TESTSEALABS®
Rapid Test Kit

www.testsealabs.ie

Email: info@testsealabs.ie

Cellife COVID-19 Antigen Test(ARTG 375418)

Cellife Covid-19 Antigen Test Cassette for self-testing (pdf,784Kb) Nasal swab	Australia Health Products Central Pty Ltd	Hangzhou Testsea Biotechnology Co Ltd	375418	Very high sensitivity	12 January 2022

TESTSEALABS.IE

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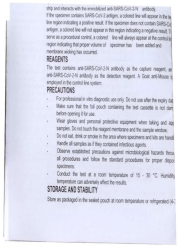
Cellife COVID-19 Antigen Test(ARTG 375418)

- **Sample type**: anterior nasal swab, noninvasive and painless sampling;
- **Easy to operate**, suitable for family and individual self test of COVID-19;
- **Self-test**, continuous self-monitoring of health status,early detection, early isolation, early treatment
- **High sensitivity,** form the first line of defense of COVID-19 screening, reduce the pressure of medical institutions
- **Suitable for multiple scenarios**: medical institution testing; screening before resumption of work and school,continuous monitoring, etc.
- **All necessary reagent provided & No equipment required;**
- **Time saving procedures**, results are available in 15 minutes;
- **Storage temperature**: 4~30 ℃ . No cold-chain
- **transportation needed**; Specification: 5 tests/box, 1 test/box;



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Email: info@testsealabs.ie

Cellife

Package Insert

COVID-19 Antigen Test Cassette

Version 3 Effective date: 11/2021

【INTENDED USE】

The COVID-19 Antigen Test Cassette is a rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal swabs. It is used to aid in the diagnosis of SARS-CoV-2 infection that may lead to COVID-19 disease.

The test is suitable for people with symptoms. Minors must be tested with the assistance of an adult.

The test is single use only and intended for self-testing, it is recommended to use this test within 7 days of symptom onset.

【PRINCIPLE】

The COVID-19 Antigen Test Cassette is a qualitative immunoassay based on a membrane for the detection of SARS-CoV-2 Nucleocapsid (N) antigen in nasal swabs. In this assay, an anti- SARS-CoV-2-N antibody is immobilised in the test zone of the membrane. After a sample is placed in the sample well, it reacts with anti-SARS-CoV-2-N antibody coated particles that are on the sample pad. This mixture migrates chromatographically along the length of the test membrane and interacts with the immobilised anti-SARS-CoV-2-N antibody

If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line region, indicating a positive result. If the sample does not contain SARS-CoV-2 antigen, no coloured line appears in this area, indicating a negative result. As a procedural control, a coloured line always appears in the control line region, indicating that the correct sample volume has been added and the membrane has been wetted through.

【REACTION SYSTEM】

The test contains an anti-SARS-CoV-2-N antibody as capture reagent and another anti-SARS-CoV-2-N antibody as detection reagent. A goat anti- mouse antibody is used in the control line system

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30 ℃). The test is stable to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【REAGENTS AND MATERIALS PROVIDED】

Pack size:

1 Test/box	1 Test device、1 Extraction tube with Extraction buffer、1 Nasal swab、1 Package insert
2 Tests/box	2 Test device、2 Extraction tubes with 2 Extraction buffer、2 Nasal swab、2 Package insert
5 Tests/box	5 Test device、5 Extraction tubes with 5 Extraction buffer、5 Nasal swab、1 Package insert
15 Tests/box	15 Test device、15 Extraction tubes with 15 Extraction buffer、15 Nasal swab、15 Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

Timer

【PRECAUTIONS】

1 Do not use after the expiry date.

2 Read the Package insert carefully before use and use only the ingredients included in this test cassette

3 Make sure that the foil pouch containing the test cassette is not damaged before opening it for use. The test cassette should be used within 30 minutes after opening the foil pouch.

