VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test (Anterior nasal swab) Package Insert for Self-Testing

Before testing, please scan the QR code to watch the instructional video.

Scan to watch the instructional video

CUSTOMER SUPPORT HELP LINE
(Customer Service Hours: 24 hours, 7 days)
1800 726 696

REF VCD16-10-011/VCD16-10-013/VCD16-10-014/VCD16-10-015	English

PRINCIPLE AND INTENDED USE

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in humans. The test is for in vitro diagnostic use only. It is for self-testing. The results are used to identify SARS CoV-2 within the first 7 days of symptom onset, when viral shedding/viral load is at its highest. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance. This product is intended for self-collected nasal swabs in individuals aged 18-69, sampling and testing from anyone under the age of 18 or over 69 years should be under the guidance of a competent adult. People with illnesses, disabilities or other impairments (including vision impairment) should have a competent adult to conduct the test for them.

The most common symptoms of COVID-19 infection 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.

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). The extracted specimen will react with the coated anti-SARS-CoV-2 antibody on the detection line. It indicates a positive result if the detection line appears red. Otherwise, the test result will be negative. The test device also contains a quality control line, which should appear red for all valid tests. If the quality control line does not appear, the test result will be invalid even if the detection line appears.

COMPOSITION

REF NO.	PACK	COMPONENT LIST
VCD16-10-013	1 test /box	1×test device, 1×sealed tube,1×tube tip, 1×sterile swab, 1×biohazard bag, 1×tube stand, 1×package insert
VCD16-10-015	3 tests /box	3× test devices, 3×sealed tubes, 3×tube tips, 3× sterile swabs, 3×biohazard bags, 1×tube stand, 1×package insert
VCD16-10-014	5 tests /box	5×test devices, 5×sealed tubes, 5×tube tips, 5×sterile swabs, 5×biohazard bags, 1×tube stand, 1×package insert
VCD16-10-011	25 tests /box	25×test devices, 25×sealed tubes, 25×tube tips, 25×sterile swab, 25×biohazard bags, 1×tube stand, 25×package insert

Extraction solution composition: Phosphate buffer, Surfactant, Casein Na
Materials required but not provided: timer

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. Use the test kit between 10-90% humidity.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- 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

- Unless directed by your local State or Territory Health Department, results from SARS-CoV-2 antigen testing should not be used as the sole basis to diagnose, exclude SARS-CoV-2 infection or to inform infection status.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
- Positive results may be due to present infection with SARS-coronavirus strains, see "cross-reactivity" for details.
- False negative results may occur if the level of antigen in the sample is below the detection limit of the test, or if testing is not performed within the first 7 days of symptom onset.
- Inaccurate results may be due to visibly bloody or excessively thick / sticky specimen, insufficient specimen volume or bubbles during applying.
- Test swab specimens immediately, and no more than one hour after collection.
- Do not use swab that is damaged or already used.
- Individuals with colour-impaired vision may not be able to adequately interpret test results.

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- For in vitro diagnostic use and self-testing use only.
- Keep out of reach of children.
- Do not open the foil pouch until you are ready to perform the test, as the test device must be used within 60 minutes of opening the 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, can be disposed of as general waste.
- 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, rinse 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 before and after 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.
- The test device is less reliable in the later phase of infection and when testing asymptomatic individuals.
- It is recommended to repeat testing every 24 hours for 3 days if there is suspicion of infection, exposure to high-risk settings or other occupational risks.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured 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.

2. Clinical Sensitivity/Clinical Specificity

From the test results above, the sensitivity of the VivaDiag™ Pro SARS-CoV-2 Ag test is about 95.24% and the specificity of the VivaDiag™ Pro SARS-CoV-2 Ag test is about 99.38% for symptomatic subjects.

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	460	2	462
Negative	23	320	343
Total	483	322	805
Sensitivity	95.24% (460/483, 95%CI, 92.96%~96.81%)		
Specificity	99.38% (320/322, 95%CI, 97.76%~99.83%)		
Accuracy	96.89% (780/805, 95%CI, 95.46%~97.89%)		

From the test results above, the sensitivity of the VivaDiag™ Pro SARS-CoV-2 Ag test is >99.99% for samples with Ct≤25, 97.07% for samples with 25<Ct≤30, and 83.84% for samples with Ct>30.

Ct Value	PCR positive	SARS-CoV-2 Antigen Rapid Test Positive	Sensitivity
Ct≤25	145	145	>99.99%
25<Ct≤30	239	232	97.07%
Ct>30	99	83	83.84%

From the test results above, the sensitivity of the VivaDiag™ Pro SARS-CoV-2 Ag test is 96.10% for 0~3 days post onset of symptoms, 94.44% for 4~7 days post onset of symptoms.

Days Post Onset of Symptoms	PCR positive	SARS-CoV-2 Antigen Rapid Test Positive	Sensitivity
0~3	231	222	96.10%
4~7	252	238	94.44%

3. Usability Study
A usability study was performed by lay persons, 146 participants were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 100.00% (30/30), relative specificity was 100.00% (116/116). The results showed that the labeling provided with the test kit was comprehensive for its intended population, the ease of use was suitable for its intended population.

CROSS-REACTIVITY AND INTERFERENCE

1. Cross-Reactivity
There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus. Influenza A, Influenza B, Adenovirus, Respiratory syncytial virus, Coronavirus, MERS-Coronavirus, Parainfluenza virus, Rhinovirus A16, Human Metapneumovirus, Enterovirus, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumonia, Streptococcus pyrogens, Mycoplasma pneumonia, Chlamydia-longontsteking, Haemophilus influenza, Candida albicans, Bordetella pertussis, Staphylococcus aureus, Staphylococcus epidermidis, Pneumocystis jirovecii, Pooled human nasal wash (14% v/v).

