

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test (Self-Test) Product Dossier

Part 1--About VivaChek



Products: BGM & POCT & PCR

Mfg facility location: Hangzhou, China

Number of employees: ~800

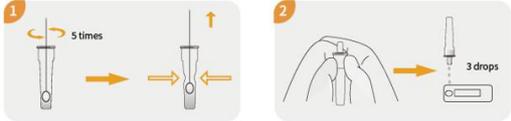
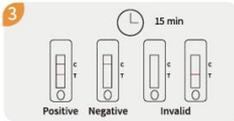
Investors:

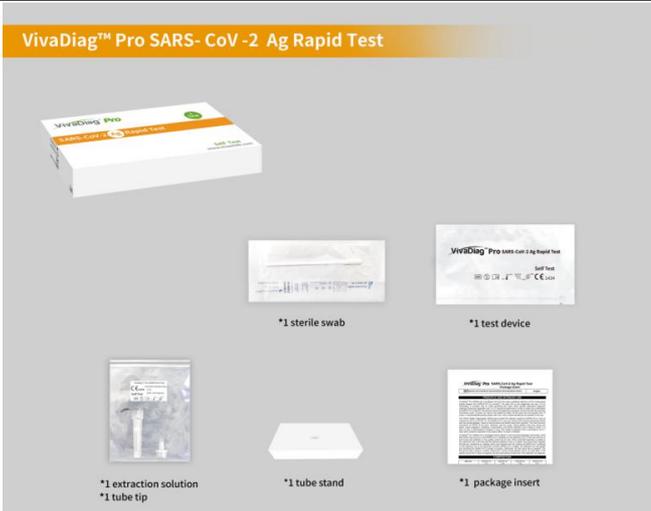
Shenzhen Gaotejia

Oriental International Holdings (China Top 500 company)

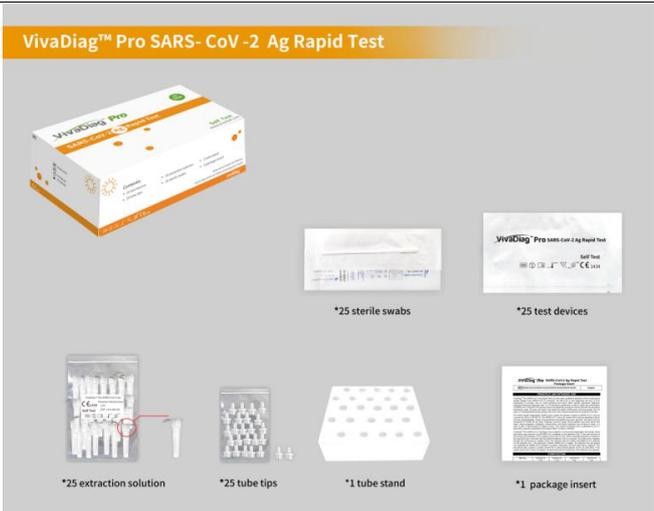
Wuchan Zhongda Group (Global Top 500 company)

Part 2- Product Information

Product Information		
Product Name	VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test (Self-Test)	
Manufacturer	VivaChek Biotech (Hangzhou) Co., Ltd	
Catalog	VCD16-10-011/VCD16-10-013/VCD16-10-014/VCD16-10-015	
Packing	1 test/box, 3 tests/box, 5 tests/box, 25 tests/box	
Test Principle	Immunochromatography	
Sample Type	Anterior nasal swab	
Sample Volume	3 drops	
Test Time	15 min	
Operation Temperature	15-30°C	
Storage Temperature	2-30°C	
Shelf Life (Unopened)	24 months	
Test Procedure		
----Specimen Collection  Anterior nasal swab	----Solution Preparation  1. Prepare the specimen 2. Apply the extracted specimen	----Detection  3. Read the test result
Performance		
Sensitivity	99.13%	

Specificity	>99.99%
Accuracy	99.83%
Cross-Reactivity	There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus
Packing Information	
VCD16-10-013	
Packing	1 test/box
Components	1 test device, 1 extraction solution (in the sealed tube), 1 tube tip, 1 tube stand, 1 sterile swab, 1 package insert
Box Size	115/23/58 mm
Single Box Weight	24 g
Boxes/Carton	500
Carton Size	595/495/330 mm
GW/Carton	13.00 kg
NW/Carton	12.00 kg
Product Picture	 <p>VivaDiag™ Pro SARS- CoV -2 Ag Rapid Test</p> <p>*1 extraction solution *1 tube tip</p> <p>*1 sterile swab</p> <p>*1 test device</p> <p>*1 tube stand</p> <p>*1 package insert</p>
VCD16-10-015	
Packing	3 tests/box
Components	3 test devices, 3 extraction solution (in the sealed tube), 3 tube tips, 1 tube stand, 3 sterile swabs, 1 package insert
Box Size	122/35/68 mm
Single Box Weight	47 g
Boxes/Carton	84
Carton Size	385/265/325 mm
GW/Carton	4.75 kg
NW/Carton	3.95 kg

