ArtecMed® **Green Spring**

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

About Us

ARTEC Group has over 20 years of history. Based in Hong Kong, the business has expanded to 19 subsidiaries in response to different areas and established offices in 7 countries around the world. ARTEC has been committed to utilizing technology to improve human life from cosmetics to medical supplies industry.
ArtecMed is an ARTEC brand dedicated to medical development.

Artenano in the ARTEC Group has been engaged in nanotechnology and environmental technology research since 2005. Nanostructures have provided particles and material new chemical and physical properties, allowing existing raw materials to breakthrough for new applications.

Artenano has established a laboratory in Hong Kong, which is committed to researching nano-precious metals and nano catalyst technology and applying it to the development of personal use products. The collaboration between Artenano and the Hong Kong Science Park has contributed to the development of local technology through research projects with universities. It also received interviews and reports from multiple medias.

ArtecMed applies Artenano’s nanotechnology to improve the quality of human life, providing expertise and products in scientific analysis, antibacterial, indoor air and UV protection. We strive to bring everyone a safe and healthy life with technology.

Our PRODUCTS

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

ANTI-EPIDEMIC SERIES

ANTI-EPIDEMIC SERIES

ETHANOL SANITIZERS

CHG SANITIZERS

We do our best for you and your health

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold)

Utilizing Lateral Flow Immunoassay and Colloidal Gold technology to effectively, speedily and accurately detect SARS-CoV-2 antigens of novel coronavirus variants. Available for self-testing at home, the Test Kits let you or your family know your health status promptly and take immediate action to terminate widespread of CoVID-19.

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

CE-certified : European Centre for Disease Prevention and Control (ECDC) data confirms that the sensitivity of the Test Kit is higher than that of similar products[1]

WHO-recommended : Sensitivity and Specificity of the Test Kit achieves far beyond World Health Organization (WHO) Recommendation[2]

Excellent Sensitivity : Clinically proven sensitivity of 96.77%*

Extreme Specificity : Clinically proven specificity of 100%**

* Sensitivity - the sensitivity of a screening test is to identify positive results from individuals with infection. Tests with low sensitivity will result in more false-negatives, which means missed diagnosis for infected people causing false sense of security. [3]

** Specificity - the specificity of a screening test is its ability to identify negative results from individuals without infection. Tests with low specificity will result in more false-positives, causing unnecessary anxiety for non-infected people.

Reference:

1. Scheiblauer H, Filomena A, Nitsche A, Puyskens A, Corman VM, Drosten C, Zwirglmaier K, Lange C, Emmerich P, Müller M, Knauer O, Nübling CM. Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen, Germany, September 2020 to April 2021. Euro Surveill. 2021 Nov;26(44):2100441.
2. World Health Organization. (2021). Antigen-detection in the diagnosis of SARS-CoV-2 infection:interim guidance, 6 October 2021. World Health Organization. https://apps.who.int/iris/handle/10665/345948. License: CC BY-NC-SA 3.0 IGO.
3. Performance of Rapid Antigen Test for Coronavirus Disease 2019 (COVID-19), Department of Health, The Government of Hong Kong SAR https://www.mdd.gov.hk/filemanager/common/mdacs/RAT-pamphlet-EN.pdf

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Rapid Analysis : Result available in 15 minutes

Simple Steps : 4 simple steps involved. Applicable for nasal-pharynx / anterior nasal / pharynx / saliva sampling

Variants Detection : Effectively detect variants of the novel coronavirus, including Alpha, Beta, ***Delta***, Epsilon, Zeta and ***Omicron***, etc.

Individual Packaging : Each box contains 10 individual Test Kits

Global Bestsellers : Bestsellers in UK, Germany, Belgium and Spain

Cq Value and Virus

Cq value (cycle threshold) is an indicator of the patient's virus content and its infectivity. The higher the Cq value, the lower the viral load of a patient is, and more sophisticated instrument is required for detection.

Virus content carried by the patient was limited just after infection. It contributes a higher Cq value and lower risk transmission.

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) achieves high sensitivity even in high Cq value cases.

Choose ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) for a rapid test to avoid the widespread of the novel coronavirus to **your loved ones** as soon as possible.

Reference:

1. Scheiblauer H, Filomena A, Nitsche A, Puyskens A, Corman VM, Drosten C, Zwirglmaier K, Lange C, Emmerich P, Müller M, Knauer O, Nübling CM. Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen, Germany, September 2020 to April 2021. Euro Surveill. 2021 Nov;26(44):2100441.

