Date of issue: Nov 29 2021 Ver 1.0

Verino® 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	Verino® Pro SARS-CoV-2 Ag Rapid Test (Self-Test)
Manufacturer	VivaChek Biotech (Hangzhou) Co., Ltd
Catalog	VCD16-10-041/VCD16-10-043/VCD16-10-044/VCD16-10-045
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℃
Storage Temperature	2-30℃
Shelf Life (Unopened)	24 months
Test Procedure	

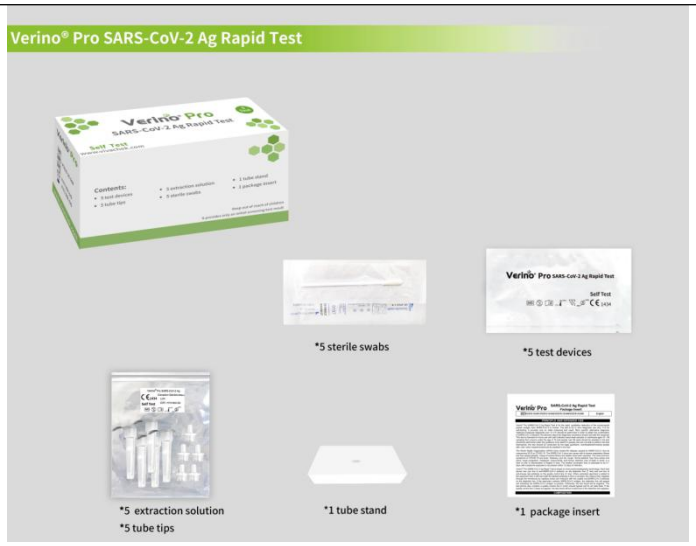
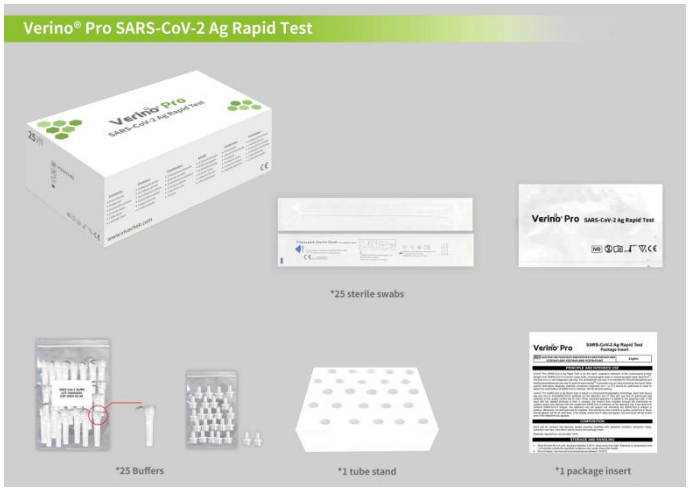
VivaChek Biotech (Hangzhou) Co., Ltd
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
Tel: +86-571-89182700 Fax: +86-571-89182733 Email: info@vivachek.com www.vivachek.com

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	
VCD16-10-043	
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
VCD16-10-045	
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
VCD16-10-044	
Packing	5 tests/box
Components	5 test devices, 5 extraction solution (in the sealed tube), 5 tube tips, 1 tube stand, 5 sterile swabs, 1 package insert
Box Size	115/49/58 mm
Single Box Weight	72 g
Boxes/Carton	125
Carton Size	595/265/325 mm
GW/Carton	10.20 kg
NW/Carton	9.00 kg

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

Product Picture	
VCD16-10-041	
Packing	25 tests/box
Components	25 test devices, 25 extraction solution (in the sealed tube), 25 tube tips, 1 tube stand, 25 sterile swabs, 1 package insert
Box Size	230/140/80 mm
Single Box Weight	342 g
Boxes/Carton	24
Carton Size	480/440/370 mm
GW/Carton	9.8 kg
NW/Carton	8.21 kg
Product Picture	

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 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