<p>Product Picture</p>	<p>VivaDiag™ Pro SARS- CoV -2 Ag Rapid Test</p> <p>*3 extraction solution *3 tube tips</p> <p>*3 sterile swabs</p> <p>*1 tube stand</p> <p>*3 test devices</p> <p>*1 package insert</p>
<p>VCD16-10-014</p>	
<p>Packing</p>	<p>5 tests/box</p>
<p>Components</p>	<p>5 test devices, 5 extraction solution (in the sealed tube), 5 tube tips, 1 tube stand, 5 sterile swabs, 1 package insert</p>
<p>Box Size</p>	<p>115/49/58 mm</p>
<p>Single Box Weight</p>	<p>72 g</p>
<p>Boxes/Carton</p>	<p>125</p>
<p>Carton Size</p>	<p>595/265/325 mm</p>
<p>GW/Carton</p>	<p>10.20 kg</p>
<p>NW/Carton</p>	<p>9.00 kg</p>
<p>Product Picture</p>	<p>VivaDiag™ Pro SARS- CoV -2 Ag Rapid Test</p> <p>*5 extraction solution *5 tube tips</p> <p>*5 sterile swabs</p> <p>*1 tube stand</p> <p>*5 test devices</p> <p>*1 package insert</p>
<p>VCD16-10-011</p>	
<p>Packing</p>	<p>25 tests/box</p>
<p>Components</p>	<p>25 test devices, 25 extraction solution (in the sealed tube), 25 tube tips, 1 tube stand, 25 sterile swabs, 1 package insert</p>
<p>Box Size</p>	<p>230/140/80 mm</p>
<p>Single Box Weight</p>	<p>342 g</p>

Boxes/Carton	24
Carton Size	480/440/370 mm
GW/Carton	9.8 kg
NW/Carton	8.21 kg
Product Picture	 <p>The product picture displays the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test kit components. At the top left is the main product box. Below it are several smaller items: a package of 25 sterile swabs, a package of 25 test devices, a package of 25 extraction solutions, a package of 25 tube tips, a white tube stand, and a package insert. Each item is labeled with its quantity: '*25 extraction solution', '*25 tube tips', '*1 tube stand', '*25 sterile swabs', '*25 test devices', and '*1 package insert'.</p>

Part 3- Certificates

1) CE 1434-IVDD-478/2021



CERTIFICATE

EC Certificate No. 1434-IVDD-478/2021

**EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices**

Polish Centre For Testing and Certification certifies
that manufactured by:

**VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang
Economy Development Zone,
Hangzhou, Zhejiang 311100, China**

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the annex I

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.10.2021 to 27.05.2024

The date of issue of the Certificate: 28.10.2021

The date of the first issue of the Certificate: 28.10.2021



Issued under the Contract No. MD-91/2021
Application No: 146/2021
Certificate bears the qualified signature.
Warsaw, 28/10/2021
Module A1

Anna
Małgorzata
Wyroba
Vice-President
Mgr. Anna Wyroba
Elektronicznie
podpisany przez: Anna
Małgorzata Wyroba
Data: 2021.10.28
122942 402007

2) ISO 13485:2016



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

<p>This is to certify that: VivaChek Biotech (Hangzhou) Co., Ltd. Level 2, Block 2 146 East Chaofeng Rd. Yuhang Economy Development Zone Hangzhou Zhejiang 311100 China</p>	<p>杭州微策生物技术有限公司 中国 浙江省 杭州市 余杭区 余杭经济技术开发区 超峰东路146号2幢二楼 邮编: 311100</p>
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Holds Certificate No: **MD 726764**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits (Colloidal Gold).
设计、开发、制造和销售胶体金体外诊断试剂盒。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-24
Latest Revision Date: 2020-07-24

Effective Date: 2020-07-24
Expiry Date: 2023-07-23

Page: 1 of 1



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780
BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A Member of the BSI Group of Companies.

3) CIBG



 **CIBG**
*Ministerie van Volksgezondheid,
Welzijn en Sport*

> Retouradres Postbus 16114 2500 BC Den Haag

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

Datum: 16 november 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 2 november 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam VivaChek Biotech (Hangzhou) Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

Verino® Pro SARS-CoV-2 Ag Rapid Test (self-test)
VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test (self-test)
(geen merknaam) (NL-CA002-2021-63096)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

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

Farmatec
Bezoekadres:
Halteren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
<http://hulpmiddelen.farmatec.nl>

Inflictingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20216583

Bijlagen
-

Uw aanvraag
2 november 2021

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en
het kenmerk van deze brief.*

Pagina 1 van 2

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, VivaChek Biotech (Hangzhou) Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

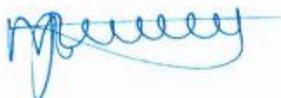
Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

Let op:
de notificatie van uw IVD Klasse other product vervalt per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product.