Sterile swab

Name	Box Set	Size	Outer size (L*W*H/cm)	Weight (Kg)
ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit Colloidal Gold)	10 tests/box	21.5*13.5*7.5 inner box 21*7*1.3	70.3*44.9*32 .4	15.5

Extraction tube with buffer

Table 1: Clinical Study (nasopharyngeal)

ArtecMed Green Spring SARS CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	PCR-Comparator		Total
	Positive	Negative	
Positive	150	0	150
Negative	5	210	215
Total	155	210	365
Sensitivity	96,77% (95%CI: 92,24-98,81%)		
Specificity	100,00% (95%CI: 97,76-100%)		
Accuracy	98,63% (95%CI: 96,89-100%)		

PPA(Ct< 37): 96,77% (150/155), (95%CI: 92,24-98,81%)
NPA(Ct< 37): 100,00% (21&210), (95%CI: 97,76-100%)

Product Details

Comparative evaluation results of SARS-CoV-2 antigen rapid diagnostic tests passing the sensitivity criteria

According to the requirements of the German healthcare system, only rapid antigen detection kits that can achieve a minimum sensitivity of 75% in samples with a Cq value of ≤ 25 are eligible for reimbursement.

ArtecMed® Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) achieves 100% (perfect) sensitivity in samples with Cq value ≤ 25.
The Test Kit achieves an excellent 95.7% sensitivity in samples with Cq value >25 – <30, ranking top in the world.

TABLE 3A

Comparative evaluation results of SARS-CoV-2 antigen rapid diagnostic tests passing the sensitivity criteria (sorted by performance in the subgroups of the evaluation panel), Germany, 2020–2021 (n = 96)

	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25– <30	Cq ≥ 30	Cq 17–36
Subgroup of RDT with detection rates of 100% for Cq ≤ 25 and of ≥75% for Cq >25– <30						
84						
79						
86						
50						
72						
7						
18						
60						
85	Triplex International Biosciences (China) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	100.0%	87.0%	20.0%	78.0%
96	Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	100.0%	87.0%	0.0%	76.0%
82	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	100.0%	87.0%	0.0%	76.0%
33	Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	100.0%	82.6%	0.0%	72.0%
53	Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	100.0%	82.6%	0.0%	72.0%
22	BioRapid GmbH	Covid 19 Antigen Schnelltest	100.0%	78.3%	0.0%	70.0%
4	Amedo Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	100.0%	78.3%	0.0%	70.0%
23	BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	100.0%	78.3%	11.1%	74.0%
41	Hangzhou Lysun Biotechnology Co., Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	100.0%	78.3%	0.0%	70.0%
45	Hangzhou Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	100.0%	78.3%	0.0%	68.0%
88	Mental (Beijing Mental Biological Pharmacy Enterprise Co., Ltd.)	SARS-CoV-2 Ag Rapid Test (FIA)	100.0%	78.3%	0.0%	70.0%
Subgroup of RDT with detection rates of 100% for Cq ≤ 25 and of ≥75% for Cq >25 - <30						
83	Sugentech, Inc.	SGTi-flex COVID-19 Ag	100.0%	73.9%	0.0%	68.0%
89	Wuhan EasyDiagnosis Biomedicine Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit	100.0%	73.9%	0.0%	68.0%
10	ASAN PHARM.CO.,LTD.	Asan Easy Test COVID-19 Ag	100.0%	69.6%	0.0%	66.0%
49	Lumigenex (Suzhou) Co., Ltd.	Pockac SARS-CoV-2 Antigen Schnelltest Set (Kolloidales Gold)	100.0%	65.2%	0.0%	64.0%
75	SD BIOSENSOR	STANDARD F COVID-19 Ag FIA	100.0%	65.2%	0.0%	66.0%
31	BIONOTE	NowCheck COVID-19 Ag Test	100.0%	65.2%	0.0%	66.0%
1						
11						
25						
47						
63	Precision Biosensor Inc. (Axon Laboratory AG)	Exdia COVID-19 Ag Test	100.0%	60.9%	0.0%	64.0%
70	Safecare Biotech Hangzhou Co., Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	100.0%	60.9%	0.0%	62.0%
80	Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	100.0%	60.9%	0.0%	62.0%

