SARS-CoV-2 Antigen Rapid Test Cassette

(Colloidal Gold)





CE 2934 IVD

Merlin Biomedical (Xiamen) Co., Ltd.
4th Floor, Building B3, No. 2054 West Wengjiao Rd.,
Haicang, Xiamen 361028, China
Mobile: +86 1391 056 5056
Email: minfenglin@merlinbio.com.cn
www.merlinbio.com.cn

TÜV SÜD EN ISO 13485
tuv-sud.com/ps-cert

EC REP

Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

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SARS-COV-2 Antigen Rapid Test Cassette
For self-testing

- Qualitative detection of antigen of SARS-CoV-2
- Rapid result in 15min
- Human secreta specimen(Nasal swabs)
- Easy to use no analyzer required
- Store at room temperature or refrigerator

Merlin Biomedical (Xiamen) Co.,Ltd

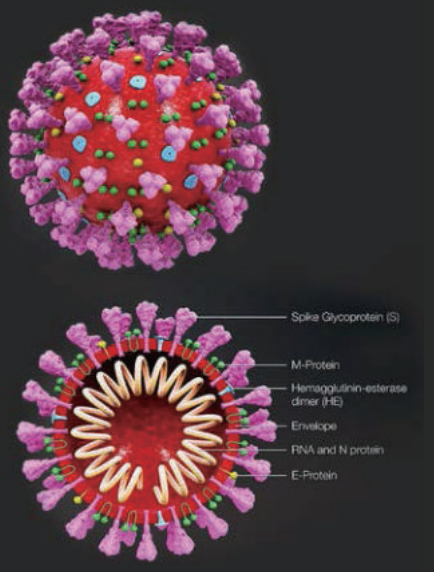
CE 2934 IVD

The COVID-19

The COVID-19 is a respiratory disease caused by infection with SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breathing difficulties. In severe cases, infection can cause pneumonia, server acute respiratory syndrome (SARS), kidney failure and death.

The cassette is used for qualitative detection of **antigen of SARS-CoV-2** in human nasal swabs .The cassette is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19).

Merlin Biomedical is now offering a **SARS-CoV-2 Antigen Rapid Test Cassette** offering high accuracy and quick result.



Specificity and Sensitivity

The SARS-CoV-2 Antigen Rapid Test Cassette has been compared with a commercial PCR test,the results indicating high specificity and sensitivity:

- Relative Sensitivity: 94.70%,(95% CI: 89.46%-97.41%);
- Relative Specificity : 99.22%,(95% CI: 95.74%-99.86%);
- Accuracy: 96.93%,(95% CI: 94.07%-98.44%).

*95% Confidence Interval

Visual result read in 15 min.



Positive Negative Invalid

Cat No.	Description	Store Temp.	size
CP01750011	SARS-CoV-2 Antigen Rapid Test Cassette	2 - 30°C	1 T
CP01760011			20 T
CP01770011			50T
CP01800011	SARS-CoV-2 Antigen Rapid Test Cassette		1 T
CP01810011			20 T
CP01820011			50T



Merlin Biomedical (Xiamen) Co.,Ltd
Tel/Fax: 86-592-5210772 / info@merlinbio.com.cn / Homepage: www.merlinbio.com.cn
Add: Unit 01, 4th Floor, Building B3, 2054 West Wengjiao Rd., Haicang, Xiamen

Package

	1T/kit	20T/kit	50T/kit
Content	Test Cassette ×1 Extraction solution ×1 Tube ×1 Dripper ×1 Swab x1 IFU x1	Test Cassette ×20 Extraction solution ×20 Tube ×20 Dripper ×20 Swab x20 IFU x1	Test Cassette ×50 Extraction solution ×50 Tube ×50 Dripper ×50 Swab x50 IFU x1
Kit Dimension	200x70x25mm	237*141.5*60mm	237*141.5*144.5mm
Kit Weight	44g	305g	808g
Carton	300T	1000T	1000T
Carton Dimension	73*49*32cm	73*49*32cm	73*49*32cm
Carton Weight	13.6kg	20kg	20kg





MerlinBiomedical SARS-CoV-2	SARS-CoV-2 Antigen Rapid Test Cassette

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Merlin Biomedical (Xiamen) Co., Ltd.
4th Floor, Building B3, 2054 West Wengjiao Rd.,
Haicang, Xiamen, 361028, P.R. China

in vitro diagnostic medical device for self-testing

SARS-CoV-2 Antigen Rapid Test Cassette
catalogue numbers:
CP0271-1, CP0271-2, CP0271-5,
CP0271-10, CP0271-20, CP0271-50

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 05.04.2022 – 26.05.2025

Issue date: 05.04.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/037/W/E.1

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Merlin Biomedical(Xiamen) Co., Ltd.
Address:4th Floor,Building B3,2054 West Wengjiao Rd.,Haicang,Xiamen,361028,China.
European Representative: Qarad EC-REP BV,
Address: Pas 257, 2440 Geel, Belgium

In Vitro Diagnostic Directive:

Product name	Catalogue Numbers
SARS-CoV-2 Antigen Rapid Test Cassette	CP01750011 / CP01760011 / CP01770011 CP01800011 / CP01810011 / CP01820011

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:
Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium

Signed on: 22-Oct-2020

Place: Xiamen, China

Name of authorized signatory: Yi Feng Shen

Position held in the company: General Manager

Seal/Stamp:

Merlin Biomedical(Xiamen) Co., Ltd.