4 Do not eat, drink or smoke in the area where the samples and kits are handled.

5 Carry out the test at a room temperature of 15 - 30 °C.

6 Humidity and temperature can influence the results.

【QUALITY CONTROL】

Internal quality controls are included in the test. The colour line appearing in the control area (C) is an internal positive procedure control which confirms adequate specimen volume and correct procedure technique.

【LIMITATIONS】

1 Each test can only be used once

2 Interpretation of any result after 20 minutes may result in wrong test results

3 Children aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age

4 A positive result cannot determine whether you are infectious

5 Positive results do not rule out bacterial infection or co-infection with other viruses.

6 If the result is positive, one must still confirm the results immediately by a laboratory PCR test.

7 False negative results are more likely to occur if the test is performed after 5 days of symptom onset

8 False negative results are more likely to occur in the later phase of infection and in asymptomatic individuals

9 A negative result does not rule out infection with another type of respiratory virus

10 Negative results does not predude SARS-CoV-2 infection and the person not being infectious. If symptoms persist , please confirmed via a laboratory PCR-test.

11 Even if the result is negative, you still need to observed all protective and hygienic measures

12 The test cannot differentiate between SARS-CoV-1 and SARS-CoV-2 Virus

13 Repeat testing is recommend（between 24-48 hours after your first test）if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement

【VARIANTS DETECTABLE BY THIS TEST】

The test has been tested and proven to detect multiple Variants of COVID-19, including Alpha, beta, Gamma, Kappa, Mu, and most importantly, the Delta Variant. It should be noted that the manufacturer's R&D team is constantly working to ensure that these tests can detect any new variants that become known.

【CROSS-REACTIVITY】

The COVID-19 Antigen Test Cassette has been tested for other Strain and virus (Table below). The results showed no cross-reactivity.

Candida albicans	Influenza A H3N2
Staphylococcus epidermidis	Influenza B
Corynebacterium	Human Rhinovirus 12
Streptococcus pneumoniae	Human Rhinovirus 14
Escherichia coli	Human Rhinovirus 16
Streptococcus pygenes	Measles
Moraxella catarrhalis	Mumps
Streptococcus salivarius	Parainfluenza virus 2
Neisseria lactamica	Parainfluenza virus 3
Streptococcus sp group F	Respiratory syncytial virus
Nesseria subflava	Human coronavirus 229E
Pseudomonas aeruginosa	MERS
Arcanobacterium	Human coronavirus OC 43
Influenza A H1N1	Human coronavirus NL 63

please note that the concentration levels are not listed above, however , if one would like obtain this information, please contact Cellife Health Care Pty Ltd email or phone（detail can be at the bottom of the document）

【INTERFERING SUBSTANCES】

The following compounds have been tested using the COVID-19 Antigen Test Cassette and no interference was observed with Whole Blood、Mucin、Mupirocin、Oxymetazoline、Dexamethasone、Flunisolide、Budesonide Nasal Spray、Phenylephrine、Rebetol、Relenza

【LIMIT OF DETECTION】

The limit of detection for COVID-19 Antigen Test Cassette was determined to be 50 TCID50/ml using inactivated SARS-CoV-2 Virus

【PERFORMANCE CHARACTERISTICS】

The clinical performance of the COVID-19 Antigen Test Cassette for patient self-testing was evaluated using nasal swab samples collected from 100 study participants in multiple prospective studies.

The clinical evaluations were performed by the manufacturers and

Independent laboratory. A PCR Test was collected from all 100 participants by a professional using a nasopharyngeal swab

after completing their self-test, the participant include children（age 10-17）, adults (18-84) and elders（age over 85）

And the Clinical performance was evaluated using samples that were professional tested, This included 375 partioparts in one study whereby all samples were taken using a nasal swab and second nasopharyngeal swab for PCR testing

Clinical performance with nasal swab

Self-test Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	34	35	97%	/
Negative	64	65	/	98%
95% confidence interval			84.1%-99.9%	91.0%-99.9%
Professional Clinical Result				
	Antigen	PCR	sensitivity	specificity
Positive	118	125	94.4%	/
Negative	249	250	/	99.6%
95% confidence interval			88.7%-99.5%	97.5%-99.9%