CE 1434

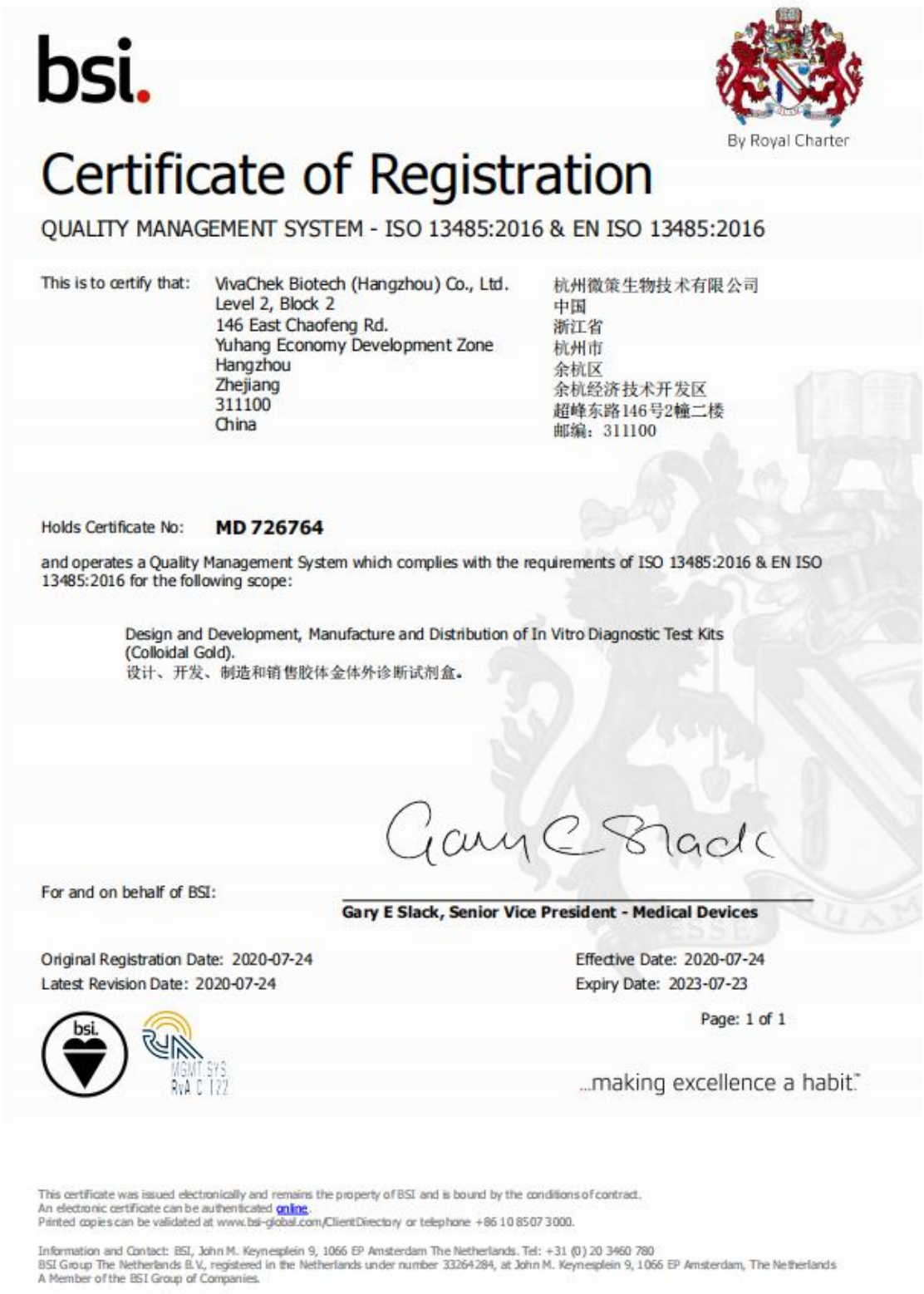
Issued under the Contract No. MD-91/2021
Application No: 146/2021
Certificate bears the qualified signature.
Warsaw, 28/10/2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.28 12:29:42 +02'00'
Vice-President
Mgr. Anna Wyroba

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

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

2) ISO 13485:2016



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.

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.

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

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. 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 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.