DECLARATION OF NOTIFICATION

Date: October 15, 2020

The undersigned, Teresa Batet, Senior Consultant of Qarad EC-REP BV, hereby declares that:

Merlin Biomedical (Xiamen) Co., Ltd

4th Floor,Building B3,2054 West Wengjiao Rd.,Haicang,

Xiamen,361028,China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue number Device
SARS-CoV-2 Antigen Rapid Test Cassette	CP01750011 / CP01760011 / CP01770011

The notification to the Belgian Competent Authorities has been carried out on October 15 2020 by Qarad EC-REP BV, the appointed Authorized Representative of Merlin Biomedical (Xiamen) Co., Ltd

Teresa Batet
Senior Consultant

Qarad EC-REP BV
Authorized Representative

DECLARATION OF NOTIFICATION

Date: October 28, 2020

The undersigned, Teresa Batet, Senior Consultant of Qarad EC-REP BV, hereby declares that:

Merlin Biomedical (Xiamen) Co., Ltd

4th Floor,Building B3,2054 West Wengjiao Rd.,Haicang,

Xiamen,361028,China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue number Device
SARS-CoV-2 Antigen Rapid Test Cassette	CP01800011 / CP01810011 / CP01820011

The notification to the Belgian Competent Authorities has been carried out on October 28 2020 by Qarad EC-REP BV, the appointed Authorized Representative of Merlin Biomedical (Xiamen) Co., Ltd

Teresa Batet
Senior Consultant

Qarad EC-REP BV
Authorized Representative

Federaal agentschap voor geneesmiddelen en gezondheidsproducten
Galileelaan 5/03
1210 BRUSSEL
www.fagg.be

DG POST / Gezondheidsproducten / Medische hulpmiddelen

Afzender : Nadya Tavajjoh

Tel. : 02/ 528 40 00
e-mail : notifications.meddev@fagg.be

Qarad EC-REP BV
Pas 257
2440 Geel
ecrep@qarad.com

Uw bericht van	Ons kenmerk	Datum	Indicateur
08/02/2021	FAGG/2021/XDC/NAT/16963		1276510

Betreft: kennisgeving door de fabrikant of door zijn gemachtigde van het in de handel brengen van medische hulpmiddelen voor in-vitro diagnostiek, conform artikel 5 van het K.B. van 14 november 2001 betreffende medische hulpmiddelen voor in-vitro diagnostiek.

Mevrouw, Mijnheer,

Ik meld u de goede ontvangst van de wijzigingen aan uw kennisgeving inzake het in de handel brengen van een medische hulpmiddel voor in-vitro diagnostiek, zoals beschreven in bijlage.

Uw kennisgeving is op 24/03/2021 geregistreerd.

Dit ontvangstbericht is in geen geval een goedkeuring van de kwalificatie en de indeling van de klasse van het betreffende medisch hulpmiddel voor in-vitro diagnostiek, noch van overeenstemming met de essentiële eisen volgens bijlage I van het K.B. van 14 november 2001 betreffende medische hulpmiddelen voor in-vitro diagnostiek.

Elke wijziging aan de gegevens meegedeeld in het kader van deze kennisgeving moet binnen de 30 dagen meegedeeld worden aan het Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten.

Met de meeste hoogachting,

De Administrateur-generaal

Xavier De Cuyper
i.o. Hugues MALONNE
Directeur-generaal DG POST Vergunningen

Productlijst

IVD voor professioneel gebruik.

IVD	**Registratienummer**	**GMDN code**
SARS-CoV-2 Antigen Rapid Test Cassette – REF: CP01750011 / CP01760011 / CP01770011 / CP01800011 / CP01810011 / CP01820011 / CP02140011 / CP02150011	BE-CA01/1-16963-00006-IVD	64787

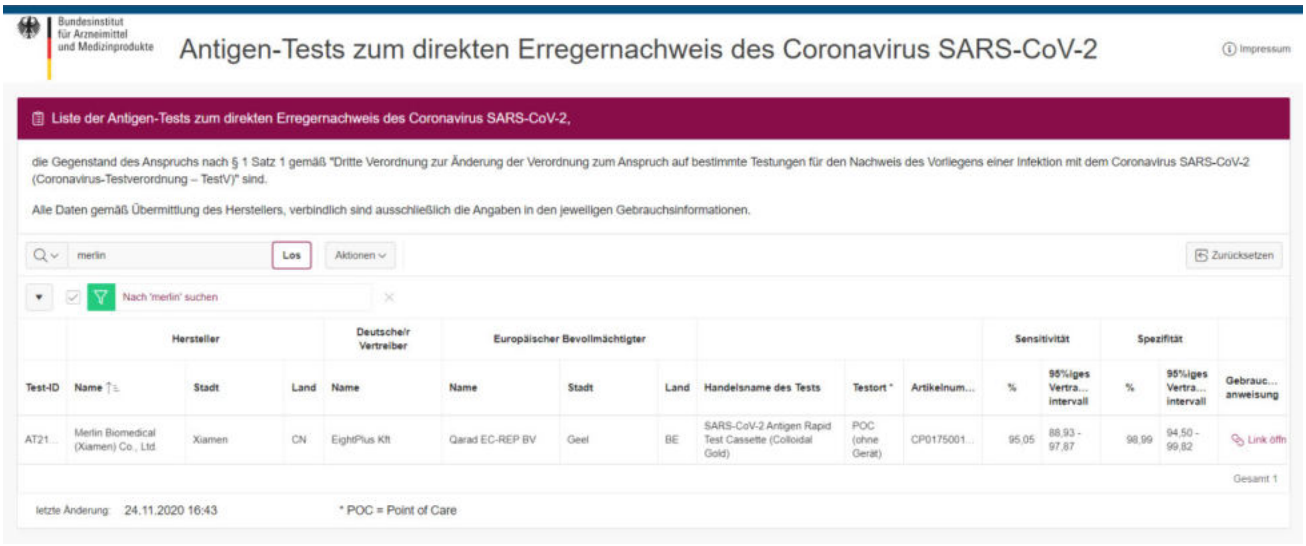
Fabrikant :