If there are poor performance or usability issues, please contact the TGA to report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

【SUPPORT SERVICES】

Information regarding available support sevices can al obtained by contacting your local state and territory l department at:

Australian Capital Territory Department of Health
02 62077244 https://www.health.act.gov.au/
New South Wales Department of Health
137788 https://www.health.nsw.gov.au/
Northern Territory Department of health
1800020080 https://www.health.nt.gov.au/
Queensland Department of health
134268 https://www.health.qld.gov.au/
South Australian Department of Health
1800253787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health
1800671738 https://www.health.tas.gov.au/
Victorian Department of Health
1800675388 https://www.dhhs.vic.gov.au/
Western Australian Department of Health
1800595206 https://www.healthywa.wa.gov.au/

Manufacturer:
HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD.
3rd Floor, Building 6,No.8-2 Keji Road,Yuhang District,Hangzhou,China，311100
WEB:www.testsealabs.com

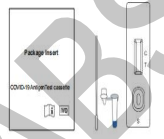
Australian Authorised Representative：
Cellife Health Care Pty Ltd
ABN 64616730888
POBOX 1090, Burwood North
NSW 2134 Australia
info@cellifehealthcare.com.au

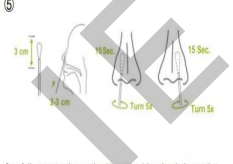
For support and user assistance，Contact us on：
+1800235543
The service is available between 9 am and 7 pm (AE 9am and
8pm (AEDT),7 days a week

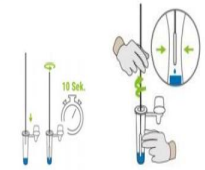
https://cellifehealthcare.com.au/shop/covid-19-antigen-cassette/cellife-covid-19-antigen-test-cassette-pack-of- or Scan QR Code

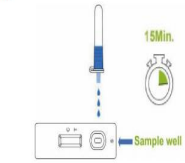
Cellife

Quick guide









INTERPRETATION OF TEST RESULT

Positive

Two colored line appear.One colored line appears in the control region (C) and one colored line appears in the test region (T).

NOTE： The test is considered positive as soon as even a faint line appears. A positive result means that SARS-CoV-2 antigens were detected in your sample.

A positive test result indicates that antigens from SARS-CoV-2 were detected，and you are likely to be infected and presumed to be contagious. you may be to follow the relevant State or Territory health authority advice

Negative

one colored line appear in the control region (C). No apparent colored line appear in the test region (T).

Negative results should be treated as presumptive only and may not mean you are not infectious.if you are experiencing COVID symptoms, you must seek immediate further laboratory PCR testing

Invalid

No colored line appears in the control region (C). The test is invalid even if there is one line in the test region (T).

Invalid result indicate that your test has experienced an error and is unable to interpret the result of test. insufficient sample volume or incorrect handling are the most likely reasons for this，**recommend to repeat test with a New test kit**. you will need to get a laboratory PCR-test if symptoms persist, you should self-isolate at home and avoid contact with others prior to the re-test

IVD	Medical in vitro diagnosis		Expiry date		Do not reuse
	Manufacturer		Date of manufacture	EC REP	Authorised Representative in the European Community
LOT	Batch code		Storage temperature Limits (4-30°C)	REF	Catalogue number
	Follow the Package insert		Tests per set		Indicates that you should keep the product dry

Manufacturer:
HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD.
3rd Floor, Building 6,No.8-2 Keji Road,
Yuhang District,Hangzhou,China，311100
WEB:www.testsealabs.com

For support and user assistance
Contact us on： 1800235543
The service is available between
9 am and 7 pm (AEST)or 9am and
8pm (AEDT),7 days a week

Australian Authorised Representative：
Cellife Health Care Pty Ltd
ABN 64616730888
POBOX 1090, Burwood North
NSW 2134 Australia

