PocRoc® SARS-CoV-2 ANTIGEN RAPID TEST KIT

(Colloidal Gold)

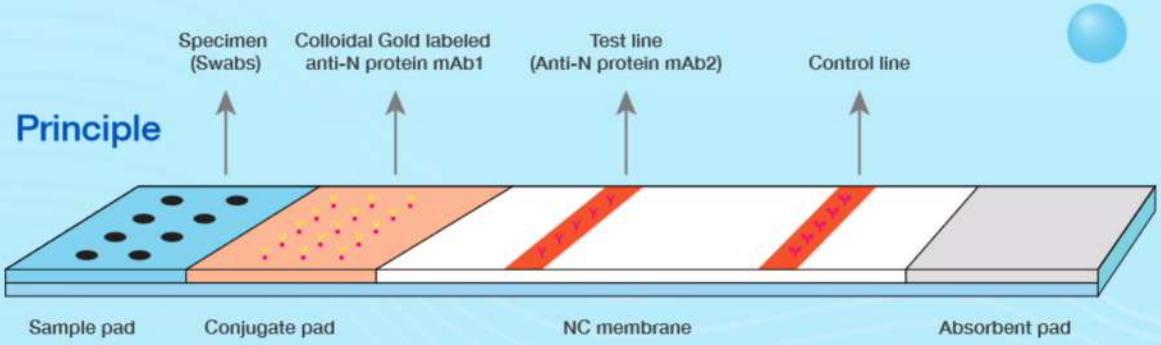
PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) is intended for qualitative detection of SARS-CoV-2 nucleocapsid antigen from Swab specimen.

Specification:

-Target: nucleocapsid antigen
-Specimens: Nasal Swab (NS) / Oropharyngeal Swab(OP)
-Detection Time: 15~20mins
-Shelf Time: 24 months

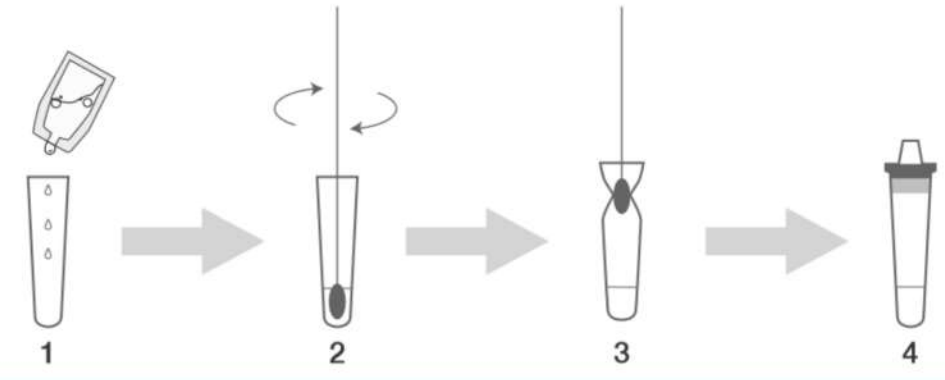
Product Name	Specification	Storage temperature
PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	1 test/box 5 tests/box 25 tests/box 50 tests/box	4°C-30°C

Principle



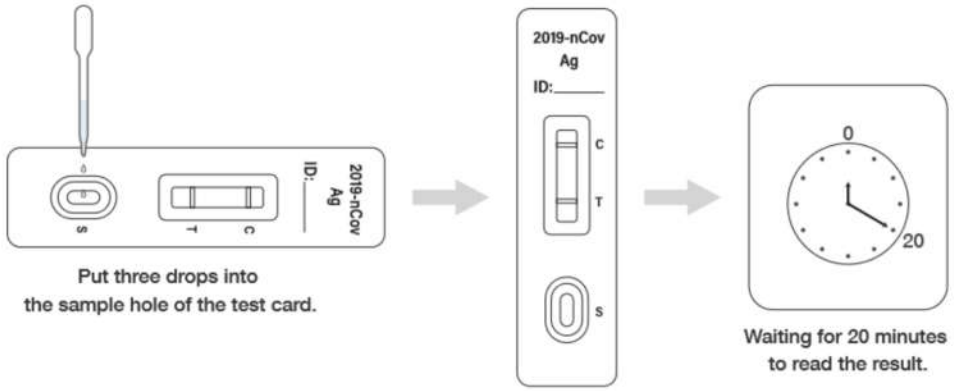
Lumigenex® Lumigenex (Suzhou) Co., Ltd.

