VivaDiag™ SARS-CoV-2 Ag Test (Colloidal Gold)

POCT Global Marketing Division

Ver 1.0 Aug 26, 2020

Lab Solutions

VivaDiag

About VivaChek

Products: BGM & POCT

Mfg facility location: Hangzhou, China

Number of employees: ~500

Investors:

Shenzhen Gaotejia

Oriental International Holdings (China Top 500 company)

Wuchan Zhongda Group (World Top 500 company)

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VivaChek

VivaChek Milestones

Established
Jun 2013

First patent granted
Jul 2014

ISO13485
CE (GOD)
ISO 15197:2013
May 2015

CE (GDH-FAD)
EN ISO 15197:2015
Apr 2016

VivaChek™ Ino BGM
US FDA 510k cleared
Apr 2017

VivaChek™ Ino Smart
& other 5 BGM
US FDA 510k cleared
Dec 2018

Launch of POCT
immunofluorescence
Mar 2019

Launch of Blood Ketone,
HB and Lipid
Oct 2019

Launch of SARS-CoV-2
IgM/IgG Rapid Test
Mar 2020

Launch of SARS-CoV-2
Ag rapid test & Ag FIA test
Aug 2020

120+ countries
60+ IP

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Management Team & Quality System

- **20+ years** R&D experience in BGM & POCT
- **~25 years** management and QA experience in top IVD companies
- Strict compliance with **ISO 9001, ISO 13485**, and the **US FDA's QSR** (Quality System Regulations)

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

VivaChek Laboratories, Inc.
913 N Market Street, Suite 200
Wilmington, DE 19081
USA

has established and applies a quality management system for medical devices for the following scope:

Design/development, Manufacture and Distribution of Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips and Blood Glucose Control Solutions)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-04-24
Certificate Registration No.: SX 60101068 0001
An audit was performed. Report No.: 15077758 001
This Certificate is valid until: 2018-03-15

Certification Body

Date: 2015-04-24

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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VivaDiag™ SARS-CoV-2 Antigen Test

01

VivaDiag™ SARS-CoV-2 Ag Rapid Test

(Colloidal Gold)

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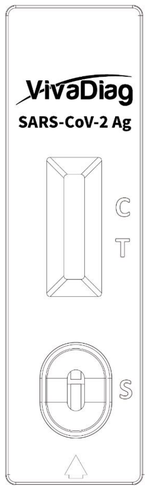
01

VivaDiag™ SARS-CoV-2 Ag Rapid Test
(Colloidal Gold)



Not for at-home testing

For professional use only

VivaDiag™ SARS-CoV-2 Ag Rapid Test is based on immunoassay technology. It is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab or throat swab specimen.

The test is for *in vitro* diagnostic use and professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.

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01

VivaDiag™ SARS-CoV-2 Ag Rapid Test
(Colloidal Gold)

Specification

Test Principle	Colloidal gold
Sample Type	Nasal swab or throat swab
Sample Volume	60 µL
Test Time	15 min
Operation Temperature	15-30℃
Storage Temperature	2-30℃
Shelf Life (Unopened)	24 months

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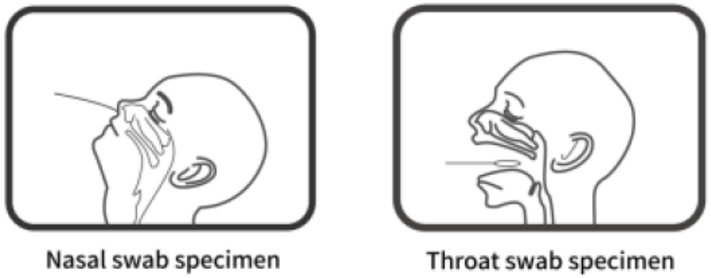
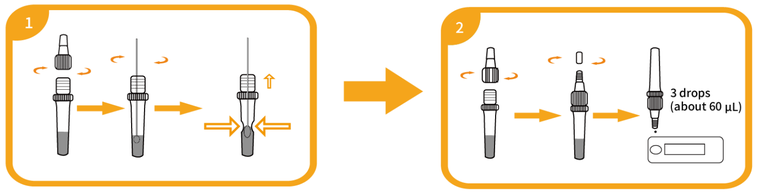
01

VivaDiag™ SARS-CoV-2 Ag Rapid Test
(Colloidal Gold)

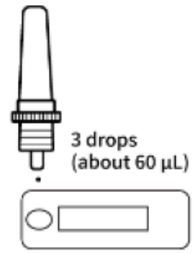
--Operation Steps



Step 1: Collect the specimen



Step 2: Prepare the specimen



Step 3: Dip 3 drops and read results at 15 minutes

Note: When performing the test, take protective measures according to local hygienic requirements, as protective clothing, goggles, gloves, etc.