De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

4) CE-DOC

Declaration of Conformity

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy
Development Zone, Hangzhou, Zhejiang,
311100, P.R.China

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

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test

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 Conformity Assessment Route: Annex
III , section 6, and the Classification/Qualification of medical device is for
self-testing

The declaration is base on the approval by the notified body

Polskie Centrum Badań i Certyfikacji S.A.ul. Puławska 469 02-844 Warszawa
(PCBC) ,notified under No.1434 to the EC commission.
The EC certificate No.is 1434-IVDD-478/2021

European Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, theHague, Netherlands.
+31644168999
peter@lotusnl.com



Date: Oct 28, 2021
Julie zhou
R.A Director

Part 4 – Labeling & brochure

1) Box



2) Sell sheet

VivaDiag™ Pro
SARS-CoV-2 Ag Rapid Test

Enhanced sensitivity

Test Procedure

----Specimen Collection

Anterior nasal swab

1. Prepare the specimen

2. Apply the extracted specimen

3. Read the test result

----Solution Preparation

----Detection

Positive Negative Invalid

Positive Negative Invalid

Note: The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test has ONLY been designed to act as a supplementary test for suspected cases of negative coronavirus nucleic acid detection or in conjunction with nucleic acid detection in the diagnosis of suspected cases. Results from nucleocapsid protein antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 (COVID-19) infection or to inform infection status.

CE 1434

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab specimen. The test is for *in vitro* diagnostic use only.

Specification

Test Principle	Immunochromatography
Sample Type	Anterior nasal swab
Sample Volume	3 drops
Test Time	15 min
Operation Temperature	15-30°C
Storage Temperature	2-30°C
Shelf Life (Unopened)	24 months

Not Available for Sales in the US

FOR SELF-TESTING USE ONLY!

VivaChek
VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, A6 East Chaofeng Rd.,
Hangzhou, 311100, China
www.vivachek.com

Number: 152000201
Effective date: 2021-1-05
© 2021 VivaChek Biotech Hangzhou Co., Ltd.

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

Tel: +86-571-89182700 Fax: +86-571-89182733

Email: info@vivachek.com

www.vivachek.com

Part 5--COA

DN WI20-1014-RE-63
Revision 2

VivaChek Biotech (Hangzhou) Co., Ltd.

Effective Date: 2021-08-30
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VivaChek Biotech (Hangzhou) Co., Ltd.

CERTIFICATE OF ANALYSIS

Product Name: SARS-CoV-2 Ag Rapid Test (self-test)
Lot No.: SE2111196
Expiry Date: 2023-11-22

Inspection Item	Acceptance Criteria		Test Result	
Appearance	1) The test board: no stains, assembled correctly; 2) The extraction solution: no turbidity, no precipitate for the solution, no leakage for the sealed bag and the self-sealed bag is marked; 3) The kit: clean with all components, and the label is clearly marked with correct information.		PASS	
Inspection Item	Reference samples	The test results compare with the color grade		Test Result
		Evaluation criteria of C line	Evaluation criteria of T line	
Positive reference samples	P1	≥ G8	G3-G4	PASS
	P2		G4-G5	PASS
	P3		G5-G6	PASS
	P4		G6-G7	PASS
	P5		G7-G8	PASS
	P6		G8-G9	PASS
	P7		G9-G10	PASS
	P8		≥ G10	PASS
Minimum detection limit reference samples	S1	≥ G8	G5-G6	PASS
	S2		G4-G5	PASS
	S3		G3-G4	PASS
	S4		G3	PASS

DN WI20-1014-RE-63
Revision 2

VivaChek Biotech (Hangzhou) Co., Ltd.

Effective Date: 2021-08-30
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	S5		≤ G3	PASS
	S6		G1-G2	PASS
Repeatability reference samples	R1	≥ G8	G3-G4	PASS
	R2		G5-G6	PASS
Negative reference samples	N1-N20	≥G8	G1-G2	PASS
	N21-N40			PASS
	N41-N60			N/A
Conclusion	PASS			

QC Supervisor:

Signature:

Date:



Part 6 -

VivaChek Biotech (Hangzhou) Co., Ltd
 Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
 311100, Zhejiang, China

TF067-021

Rev: 1.0

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY UNDERTAKING

Product name	VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test
Chemical description/Application	The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test includes test strips and extraction solution that determine whether infected with SARS-CoV-2 based on whether it appears color. For in vitro diagnostic use only.
Supplier	VivaChek Biotech (Hangzhou) Co., Ltd., Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, 311100, Zhejiang, PRC. Phone: 86-571-8918-2700 Fax: 86-571-8918-2733

Issue date: Mar 3, 2021

Version: 1.0

2. HAZARDS IDENTIFICATION

Hazard class and label elements of the product according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:

GHS Hazard class	Non-hazardous substance or mixture.
GHS label elements	Pictogram(s): None Pictogram(s): None
Hazard statements	Not applicable.
Other Hazards	None.
Hazard description	Physical and chemical hazards: Non-flammable, no special combustion and explosion characteristics. Health hazards: None Environmental hazards: None

3. COMPOSITION /INFORMATION ON INGREDIENTS

The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Strip is stored in a sealed aluminum foil bag with desiccant, and the extraction solution is pre-filled in a sealed tube. Each test kit contains the following chemicals.