SARS-CoV-2 Antigen Detection Kit

(Latex Lateral Flow Assay)

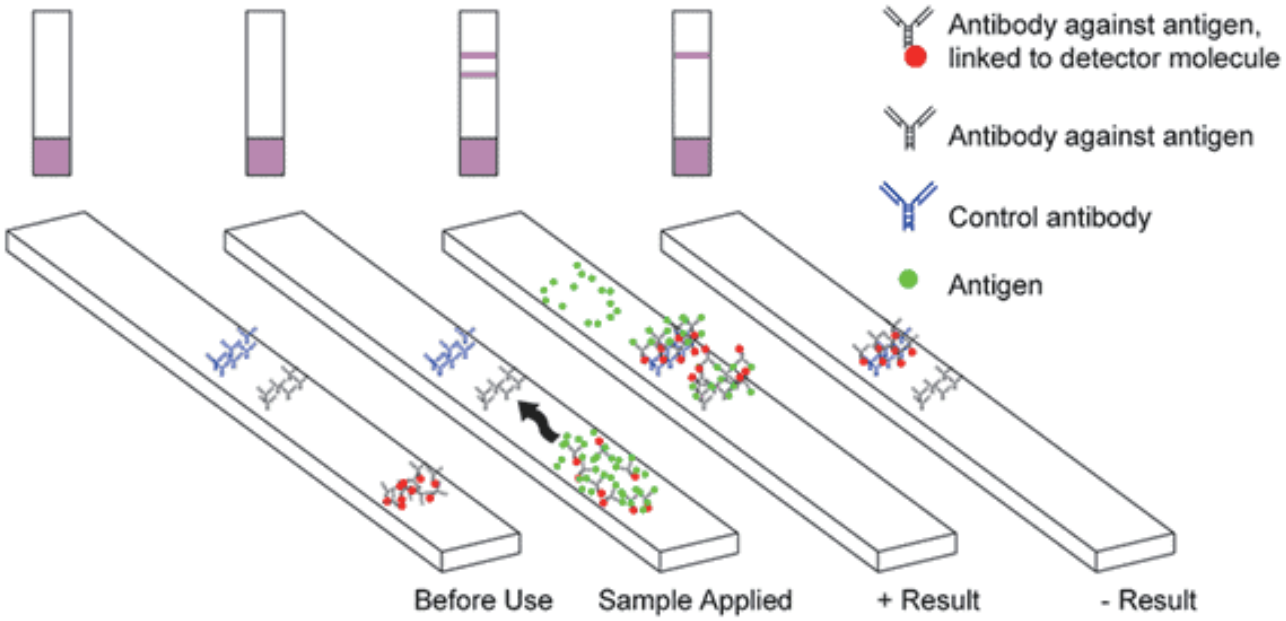
15 min

AIVD®

SARS-CoV-2 Antigen Rapid Test

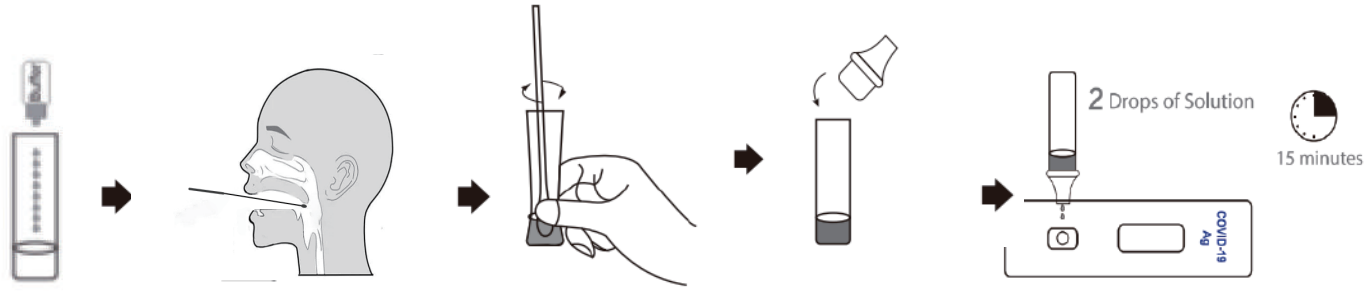
AIVD Biotech's COVID-19 Ag test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein (NP) antigen from SARS-CoV-2 in direct throat swabs from individuals suspected of COVID-19.

