INTRODUCTION

SARS-COV-2 Antigen Rapid Test Device
For Professional Use

Product

The SARS-COV-2 Antigen Rapid Test Device (Nasal/Throat/Anterior Nasal swab) is a rapid visual immunoassay for the qualitative, presumptive detection of COVID-19 antigens from nasal or throat specimens within the first 7 days of symptomonset.

Features

- **Specimen: Nasal / Throat / Anterior Nasal swab**
- **Fast test: 15 mins to read results**
- **Simple operation**
- **Convenient storage: 2-30°C**
- **Sensitivity: 99.09%, Specificity: 100%**
- **Efficiently detect Delta(B.1.617.2) and Omicron(B.1.1529)**

Kit Components

Individually Packed Test Devices	20 Tests	5 Tests	1 Test
Extraction solution	20 bottles	5 bottles	1 bottle
Extraction tubes	20 pcs	5 pcs	1 pc
Stirilie swabs	20 pcs	5 pcs	1 pc
Work Station	1 pcs	——	——
Package Insert	1 pc	1 pc	1 pcs

Package: Cassette,1T/Box,5T/Box,20T/Box
Validity:24 months

Technical Specification

Product name	SARS-COV-2 Antigen Rapid Test Device	**Automation**	None,Manual
Catalog number	RCD-802	**Reader Required**	None,visually read
Device type	In vitro diagnostic medical device	**Kit Components**	Test device,Sampling swab,Extraction tube,Work Station,Instruction for use
Indended Use	For the qualitative, presumptive detection of SARS-CoV-2 nucleocapsid (N) antigen in human nasal swab specimens	**Time to Result**	10-15 minutes
Test Priciple	Rapid visual immunoassay	**Shelf life**	24 months
Qualitative/Quanlitative	Qualitative	**Package Size**	1 test/kit,5 tests/kit,20 tests/kit
Specimen	Nasal Swab	**Storage**	2-30 ℃,Do not freeze

Order Information

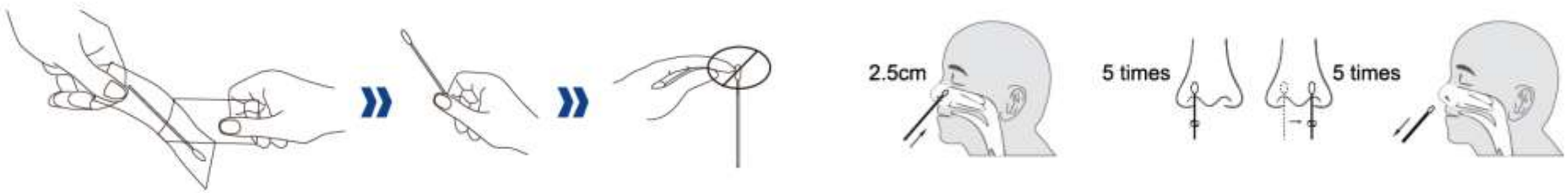
Cat No.	Picture	Description	Package size	Packing information
RCD-802		SARS-COV-2 Antigen Rapid Test Device Each kit contains 20 sets of test device,sampling swab,extraction tube and IFU	20tests/bag box folded and beside	1200 tests/Carton (59.5*49.5*33.5cm,G.W:17.1kgs)
RCD-802		SARS-COV-2 Antigen Rapid Test Device Each kit contains 20 sets of test device,sampling swab,extraction tube and IFU	20 tests/kit	1040 tests/Carton (59.5*49.5*33.5cm,G.W:13.5kgs)

TYPE A


CE
ENCODE
SARS-COV-2 Antigen
Rapid Test Device
• Immunochromatographic Assay (Colloidal gold)
• For in vitro Diagnostic Use Only
20T
SARS-COV-2 Antigen Rapid Test Device
CE
One Test
ENCODE