Sample preparation can take according to the operation steps.



1 The swab extractor bottle is pressed vertically downward to the extraction tube.
2 Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.
3 Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab.
4 Install the beater on the extraction tube.

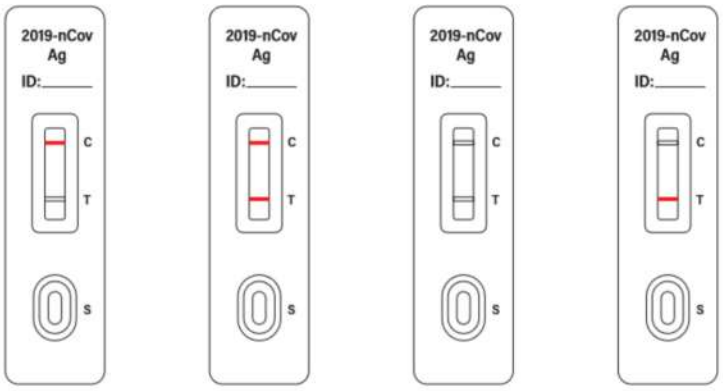
Test procedure



Put three drops into the sample hole of the test card.

Waiting for 20 minutes to read the result.

Interpretation of results



negative | positive | invalid | invalid

Lumigenex (Suzhou) Co., Ltd.
Add.: Bld. C24, 218 Xinghu Str., Suzhou 215123, P.R. China
Tel.: +86-512-80988088 (ext. 6034)
E-mail: lumi@lumigenex.com

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Lumigenex (Suzhou) Co., Ltd.
Building C24
218 Xinghu Street
Suzhou Industrial Park
215123 Jiangsu
China

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

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2019-09-30
Certificate Registration No.:	SX 60139875 0001
An audit was performed. Report No.:	15084639 004
This Certificate is valid until:	2021-12-19

Certification Body

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

Date 2019-09-30

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Herbert Zhong

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60139875 0001
Report No.: 15084639 004

Organization:
Lumigenex (Suzhou) Co., Ltd.
Building C24
218 Xinghu Street
Suzhou Industrial Park
215123 Jiangsu
China

Scope:
Design/development, Manufacture and Distribution of In-vitro Diagnostic Medical Devices, including Time-Resolved Fluorescence Immunoanalyzers and Test Kits; Dry Chemistry Analyzers and Test Kits

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-09-30

Herbert Zhong

ZERTIFIKAT ■ CERTIFICATE ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

RIOMAVIX

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Lumigenex (Suzhou) Co., Ltd.

ADDRESS: Building C24, 218 Xing Hu Street, SIP, Suzhou, P.R. China 215123

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices:

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

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notifed of the manufacture's device and has allocated registration. The registration number is RPS/2506/2020

Executive Director

RIOMAVIX R RIOMAVIX

Issue date: 1/Nov/2020
Cert. No.: R20201101-1

CE

Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

Lumigenex

GJ-CE-2020DoC(Ver.02)

Declaration of Conformity

CE

Manufacturer:
Lumigenex (Suzhou) CO., Ltd. Located at building C24, 218 Xing Hu Street, SIP,Suzhou, P.R. China 215123
TEL +86 (512) 80988088 FAX +86 (512) 80988096

European Representative:
Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

Products Name:
PocRoc ® SARS-CoV-2 Antigen Rapid Test Kit（Colloidal Gold）

Product code: P23001, P23005,P23025,P23050.

Classificaiton Under IVDD:
IVDD Other

Conformity assessment route: Annex III
We hereby declare under the sole responsibility of the manufacturer that the product mentioned above meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. All supporting documentations are retained at the premises of the manufacturer.

General applicable directive:
Directive 98/ 79/EC of European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices.