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

Pagina 1 van 2

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

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)

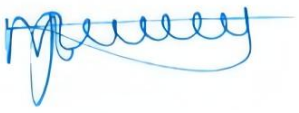
Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van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

Pagina 2 van 2

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

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:

Verino® 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

EC Declaration of Conformity
Page 1/1

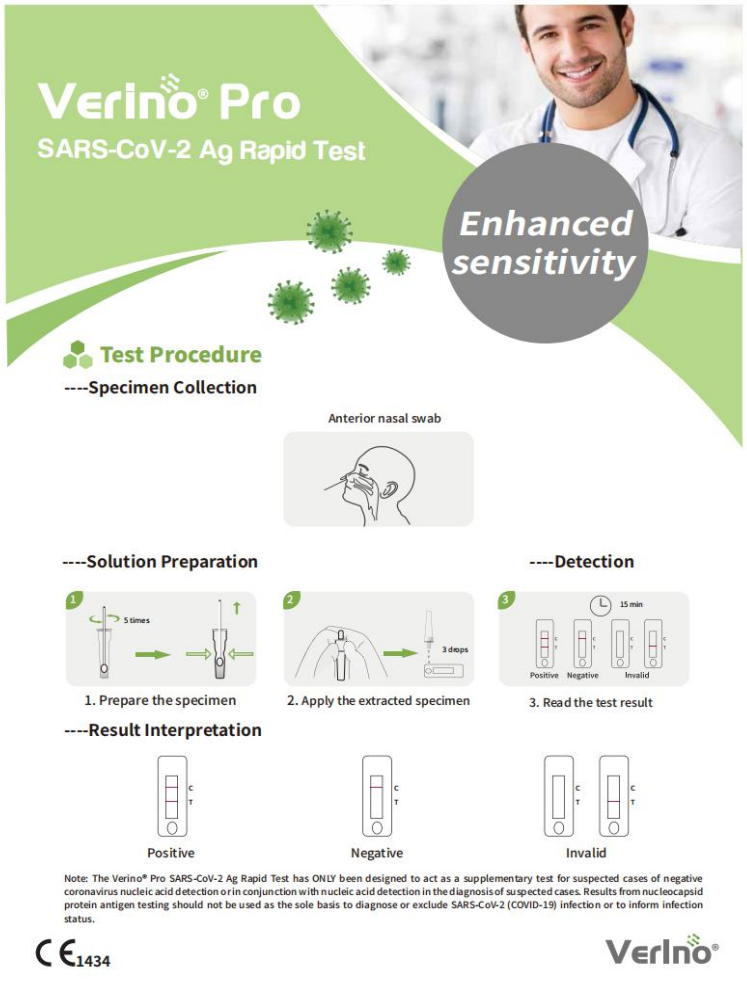
VivaChek Biotech (Hangzhou) Co., Ltd
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
Tel: +86-571-89182700 Fax: +86-571-89182733 Email: info@vivachek.com www.vivachek.com