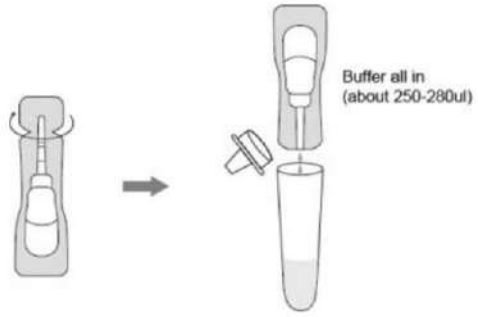
Test Procedure

Specimen collection

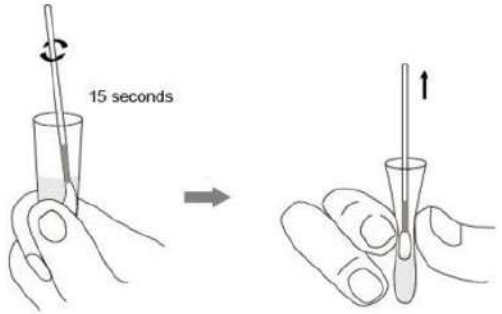


Operation procedure

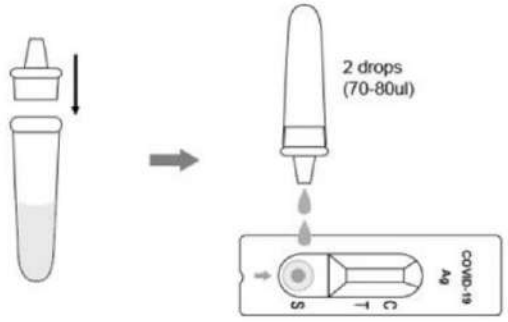
① Unscrew the lip of Extraction solution and add all the extraction solution (approx. 250-280ul) into the Extraction tube.



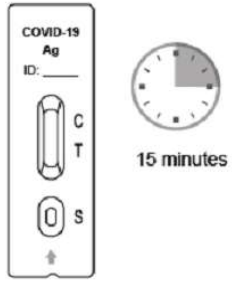
② Put the swab into extraction tube.Press the tip against the inner edge of the extraction tube with force,while rotating the swab for 15 seconds.Try to release as much liquids possible



③ Take out the test device from the sealed pouch and lay it on a clean,level surfuce,put on the tube tip,add 2 drops of extracred sample



④ Read the result at 15 minutes

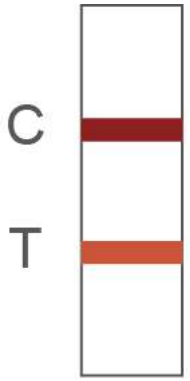


Test Procedure

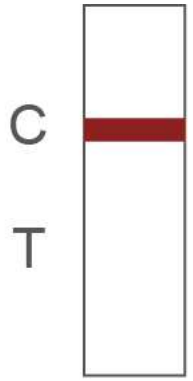
Interpretation of results

The result should be read at 15 minutes.Do not interpret the result after 30 minutes

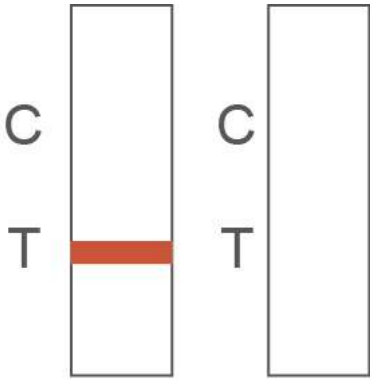
15 mins



Positive



Negative



Invalid

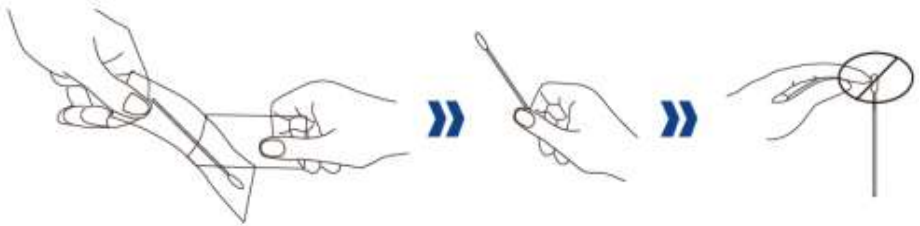
Precautions

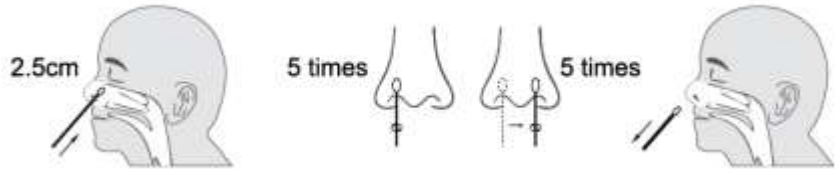
It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with novel Coronavirus.