Standards applied:
EN ISO 18113-1:2011, EN ISO 14971:2012, EN ISO 13485:2016,EN ISO 18113-2:2011, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 17511:2000, EN 13612: 2002

First start of CE-MARC: Nov.1, 2020
Signature:
Mr. Eric Liu (Vice President) Eric Liu.
Place, Date of issue: Suzhou, Nov.1, 2020

15.03.2021

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

Stand 15.03.2021

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

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

Testname	Hersteller (Vertrieb)
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.
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	Beijing Hotgen Biotech Co., Ltd.
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	AmonMed (Xiamen) Biotechnology Co., Ltd.
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
Testsealabs® 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.
Wizbiotech SARS-CoV-2 Antigen Rapid Test	Xiamen WIZ Biotech Co., Ltd.
SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	PerGrande BioTech Development Co., Ltd.
salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	Salofa OY
Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc.
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co. Ltd
Aesku Rapid SARS-CoV-2 Rapid Test	Aesku Diagnostics GmbH
Rapid Response COVID-19 Rapid Test Device	BTNX, Inc. (Biotrend Chemikalien Gmbh)
Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	Azure Biotech Inc.
Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Labnovation Technologies, Inc.
V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	SGA Mühendislik DAN. EG. Icve DIS.Ltd.STI
SGTi-flex COVID-19 Ag	Sugentech, Inc.
softec SARS COV-2 (Covid-19) Antigen Test Kit	Zet Medikal Tekstil Dis Ticaret Ltd. STI.
Genedia W Covid-19 Ag	Green Cross Medical Science Corp. (Weko Pharma GmbH)
COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	Anhui Deepblue Medical Technology Co. , Ltd.
FREND™ COVID-19 Ag	NanoEntek Inc
RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	Vitrosens Biyoteknoloji Ltd. Sti
COVID-19 (SARS-CoV-2) Antigen Test Kit	Wuhan EasyDiagnosis Biomedicine Co., Ltd
PCL COVID19 Ag Gold Saliva	PCL, Inc.
reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	Zhejiang Anji Saianfu Biotech Co.,Ltd.
IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	Hangzhou Immuno Biotech Co.,Ltd.
Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	Shenzhen Zhenrui Biotech co.Ltd.

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.

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen tests for direct pathogen detection of coronavirus SARS-CoV-2

Imprint Administration

All data according to the transmission of the manufacturer, are only binding the information in the respective usage information.

Further information on the list provided by the BfArM as well as on the list and, if necessary, also removal from the list of underlying criteria can be found on our website for antigen testing on SARS-CoV-2.

The following table shows the original tests with their trade name assigned by the manufacturer or European representative. An overview of the respective German distributors and their if necessary. different name can be found under the link in the column "German distributors".

The indication "Evaluation PEI" provides the corresponding overview of the comparative evaluation of the sensitivity of SARS-CoV-2 rapid antigen tests published on the website of the Paul Ehrlich Institute (PEI)(see pei website).

- "Yes" means that the test has already been evaluated with a positive result by the PEI.
- "No" means that no corresponding test results are available yet.

In the event of a negative evaluation by the PEI, the BfArM deletes the corresponding test with all associated distributors from its list.

Lumigenex | Los | Actions | Reset

Search for 'Lumigenex'

			Manufacturer			European Representative					Sensitivity		Specificity	
Test ID	Manufacturer's trade name / Europ. Agent	Evaluation PEI	Name	City	Co...	Name	City	Co...	German distribut...	Test locat...	%	95% confiden... interval	%	95% confidence interval
AT455/20	PocRoc ® SARS-CoV-2 Antigen Quick Detection Kit (Gold Colloidal)	Yes	Lumigenex (Suzhou) Co., Ltd.	Suzhou	Cn	Riomavix S.L.	Madrid	It	De...	POC (without device)	93,33	86,27 - 97,05	99,16	96,68 - 99,85

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

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

Manufactured by Lumigenex (Suzhou) Co., Ltd, China - http://www.lumigenex.com/

Device identification number	2128
CE Marking	Yes
HSC common list	Yes
HSC mutual recognition	Yes
Format	Manual, Near POC / POC
Physical Support	Cassette, Lateral flow
Target	Antigen