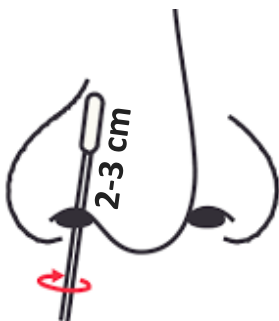


DESCRIERE și DOCUMENTAȚIE

Denumire Produs: FlowFlex (Self-Test)
Producator: ACON Biotech Hangzhou
EC REP: MedNet EC-REP GmbH



RAPID. EXACT. UȘOR DE UTILIZAT. DE ÎNCREDERE. MARCAJ CE PREZENT.



Lateral Nazal
2-3 cm



Mai ușor de utilizat
la elevi și studenți



Potrivit în activități ce
necesită monitorizare
continuă a infecției.



Produs Avizat
ANMDMR

Acesta este un dispozitiv medical de diagnosticare in vitro a antigenului SARS-COV-2 dintr-un specimen prelevat lateral (anterior) nazal (profundime de min. 2,5 cm.)

PERFORMANȚE CLINICE

Specificitate: 99,50%

Sensibilitate: 97,10%

Acuratete: 98,80%

Specimen prelevat: Anterior Nazal (2,5 cm)

Timp de testare: Rezultat afișat în 15 min.

Valabilitate: 24 luni

Depozitare: 2-30°C

- Aprobat pentru autotestare în anumite zone din Comunitatea Europeană
- Aprobat de Comisia Europeană
- Listat în BFARM (Germania)
- Depistează inclusiv tulpinele Delta și Omicron
- Avizat A.N.M.D.M.R.

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R. China, 310030

We declare under our sole responsibility that the
in vitro diagnostic device:

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

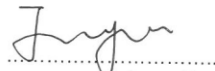
classified as self-testing according to the Annex II of the directive 98/79/EC,
meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it.

This declaration is according to Annex III.6 of the Directive and thus is
based on approval by the notified body
TÜV SÜD Product Service GmbH, Ridlerstraße 65
80339 MÜNCHEN, Germany, notified under
No. 0123 to the EC Commission.

Authorized Representative:
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

This declaration is valid until expiration of EC certificate
No. V9 042074 0032 Rev.00
Expiration Date: 2024-05-26

Signed this 17 day of May, 2021
in Hangzhou, China


Junny You
International Regulatory Affairs Senior Director
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-245.10.07
www.zlg.de



Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 042074 0032 Rev. 00

Manufacturer: Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product: In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has
been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the
devices conforms to the requirements of this Directive. 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:V9_042074_0032_Rev_00

Report No.: SH2110605

Valid from: 2021-05-14
Valid until: 2024-05-26

Date, 2021-05-14



Christoph Dicks
Head of Certification/Notified Body

Page 1 of 3
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH - Certification Body - Ridlerstraße 65 - 80339 Munich - Germany

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EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 042074 0032 Rev. 00

Model(s): SARS-CoV-2 Antigen Rapid Test (Self-Testing)
Facility(ies): Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

Model name: Model number:

Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11855
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118L5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118T5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118U5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118V5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118N5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118W5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Y5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Z5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R5

SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3E

Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11857
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R7

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EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 042074 0032 Rev. 00

SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3J

SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3D

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Nov 28, 2021,

To Whom It May Concern:

Thank you for your interest in the Flowflex SARS-CoV-2 Antigen Rapid Test.

We, ACON Biotech (Hangzhou) Co., Ltd. as the manufacturer of Flowflex SARS-CoV-2 Antigen Rapid Test, hereby declare that ACON are monitoring the emergence of a new strain of SARS-CoV-2 which has become prevalent in the UK, South Africa, Brazil/Japan, India, USA, Philippines, Peru, Colombia and other communities. SARS-CoV-2 of Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Theta (P.3), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), Mu(B.1.621), Delta plus (AY.4.2), Omicron(B.1.1.529) have several mutations in the spike protein and a few mutations in the nucleocapsid protein.

There is no obvious difference observed when testing with different nucleocapsid protein recombination antigens (Alpha, Beta, Gamma, Delta, Epsilon, Zeta, Eta, Theta, Iota, Kappa, Lambda, Mu and Delta plus) basing on these different variants of SARS-CoV-2. For Omicron, by theoretical analysis of the mutations in the nucleocapsid protein, it should not interfere the detection of Flowflex SARS-CoV-2 Antigen Rapid Test. So we do not anticipate that these variants will have any effect on test performance.

Sincerely,

ACON Biotech (Hangzhou) Co., Ltd.



Product Registration File

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

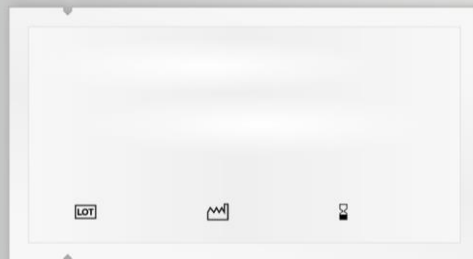
CONFIDENTIAL



ACON BIOTECH (HANGZHOU) CO., LTD.

No.210 Zhenshuhua Road, West Lake District, Hangzhou, P.R. China 310030 Tel: +86 571 8777 5528 Fax: +86 571 8786 2579 • www.aconlab.com

1/25



Pouch



Test Cassette



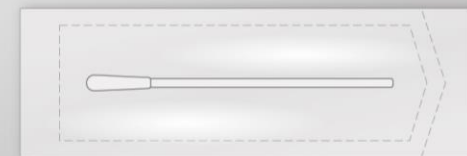
Extraction Buffer Tube



Insert



Waste Bag



Swab



Va multumim!

comenzi@medplaza.ro

www.medplaza.ro

0316.30.66.90