Cq: quantitative cycle; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

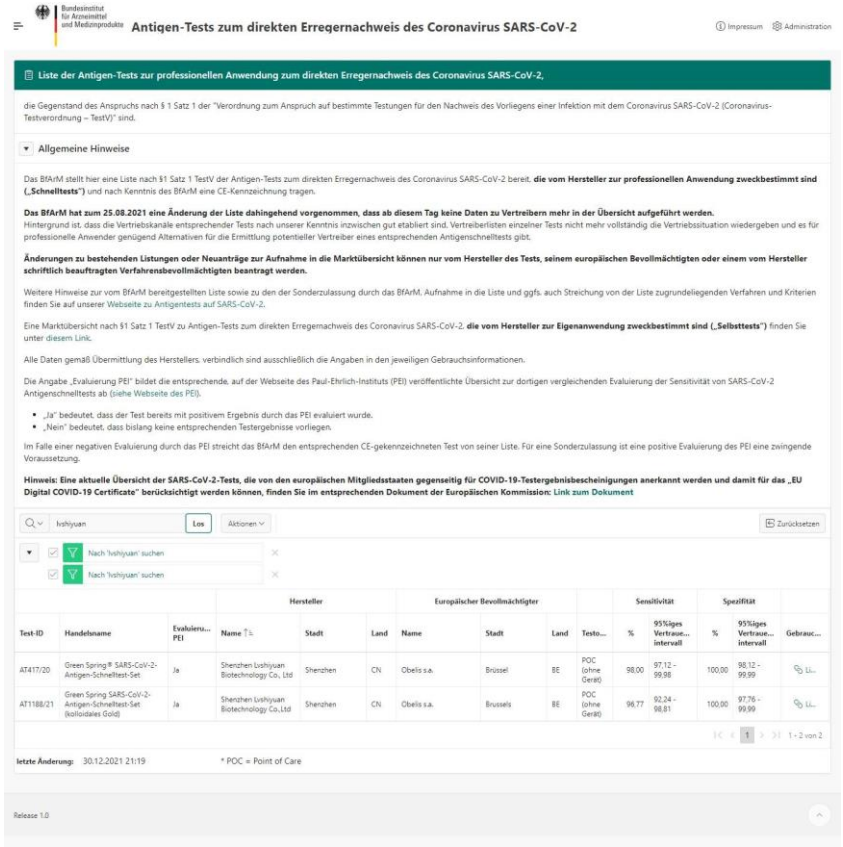
Criteria as defined by detection rate of ≥75% in panel subgroup with Cq ≤ 25.

www.autoimmunalliance.org

	Test name	Sensitivity			
		Cq ≤ 25	Cq >25– <30	Cq ≥ 30	Cq 17–36
100% for Cq ≤ 25 and of >75% for Cq >25– <30					
nology	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	95.7%	40.0%	86.0%

21	BIONOTE	NowCheck COVID-19 Ag Test	100.0%	65.2%	0.0%	66.0%
1	Abbott Rapid Diagnostics Jena GmbH	PanbioCOVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	100.0%	60.9%	0.0%	64.0%

Product Details



Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum Administration

Liste der Antigen-Tests zur professionellen Anwendung 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 professionellen Anwendung zweckbestimmt sind („Schnelltests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen.

Das BfArM hat zum 25.08.2021 eine Änderung der Liste dahingehend vorgenommen, dass ab diesem Tag keine Daten zu Vertreibern mehr in der Übersicht aufgeführt werden.
Hintergrund ist, dass die Vertriebskanäle entsprechender Tests nach unserer Kenntnis inzwischen gut etabliert sind. Vertreiberlisten einzelner Tests nicht mehr vollständig die Vertriebssituation wiedergeben und es für professionelle Anwender genügend Alternativen für die Ermittlung potentieller Vertreiber eines entsprechenden Antigenschnelltests gibt.

Änderungen zu bestehenden Listungen oder Neuanträge zur Aufnahme in die Marktübersicht können nur vom Hersteller des Tests, seinem europäischen Bevollmächtigten oder einem vom Hersteller schriftlich beauftragten Verfahrensbevollmächtigten beantragt werden.

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.

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

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.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

Ivshiyuan Los Aktionen Zurücksetzen

Nach 'Ivshiyuan' suchen

Nach 'Ivshiyuan' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluieru... PEI	Name	Stadt	Land	Name	Stadt	Land	Testo...	%	95%iges Vertraue... intervall	%	95%iges Vertraue... intervall	Gebrauc...
AT417/20	Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set	Ja	Shenzhen Lvshiyuan Biotechnology Co., Ltd	Shenzhen	CN	Obelis s.a.	Brüssel	BE	POC (ohne Gerät)	98,00	97,12 - 99,98	100,00	98,12 - 99,99	Li...
AT1188/21	Green Spring SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold)	Ja	Shenzhen Lvshiyuan Biotechnology Co.,Ltd	Shenzhen	CN	Obelis s.a.	Brussels	BE	POC (ohne Gerät)	96,77	92,24 - 98,81	100,00	97,76 - 99,99	Li...

