Cellex

# Catálogo de
# Cellex qSRAS-CoV-2 IgG/IgM Rapid Test

Viralab S.A.
Contribuyendo con la calidad de su Laboratorio
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# CELLEX qSRAS-CoV-2 IgG/IgM Rapid Test


## 25 PRUEBAS/KIT

Cada kit incluye:

- 25 cassettes de prueba
- 1 botella de diluyente de muestra
- 25 Pipetas de transferencia
- Folleto de las instrucciones de uso

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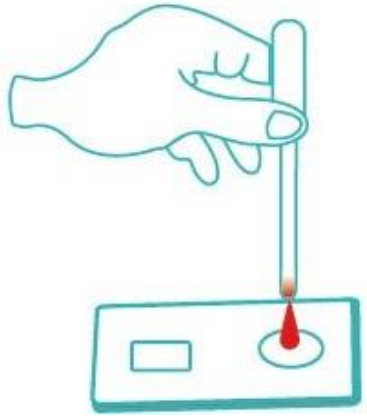
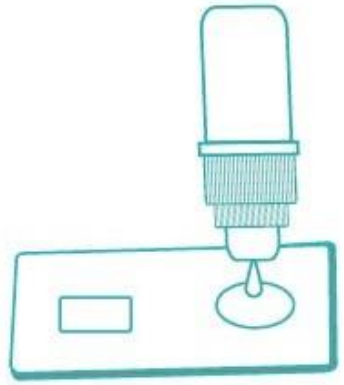
# PROCEDIMIENTO DE PRUEBA

## 3 SENCILLOS PASOS



**PASO 1: Agregue 10 µL de muestra (que puede ser suero, plasma o sangre completa)**



**PASO 2: Agregue 2 gotas de diluyente de muestra**


**PASO 3: Lea los resultados en 15-20 minutos**

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# RENDIMIENTO CLINICO

Se recolectaron un total de 378 muestras para esta prueba de evaluación clínica, de las cuales 128 confirmaron muestras positivas del hospital improvisado COVID-19 y 250 muestras negativas recolectadas antes de septiembre de 2019.

| Prueba clínica | | qSARS-CoV-2 IgG/IgM Rapid Test | | | | |
|---|---|---|---|---|---|---|
| | | IgG+ IgM+ | IgG IgM+ | IgG+ IgM- | IgG IgM- | Sub |
| Estatus Clinico | Pos. | 65 | 46 | 9 | 8 | 128 |
| | Neg. | 0 | 5 | 4 | 241 | 250 |
| Subtotal | | 65 | 51 | 13 | 249 | 378 |

- Tasa de coincidencia positiva = **93.75%** (95% CI: 88.06-97.26%)
- Tasa de coincidencia negativa = **96.40%** (95% CI: 92.26-97.78%)
- Tasa total de coincidencia = **95.50%**

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# RENDIMIENTO ANALITICO

| | |
|---|---|
| Prueba de rendimiento analítico | Cellex qSARS-CoV-2 Rapid Test |
| Tipos de muestra | Suero / Plasma / Sangre entera |
| Volumen de la muestra | 10µL |
| Estabilidad de reactivos | Hasta 30 meses a 2-30 ℃ |
| Tiempo para resultados | 15 minutos |
| Sensibilidad analítica: límite de detección | 1:60,000 |
| Precisión intra-lote | Referencias positivas y negativas probadas repetidamente por más de 10 pruebas, la tasa de concordancia es del 100% |
| Precisión entre lotes | Referencias positivas y negativas probadas repetidamente por más de 10 pruebas, la tasa de concordancia es del 100% |
| Efecto Hook | Los títulos de anticuerpos de hasta 1: 60,000 pueden no tener un efecto hook |



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# 03 CERTIFICACIONES

## ISO 13485

CERTIFICATE

No. Q5 18 02 03200 001

Holder of Certificate: Cellex, Inc.
76 TW Alexander Dr
Research Triangle Park
Durham NC 27709-0002
USA

Facility(ies): Cellex, Inc.
76 TW Alexander Dr, Research Triangle Park, Durham NC 27709-0002, USA

CELLEX BIOTECH (Suzhou) Co., Ltd.
1F, North Black, 16 Building, 8 Jinfeng Road, Suzhou New District, 215011 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostic Test Kit based on Lateral Flow Chromatographic Immunoassay and In Vitro Diagnostic Test Kit and Analyzer based on Immunofluorescence Assay, Homogeneous Biochemiluminescence Assay(HBA)

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.: SH17125501
Valid from: 2018-06-26
Valid until: 2021-06-25

Date, 2018-06-26
Stefan Preiß

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

## CE

EC-Registration Certificate

Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices (IVDD), Article 10
No. R A000 03/C Rev. 01

MedPath

Manufacturer: Cellex, Inc.
76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

Date, 2020-03-25
MedPath GmbH

MedPath GmbH • Miles. van. der. Rohe. Straße 8 • 80807 Munich • Germany

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## Certificado de Exportación de Productos Médicos

## FDA (EUA)

U.S. FOOD & DRUG ADMINISTRATION

**Acknowledgment Letter**

3/24/2020

[redacted] President and Principle Consultant
[redacted]
UNITED STATES

Dear [redacted]:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA[redacted]
Received: 3/23/2020
Applicant: Cellex Inc.
Device: qSARS-CoV-2 IgG/IgM Rapid Test

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：苏苏食药监械出 20200098
Certificate NO.：SSSYJXC20200098

产品名称：见附页
Product(s): see attachment

规格型号：见附页
Model: see attachment

生产企业：赛莱克斯生物科技（苏州）有限公司
Manufacturer: CELLEX BIOTECH (SUZHOU) CO., LTD.

生产企业住所：中国江苏省苏州市高新区锦峰路 8 号 16 号楼北一楼
Address of manufacturer: 1F, North Black, 16 Building, 8 Jinfeng Road, Suzhou New District, Jiangsu, P.R. China, 215011

医疗器械出口备案凭证号：见附页
Exportation Registration certificate(s): see attachment

兹证明上述产品已准许在中国生产和出口。
This is to certify that the above products have been registered to be manufactured and exported in China.

证明有效日期至：2022 年 3 月 22 日
This certification valid until:2022-3-22

备注：/
Remark: /

2020 年 3 月 23 日
江苏省食品药品监督管理局

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