Merlin Biomedical(Xiamen) Co., Ltd.
4th Floor,Building B3,2054 West
Wengijao Rd.,Haicang
361028 Xiamen
China

Gemachtigde :

Qarad EC-REP BV
Pas 257
2440 Geel
België

BfArM Listing



Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum

Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Verordnung zur Änderung der Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

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

merlin | Los | Aktionen | Zurücksetzen

Nach 'merlin' suchen

	Hersteller			Deutscher Vertreiber	Europäischer Bevollmächtigter						Sensitivität		Spezifität		
Test-ID	Name	Stadt	Land	Name	Name	Stadt	Land	Handelsname des Tests	Testort *	Artikelnum...	%	95%iges Vertra... intervall	%	95%iges Vertra... intervall	Gebrauc... anweisung
AT21...	Merlin Biomedical (Xiamen) Co., Ltd.	Xiamen	CN	EightPlus Kft	Qarad EC-REP BV	Geel	BE	SARS-CoV-2 Antigen Rapid Test Cassette (Colloidal Gold)	POC (ohne Gerät)	CP0175001...	95,05	88,93 - 97,87	98,99	94,50 - 99,82	Link öffn

Gesamt 1

letzte Änderung: 24.11.2020 16:43 * POC = Point of Care

Export White List

486	美林美邦（厦门）生物科技有限公司 Merlin Biomedical (Xiamen) Co., Ltd.	91350200MA2XYNBD5K	CE	福建	Novel Coronavirus (COVID-19) RT-PCR Kit 2019-nCoV IgG/IgM Rapid Test Cassette SARS-CoV-2 Antigen Rapid Test Cassette NFT SARS-CoV-2 Test - REF: CP01780011, CP01990011

An official EU website How do you know?

European Commission

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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

Previous Next

SARS-CoV-2 Antigen Rapid Test Cassette

Manufactured by Merlin Biomedical (Xiamen) Co., Ltd., China - http://www.merlinbio.com.cn/en/

Device identification number	2029
CE Marking	✓ Yes
HSC common list	✓ Yes

HSC mutual recognition	✓ Yes
Format	Near POC / POC
Physical Support	Cassette
Target	Antigen
Specimen	Nasal swab, Nasopharyngeal swab
Commercial Status	Commercialised
Last Update	2021-07-07 05:23:09 CET
Comments	BfArM Vorgangsnummer: AT214/20 Certificate TÜV Süd No. Q5 106286 0001 Rev. 00 CE number: BE-CA01/1-16963-00006-IVD

Show HSC list status history

Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	No
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
LOD	160 AU
Calibration	Evaluated

Crossreactivity	Evaluated
Fp	5 AU
Fn	1 AU
Precision	Evaluated
Accuracy	97 %
Reproducibility	Evaluated
Robustness	Evaluated
Clinical Sensitivity	95.05 %
Clinical Specificity	98.99 %
Type of antigen	Nucleoprotein

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.
Acknowledgements

More information on:

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

Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 gemäß "Dritte Verordnung zur Änderung der Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

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.

Die nachfolgende Tabelle zeigt die Original-Tests mit ihrem vom Hersteller bzw. europäischen Bevollmächtigten vergebenen Handelsnamen. Eine Übersicht der jeweiligen deutschen Vertreiber und deren ggfs. abweichender Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

ja Los Aktionen

Nach 'merlin' suchen

Nach 'ja' suchen

			Hersteller			Europäischer Bevollmächtigter				
Test-ID	**Handelsname des Herstellers / Europ. Bevollmächtigten**	**Evaluierung PEI**	**Name**	**Stadt**	**Land**	**Name**	**Stadt**	**Land**	**Deutsche(r) Vertreiber**	**Testort***
AT214/20	SARS-CoV-2 Antigen Rapid Test Cassette (Colloidal Gold)	Ja	Merlin Biomedical (Xiamen) Co., Ltd.	Xiamen	CN	Qarad EC-REP BV	Geel	BE	Details	POC (ohne Gerät)

letzte Änderung: 07.05.2021 17:03

* POC = Point of Care

Liste der Antigen-Tests zur Eigenanwendung zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 der "Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen oder deren erstmaliges Inverkehrbringen in Deutschland ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird („Sonderzulassung des BfArM").