How It Works



SARS-CoV-2 Antigen Rapid Test

Pharyngeal and nasal swabs Steps



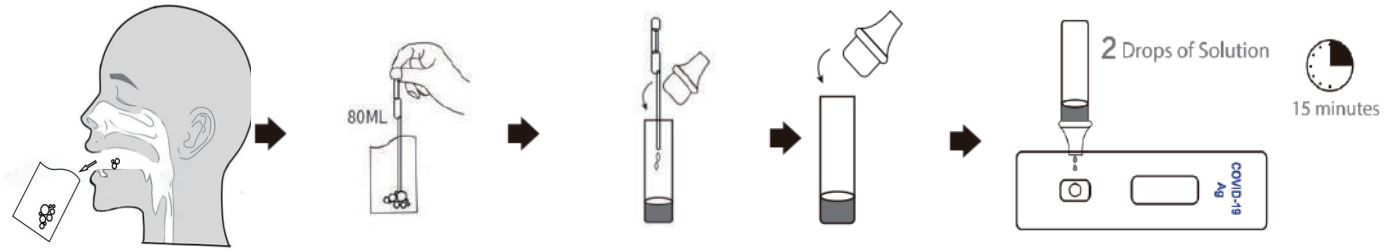
Products Name	Main Features	Intended Use
SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)	15-minute rapid detection CE-IVD marked Export White List pharyngeal or nasal swab collection	For in vitro qualitative detection of COVID-19 in human pharyngeal or nasal secretions samples.

Perform manually.No special instrument required.

Swab Lysate Desiccant Reagent cards Test card

SARS-CoV-2 Antigen Rapid Test

Saliva swabs Steps



Products Name	Main Features	Intended Use
SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)	15-minute rapid detection CE-IVD marked Export White List saliva swab collection	For in vitro qualitative detection of COVID-19 in human saliva secretions samples.

Perform manually.No special instrument required.

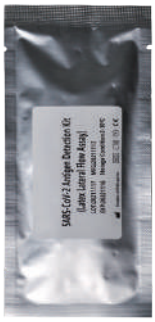
Dropper Salivasample kit Lysate Reagent cards Test card

