials to avoid : Fluorides, hydrogen fluoride, strong acids and strong alkalis(desiccant only).

Other data : Hazardous decomposition products formed under fire conditions.
- Carbon oxides.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Contains no ingredient with known occupational exposure limit.

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
				GBZ 2.1-2007

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection : Protective gloves.

Eye protection : Safety glasses.

Skin and body protection : Protective clothing.

Hygiene measures : In accordance with good hygiene practice.
Wash hands before breaks and at the end of workday.
When using do not eat or drink.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state/appearance	:	Diagnostic kit containing a diagnostic test card and a desiccant.
Color	:	White
Odor	:	No odor
Odor Threshold	:	No data available

Safety data

Flash point	:	Does not flash
Ignition temperature	:	No data available
Lower explosion limit	:	No data available
Upper explosion limit	:	No data available
Flammability (solid, gas)	:	Non flammable
Oxidizing properties	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Molecular weight	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point	:	No data available
Sublimation point	:	No data available
Vapour pressure	:	No data available
Density	:	No data available
Bulk density	:	No data available
Water solubility	:	Insoluble in water
Partition coefficient: n-octanol/water	:	No data available
Solubility in other solvents	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Impact sensitivity	:	No data available
Relative vapour density	:	No data available
Surface tension	:	No data available
Evaporation rate	:	No data available

10. STABILITY AND REACTIVITY

Zertifikate

Hazardous reactions	:	This product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	:	The product is chemically stable under standard ambient conditions (room temperature).
Conditions to avoid	:	Keep away from heat, flame, sparks and other ignition sources.
Materials to avoid	:	Fluorides, hydrogen fluoride, strong acids and strong alkalis(desiccant only).
Hazardous decomposition products	:	Hazardous decomposition products formed under fire conditions. - Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

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Aspiration toxicity

Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicology Assessment

Acute aquatic toxicity	:	Not classified based on available information.
Chronic aquatic toxicity	:	Not classified based on available information.

Persistence and degradability

No data available

Bioaccumulative potential

Partition coefficient: n-octanol/water	:	No data available

Mobility in soil

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

General advice	:	Dispose of in accordance with all applicable local, state and federal regulations.

14. TRANSPORT INFORMATION

International transport regulations

CHINA ROAD(Land transport, JT/T 617-2018)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

INTERNATIONAL MARITIME DANGEROUS GOODS(IMDG, 39-18)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

Zertifikate

INTERNATIONAL AIR TRANSPORT ASSOCIATION(IATA, 61th edition)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

15. REGULATORY INFORMATION

Regulations on the Control over Safety of Dangerous Chemicals (Decree No. 591 of the State Council of the People's Republic of China)
General rules for preparation of chemical safety data sheet （GB16483-2008）
Rules for classification and labelling of chemicals(GB30000-2013)
Classification and labels of dangerous chemical substances commonly used （GB13690-2009）
List of dangerous goods (GB12268-2012)
Classification and code of dangerous goods （GB6944-2012）

16. OTHER INFORMATION

Further information
Revision Date: 30/09/2020

Disclaimer:
This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by us to be dependable and is accurate to the best of our knowledge.

This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate protective mechanisms to prevent employee exposures, property damage or release to the environment. We assumed no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.

****End of Material Safety Data Sheet*****

EN 62366-1:2015 availability assessment report			
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?	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	Does the Process addressed user interactions with the medical device according to the accompanying document including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
4.1.2	Residual risk		
	Are Residual Risks associated with Usability of the medical Device presumed to be acceptable, unless there is objective evidence to the contrary and documented?	CE-01-09 Risk Management Report	OK
4.1.3	Information for Safety		
	manufacturer subject the information for safety used as a risk control to the usability engineering process (e.g., warnings or limitation of use in the accompanying documents, marking, etc.) in the UE file and Accompanying documents.	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	Disregarding such information for safety is considered beyond any further reasonable means of risk control	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
4.2	Usability Engineering File		
	The results of the usability engineering process are recorded in the usability engineering file	CE Technical Files	OK
	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), (see List of documents make up the UE file)	CE Technical Files	OK
4.3	Scaling of the Usability Engineering effort		