TYPE B (Prefilled buffer Extraction tube)

Test Procedure

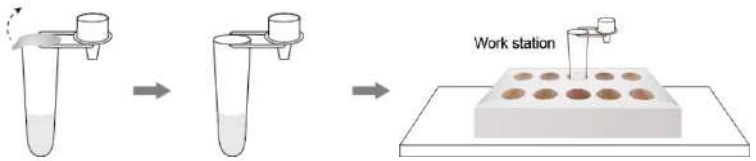
Specimen collection



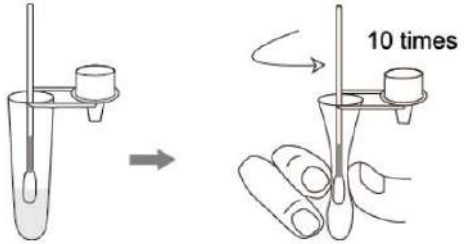


Operation procedure

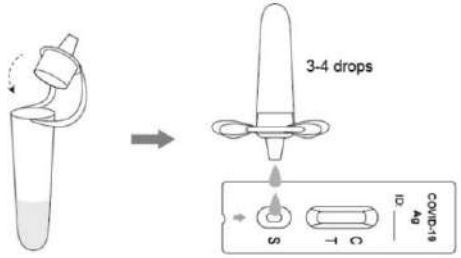
① Ripped the membrane of extraction tube,place and soak the swab into the tube.



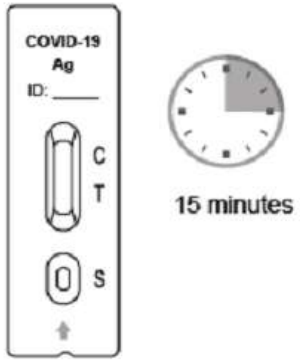
② Pick up the extraction rube and put the swab into extraction tube.Press the tip against the inner edge of the extraction tube with force,while rotating the swab for 15 seconds,Try to release as much liquids possible



③ Take out the test device from the sealed pouch and lay it on a clean,level surfuce,put on the tube tip,add 3-4 drops of extracred sample



④ Read the result at 15 minutes



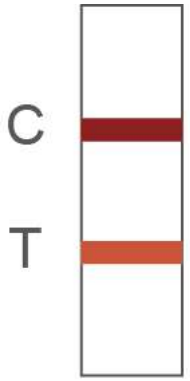
15 minutes

Test Procedure

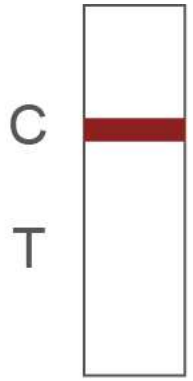
Interpretation of results

The result should be read at 15 minutes.Do not interpret the result after 30 minutes

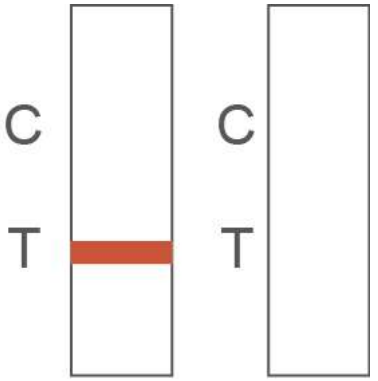
15 mins



Positive



Negative



Invalid

Precautions

It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with novel Coronavirus.

Certification-CE Declaration of Conformity

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/04092020.2

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Zhuhai Encode Medical Engineering Co., Ltd.
No.020,Honghui 2nd RD Hongqi Industrial Zone,Jinwan District,Zhuhai, P.R China (519090)

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.
From 26 May 2022, manufacturer must fully comply with the IVDR in order to be placed their products in the European market.

The products in Annex I was registered in Spanish MOH with number **RPS/2079/2020**

CE

Issued on: 08/04/2021 Valid until: 07/04/2023

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

The SARS-COV-2 Antigen Rapid Test Device

CE

www.cmcmedicaldevices.com

CE EC Declaration of Conformity CE

Manufacturer:	Zhuhai Encode Medical Engineering Co., Ltd. Add:No.020,Honghui 2nd RD Hongqi Industrial Zone,Jinwan District,Zhuhai,P.R China(519090)
Whose Single Authorized EU-Representative:	CMC Medical Devices& Drugs S.L. Add:C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Name:	SARS-COV-2 Antigen Rapid Test

Classification : **Others of ANNEX II of IVDD**
Conformity Assessment Route: **Annex III**

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

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

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

Signature:
Name: Sun Yifeng
Title: General manager
Place/Date: Zhuhai.2020-09-01

EC Declaration of Conformity
Page 1/1

No.YK-DoC-02,A/0

Certification-EU Common List

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests;
A common standardised set of data to be included in COVID-19 test result certificates; and
A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Common list of COVID-19 rapid antigen tests (Annex I)

Agreed by the Health Security Committee on 17 February 2021.