Packing inform

Contents/Packing Sizes-AP

① test cassette ×1

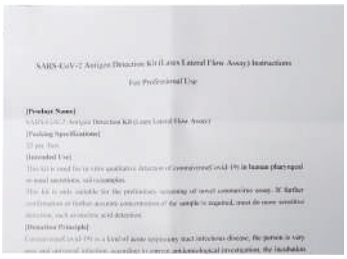
② desicxant ×1



Test Kit Pouch ×1

Extraction buffer ×1

Swab ×1



Instruction for use ×1

× 25

25 Tests

200* 135* 88mm

× 36

900 Tests

700* 400* 320mm
G.W. 13.6 KG

Packing inform

Contents/Packing Sizes-AP

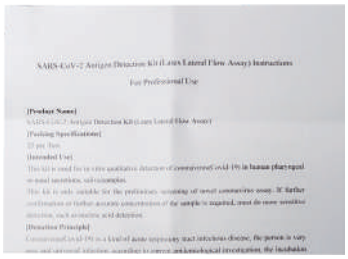
Test cassette ×1

Bio waste bag ×2

Test Kit Pouch ×1

Extraction buffer ×2

Nasal Swabs ×2



Instruction for use ×1

128*66*22mm
1 Tests

200*135*88mm
25 Tests

694*610*280mm
500 Tests

About us

Shenzhen Aivd Biotech Inc.,founded in 2014, is a company dedicated to in vitro diagnostic reagents, medical testing equipment, biomedical high-tech enterprises, and has successively obtained the "Shenzhen High-tech Enterprise", "National High-tech Enterprise" ISO9000,ISO13485 quality management system cert fication and CE certification.In the process of production and development, Aivd always (ISO9001 and ISO13485) quality management system as the standard, customer demand as the purpose, to provide customers with high-quality products and professional technical services,for many years by Shenzhen city as a high-tech enterprise. At present, we have more than 50 kinds of immunization products and a variety of immunoquantitative analysis technology platforms, and our sales network covers all provinces in China, which is highly recognized and praised by the majority of users. Aivd provides complete IVD service solutions and is a leading manufacturer and supplier of a board range of highest quality OEM raw materials, antibodies, antigens, enzymes, reagents, kits, uncut sheets and services for the academic, biopharma, and diagnostic industries.Aivd has developed its own processing techniques to satisfy the raw material requirements of the IVD industry.

In-vitro Diagnostics Raw Material Technology R&D Center. The center includes genetic, protein and enzyme engineering platforms;In-vitro Diagnostics Assay Development Center. We assist our clients in developing a point of care lateral flow, including colloidal gold, fluorescent signal, and paramagnetic labels - based assays, ELISA, chemiluminescent immunoassays and molecular diagnostic assays.New Products R&D center. The center primarily focuses on research in the biomedical field, includes Liquid Biopsy and Microfluidics platforms.

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00166968

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority

	Code **DE/CA73**		
	Bezeichnung / Name **Landesamt für Gesundheit und Soziales, Referat I F**		
	Staat / State **Deutschland**		Land / Federal state **Berlin**
	Ort / City **Berlin**		Postleitzahl / Postal code **10559**
	Straße, Haus-Nr. / Street, house no. **Turmstraße 21**		
	Telefon / Phone **+49-30-902292908**		Telefax / Fax **+49-30-90285052**
	E-Mail / E-mail **medizinprodukte@lageso.berlin.de**		

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00166968

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority **29.11.2021**	Registriernummer / Registration number **DE/CA73/236677-88**

Rechtsgrundlage / legal basis
☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG)
☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)

Typ der Anzeige / Notification type
☒ Erstanzeige / Initial notification
☐ Änderungsanzeige / Notification of change
☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG
☐ Hersteller / Manufacturer
☒ Bevollmächtigter / Authorised Representative
☐ Einführer / Importer
☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG
☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV
☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anzeigender / Reporting organisation (person)

Code **DE/0000047267**	
Bezeichnung / Name **Osmunda Medical Technology Service GmbH**	
Staat / State **Deutschland**	Land / Federal state **Berlin**
Ort / City **Berlin**	Postleitzahl / Postal code **10318**
Straße, Haus-Nr. / Street, house no. **Treskowallee 108,**	
Telefon / Phone **+49-30-81865123**	Telefax / Fax
E-Mail / E-mail **eu@osmundacn.com**	

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00166968

Hersteller / Manufacturer

Bezeichnung / Name	**Shenzhen Aivd Biotechnology Co., LTD.**
Staat / State	**CN**
Ort / City	**Shenzhen, Guangdong**
Postleitzahl / Postal code	**518116**
Straße, Haus-Nr. / Street, house no.	**C501, Building B5, China Merchants Bright Technology Park, Fenghuang Community Sightseeing Road,Fenghuang Street, GuangminDistrict**
Telefon / Phone	**0755-26165742**
Telefax / Fax	
E-Mail / E-mail	**sales@aivdbiotech.com**

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG

Bezeichnung / Name	**Min Yang**
Staat / State	**Deutschland**
Land / Federal state	**Berlin**
Ort / City	**Berlin**
Postleitzahl / Postal code	**10318**
Straße, Haus-Nr. / Street, house no.	**Treskowallee 108,**
Telefon / Phone	**+49-30-81865123**
Telefax / Fax	
E-Mail / E-mail	**min.yang@osmundacn.com**

Vertreter / Deputy (optional)

Bezeichnung / Name	
Telefon / Phone	
Telefax / Fax	
E-Mail / E-mail	

☐ Erstanzeige / Initial notification
☒ Änderungsanzeige / Notification of change

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00166968

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification
☐ Produkt der Liste A, Anhang II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung / Device for self-testing
☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG
Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG
☒ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device
SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)