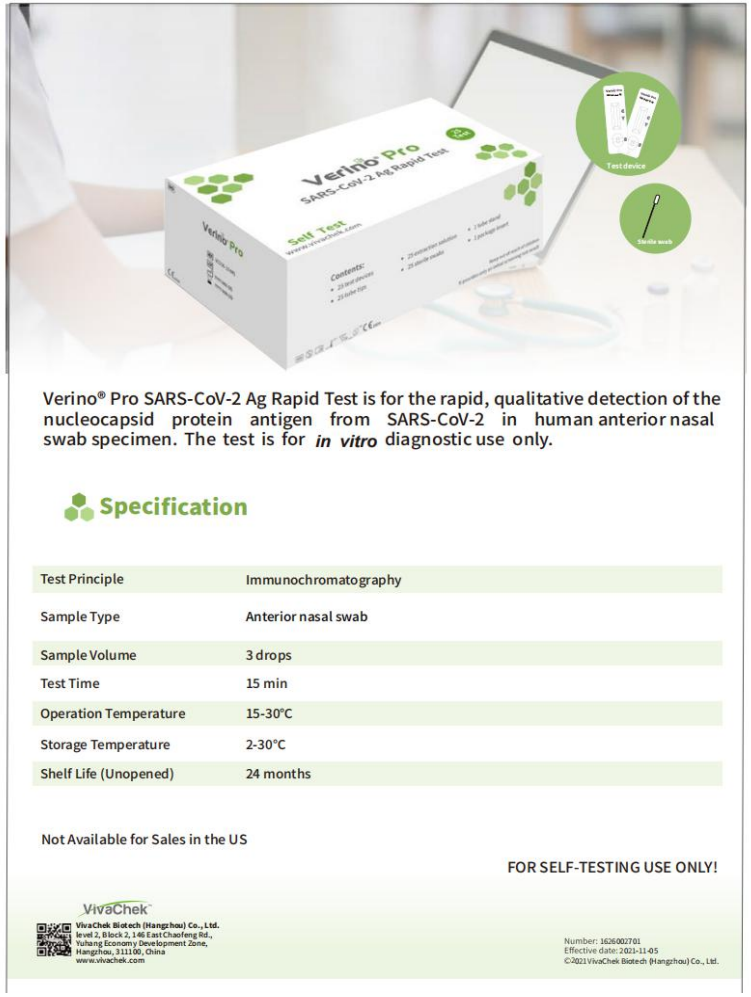
Part 4 – Labeling &brochure

1) Box

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

3) Sell sheet





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

4) IFU

Verino® Pro

SARS-CoV-2 Ag Rapid Test (self-test) Package Insert

REF	English
VCD16-10-041/VCD16-10-042/VCD16-10-043/VCD16-10-044/VCD16-10-045/VCD16-10-046/VCD16-10-047/VCD16-10-048/VCD16-10-049/VCD16-10-04A/VCD16-10-04B/VCD16-10-04C/VCD16-10-04D/VCD16-10-04E/VCD16-10-04F/VCD16-10-04G/VCD16-10-04H/VCD16-10-04J/VCD16-10-04K	

PRINCIPLE AND INTENDED USE

Verino® Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human. The test is for in vitro diagnostic use only. It is for self-testing. It provides only an initial screening test result. More specific alternative diagnosis methods (molecular diagnostic and / or CT) should be performed in order to obtain the confirmation of SARS-CoV-2 infection,The decision about the diagnostic procedure should rest with the physician. This test is intended for home use with self-collected nasal swab samples in individuals aged 16 -69, sampling and testing from anyone under the age of 16 and people over 69 years should be under the guidance of an adult. For people who are not able to perform the test themselves, the test should be conducted by the legal guardians, sick/disabled (Including people with color vision impairment) should be assisted in the test.

The World Health Organisation (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-19. The SARS-CoV-2 virus can cause mild to severe respiratory illness and has spread globally. Cases of severe illness and deaths have been reported. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.

Verino® Pro SARS-CoV-2 Ag Rapid Test is based on immunochromatography technology. Each test device has one line of anti-SARS-CoV-2 antibody on the detection line (T line) and one line of anti-mouse IgG antibody on the quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-SARS-CoV-2 antibody on the detection line. If the specimen contains SARS-CoV-2 antigen, the detection line will appear red indicating the SARS-CoV-2 antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

COMPOSITION

REF No.	VCD16-10-043	VCD16-10-045	VCD16-10-044	VCD16-10-046	VCD16-10-047
	VCD16-10-04A	VCD16-10-04C	VCD16-10-04D	VCD16-10-04E	VCD16-10-04F
Components	1 test	3 tests	5 tests	6 tests	7 tests
test device	1	3	5	6	7
extraction solution (in the sealed tube)	1	3	5	6	7
tube tip	1	3	5	6	7
sterile swab	1	3	5	6	7
tube stand	1	1	1	1	1
package insert	1	1	1	1	1
REF No.	VCD16-10-048	VCD16-10-049	VCD16-10-042	VCD16-10-041	/
	VCD16-10-04G	VCD16-10-04H	VCD16-10-04J	VCD16-10-04K	/
Components	10 tests	15 tests	20 tests	25 tests	/
test device	10	15	20	25	/
extraction solution (in the sealed tube)	10	15	20	25	/
tube tip	10	15	20	25	/
sterile swab	10	15	20	25	/
tube stand	1	1	1	1	/
package insert	1	1	1	1	/

Materials required but not provided: timer and plastic bag for waste.