	The usability engineering process is scaled based on the significance of any modifications depending on the results of the risk analysis and documented	CE-01-09 Risk Management Report	
5	USABILTY ENGINEERING PROCESS		
5.1	Application specification		
	Application of Medical Device in the usability engineering file is specified by the manufacturer and includes	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	– 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 conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); and		
	– operating principle(s)		
5.2	Frequently used functions		
	Are frequently used functions that involve User interaction with the Medical Device are determined and recorded in the usability engineering file?	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
5.3	Identification of hazards and hazardous situations related to usability		
5.3.1	Identification of characteristics to safety		
	Identification of characteristics related to safety (part of a risk analysis) that focuses on usability performed according to ISO 14971:2019.	CE-01-09 Risk Management Report	OK
	During the identification characteristics related to safety, the following are considered: – application specification, including user profile(s); and –frequently used functions.		
	Results of this identification characteristics related to safety recorded in the usability engineering file		
5.3.2	Identification of known or foreseeable hazards and hazardous situations		

	manufacturer has identified known or foreseeable hazards (part of a risk analysis) related to usability according to ISO 14971:2019.	CE-01-09 Risk Management Report	OK
	Identification of hazards considered hazards to patients, users and other persons	CE-01-09 Risk Management Report	OK
	Reasonably foreseeable sequences or combinations of events involving the user INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE were identified. The SEVERITY of the resulting possible HARM is determined.	CE-01-09 Risk Management Report	OK
	During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered: – application specification, including user rofile(s); – task related requirements; – context of use; – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; – preliminary USE SCENARIOS; – possible USE ERRORS; – if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION; and – results of the review of the USER INTERFACE	CE-01-09 Risk Management Report	OK
	The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY are recorded in the USABILITY ENGINEERING FILE.	CE-01-09 Risk Management Report	OK
5.4	Primary operating functions		
	The manufacturer has determined the primary operating functions and recorded in the usability engineering file	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	The inputs to the primary operating functions include frequently used functions and functions related to Safety of the Medical Device	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
5.5	Usability Specification		
	manufacturer developed a usability specification recorded in the usability engineering file as part of the usability engineering process	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK

	The usability specification recorded in usability engineering file. The usability specification may be integrated into other specifications	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	The usability specification includes: – application specification; – primary operating functions – hazards and Hazardous Situations related to the Usability; and – known or foreseeable use errors associated with the Medical Device	CE-01-07.1 Labels CE-01-07.2 Instruction For Use CE-01-09 Risk Management Report	OK
	The usability specification describes at least:	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
	– use scenarios related to the primary operating functions equipment, including – frequent Use Scenarios, and – reasonably foreseeable worst case Use Scenarios;	CE-01-09 Risk Management Report	OK
	– User Interface requirements for the primary operating functions equipment including those to mitigate Risk;	CE-01-07.1 Labels CE-01-07.2 Instruction For Use CE-01-09 Risk Management Report	OK
	– Requirements for determining whether primary operating functions are easily recognizable by the User.	CE-01-07.1 Labels CE-01-07.2 Instruction For Use	OK
5.6	Usability validation plan		
	The manufacturer has developed and maintains a usability validation plan specifying:	CE-01-15 Test Reports	OK
	– any method used for validation of the usability of the primary operating functions;	CE-01-15 Test Reports	OK
	– the criteria for determining successful validation of the usability of the primary operating functions based on the usability specification; and	CE-01-15 Test Reports	OK
	– the involvement of representative intended users	CE-01-15 Test Reports	OK
	usability validation performed in a laboratory setting ..... :	CE-01-15 Test Reports	OK

	usability validation performed in the actual use environment.....: 	CE-01-15 Test Reports	OK
	The usability validation plan addresses: – frequent Use Scenarios, and – reasonably foreseeable worst case use scenarios that are identified in the usability specification	CE-01-15 Test Reports	OK
	The usability validation plan recorded in the usability engineering file	CE-01-15 Test Reports	OK
5.7	User interface design and implementation		
	Manufacturer designed and implemented the user interface as described in the usability Specification utilizing, as appropriate, usability engineering methods and techniques	CE Technical Files	OK
5.8	Usability verification		
	Manufacturer verified the implementation of the Medical Device User interface design according to the usability specification	CE-01-15 Test Reports	OK
	The results of the verification are recorded in usability engineering file	CE-01-15 Test Reports	OK
5.9	Usability Validation		
	The manufacturer has validated the Usability of the Medical Device according to the usability validation plan	CE-01-11 Clinic Evaluation Report	OK
	The results are recorded in the usability engineering file	CE-01-11 Clinic Evaluation Report	OK
	For the acceptance criteria documented in the usability validation plan that are not met: - further User Interface design and implementation activities are performed; or - if further improvement is not practicable, the MANUFACTURER may gather and review data and literature to determine if the medical benefits of the INTENDED USE outweigh the RISK arising from USABILITY problems To perform this step, the MANUFACTURER needs to estimate the RISK arising from USABILITY problems.	CE-01-11 Clinic Evaluation Report	OK