A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021; A sixth update was agreed by the HSC on 20 October 2021.

Common standardised data set to be included in COVID-19 test result certificates (Annex II)

Agreed by the Health Security Committee on 17 February 2021.

An update to Annex II was agreed by the HSC on 19 March 2021

Common list of COVID-19 laboratory based antigenic assays (Annex III)

Agreed by the Health Security Committee on 20 October 2021

Manufacturer	RAT commercial name	Device ID # [1]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
Zhuhai Encode Medical Engineering Co.,Ltd	ENCODE SARS-COV-2 Antigen Rapid Test Device	1902	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%	Throat swab/Nasal Swab: Sensitivity 96.49%, Specificity 100% Anterior Swab: Sensitivity 94.74%, Specificity: 100%	DE[2]		DE[2] UK	Nucleo-capsid protein	20 October 2021
Zhuhai Lituo Biotechnology Co., Ltd.	COVID-19 Antigen Detection Kit (Colloidal Gold)	1957	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut: Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.12% sensitivity Nasal swab (CT≤33); 99.59% sensitivity NP swab; 100% specificity Nasal swab (CT≤33)	CZ, DE[3], SI		DE[3]	Nucleo-protein	14 July 2021

https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

Certification-Germany Bfarm(PEI)

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

Paul-Ehrlich-Institut

28.09.2021

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

Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen, Germany

www.pei.de

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

Paul-Ehrlich-Institut

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

Testname	Hersteller
Tebsun 2019-nCoV Antigen Test Kit	Ltd.
ENCODE SARS-COV-2 Antigen Rapid Test Device	Zhuhai Encode Medical Engineering Co., Ltd.

Certification-UK DHSC 3A Validation

GOV.UK Topics Government activity

→ Coronavirus (COVID-19) | Latest updates and guidance

Home > Coronavirus (COVID-19) > Testing for coronavirus (COVID-19) > Assessment and procurement of coronavirus (COVID-19) tests

Department of Health & Social Care

UK Health Security Agency

Guidance

Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices)

Updated 20 January 2022

Background

Since its establishment in August 2020, the joint UK Health Security Agency (UKHSA) Porton Down and University of Oxford SARS-CoV-2 lateral flow antigen test validation cell has evaluated over 160 lateral flow devices that have been referred by the Department of Health and Social Care.

Approximately 30% of the tests that were referred for validation met the standards for phase 2 validation, which are set out in the protocol for evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens.

UKHSA Porton Down subsequently performed phase 3 testing to assess whether the lateral flow devices that passed phase 2 displayed performance characteristics desirable for mass population, community-based testing.

The desirable performance characteristics are:

- very high specificity
- very high sensitivity against viral loads associated with infectiousness

The lateral flow devices that display the desirable performance characteristics are summarised in table 1 below.

Table 1: summary of lateral flow devices that have passed phase 3a validation

Lateral flow device	Status	Date evaluation completed
Zhuhai ENCODE - SARS-COV-2 Antigen Rapid Test Device	Pass	29 September 2021

https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices

Certification-Singapore HSA&Pilippine FDA

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

14 December 2020

[redacted]

Dear Professor Lawrence Chan,

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation (MDPA2020-162) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	V-CODE ENCODE SARS-COV-2 Antigen Rapid Test Device (20 tests)	The SARS-COV-2 Antigen Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of COVID-19 antigens from throat swabs and nasal swab specimens. It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with novel Coronavirus. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of COVID-19 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Product Owner: [redacted]

Manufacturing Site(s): Zhuhai Encode Medical Engineering Co., Ltd
No. 20, Honghui 2nd Road, Hongqi Industrial Zone,
Jinwan District, Zhuhai,
China

[redacted]

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR LAKSHMIDEVI BALAKRISHNAN
REGULATORY CONSULTANT
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

FDA

CERTIFICATION

To Whom This May Concern:

This is to certify that the **V-CODE ENCODE SARS-COV-2 Antigen Rapid Test Device** manufactured by Zhuhai Encode Medical Engineering Co., Ltd – No. 20, Honghui 2nd Road, Hongqi Industrial Zone, Jinwan District, Zhuhai, China has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has a Provisional Authorization from Health Sciences Authority (HSA) of Singapore. With this approval, the company is required to indicate in the product label or in the accompanying product insert the following statement:

"This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required"

This certification is issued upon the request of K[redacted]SC, with business address at Suite 1017 Cityland Herrera Towe[redacted]

This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

Done this 4th February 2021 at Alabang, Muntinlupa City.