Die Liste wird kontinuierlich aktualisiert, sobald seitens des BfArM weitere entsprechende Sonderzulassungen erteilt wurden, diese, z.B. durch Ablauf der Befristung der Sonderzulassung oder Abschluss der regulären Konformitätsbewertung und CE-Kennzeichnung, nicht mehr bestehen oder das Verfahren zur Aufnahme CE-gekennzeichneter Tests zur Eigenanwendung in die Liste erfolgreich abgeschlossen wurde.

Eine entsprechende Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** finden Sie unter folgendem Link.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

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

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

merlin | Los | Aktionen | Zurücksetzen

Nach 'merlin' suchen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität		
Test-ID	Name des Tests	Evaluierung PEI	Name	Land	Name	Land	Probennahme	%	95%iges Vertrauensinte...	%	95%iges Vertrauensinte...	Gebrauchs...
5640-S-379/21	SARS-CoV-2 Antigen Rapid Test Casse...	Ja	Merlin Biomedical (Xiamen) Co., Ltd.	CN	Qarad EC-REP BV	BE	nasal	94,70	89,46 - 97,41	99,22	95,74 - 99,86	Link öf...

1 - 1 von 1

letzte Änderung: 15.07.2021 19:18

SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Shenzhen Watmind Medical Co.,Ltd.
2019-nCoV Antigen Test Kit(colloidal gold method)	Guangdong Hecin Scientific,Inc.
Asan Easy Test COVID-19 Ag	ASAN PHARM.CO.,LTD.
COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	Nantong Diagnos Biotechnology Co., Ltd.
Axiom Diagnostics COVID-19 Ag Schnelltest	AXIOM Gesellschaft für Diagnostica und Biochemica mbH
Tigsun COVID-19 Saliva Antigen Rapid Test	Beijing Tigsun Diagnostics Co.;Ltd.
PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)	Lumigenex (Suzhou) Co., Ltd.
Flowflex SARS-CoV-2-Antigenschnelltest (Nasopharynxtupfer)	ACON Biotech (Hangzhou) Co., Ltd
SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	Shenzhen Watmind Medical Co.,Ltd.
Covid-19-Antigen-Testkit	New Gene (Hangzhou) Bioengineering Co., Ltd.
CoroVisio Covid-19 Ag Versieglungsröhrchen Teststreifen (Kolloidales Gold)	Amazing Biotech (Shanghai) Co., Ltd
COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)	Chil Tibbi Mal. San. Tic. Ltd. Şti
SARS-CoV-2-Antigen-Testkit (LFIA)	Jiangsu Medomics Medical Technology Co., Ltd
SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	Wuhan Life Origin Biotech Joint Stock Co., Ltd.
COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	BIOMERICA Inc.
Covid-19 Antigen Schnelltest	Beijing Beier Bioengineering Co., Ltd.
Ksmart® SARS-COV2 Antigen Rapid Test	Avalun
Rapid Test Ag 2019-nCoV	ProGnosis Biotech
SARS-CoV-2 Antigen Rapid Test Kit	Wuhan UNscience Biotechnology Co., Ltd.
One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Triplex International Biosciences (China) Co., Ltd.
Novel Coronavirus (2019-nCOV) Antigen Testing Kit (Colloidal Gold)	Nanjing Norman Biotechnology Co.,Ltd
SARS-CoV-2 Antigen Rapid Test Cassette	Merlin Biomedical (Xiamen) Co., Ltd.
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	Edinburgh Genetics Limited
Covid-19 Antigen Detection Kit	DNA Diagnostic A/S.
COVID-19 Antigen Speicheltest (Immunochromatographie)	ulti med Products (Deutschland) GmbH
EBS SARS-CoV-2 Ag Rapid Test	Eurobio Scientific
COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	Jiangsu Diagnostics Biotechnology Co., Ltd

Acknowledgment Letter

3/1/2021

Fiona Wang
Salude LLC
19 Calle Arcos
Rancho Santa Margarita, CA 92688
UNITED STATES

Dear Fiona Wang:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA210184
Received: 3/1/2021
Applicant: Merlin Biomedical (Xiamen) Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Cassette

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Medicines & Healthcare products Regulatory Agency

MHRA

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

Qarad UK Ltd.
8 Northumberland Ave
London
Westminster
WC2N 5BY
England, United Kingdom

07 May 2021

Dear **Kirsten Van Garsse**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **04 May 2021** has been reviewed:

Application reference: **2021050401201979**

Manufacturer organisation: **Merlin Biomedical (Xiamen) Co., Ltd.**
Address:
4th Floor,Building B3,2054 West Wengjiao Rd.
Xiamen
Haicang
361028
China

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
60736 - Nucleic acid sample preparation instrument IVD, automated	Registered	
64787 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is **0000013061.**

Yours sincerely,



Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

CE IVD

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

Instruction for Use

Package Information

REF CP01750011

Components	1 T
Test Cassette	×1
Sample extraction solution	×1 vial
Tube	×1
Dripper	×1

REF CP01760011

Components	20 T
Test Cassette	×20
Sample extraction solution	×1 vial
Tube	×20
Dripper	×20

REF CP01770011

Components	50 T
Test Cassette	×50
Sample extraction solution	×2 vial
Tube	×50
Dripper	×50

REF CP01800011

Components	1 T
Test Cassette	×1
Sample extraction solution	×1 vial
Tube	×1
Dripper	×1
Specimen Collection Swab Model N150 CE 93/42/EC	×1
Specimen Bag	×1

REF CP01810011

Components	20 T
Test Cassette	×20
Sample extraction solution	×1 vial
Tube	×20
Dripper	×20
Specimen Collection Swab Model N150 CE 93/42/EC	×20
Specimen Bag	×20
Positive control (Optional Accessories)	×1
Negative control (Optional Accessories)	×1

REF CP01820011

Components	50 T
Test Cassette	×50
Sample extraction solution	×2 vial
Tube	×50
Dripper	×50
Specimen Collection Swab Model N150 CE 93/42/EC	×50
Specimen Bag	×50
Positive control (Optional Accessories)	×1
Negative control (Optional Accessories)	×1

Positive control: Recombinant SARS-CoV-2 nucleocapsid protein antigen is dried on the flock swab head.