TESTSEALABS IE

TESTSEALABS®
Rapid Test Kit

www.testsealabs.ie

Email: info@testsealabs.ie

Specification Package

1 Tests/box
300pcs/CTN
CTNSize:57*37.5*34.5cm
N.W/G.W:7.5/8.5KG

5 Tests/box
600pcs/CTN
CTN Size:59.5*42.5*37.5cm
N.W/G.W:9.5/10.5KG

TESTSEALABS.IE

TESTSEALABS®

Rapid Test Kit

www.testsealabs.ie

Email: info@testsealabs.ie

统一社会信用代码

91330110MA27W8H87B (1/1)

营业执照

(副本)

名　称	杭州泰熙生物技术有限公司	注册资本	捌仟万元整
类　型	有限责任公司（自然人投资或控股的法人独资）	成立日期	2015 年 11 月 12 日
法定代表人	何鲁江	营业期限	2015 年 11 月 12 日 至 长期
经营范围	食品安全检测试剂、农兽药残留检测试剂、体外诊断检测试剂、生物原料、生物制品生产、研发、销售；批发、零售：光学分析仪器，化学试剂（除化学危险品及易制毒化学品），化工产品及原料（除化学危险品及易制毒化学品），医疗器械：第一、二、三类 6840 体外诊断试剂，机电设备；技术开发、技术咨询、技术服务、技术成果转让；生物科技，检测技术，非治疗性生物原料（抗原、抗体）；计算机软件；货物和技术进出口（法律、法规禁止经营的项目除外，法律、法规限制经营的项目取得许可后方可经营）。（依法须经批准的项目，经相关部门批准后方可开展经营活动）	住　所	浙江省杭州市余杭区瓶窑镇观山路 13-2 号 1 幢二层

登记机关

2021 年 08 月 11 日

国家企业信用信息公示系统网址 http://www.gsxt.gov.cn

市场主体应当于每年 1 月 1 日至 6 月 30 日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制

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

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

TÜV SÜD Product Service

Certificate

No. Q5 104467 0001 Rev. 00

Holder of Certificate: **Hangzhou Testsea Biotechnology Co., Ltd.**
3rd Floor, Building 6 north, No. 8-2 Keji Avenue
Yuhang District
311121 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Hangzhou Testsea Biotechnology Co., Ltd.
3rd Floor, Building 6 north, No. 8-2 Keji Avenue, Yuhang District,
311121 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Kits for Fertility, Drug of abuse and Infectious Diseases**

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

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). See also notes overleaf.

Report No.: SH19155901

Valid from: 2020-02-21
Valid until: 2023-02-20

Date, 2020-02-21

Christoph Dicks
Head of Certification/Notified Body

TÜV®

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

TESTSEALABS.IE

Our Registration ONLY PART

FSC

CE CERTIFICATE -DOC

CE CERTIFICATE -CIBG REGIS

Russia Register

DUBAI

UK – MHRA

Mexico

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE

证书编号: 浙杭食药监
Certificate NO.: 浙

产品名称: 新型冠状病
(共 1 页)
Product(s): SARS-CoV2
,etc. See Attachment (

规格型号: 见附件(共 N
Model: See Attachment

产品注册或备案凭证号:
Registration certifica

生产企业: 杭州泰熙生物
Manufacturer: HangZhou

生产企业住所: 浙江省杭
Address of manufacture
and Technology Avenue,

生产许可或备案凭证号:
Manufacturing License(

兹证明上述产品未在中国
This is to certify t
China and not distribu
product(s) is not rest

证明有效日期至: 2022年
This certification val

备注: /
Remark: /

> Retouradres Postbus 16114 2500 BC Den

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 28 september 2020
Betreft: aanmelding In-vitro diag

Geachte heer Wei,

Op 25 september 2020 ontving i
het Nederlandse Besluit in-vitro
HANGZHOU TESTSEA BIOTECH
Lotus NL B.V. onderstaand pro
markt te brengen.