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health, and Research

Not valid without FDA Seal

OR No. : 0127212321 35
Amount : PhP 510.00
Date : 27 January 2021
SC-COVID19-2021-031
DTN: 20210126105236

FDA-0475262

Certification-France MOH

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ
Liberté
Égalité
Fraternité

PLATEFORME COVID-19

Se connecter

VISUALISATION TESTS COVID-19

- Accueil
- Tests
- Outil criblage
- Projets
- Veille
- Eaux usées
- Ressources
- Surveillance épidémiologique

DaPRI

Mentions légales CGU
olitique de confidentialité
RGAA

Nombre de tests

2/591

Les Tests antigéniques sur prélèvement nasal sont réservés aux mineurs de moins de 12 ans symptomatiques ou identifiées comme personnes contacts, en deuxième intention, lorsque le prélèvement nasopharyngé est rendu difficile ou impossible.

Cliquez pour accéder à la liste commune européenne TAG

Signalement

JE SIGNALE

Contextes juridiques — Cliquez pour déplier et télécharger les fichiers des contextes juridiques

Statut: ☐ CE ☐ CNR ☐ UE ☐ HAS | Type de test: ---- | Sous-type de test: ---- | Cibles: -- | Type prélèvement: ---- | Rechercher: Zhuhai Encode

Tableau de bord des tests — Cliquez pour déplier et visualiser les graphes du tableau de bord

2 tests affichés

Options

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLÈVEMENT
SARS-CoV-2 IgG/IgM rapid test	ZHUHAI ENCODE MEDICAL ENGINEERING	MEDISUR	✓		✓	Sérologie rapide (dont TDR et TROD)	IgG, IgM, IgG protéine N	Sang total
The SARS-COV-2 Antigen Rapid Test Device	Zhuhai Encode Medical Engineering Co., Ltd.		✓			Antigénique non automatisé (dont TROD)	N	Nasopharyngé

Certification-Brunei MOH&Bulgaria MOH

Ministry of Health
Brunei Darussalam

COVID-19 RAPID TESTS KITS (ART)
AUTHORISED FOR USED IN BRUNEI DARUSSALAM.

The listed Covid-19 antigen rapid test kits that are recommended and authorized for use are based on the evaluation done by Ministry of Health, Brunei Darussalam. The results of the evaluations are determined according to the clinical and analytical performance of the test kits (sensitivity and specificity claimed by the manufacturers), safety standards, quality and efficacy of the test kits.

Ministry of Health, through the Department of Laboratory Services will continue to update the list of authorized Covid-19 rapid test kits in order to ensure the supplied antigen rapid tests kits are meeting the required standards.

This list is updated as at **30 December 2021**.

NO	PRODUCT NAME	MANUFACTURER	DETECTION	SAMPLE TYPE
41	Norman Novel Coronavirus Antigen Testing Kit	Nanjing Norman Biological Technology Co., Ltd., China	Antigen	Nasal / Saliva
42	Lysun COVID-19 Antigen Rapid Test Device	Hangzhou Lysun Biotechnology Co., Ltd., China	Antigen	Nasal
43	INVBIO Coronavirus (SARS-CoV-2) Antigen Rapid Test Cassette	Innovation Biotech (Beijing) Co., Ltd., China	Antigen	Nasal
44	AndLucky® COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co., Ltd., China	Antigen	Nasal / Nasopharyngeal / Oropharyngeal
45	eDiagnosis COVID-19 (SARS-CoV-2) Antigen Test Kit	Wuhan EasyDiagnosis Biomedicine Co., Ltd., China	Antigen	Nasal / Nasopharyngeal / Oropharyngeal
46	ENCODE SARS-COV-2 Antigen Rapid Test Device	Zhuhai Encode Medical Engineering Co., Ltd., China	Antigen	Nasal / Oropharyngeal
47	Multi G COVID-19 Check-Sal Antigen Rapid Test	Multi-G bvba, Belgium	Antigen	Saliva