Negative control: Blank Viral Transport Media (VTM, Hank's based solution) is dried on the flock swab head.

Specification:

1 Test Cassette/Kit, 20 Test Cassettes/Kit, 50 Test Cassettes/Kit.

Test Cassette:

Rapid Test for Detection of SARS-CoV-2's Nucleocapsid protein in white plastic cassette packed in aluminum foil bag. For single use only.

Sample extraction solution:

1 mL/vial (1T), 12mL/vial (20T, 50T). The sample extraction solution shall be stored at room temperature.

Others:

-Instructions for use

Materials required but not provided:

Clock or timer, specimen collection container, biohazard waste container.

Intended Use

The cassette is used for qualitative detection of antigen of SARS-CoV-2 in human nasal swabs and nasopharyngeal swabs.

The cassette is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19).

For single use only.

Summary

COVID-19 is a respiratory disease caused by infection with SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breathing difficulties. In severe cases, infection can cause pneumonia, server acute respiratory syndrome (SARS), kidney failure and death.

Method

God Immunochromatographic Assay (GICA).

Principle

→ The Cassette is a one-step lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing anti-SARS-CoV-2's Nucleocapsid protein antibody, Chicken IgY antibody, all of which are conjugated to colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line).

→ The T line is coated with anti-SARS-CoV-2's Nucleocapsid protein antibody, when the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate, if present in specimen, SARS-CoV-2's Nucleocapsid protein and its antibody labeled with colloidal gold formed antigen-antibody complexes. These complexes will continue to migrate along the strip until the T line, where they are captured by the anti-SARS-CoV-2's Nucleocapsid protein antibody generating a visible red violet line in T line. If the specimen does not contain SARS-CoV-2 or the SARS-CoV-2 level is below the lower level, the T line will not appear.

→ The C line is coated with Goat anti-chicken antibodies, which should bind to the gold-chicken IgY antibodies conjugate and form a red violet line regardless of the presence of SARS-CoV-2's Nucleocapsid protein.

Storage and validity

1. Sealed in aluminum foil bag at 2-30℃.Valid for 12 months.
2. Protect from light and don't freeze.

Specimen collection

1. Type: Nasal Swabs
   To collect a nasal swab sample, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
   Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.
2. Type: Nasopharyngeal Swabs
   To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

Specimen transport and storage

1. The samples should be used as soon as possible after collected within 1 hour at room temperature (15-30°C).
2. After processing the swab in the extraction solution, the sample should be analyzed within 30 minutes.

TEST PROCEDURE

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

1. Allow all cassette components and specimens to reach room temperature between 15°C~30°C prior to testing.
2. Remove the test cassette from the foil pouch and place on a clean dry surface.
3. Identify the test cassette for each specimen.

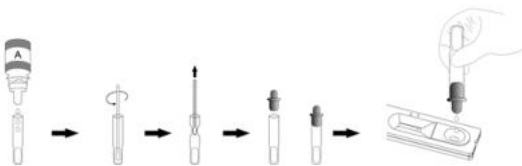
Sample processing:

→Elute swab with Sample extraction solution

→Add 300μL (~10 drops) of sample extraction solution to the extraction tube, and then completely immerse the swab head in the sample extraction buffer in the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) for about 1 minute and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction solution.

→Squeeze the swab head along the inner wall of the extraction tube to keep the liquid in the tube as much as possible. Discard the swab and cover the drip head to mix the liquid thoroughly.

* **Note**：Recommend to use a pipette to transfer the samples to reduce deviations.



300μL (~10 drops) Extraction solution	Vigorously mix at least 10 times for about 1 minute	Squeeze liquid from swab	Cover the dripper	80μL (3 drops)

Test operation

1. Remove the test cassette from the foil pouch and place on a clean dry surface. Dispense 80μL (3 drops) of the specimen into the circular sample well on the cassette.
2. Interpret the test results at 15~20 minutes. Do not interpret the results after 20 minutes.
3. Discard used test tubes and Test device in suitable biohazards waste container.

Interpretation of results

1. Invalid: If C line does not appear, the result is

invalid whether the T line appear or not, as shown in the figure. Prepare another cassette and specimen to test again. Tips: please analysis the volume of sample addition.

2. Positive: Both of T line and C line appear, as shown in the figure.
3. Negative: T line do not appear, while C line appear, as shown in the figure.