1 - 2 von 2

letzte Änderung: 30.12.2021 21:19

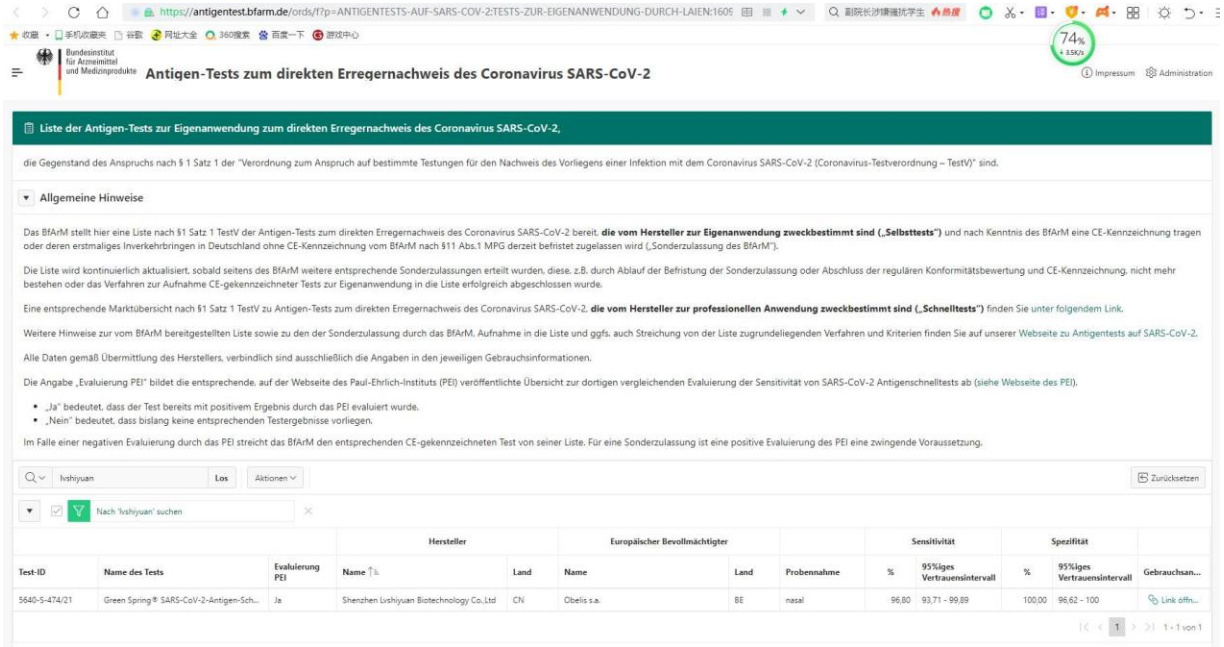
* POC = Point of Care

Release 1.0

MediGermany BfArM Approval of Green Spring Antigen test for professional use

BfArM (German Governmental Autority)cal Infographic

Germany BfArM Approval of Green Spring Antigen test for self-testing



Paul-Ehrlich-Institut Certification

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

12.02.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim

Comparison of different antigen rapid tests with using identical sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^6 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that many other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact

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Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Last updated: 12.02.2021

Overview of SARS-CoV-2 Antigen Rapid Tests Assessed as Reflecting the Current State of the Art

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

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Name of Test	Manufacturer (Distributor)
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co., Ltd.
Toda Coronadiag Ag	Toda Pharma
Humasis COVID-19 Ag Test	Humasis Co., Ltd.
Beijing Hotgen Biotech Co., Ltd.	Neuartiges Coronavirus (2019-nCoV)-Antigentest (Kolloidales Gold); Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)
Xiamen AmonMed Biotechnology Co.,Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Canea COVID-19 Antigen Schnelltest	Core Technology Co., Ltd.
fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Tetsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd
Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co., Ltd.

CE Certification

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 0171-2020
Order No.: OG 0117-2020

BELGIUM

Date: 19/11/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: SHENZHEN LVSHIYUAN BIOTECHNOLOGY CO., LTD.

ADDRESS: 101, 201, 301, D BUILDING, NO. 2 INDUSTRIAL AVENUE, BUXIN VILLAGE, BUXIN COMMUNITY, DAPENG SUBDISTRICT OFFICE, DAPENG NEW DISTRICT, SHENZHEN, 518120, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 18/11/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 19/11/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a reminder for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B - 1200 Brussels - Belgium

Order No.: OG 0117-2020
Ref No.: BS 0171-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1	GF102B1	SARS-CoV-2 Antigen Rapid Test Kit	SARS-CoV-2 (COVID-19) Antigen Rapid Test Kit (Colloidal Gold)	SARS-CoV-2 (Covid-19) Antigen Rapid Test Kit is used to quanlitatively detect antigen of the novel coronavirus in nasal swab.	15.04.80.19	Others

Obelis s.a.

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles

Thank You