Het product staat geregistreerd

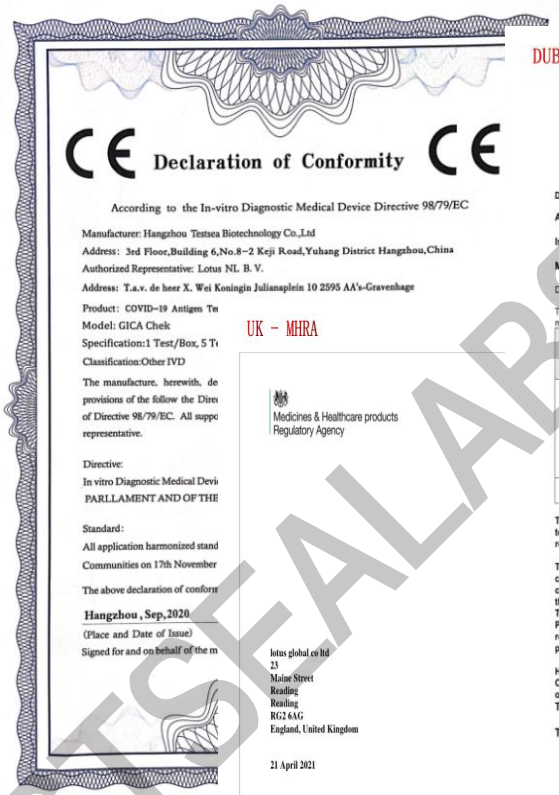
COVID-19 Antigen Test Cass
(geen merknaam) (NL

Hiermee heeft u voldaan aan uw

In alle verdere correspondentie
dit nummer te vermelden. A
ontleend worden, het dient
vergemakkelijken.

De registratie van in-vitro diag
Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische
hulpmiddelen voor in-vitro diagnostiek is gedeeltelijk aan mogelijke revisies van
Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan
voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van
Richtlijn 98/79/EG).

Pagi


CE Declaration of Conformity CE

According to the In-vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer: Hangzhou Testsea Biotechnology Co.,Ltd
Address: 3rd Floor,Building 6,No.8-2 Keji Road,Yuhang District Hangzhou,China
Authorized Representative: Lotus NL B. V.
Address: T.a.v. de heer X. Wei Koningin Julianaplein 10 2595 AA's-Gravenhage
Product: COVID-19 Antigen Te
Model: GICA Chek
Specification:1 Test/Box, 5 T
Classification:Other IVD

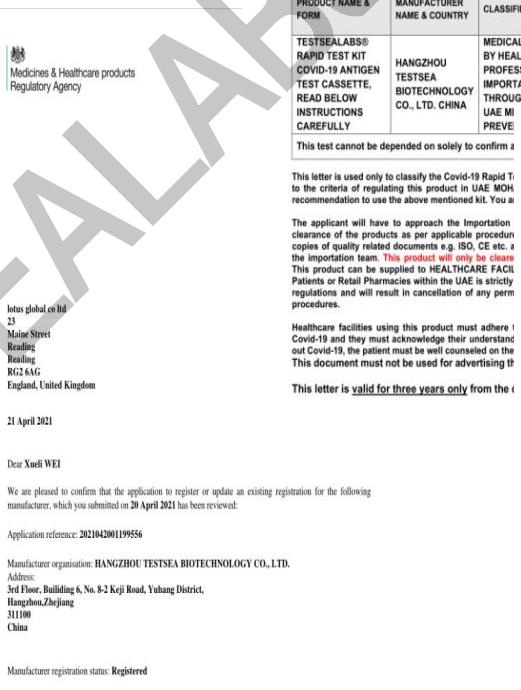
The manufacture, herewith, de
provisions of the follow the Direc
of Directive 98/79/EC. All suppo
representative.