Positive Negative Invalid

Limitation of Test Methods

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2. The contents of this cassette are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab, nasopharyngeal swab.
3. Sensitivity of the test after the first seven days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
4. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
5. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
6. The Sample buffer and test cassette must be equilibrated to room temperature (15℃~30℃) before used, otherwise the results may be incorrect.
7. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
8. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
9. React less than 15 minutes may lead a false negative result; React more than 20 minutes may lead a false positive result.
10. Positive test results do not rule out co-infections with other pathogens.
11. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
12. Negative results should be treated as presumptive and confirmed with a molecular assay.
13. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
14. Users should test specimens as quickly as possible after specimen collection within 1 hour.
15. After processing the swab in the extraction solution, the sample should be analyzed within 30 minutes.

Performance Data

1. Clinical validation:

Method		PCR		Total Results
SARS-Cov-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	96	1	97
	Negative	5	98	103
Total Results		101	99	200

Positive coincidence rate =95.05%, (95% CI: 88.93%-97.87%);
Negative coincidence rate =98.99%, (95% CI: 94.50%-99.82%);
Total coincidence rate =97.00%, (95% CI: 90.61%-98.62%)

2. Positive coincidence rate:
The positive reference products of manufacturer coincidence were 5/5.

3. Negative coincidence rate:
The negative reference products of manufacturer coincidence were 10/10.

4. Sensitivity:
The S1 reference of manufacturer with the minimum detection limit was negative, and S2, S3 reference were positive.

5. Precision:
1 precise reference product of manufacturer (J) was test 10 times individually, the color development depth of T line should be uniform and consistent, and the results should all be positive.

6. Cross-reactivity
Cross-reactivity of the cassette was evaluated. The results showed no cross reactivity with the following microorganism.

No.	Microorganism	Conc.
1	Human Coronavirus OC43	10^5 pfu/mL
2	Human Coronavirus 229E	10^5 pfu/mL
3	Human Coronavirus NL63	10^5 pfu/mL
4	Influenza A H1N1 (2009)	10^5 pfu/mL
5	Influenza A H3N2	10^5 pfu/mL
6	Influenza B Yamagata	10^5 pfu/mL
7	Influenza B Victoria	10^5 pfu/mL
8	Respiratory syncytial virus A	10^5 pfu/mL
9	Respiratory syncytial virus B	10^5 pfu/mL
10	Adenovirus type 1	10^5 pfu/mL
11	Adenovirus type 2	10^5 pfu/mL
12	Adenovirus type 3	10^5 pfu/mL
13	Adenovirus type 4	10^5 pfu/mL
14	Adenoviridae 1	10^5 pfu/mL
15	Adenoviridae 2	10^5 pfu/mL
16	Adenoviridae 3	10^5 pfu/mL
17	Adenoviridae 4	10^5 pfu/mL
18	Adenoviridae 5	10^5 pfu/mL
19	Adenoviridae 7	10^5 pfu/mL
20	Adenoviridae 55	10^5 pfu/mL
21	Enterovirus EV71	10^5 pfu/mL
22	Enterovirus CA16	10^5 pfu/mL
23	Enterovirus CA10	10^5 pfu/mL
24	Enterovirus CB5	10^5 pfu/mL
25	Enterovirus CA24	10^5 pfu/mL
26	Enterovirus CB4	10^5 pfu/mL
27	Enterovirus CB3	10^5 pfu/mL
28	Enterovirus CB2	10^5 pfu/mL
29	Enterovirus CB1	10^5 pfu/mL
30	Enterovirus CA6	10^5 pfu/mL
31	EB virus	10^5 pfu/mL
32	Human cytomegalovirus	10^5 pfu/mL
33	Mycoplasma pneumoniae	10^5 pfu/mL
34	Chlamydia pneumoniae	10^5 pfu/mL
35	Human Rhinovirus A30	10^5 pfu/mL
36	Human Rhinovirus A31	10^5 pfu/mL
37	Human Rhinovirus A2	10^5 pfu/mL
38	Human Rhinovirus A81	10^5 pfu/mL
39	Human Rhinovirus B52	10^5 pfu/mL
40	Human Rhinovirus B70	10^5 pfu/mL
41	Human Rhinovirus B72	10^5 pfu/mL
42	Metapneumovirus A2	10^5 pfu/mL
43	Metapneumovirus Type B1	10^5 pfu/mL
44	Metapneumovirus Type B2	10^5 pfu/mL
45	Measles virus	10^5 pfu/mL
46	Rubella virus	10^5 pfu/mL
47	Mumps virus	10^5 pfu/mL
48	Boca virus	10^5 pfu/mL
49	Parainfluenza Virus 1	10^5 pfu/mL
50	Parainfluenza Virus 2	10^5 pfu/mL
51	Parainfluenza Virus 3	10^5 pfu/mL
52	Parainfluenza Virus 4	10^5 pfu/mL
53	Bordetella pertussis	10^5 pfu/mL
54	Candida albicans	10^5 pfu/mL
55	Legionella pneumophila	10^5 pfu/mL
56	Haemophilus influenzae	10^5 pfu/mL
57	Human Metapneumovirus	10^5 pfu/mL
58	Streptococcus pneumoniae	10^5 pfu/mL
59	Streptococcus pyogenes	10^5 pfu/mL
60	Mycobacterium tuberculosis	10^5 pfu/mL
61	Pneumocystis jirovecii (PJP)	10^5 pfu/mL
62	Staphylococcus aureus	10^5 pfu/mL
63	Staphylococcus epidermidis	10^5 pfu/mL