6	Accompanying documents		
	The Accompanying document includes a summary of the Medical Device application specification	CE-01-05 Product Description	OK
	A concise description of the Medical Device, its operating principles, significant physical and performance characteristics and intended User Profile are included in the Accompanying document	CE-01-05 Product Description	OK
	The Accompanying document is written at a level consistent with the intended operator profile	CE-01-05 Product Description	OK
	The Accompanying document for equipment are, optionally, provided electronically	CE-01-05 Product Description	OK
	Usability engineering process includes the information that will need to be provided as a hard copy or as markings on Medical Device when accompanying documents are provided electronically	CE-01-05 Product Description	OK
7	training and materials for training		
	The required training on the MEDICAL DEVICE for safe and effective use of PRIMARY OPERATING FUNCTIONS by the intended USER is given by:	CE-01-07.1 Labels CE-01-05 Product Description	OK
	– necessary training materials provided by the manufacturer;		
	– necessary training materials are available; or		
	– the manufacturer provides TRAINING		
	The ACCOMPANYING DOCUMENT describes the available training options (Recommendation: ACCOMPANYING DOCUMENT include the suggested duration and frequency of such training)		
	INTENDED USE AND USER PROFILE(S) are the basis for TRAINING and TRAINING material		

Zertifikate

EC Technical Documentation (Part B) **CE-01**

17 availability assessment report **A/0**

EN 62366-1:2015 availability assessment report			
Clause	Requirement + Test	Result - Remark	Verdict

List of documents make up the UE file		
4.2	Document title	Version

05.11.2021

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 10^6 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 manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:

E-Mail: sarscov2ivd@pei.de

SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	Hubei Jinjian Biology Co.,Ltd.
Cora Gentest-19	Abioteq
Jinwofu Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Kit	Beijing Jinwofu Bioengineering Technology Co.,Ltd.
STANDARD i-Q COVID-19 Ag Home Test	SD Biosensor, Inc.
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) SPUCKTEST	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Shenzhen Dymind Biotechnology Co., Ltd.
WANTAI SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)	Beijing WANTAI Biological Pharmacy Enterprise Co., Ltd.
Covid-19 Antigen Rapid Test (Colloidal Gold)	Beijing O&D Biotech Co., Ltd.
OnSite COVID-19 Ag Rapid Test	CTK Biotech, Inc.
COVID 19 Antigen Test Kit (Colloidal Gold Method)	Neo-nostics (Suzhou) Bioengeneering Co., Ltd.
Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	Hoyotek Biomedical Co., Ltd.
SARS-CoV-2 Antigen test Kit (Colloidal Gold Method)	Changsha Sinocare Inc.
FUJIFILM COVID-19 Ag Test	FUJIFILM Corporation
GreenLight SARS-CoV-2 Antigen-Test	Senova Gesellschaft für Biowissenschaft und Technik mbH
SARS-CoV-2 Antigen IVD kit SWAB	Shenzhen Reagent Technology Co., Ltd.
Novel Coronavirus (SARS-CoV-2) Ag Rapid Test Kit	Jiangsu Bioperfectus Technologies Co., Ltd.
Rapid SARS-CoV-2 Antigen Test Colloidal Gold (Nasopharyngeal specimen)	InTec Products, Inc.
INNOVA SARS-CoV-2 Selbsttest (Qualitativer-Antigen-Schnelltest)	Innova Medical Group,Inc.
Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)	Goldsite Diagnostics Inc.
Novel Corona Virus (2019-nCoV) Ag Rapid Test Kit	Glallergen CO., LTD.
KISSH SARS-CoV-2 Antigen Test Kit(GICA)	Shenzhen Kisshealth Biotechnology Co., Ltd.
Longsee 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Guangdong Longsee Biomedical Co.,Inc.
Tell Me Fast Rapid Diagnostic Test	Biocan Diagnostics Inc.
Fosun Covid-19 Ag Card	Shanghai Fosun Long March Medical Science Co., Ltd.
COVID-19 Antigen Rapid Test (Oral Fluid)	CITEST Diagnostics Inc.
INVBIO Antigen Rapid Test Device (Saliva)	Innovation Biotech (Beijing) Co.,Ltd
Saliva SARS-CoV-2(2019-nCoV) Antigen Test Kit (Nanocarbon Assay)	Ningbo Beautiful Life Medical Biotechnology
Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based)	Nanjing Vazyme Medical Technology Co., LTD.
COVID-19 antigen Schnelltest (Kolloidales Gold) / Novel Coronavirus(SARS-CoV-2) Antigen Rapid Detection Kit	Jiangxi Province JinHuan Medical Instrument Co.,LTD.
Amper COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)	Amper,Inc.
SARS-CoV-2Antigen Test Kit (Colloidal Gold)	Shenzhen Huian Biosci Technology Co.,Ltd
Konsung COVID-19 Antigen Rapid Test Kit	Jiangsu Konsung Bio-Medical Science And Technology Co.,Ltd
TBG SARS-CoV-2 Antigen Rapid Test	TBG Biotechnology Xiamen Inc.
Tebsun 2019-nCoV Antigen Test Kit	Gunagzhou Tebsun Bio-Tech Development Co., Ltd.
ENCODE SARS-COV-2 Antigen Rapid Test Device	Zhuhai Encode Medical Engineering Co., Ltd.