Directive:
In vitro Diagnostic Medical Devi
PARLLAMENT AND OF THE

Standard:
All application harmonized stand
Communities on 17th November

The above declaration of conform

Hangzhou , Sep,2020
(Place and Date of Issue)
Signed for and on behalf of the m


Medicines & Healthcare products Regulatory Agency

lotus global co ltd
23
Maine Street
Reading
Reading
RG2 6AG
England, United Kingdom

21 April 2021

Dear Xueli WEI

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 20 April 2021 has been reviewed:

Application reference: 2021042001199556

Manufacturer organisation: HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD.
Address:
3rd Floor, Building 6, No. 8-2 Keji Road, Yuhang District,
Hangzhou,Zhejiang
311100
China

Manufacturer registration status: Registered

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

DRUG DEPARTMENT

Application No: DRCLAS-2021-003437

Issue Date: 12/07/2021, Expiry Date: 11/07/2024

M/S.: MODERN PHARMACEUTICAL COMPANY, ABUDHABI

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 30/21 Dated 08/07/2021 has Classified your mentioned below

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS	MAXIMUM PRI CHARGED BY HOSPITAL FO THIS DEVICE
TESTSEALABS® RAPID TEST KIT COVID-19 ANTIGEN TEST CASSETTE, READ BELOW INSTRUCTIONS CAREFULLY	HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD. CHINA	MEDICAL DEVICE FOR USE BY HEALTHCARE PROFESSIONALS ONLY IMPORTATION RESTRICTED THROUGH CLEARANCE FROM UAE MI PREVE	50 DHS FOR WHOLE SERV INCLUDING S COLLECTION

This test cannot be depended on solely to confirm a

This letter is used only to classify the Covid-19 Rapid T to the criteria of regulating this product in UAE MOH recommendation to use the above mentioned kit. You a

The applicant will have to approach the Importation clearance of the products as per applicable procedur copies of quality related documents e.g. ISO, CE etc. a the importation team. This product will only be cleare This product can be supplied to HEALTHCARE FACIL Patients or Retail Pharmacies within the UAE is strictly regulations and will result in cancellation of any perm procedures.

Healthcare facilities using this product must adhere Covid-19 and they must acknowledge their understand out Covid-19, the patient must be well counseled on th This document must not be used for advertising th

This letter is valid for three years only from the

SALUD

COMISION FEDERAL PARA LA PROTECCION CONTRA RIESGOS SANITARIOS
COMISIÓN DE AUTORIZACIÓN SANITARIA

Oklahoma Núm. 14, Nápoles, Alcaldía Benito Juárez, Ciudad de México, C.P. 03810

Permiso Sanitario de Importación de Insumos	Fecha Expedición: 28 de julio de 2020
Número de autorización: 0402600201202040060040691	Vigencia: Desde: 28/07/2020 Hasta: 24/01/2021

Con fundamento en el Artículo 39 fracciones III y XV de la Ley Orgánica de la Administración Pública Federal, en los Artículos 194 y 283 de la Ley General de Salud, Artículo 14 del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios y sin interferir con las disposiciones de otras Dependencias Oficiales, se autoriza la Importación.

IMPORTADOR EVALUACION AMBIENTAL Y SANITARIA SA DE CV EAS170727MFA	RAZON SOCIAL: EVALUACION AMBIENTAL Y SANITARIA SA. DE C.V. DOMICILIO DE ESTABLECIMIENTO: Cerrada Tlapexco 12, Ocotepec, Cuernavaca, Cuernavaca, MORELOS MEXICO, CP 62220
DOMICILIO FISCAL: TLAPEXCO, 12, OCOTEPEC, CUERNAVACA, MORELOS, MEXICO (ESTADOS UNIDOS MEXICANOS) CP 62220	REGIMEN: Definitivos / ADUANA: AEROPUERTO INT. DE LA CD DE MEXICO
Fabricante(s):	Hangzhou Testsea Biotechnology Co., Ltd., Keji Road, B-2, 3rd Floor, Building 6, Yuhang District, Hangzhou, Yuhang District, CHINA (REPUBLICA POPULAR), CP 31122
Destinatario(s):	EVALUACION AMBIENTAL Y SANITARIA S.A. DE C.V., Cerrada Tlapexco, 12, OCOTEPEC, CUERNAVACA, CUERNAVACA, MORELOS, MEXICO (ESTADOS UNIDOS MEXICANOS), CP 62220
Proveedor(s):	Hangzhou Testsea Biotechnology Co., Ltd., Keji Road, B-2, 3rd Floor, Building 6, Hangzhou, Yuhang District, CHINA (REPUBLICA POPULAR), CP 31122
Facturador(s):	Hangzhou Testsea Biotechnology Co., Ltd., Keji Road, B-2, 3rd Floor, Building 6, Hangzhou, Yuhang District, CHINA (REPUBLICA POPULAR), CP 31122

Producto Terminado o Materia Prima a Importar.