REPUBLIC OF BULGARIA
Ministry of Health
Minister of Health

ORDER

X

Pursuant to Art. 61, para. 2, Art. 63, para. 4, 5 and 11 and Art. 63c of the Health Act, Art. 73 of the Code of Administrative Procedure, and in conjunction with Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a Framework for the Issuance, Verification and Adoption of Interoperable Vaccination Certificates against a examination for and recovery from COVID-19 (EU Digital COVID Certificate), in order to facilitate free movement during the pandemic of COVID-19, and Decision No. 826 of the Council of Ministers of November 25, 2021 for the extension of the term of the emergency epidemic situation announced by Decision no. 325 of the Council of Ministers of 14 May 2020, extended by Decision No. 378 of the Council of Ministers of 12 June 2020, Decision No. 418 of the Council of Ministers of 25 June 2020, Decision No. 482 of the Council of Ministers of 15 July 2020, Decision No. 525 of the Council of Ministers of 30 July 2020, Decision No. 609 of the Council of Ministers of 23 August 2020, Decision No. 673 of the Council of Ministers of 25 September 2020, Decision No. 855 of the Council of Ministers of 25 November 2020, Decision No. 72 of the Council of Ministers of 26 January 2021, Decision No. 395 of the Council of Ministers of 28 April 2021, Decision No. 426 of the Council of Ministers of 26 May 2021, Decision No. 547 of the Council of Ministers of 28 July 2021 and Decision No. 629 of the Council of Ministers of 26 August 2021, and a proposal by the Chief State Health Inspector.

[illegible]	Ltd
Rapid SARS-CoV-2 Antigen Test Card	Xiamen Boson Biotech Co. Ltd
SARS-CoV-2 Antigen Rapid Test	Xiamen Wiz Biotech Co., Ltd
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Xiamen Wiz Biotech Co., Ltd
AndLucky COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co.., Ltd
reOpenTest COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co.., Ltd
Pantest Coronavirus Ag (Nasopharyngeal Swab)	Pantest SA
Novel Coronavirus (COVID-19) Antigen Detection Kit (Swab)	Zhejiang GENE SCIENCE Co., Ltd
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co., Ltd
ENCODE SARS-COV-2 Antigen Rapid Test Device	Zhuhai Encode Medical Engineering Co.,Ltd
COVID-19 Antigen Detection Kit (Colloidal Gold)	Zhuhai Lituo Biotechnology Co., Ltd.

"

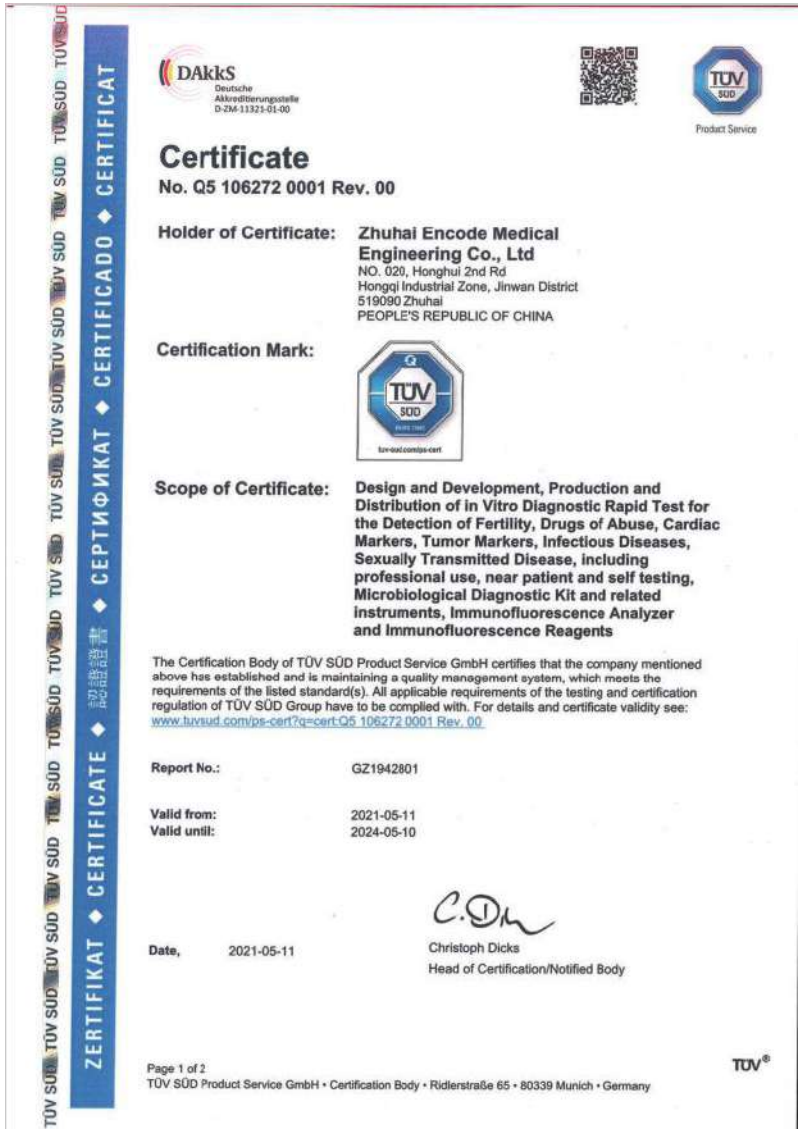
4. Annex No. 4 to item I, 11 is amended as follows:

„Annex No. 4 to item I, 11

List of countries whose COVID-19 vaccination, testing and recovery certificates are considered equivalent to the EU digital COVID certificate

Republic of Northern Macedonia, Republic of San Marino, Swiss Confederation, Turkish Republic, Ukraine, Vatican City State (only for vaccination certificates issued),

Company Qualifications



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

TÜV SÜD Product Service

Certificate

No. Q5 106272 0001 Rev. 00

Holder of Certificate: Zhuhai Encode Medical Engineering Co., Ltd
NO. 020, Honghui 2nd Rd
Hongqi Industrial Zone, Jinwan District
519090 Zhuhai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of in Vitro Diagnostic Rapid Test for the Detection of Fertility, Drugs of Abuse, Cardiac Markers, Tumor Markers, Infectious Diseases, Sexually Transmitted Disease, including professional use, near patient and self testing, Microbiological Diagnostic Kit and related instruments, Immunofluorescence Analyzer and Immunofluorescence Reagents

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 106272 0001 Rev. 00

Report No.: GZ1942801

Valid from: 2021-05-11
Valid until: 2024-05-10

Date, 2021-05-11

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

Business license

营 业 执 照

统一社会信用代码：91440400789435684P

名　　称　珠海市银科医学工程股份有限公司

商事主体类型　股份有限公司（未上市）

住　　所　珠海市金湾区红旗工业区虹晖二路020号

法定代表人　孙宜峰

成立日期　2006年05月31日

重要提示

1.经营范围：商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，在依法取得许可审批后方可从事该经营活动。
2.年度报告：商事主体应当在每年的成立周年之日起两个月内提交上一年度的年度报告。
3.信息查询：商事主体经营范围、出资情况、营业期限、许可审批项目等有关事项和其他监管信息，请登录珠海市商事主体登记许可及信用信息公示平台（网址：http://sxgs.zhuhai.gov.cn）或扫描执照上的二维码查询。

登记机关　珠海市工商行政管理局

2016年7月13日

中华人民共和国国家工商行政管理总局监制

医疗器械生产许可证

Manufacture license

许可证编号：粤食药监械生产许 20010311 号

企业名称：珠海市银科医学工程股份有限公司　生产地址：珠海市金湾区红旗工业区虹晖二路 020 号

法定代表人：孙宜峰　生产范围：见医疗器械生产产品登记表

企业负责人：孙宜峰

住　　所：珠海市金湾区红旗工业区虹晖二路 020 号　发证部门：广东省药品监督管理局

有效期限：至 2025 年 04 月 14 日　发证日期：2020 年 04 月 15 日

国家食品药品监督管理总局制

Company Production

Brand

Encode Medical has a good brand awareness and user recognition in China's IVD industry.

Basic hardware

Encode Medical has a modern production base of 15000 square meters. 3000 square meters cleaning workshop and automatic production equipment.

Team of talent

It has an efficient, knowledgeable and stable staff team from R&D, production, quality control, marketing and service.

R & D capabilities

Encode Medical has been recognized as: Guangdong Province Pathogenic Microorganism Diagnostic Engineering Technology Research Center, Zhuhai Municipal Key Enterprise Technology Center, Guangdong Province Infectious Disease Diagnostic Reagent Industry Technology Innovation Alliance Unit.

Quality system

The company strictly implements in-vitro diagnostic regulations in China and has passed ISO13485 and CE quality system certification.

Business resources

Sales channels in the domestic market cover all provinces and cities; overseas markets have opened business markets in Europe, Southeast Asia, the Middle East, Africa and South America. It has more than 3,000 channel distributors and is providing services to more than 50,000 clinical end users.