7. Interference Substances
The test results do not be interfered with the substance at the following concentration:

No.	Substances	Conc.
1	Ibuprofen	1mg/mL
2	Tetracycline	3μg/mL
3	Chloramphenicol	3μg/mL
4	Erythromycin	3μg/mL
5	Tobramycin	5%
6	Throat spray (Menthol)	15%
7	Mupirocin	10mg/mL
8	Throat lozenge (Menthol)	1.5mg/mL
9	Oseltamivir	5mg/mL
10	Naphthoxoline hydrochloride nasal drops	15%
11	Mucin	0.50%
12	Fisherman's Friend	1.5mg/mL
13	Compound Benzocain Gel	1.5mg/mL
14	Cromoglycate	15%
15	Phenylephrine Hydrochloride	15%
16	Afrin (Oxymetazoline)	15%
17	Fluticasone propionate spray	15%
18	Whole Blood	4%

Precautions

→For in vitro diagnostic use only.
→Do not use package when damaged, unclear label or even expired.
→The test shall be operated in strict accordance with the instructions.
→The results must be interpreted within 15 minutes.
→The disposable cassette is referred to biological waste when used.

References

1.Chen Wei, Zhang Chunyang, Zhu Ying, Zhang Yanhua, You Libin, Wu Bingshan, Huang Zhimiao, Zheng Kuicheng, Weng Yuwei. Comparison of nucleic acid detection in pharyngeal swabs and sputum specimens in 4 cases of new coronavirus infection. Chinese Journal of Zoonoses 2020; 1-7 (in Chinese)
2.Guo Yuanyuan, Wang Kun, Zhang Yu, Zhang Wenjia, Wang Liying, Liao Yi. Comparison and analysis of detection

performance of six domestic new coronavirus nucleic acid detection reagents. Chongqing Yixue 2020; 1-10 (in Chinese).

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Pas 257, 2440 Geel, Belgium

Instruction Approval and Revision Date

Approval Date: 12 Aug 2020

Revision Date: 01 Dec 2020

Date of Issue: 01 Dec 2020

REF	Catalogue number
	Consult instructions for use
IVD	*In vitro* diagnostic medical device
	Manufacturer
	Temperature limit
LOT	Batch code
	Use-by date
	Biological risks
EC REP	Authorized representative in the European Community
	Don't use the product when the package is damaged
	Do not re-use
	Warning
	Contains sufficient for <n> tests

UCK Uniwersyteckie Centrum Kliniczne

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Clinical Performance Evaluation Report for SARS-CoV-2 Antigen Rapid Test Cassette by Merlin Biomedical (Xiamen) Co., Ltd.

Study Site and Personnel

Research unit: Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne, 80-214 Gdańsk, ul. Mariana Smoluchowskiego 17 (University Clinical Center, 80-214 Gdansk Mariana Smoluchowskiego 17 street)

Person in charge of statistics and unit: Pawel Chrzan PhD

Research Period: From 2022.01.30 to 2022.3.15

Contact person: Paweł Chrzan

Contact number: +48 585844380

Original data storage location: Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne, 80-214 Gdańsk, ul. Mariana Smoluchowskiego 17 (University Clinical Center, 80-214 Gdansk Mariana Smoluchowskiego 17 street)

Institutions and researchers involved in clinical evaluations:

Researchers	Title	Take responsibility
Aneta Birkholz Gołaszewska MSc	Operator	Test implementation, collect samples, report drafting
Pawel Chrzan PhD	Reviewer	Report reviewing and approval

116	T78.4	Allergy, unspecified Allergy, unspecified
117	U07.1	COVID-19, virus identified. Hospitalization symptoms are positive. Test result is negative
118	U07.1	COVID-19, virus identified. Hospitalization symptoms are positive. Test result is negative
119	Z03.9	Observation for suspected disease or condition, unspecified
120	Z51.0	Radiotherapy session
121	Z51.1	Chemotherapy session for neoplasm
122	Z71.0	Person consulting on behalf of another person
123	Z94.0	Kidney transplant status
124	Z94.8	Other transplanted organ and tissue status

6. Clinical evaluation criteria

1) Clinical sensitivity and specificity: the value range is between 0% and 100%. The test requires that clinical sensitivity is greater than 80% of PCR-positive samples without preselection, clinical specificity is greater than 98%.

2) Total coincidence rate: The range of values is between 0% and 100%,the coincidence rate of this test requirement is greater than 90%.

3) Kappa statistical analysis: Kappa value between 0 and +1 is meaningful to judge the consistency. The larger the Kappa value, the better the consistency. It is generally believed that the Kappa value is greater than or equal to 0.75, indicating that a satisfactory degree of agreement has been achieved.

4) Operating procedures for SARS-CoV-2 Antigen Rapid Test Cassette and the PCR reagent are strictly followed to the instructions for use by manufacturers. If the result of antigen test is inconsistent with PCR, review of the clinical status and diagnosis by reviewing the PCR report and analyzing the N gene Ct value, and the result and conclusion can be obtained according to the comprehensive review. Before the evaluation start, the medium used to preserve samples should be examined to exclude the risk of cross-reaction with the SARS-CoV-2 Antigen Rapid Test Cassette.

7. Result analysis

Test results of the candidate kit and the reference kit are summarized in 2×2 table below.