Extraction solution composition: Phosphate buffer、Surfactant、BSA

STORAGE AND HANDLING

- Store the test kit in a dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

***Note:** All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

WARNINGS, PRECAUTIONS AND LIMITATIONS

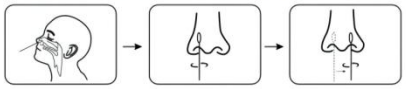
- Results from SARS-CoV-2 antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Should not take any decision of medical relevance without first consulting with the physician.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic and / or CT should be considered to rule out infection in these individuals.
- Positive results may be due to present infection with SARS-coronavirus strains, see "cross-reactivity" for details. Follow-up testing with a molecular diagnostic and / or CT should be considered to confirm the testing result.
- Negative results may occur if the level of antigen in the sample is below the detection limit of the test.
- Inaccurate results may be due to visibly bloody or excessively thick / sticky specimen, insufficient specimen volume or bubbles during applying.
- Do not use swab that is damaged or cannot use.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- For in vitro diagnostic use only, It is for self-testing.
- Keep out of reach of children.
- Use the test device within 60 minutes after opening the foil pouch.
- Do not perform the test in direct sunlight.
- Do not use the test device if it has been exposed to household cleaning products (especially bleach).
- Keep foreign substances away from the test device during the testing process.
- Please take the necessary safety measures (e.g. face mask, gloves) when testing for other people.
- The test equipment used and all parts tested need to be disposed of in accordance with local requirements, and can be placed in a well-sealed bag for disposal as domestic waste.
- Further molecular diagnostic and / or CT is recommended to identify the actual physical situation.
- Do not open the foil pouch of the test device exposing it to the ambient environment until the test device is ready for immediate use.
- Do not use any damaged test device or material.
- Do not reuse the test device.
- Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Do not use test kit beyond the expiration date.
- Only use anterior nasal swab as specimen. Follow the package insert to obtain accurate results.
- Wash hands thoroughly after handling and Wash your hands before sampling and testing.
- This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2 virus.
- The accuracy of the test, depends on the quality of the swab sample-false negative results may be given following poor sampling.
- Any failure to respect the test procedure may negatively impact the performance of the test and/or. invalidate the test result.
- Since the outbreak of the pandemic, the SARS-CoV-2 variant with D614G mutations in the spike protein has replaced the original form in the most regions all over the world. In December 2020, a novel strain of the virus, named 'VUI-202012/01', was identified in the England with a set of 17 mutations. Another mutant strain 501Y.V2 of SARS-CoV-2, originally detected in South Africa, shares the same key mutation N501Y. The N501Y mutation locates the receptor-binding domain (RBD) of the spike protein that the virus uses to bind to the human ACE2 receptor, which might be associate with increased transmissibility.
- The nucleocapsid phosphoprotein (N Protein), linking the viral envelope to the viral RNA, plays a central role in the packaging signal RNA recognition and subsequent RNA encapsidation. Based on its vital role in transcription and replication of the virus, the N protein is suggested to be more sensitive for the early detection of infections. SARS-CoV-2 Ag rapid tests produced by VivaChek employ the interaction with antigen sites in N protein. Till now, there is no clear evidence indicating that mutations found in Spike protein can affect the performance of N protein based antigen tests.

SPECIMEN COLLECTION AND HANDLING

1) Specimen collection

Anterior nasal swab specimen

Wash hands with soap and water or use hand sanitizer.It is important to obtain as much secretion as possible. Open swab package at stick end and take swab out. Do not touch the swab head. Insert the sterile swab into one nostril. Make sure the entire tip of the swab is in your nostril (about 1.5 cm). Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).



2) Specimen handling

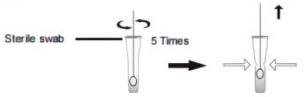
The Specimens should be tested as soon as possible after collection (we recommend to test it within 5 minutes).

TEST PROCEDURE

Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

1. Open the extraction solution (in the sealed tube).

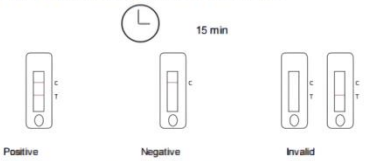
2. Collect specimen refer to **Specimen Collection**.
3. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.



4. Put on the tube tip.

5. Take out a test device from sealed foil pouch and put it on a clean and level surface.
6. Apply 3 drops of the extracted specimen into the specimen well. Please avoid bubbles during applying.

7. Read the test result at 15 minutes. Don't read the result after 20 minutes.



Note:

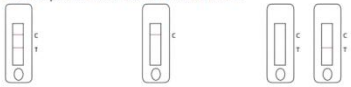
- *Do not interchange or mix extraction solution from different lots.*
- *Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*

INTERPRETATION OF TEST RESULTS

1. Positive Result:
Both the quality control line C and the detection line T appear. Any shade of color in the test line region (T) should be considered positive.

2. Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.

3. Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.



Positive：Both the quality control line C and the detection line T appear.