NOMBRE	ORIGEN	PROCEDENCIA	CANTIDAD	UNIDAD	PRESENTACIÓN	FRACCIÓN	REG. SAN.	CANT/UMT
COVID-19 IGG/IGM TEST CASSETTE (TESTSEALABS) Prueba rápida para SarS-CoV-2 (Covid-19) IgG / IgM (sangre completa, suero o plasma)	CHN	CHN	5000000	Pieza	TIC19-0	30021019	CAS/DEAP/ 0963/2020 0	50000 / Kilogramo

Destinados para: VENTA

2020
LEONA VICARIO

TESTSEALABS - IE

Clinical report

UCK Uniwersyteckie Centrum Kliniczne

CENTRALNE LABORATORIUM KLINICZNE
UNIWERSYTECKIE CENTRUM KLINICZNE
80-214 Gdańsk, ul. Mariana Smoluchowskiego 17
tel. +48 58 584 43 80
REGON 000288640, NIP 957 07 30 409

Evaluation Report for
Testsealabs SARS-CoV-2 Antigen Test Cassette
by
HANGZHOU TESTSEA BIOTECHNOLOGY Co.,LTD

was conducted using the SARS-CoV-2 Antigen Test Cassette
say Healthcare S.L.U. kit (PCR). Compare with RT-PCR:

: 95%, the Relative Specificity is 100%, the Overall
st results meet the recommended performance standards
Health Organization. [1]

wed that there is a high coincidence rate between the
sette and referencing r

1. Purpose

To access the specificity and sensitivity of the SARS-CoV-2 Antigen Test Kit, manufactured by **HangZhou Testsea Biotechnology Co., Ltd,** by comparison with one selected CE-approved Vitassay Healthcare S.L.U. SARS-CoV-2 Test Kit (Real-time PCR), aiming to verify the effectiveness of the **SARS-CoV-2 Antigen Test Cassette** for the detection of SARS-CoV-2 Antigen.

Statistic	Value	95% CI
Sensitivity	100.00%	47.82% to 100.00%
Specificity	100.00%	98.56% to 100.00%
Accuracy (*)	100.00%	98.59% to 100.00%

The 95% Confidence Intervals of sensitivity, specificity, and total accuracy are calculated following the binomial distribution.

Analysis results by Kappa consistency test shows that the Kappa value = 1. As Kappa≥0.75, it suggests good consistency between the candidate kit and the reference kit.

8. Conclusion

In the present study, the Testsealabs SARS-CoV-2 Antigen Test Cassette-anterior nasal swabs by HANGZHOU TESTSEA BIOTECHNOLOGY Co.,LTD has shown high sensitivity, specificity, and total accuracyon anterior nasal 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 only 20 to 25 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 Testsealabs SARS-CoV-2 Antigen Test Cassette-anterior nasal swab has shown satisfying sensitivity, specificity, and total accuracy in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19 cases.

Signatures

Operator: mgr Janusz Partyka DIAGNOSTA LABORATORYJNY Date: 28.09.2021

Reviewer: dr Paweł Chrzan DIAGNOSTA LABORATORYJNY Date: 28.09.2021

Uniwersyteckie Centrum Kliniczne
80-952 Gdańsk, ul. Dębinki 7
tel. 58 349 20 00
fax 58 346 11 78
Regon: 000288640
NIP: 957-07-30-409
info@uck.gda.pl
www.uck.gda.pl

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