		Vitassay qPCR SARS-CoV-2		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	104	0	104

Rapid Test Cassette	Negative	6	470	476
Total		110	470	580

Statistic	Value	95% CI
Sensitivity	94.55%	(88.51% to 97.97%)
Specificity	100.00%	(99.22% to 100.00%)
Total coincidence rate	98.97%	(97.76% to 99.62%)

The 95% confidence intervals of sensitivity, specificity, the total coincidence rate is calculated based on the binomial distribution.

Analysis results by Kappa consistency test shows that the Kappa= 0.9656. (As Kappa≥0.75, it suggests good consistency between the candidate kit and the reference kit.

8. Conclusion

In the present study, the SARS-CoV-2 Antigen Rapid Test Cassette by Merlin Biomedical (Xiamen) Co., Ltd. has shown high sensitivity, specificity, and total coincidence rate on nasal swabs samples from SARS-CoV-2 suspects. The test results are highly accurate and not affected by other respiratory pathogens that commonly found in clinical samples.

As the antigen tests take about 20 to 30 minutes, they are feasible for use in emergency scenarios where a test result is demanded immediately. Also, the rapid antigen tests doesn't require special instruments and training to use, they are also capable for resource limited scenarios like point-of-care testing and self-test by laypeople. Therefore, the implementation of rapid antigen test may totally change the strategies to control COVID-19. Community residents can conduct the rapid antigen test in a frequent manner, like twice or three times a week, to identify COVID-19 cases in the early stage of infection. This strategy may help to stop the transmission of COVID-19 as early as possible.

In summary, the SARS-CoV-2 Antigen Rapid Test Cassette has shown satisfying sensitivity, specificity, and total coincidence rate in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19 cases.

9. Reference

MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices.

Directive 98/79/EC -In vitro diagnostic medical devices.

TEST DIRECTORY

This fully searchable directory currently lists all commercially available immunoassays and molecular tests for COVID-19 of which FIND is aware. Manufacturer performance data (sensitivity and specificity) are included, where known, alongside data from independent evaluations conducted by FIND, where applicable. We are continuing to build this database, and will be adding other tests (which for the moment are still listed here), as well as data from independent evaluations by other entities. This project is part of our work on the ACT-Accelerator Diagnostics Pillar. If you have any queries on the information included or updates to share on your test(s), please contact us.

It has come to our attention that certain companies and websites are claiming to hold certificates endorsed by FIND and referring to the FIND name and logo. Third-party usage of the FIND logo to imply endorsement of services or diagnostic tools is not and has never been, authorized by FIND.

Last updated: 10 December 2021

REQUEST TO ADD A NEW TEST

RETURN TO MAIN SCREEN

SARS-COV-2 ANTIGEN RAPID TEST CASSETTE

Merlin Biomedical (Xiamen) Co., Ltd.
http://www.merlinbio.com.cn/en/

EXPORT THIS PAGE IN PDF

REGULATORY STATUS
CE-IVD

TIME TO RESULT
0.25

ASSAY TARGET
Antigen

TEST FORMAT
Lateral flow assay (strip or cassette)

TECHNOLOGY PRINCIPLE
Antibody-based detection

TARGET ANALYTE
N protein

LEVEL OF AUTOMATION
Manual

LABORATORY/POINT-OF-CARE
True Point of Care

SELF-TESTING/SELF-COLLECTION
Intended for professional use only

VALIDATED SAMPLE TYPES
Nasal swab
Nasopharyngeal swab

CONNECTIVITY
No

IMPACT OF SARS-COV-2 VARIANT:
Alpha - No expected impact (in silico analyses)
Beta - No expected impact (in silico analyses)
Gamma - Unknown

Manufacturer performance data

SENSITIVITY
95.051002%

SPECIFICITY
98.99%

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

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

Product Service

Certificate

No. Q5 106286 0001 Rev. 01

Holder of Certificate: **Merlin Biomedical (Xiamen) Co., Ltd.**
Unit 01, 4th Floor, Building B3
Xiamen Biological Medicine Industrial Park
2054 West Wengjiao Road, Haicang
361028 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Medical Devices for Detection Kit of 5 Urogenital Tract Pathogens Nucleic Acid (Fluorescence PCR method), Single Use Specimen Container, DNA/RNA Extraction Kit, IVD Equipment for Nucleic Acid Purification integrated with Amplification based on Fluorescence PCR Method**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 106286 0001 Rev. 01

Report No.: GZ2135501

Valid from: 2021-08-02
Valid until: 2023-06-08

Date, 2021-08-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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

TÜV SÜD Product Service

Certificate

No. Q5 106286 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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Unit 01, 4th Floor, Building B3, Xiamen Biological Medicine Industrial Park, 2054 West Wengjiao Road, Haicang, 361028 Xiamen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of IVD Equipment for Nucleic Acid Purification integrated with Amplification based on Fluorescence PCR Method.
Production of In Vitro Diagnostic Medical Devices for Detection Kit of 5 Urogenital Tract Pathogens Nucleic Acid (Fluorescence PCR method), Single Use Specimen Container, DNA/RNA Extraction Kit

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Design and Development, Production and Distribution of Detection Kit of 5 Urogenital Tract Pathogens Nucleic Acid (Fluorescence PCR method), Single Use Specimen Container, DNA/RNA Extraction Kit.
Production and Distribution of IVD Equipment for Nucleic Acid Purification integrated with Amplification based on Fluorescence PCR Method.

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