Negative：Only the quality control line C appears, with no other line appearing on the detection line.

Invalid：Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not.

Actions to take depending on test result

1.Positive Result:

- There is currently a suspicion of a COVID-19 infection.
- Immediately contact your doctor/family doctor or the local health department.
- Follow local guidelines for self-isolation.
- Have a confirmatory PCR test performed.
- In case of suspicion, immediately contact your doctor/family doctor or the local health department.

2.Negative Result:

- Continue to follow all applicable rules regarding contact with others and protec- tive measures.
- An infection can also be present if the test is negative.
- In case of suspicion, as the coronavirus cannot be precisely detected in all phases of an infection; immediately contact your doctor/family doctor or the local health department.

3.Invalid Result:

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

- Possibly caused by incorrect testing.
- Repeat the test.
- If the test results are still invalid, immediately contact your doctor/family doctor or the local health department.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained.

PERFORMANCE

1. Limit of Detection

Limit of detection (LoD) per inactivated Virus Culture : 75.5 $TCID_{50}$/mL

The LoD for the Verino® Pro SARS-CoV-2 Ag Rapid Test was established using dilutions of an inactivated virus culture(heat-inactivated SARS-CoV-2 isolate USA-WA1/2020, NR-52281). The starting material was supplied at a concentration of 1.51×10^6 $TCID_{50}$/mL. Studies were designed to estimate the LoD of the assay using anterior nasal swab specimens, the starting material was spiked into a volume of pooled human anterior nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2 to obtain a series of different concentrations.

2. Clinical Sensitivity/Clinical Specificity

A total of 575 specimens were tested using the Verino® Pro SARS-CoV-2 Ag Rapid Test. These anterior nasal swab specimens were obtained from symptomatic subjects. The performance of the Verino® Pro SARS-CoV-2 Ag Rapid Test was compared to a commercialized molecular assay.

Table Summary of sensitivity/specificity of the Verino® Pro SARS-CoV-2 Ag Rapid Test compared to PCR.

Verino® Pro SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	114	0	114
Negative	1	460	461
Total	115	460	575
Sensitivity	99.13% (114/115, 95%CI, 95.24%~99.85%)		
Specificity	>99.99% (460/460, 95%CI, 99.17%~100%)		
Accuracy	99.83% (574/575, 95%CI, 99.02%~99.97%)		

A sensitivity of 99% means that out of 100 only 1 tests are false negative.
A specificity of 99% means that only 1 in 100 tests is false positive.
Sensitivity and specificity together give the accuracy of how many tests are really positive and correctly negative, so 99% means 1 out of 100 tests are false.

CROSS-REACTIVITY AND INTERFERENCE

1. Cross-Reactivity: there was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

1) Cross-reaction with SARS-coronavirus.

Virus	Strain	Concentration
SARS-coronavirus	Urbani	1×10^6 PFU/mL

2) No cross-reaction with potential cross-reactive substances.

Virus/Bacteria/Parasite	Strain	Concentration Range
Influenza A	H1N1	1×10^4~1×10^6 $TCID_{50}$/mL
	H3N2	
	H5N1	
	H7N9	
Influenza B	N/A	
Adenovirus	Type1	
	Type2	
	Type3	
	Type5	
	Type7	
	Type55	
Respiratory syncytial virus	Type A	
	Type B	
Coronavirus	229E	1×10^6 PFU/mL
	OC43	
	NL63	
	HKU1	
MERS-Coronavirus	Florida/USA-2_Saudi Arabia.2014	
Parainfluenza virus	Type1	1×10^4~1×10^6 $TCID_{50}$/mL
	Type2	
	Type3	
	Type4	
Rhinovirus A16	N/A	
Human Metapneumovirus	A1 (IA10-s003)	
Enterovirus	Type 68	
Legionella pneumophilia	Bloomington-2	1×10^6 cells/mL
	82A3105	
Mycobacterium tuberculosis	K	
	Erdman	
	HN878	
	CDC1551	
	H37Rv	
Streptococcus pneumonia	475298 [Maryland(D1)6B-17]	
	178[Poland23F-16]	
	262[CIP 104340]	
	Slovakia14-10 [29055]	
Streptococcus pyrogens	Typing stain T1	
Mycoplasma pneumoniae	Mutant22	
	FH strain of Eaton Agent	
	M129-B7	
Chlamydia-longontsteking	AR-39	1×10^6 IFU/mL
Haemophilus influenza	Type b; Eagan	1×10^6~1×10^8 CFU/mL
Candida albicans	CMCC(F)98001	
Bordetella pertussis	A639	
Staphylococcus aureus	NCTC 8325	
Staphylococcus epidermidis	MRSE; RP62A	
Pneumocystis jirovecii	W303-Pji	
Pooled human nasal wash	N/A	14% v/v

2. Endogenous/Exogenous Interference Substances: there was no interference for potential interfering substances listed below.