01

VivaDiag™ SARS-CoV-2 Ag Rapid Test
(Colloidal Gold)

-- Clinical Performance

VivaDiag™ SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	29	0	29
Negative	6	121	127
Total	35	121	156
Sensitivity	82.86% (29/35, 95%CI, 67.21%~94.72%)		
Specificity	100% (121/121, 95%CI, 97.85%~100%)		
Accuracy	96.15% (150/156, 95%CI, 93.85%~98.90%)		

VivaDiag™ SARS-CoV-2 Ag Rapid Test

--Packing Information

- 25 test devices
- 25 swabs
- 25 extraction tubes (prefilled 300 μL extraction solution)
- 1 tube stand
- 1 package insert

Catalog	Tests/box	Contents/box	Boxes/carton	Tests/ Carton	Carton size	Carton volume (CBM)	GW/ carton (Kg)	NW/ carton (Kg)
VCD05-01-01 (Colloidal Gold) VCD044-08-011 (FIA)	25	25 devices, 25 extraction tubes, 25 Swabs, 1 package insert	18	450	475/355/270mm	0.05	7.0	5.0

VivaDiag

Certificates

bsi.

By Royal Charter

Certificate of Registration

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

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

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

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:

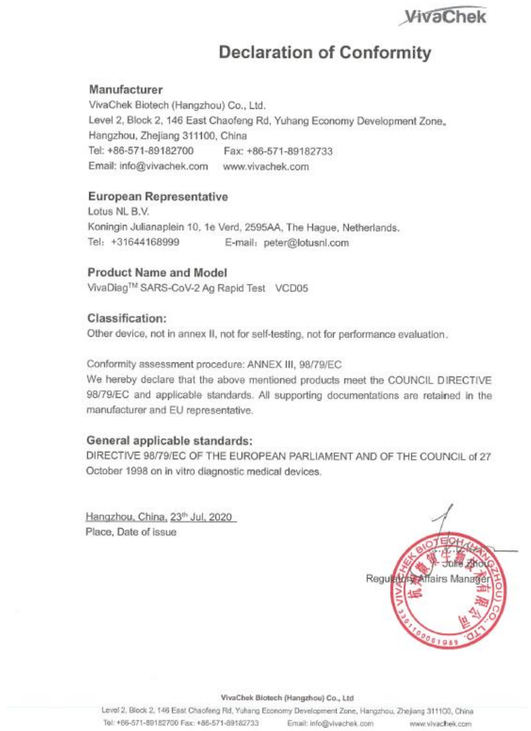
Gary E Slack, Senior Vice President - Medical Devices

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.

ISO 13485:2016



VivaChek

Declaration of Conformity

Manufacturer
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

European Representative
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999 E-mail: peter@lotusnl.com

Product Name and Model
VivaDiag™ SARS-CoV-2 Ag Rapid Test VCD05

Classification:
Other device, not in annex II, not for self-testing, not for performance evaluation.

Conformity assessment procedure: ANNEX III, 98/79/EC
We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable standards. All supporting documentations are retained in the manufacturer and EU representative.

General applicable standards:
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Hangzhou, China, 23th Jul, 2020
Place, Date of issue

Julia Zhou
Regulatory Affairs Manager

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

CE DOC

Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: IVD001124

Mr Petere Wei
Lotus Global Co Ltd
1 Fourseasons Terrace
West Drayton
Middlesex
UB7 9GG

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

23 March 2020

Dear Mr Wei

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- VivaChek Biotech (Hangzhou) Co., Ltd.** located at **Manufacturers Address:- Level 2, Block 2, 146 East Chao Feng Rd, Yu Hang Economy Development Zone Hangzhou, Zhejiang China 311100 for whom you are acting as** the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly considering the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon the declaration submitted on online via the Devices Online Registration System (DORS) and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any of the following changes;

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

You should submit your change of registration via DORS with the required statutory fee, which should be accompanied with the information when it is supplied, (the fee is payable for each record notified, and you may place multiple changes on one record).

UK MHRA

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

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

Inlichtingen bij:
M.P. Meijer - Michiels
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203931

Bijlagen
-

Uw aanvraag
10 augustus 2020

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

Datum: 12 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 10 augustus 2020 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:

In Vitro Diagnostic Test Kits(Colloidal Gold),VivaDiag SARS-CoV-2 Ag Rapid Test VCD05,VivaDiag SARS-CoV-2 Ag FIA Test VID44,VivaDiag POCT Analyzer VIM1000
(geen merknaam) (NL-CA002-2020-52905)

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 artikel 10, eerste lid van Richtlijn 98/79/EG).

Netherlands CIBG

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VivaChek

Attention

The VivaDiag™ SARS-CoV-2 Ag Rapid Test FIA 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 our testings should not be used as the sole basis to diagnose or exclude SARS-CoV-2 (COVID-19) infection or to inform infection status.