Medical Production Base

15,000 square meters industrial park

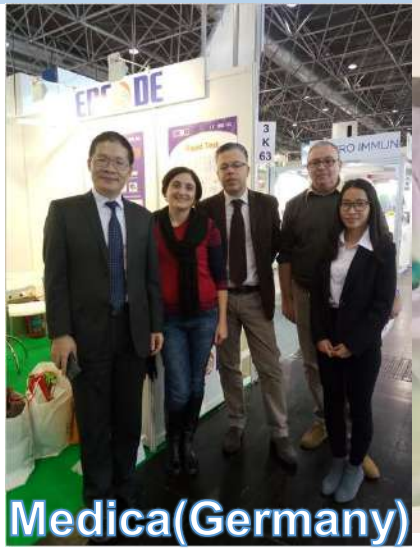
GMP standard purification workshop

Automated production line

A corner of the standard laboratory

- Established in1994，27 years manufacturer of in-vitro diagnostic products
- Set up Hongkong IVD Industrial Company at 2013
- 3000m^2 GMP standard clean workshop
- More than 300 employees，production capacity >500,000 Tests/day
- SFDA,GDFDA,CE, ISO13485 certified
- Main products:Immunology diagnostic rapid tests Microbiological diagnostic products

International Fair

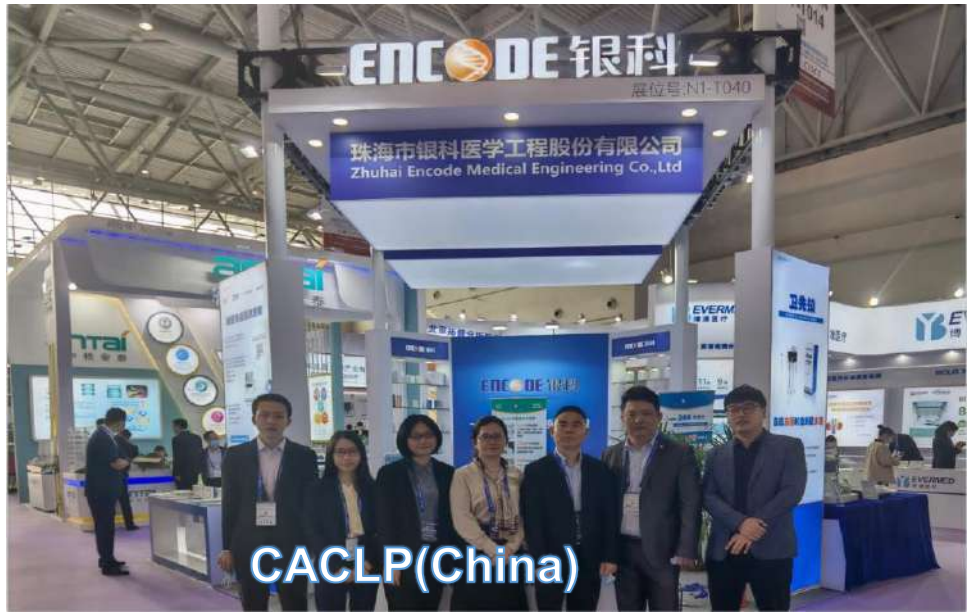

Medica(Germany)

Medlab(Dubai)

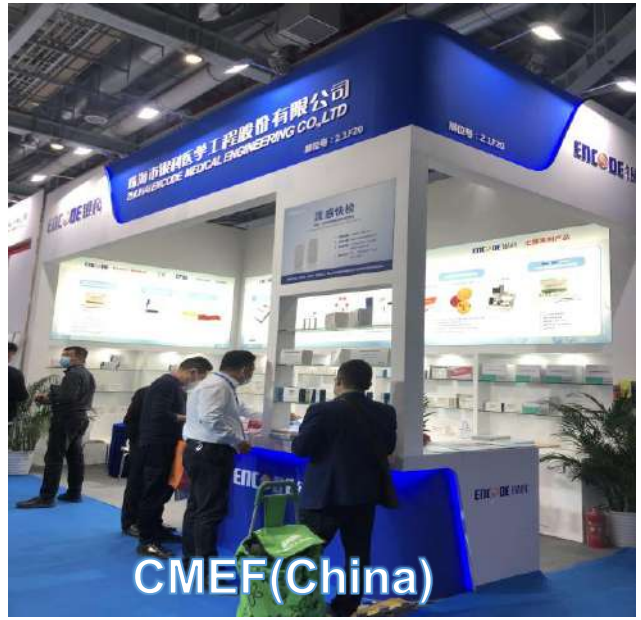
Medical Fair (Singapore)

Medical Fair (Thailand)


EkspoNED Fair (Turkey)



CACLP(China)



CMEF(China)

THANKS

A supplier of in vitro diagnostic products with great development potential