Potential Interfering Substance		Concentration
Anti-viral drugs	Zanamivir (Influenza)	5 mg/mL
	Oseltamivir (Influenza)	10 mg/mL
	Artemether-lumefantrine (Malaria)	50 µM
	Doxycycline hyclate (Malaria)	70 µM
	Quinine (Malaria)	150 µM
	Lamivudine (Retroviral medication)	1 mg/mL
	Ribavirin (HCV)	1 mg/mL
	Daclatasvir (HCV)	1 mg/mL
Respiratory Specimens	Mucin: bovine submaxillary gland, type I-S	100 µg/mL
	Blood (human), EDTA anticoagulated	5% (v/v)
	Biotin	100 µg/mL
Nasal sprays or drops	Neo-Synephrine (Phenylephrine)	10% (v/v)
	Afrin Nasal Spray (Oxymetazoline)	10% (v/v)
	Saline Nasal Spray	10% (v/v)
Homeopathic allergy relief medicine	Homeopathic Zicam Allergy Relief Nasal Gel	5% (v/v)
	Sodium Cromoglycate	20 mg/mL
	Olopatadine Hydrochloride	10 mg/mL
Anti-inflammatory medication	Acetaminophen	199 µM
	Acetylsalicylic acid	3.62 mM
	Ibuprofen	2.425 mM
Antibiotic	Mupirocin	10 mg/mL
	Tobramycin	5 µg/mL
	Erythromycin	81.6 µM
	Ciprofloxacin	30.2 µM

3. High-dose Hook Effect: cultured SARS-CoV-2 virus was spiked into specimen. No hook-effect was observed at 1.51×10^6 $TCID_{50}$/mL of cultured SARS-CoV-2 virus.

REFERENCES

1. Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. The species severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2 [J]. Nature Microbiology, 5, 536-544 (2020).
2. Perlman, S. Netland, J. Coronaviruses post-SARS: update on replication and pathogenesis. Nature Reviews Microbiology 7, 439-450, doi: 10.1038/nrmicro2147 (2009).
3. McCarron, MM, et al. Detection of Phencyclidine Usage by Radioimmunoassay of Saliva. J Anal Tox.1984 Sep-Oct.; 8 (5), pp 197-201.
4. B. Korber et al. Tracking Changes in SARS-CoV-2 Spike: Evidence that D614G Increases Infectivity of the COVID-19 Virus. Cell, vol. 182, no. 4, pp. 812-827.e19, Aug. 2020, doi: 10.1016/j.cell.2020.06.043.
5. Investigation of novel SARS-CoV-2 variant: Variant of Concern 202012/01, GOV.UK.
6. New SARS-CoV-2 variant, GOV.UK.
7. D. C. Dinesh et al. Structural basis of RNA recognition by the SARS-CoV-2 nucleocapsid phosphoprotein. PLoS Pathog, vol. 16, no. 12, p. e1009100, Dec. 2020, doi: 10.1371/journal.ppat.1009100.
8. J. Mariën et al. Evaluating SARS-CoV-2 spike and nucleocapsid proteins as targets for antibody detection in severe and mild COVID-19 cases using a Luminex bead-based assay. Journal of Virological Methods, vol. 288, p. 114025, Feb. 2021, doi: 10.1016/j.jviromet.2020.114025.

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

VivaChek™
VivaChek Biotech (Hangzhou) Co., Ltd. EC REP
Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, China
Email: info@vivachek.com
www.vivachek.com

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

CE 1434 IVD

Number: 1624006802
Effective date: 2021-11-29

Part 5 - COA

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

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

	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:

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

SAFETY DATA SHEET

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

Product name	Verino® Pro SARS-CoV-2 Ag Rapid Test
Chemical description/Application	The Verino® 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 prefilled in a sealed tube. Each test kit contains the following chemicals.

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