Produktbezeichnung / Name of device
SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)

Angabe der benutzten Nomenklatur / Nomenclature used
☒ EDMS-Klassifikation / EDMS Classification
☐ GMDN

Nomenklaturcode / Nomenclature code
15-04-80-90-00

Nomenklaturbezeichnung / Nomenclature term
OTHER VIRAL ANTIGEN/ANTIBODY DETECTION

Kurzbeschreibung / Short description
In Deutsch / In German

In Englisch / In English
This kit is used for in vitro qualitative detection of coronavirus(Covid-19) in human pharyngeal or nasal secretions, saliva samples. This kit is only suitable for the preliminary screening of novel coronavirus assay. If further confirmation or further accurate concentration of the sample is required, must do more sensitive detection, such as nucleic acid detection.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices

Nummer(n) der Bescheinigung(en) / Certificate number(s)

☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A)
In conformity with Common Technical Specifications (for Annex II List A devices)

Ergebnisse der Leistungsbewertung
Outcome of performance evaluation

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00166968

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort City	**Berlin**	Datum Date	**2021-11-25**
		Name	**Min Yang**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible **Frau Sharon Prinz**	Telefon / Phone **030-902293328**

EC Declaration of Conformity

Manufacturer: Shenzhen Aivd Biotechnology Co., LTD.
Address: C501, Building B5, China Merchants Bright Technology Park, Fenghuang Community Sightseeing Road,Fenghuang Street, GuangminDistrict,Shenzhen, Guangdong Province, China

EU Authorised Representative:
Osmunda Medical Technology Service GmbH
Treskowallee 108, 10318 Berlin, Germany
Tel: +49-30-81865123 Fax: +49 30 4699 5929

Product name: SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)
Classification (IVDD, Annex II): IVD Device other than the ones listed in Annex II-IVDD 98/79 as List A, List B and Self testing
Conformity assessment route: ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directives and Standards (IVDD 98/79/EC). All supporting documentations are retained under the premises of the manufacturer.

CE

General applicable directives:

In Vitro Diagnostic Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 (IVDD 98/79/EC).

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 13641:2002
EN ISO 18113-1:2011	EN ISO 18113-2:2011	BS EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640: 2015	

Place, Date of Issue:

Shenzhen, November 5th, 2021

Represented by General Manager
Name: Hongyan Li
Function: General Manager
Signature:

The signature is signed on behalf of Shenzhen Aivd Biotechnology Co., LTD.

European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Home > COVID-19 In Vitro Diagnostic Medical Devices

COVID-19 In Vitro Diagnostic Medical Devices

Show advanced filters

1 records found

Download as JSON, XML, CSV

CE Marking	Manufacturer	Commercial Name	ID	Method	Target	Format
Yes	Shenzhen Aivd Biotechnology Co., LTD.	SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)	2834	Other	Antigen	Manual

SGS

Certificate CN21/42787

The management system of

Shenzhen AIVD Biotech Inc.

C501, Building B5, Guangming Science and Technology Park, China Merchants Bureau, Guanguang Road, Fenghuang Community, Fenghuang Street, Guangming District, Shenzhen, Guangdong Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 23 December 2021 until 22 December 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 1. Certified since 23 December 2021

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421 M2

SGS

Certificate CN20/31063.00

The management system of

SHENZHEN AIVD BIOTECH INC.

Business Registration Address: C501, B5 Building, China Merchants Guangming Science Park, Guanguang Road, Fenghuang Community, Fenghuang Street, Guangming District, Shenzhen City, Guangdong Province, P.R. China
Business Operation Address: Room 211 and 01-22 of 101, C3 Building, 1983 Creative Town, No. 15, Nanxin Road, Nanlingcun Community, Nanwan Street, Longgang District, Shenzhen City, Guangdong Province, P.R. China

Unified Social Credit Code 91440300094245489W

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 6 December 2021 until 5 July 2023
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 1. Certified since 6 July 2020

Multiple certificates have been issued for this scope
The main certificate is numbered CN20/31063.00

This is a multi-site certification.
Additional site details are listed on the subsequent pages

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001 2015 0118 M3