2. Interference Substances

There was no interference for the substances listed below.

Anti-viral drugs: Zanamivir, Oseltamivir, Artemether-lumefantrine, Dorxoycline hyclate, Quinine, Lamivudine, Ribavirin, Daclatasvir.

Respiratory Specimens: Mucin: bovine submaxillary gland, type I-S, Blood (human), EDTA anticoagulated, Biotin.

Nasal sprays or drops: Neo-Synephrine, Afrin Nasal Spray, Saline Nasal Spray.

Homeopathic allergy relief medicine: Homeopathic Zicam Allergy Relief Nasal Gel, Sodium Cromoglycate, Olopatadine Hydrochloride.

Anti-inflammatory medication: Acetaminophen, Acetylsalicylic acid, Ibuprofen.

Antibiotic: Mupirocin, Tobramycin, Erythromycin, Ciprofloxacin.

FREQUENTLY ASKED QUESTIONS

1. What do I have to do if the result is negative?

A negative result means that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, please contact your local support services as listed below.

2. What do I have to do if the result is positive?

A positive result means it is very likely you have SARS-CoV-2. Please refer to the table of table of state and territory below to contact the appropriate service for your state or territory for further instructions.

3. Can VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test detect variants of SARS-CoV-2?

Yes, VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test can detect Alpha, Beta, Epsilon, Gamma and Delta SARS-CoV-2 mutants based on the studies conducted so far.

4. Information of how to contact locally available support services.

To report any issue via the Users Medical Device Incident Report, email iris@tga.gov.au.

Report any performance or usability issues to TGA by e-mail (iris@tga.gov.au) or call 1800 809 361. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

SUPPORT SERVICE CONTACT INFORMATION

	SERVICE	WEBSITE AND CONTACT NO.
ACT	Australian Capital Territory Coronavirus Hotline	www.covid19.act.gov.au/ ☎: (02) 6207 7244 (8AM-8PM)
NSW	Service NSW (Coronavirus Helpline)	www.service.nsw.gov.au/covid-19 ☎: 137 788 (24/7)
NT	Northern Territory COVID-19 Hotline	https://coronavirus.nt.gov.au/ ☎: 1800 490 484 (8AM-4:30PM)
QLD	Queensland Coronavirus Helpline (134COVID)	www.covid19.qld.gov.au/ ☎: 134 268
SA	South Australia Coronavirus Helpline	www.covid-19.sa.gov.au/ ☎: 1800 253 787 (9AM-5PM)
TAS	Tasmanian Public Health Hotline (Coronavirus)	www.coronavirus.tas.gov.au/ ☎: 1800 671 738
VIC	Victoria Coronavirus Hotline (24/7)	www.coronavirus.vic.gov.au/ ☎: 1800 675 398 (24/7)
WA	Western Australia Coronavirus Hotline 13COVID	www.healthywa.wa.gov.au/COVID19 ☎: 1800 595 206 (8AM-6PM MON-FRI)
AUS	National Advice Hotline (COVID-19)	www.health.gov.au/campaigns/coronavirus-covid-19 ☎: 1800 020 080

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.
Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, China
Email: info@vivachek.com
www.vivachek.com

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

CE IVD

Number: 1624006904
Effective date: 2024-02-21

Australian Sponsor: Stonestar Wholesale Pty Ltd
305-307 Boundary Rd, Mordialloc VIC 3195
T. 03 9580 9788

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test

(SELF-TEST Quick Reference Guide)

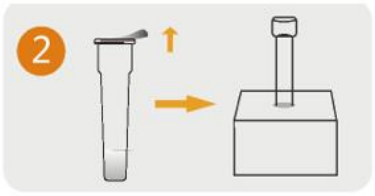
Note: Before testing, please scan the QR code to watch the instructional video.

Scan to watch the instructional video

Scan to open the instructions for use

Test Procedure

1. Wash your hands.

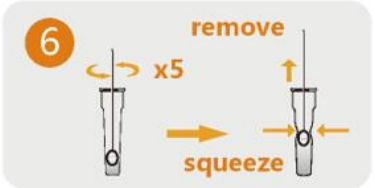


2. Open the extraction solution, place the tube on the tube stand.

3. Open the swab.
DO NOT TOUCH the sterile swab tip.

4. Insert the swab is into one nostril **(about 1.5 cm).**

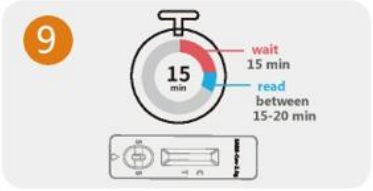
5. Roll the swab **5 times** along the mucous. **Repeat** this process for the other nostril.



6. Insert and roll the swab **5 times** in the extraction tube. Remove the swab while **squeezing** the sides of the tube.

7. Put on the tube tip firmly.

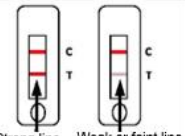
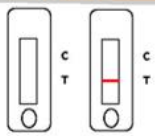
8. Remove the device from the foil pouch. Apply 3 drops of the extracted specimen into the specimen well.



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

10. Dispose of the used device in biohazard bag.

11. Wash your hands.

Positive	Negative	Invalid
 Strong line Weak or faint line		
A positive result means it is very likely you have SARS-CoV-2. Follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.	A negative result means that you are negative or that the viral load is too low to be recognized by the test.	Re-test with a new test device and sterile swab. Call 1800 726 696 for further assistance.

VivaChek™

For customer support please call our help line below: 1800 726 696. Customer Service Hours: 24 Hours , 7 Days.