Scan to watch the instructional video

VivaDiag

SARS-CoV-2/Flu A/Flu B Ag Rapid (Anterior nasal swab) Package Insert for Self-Testing

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

Scan to open the instructions for use

REF VCD24-10-011/ VCD24-10-012/ VCD24-10-013	English

INTENDED USE AND PRINCIPLE

VivaDiag SARS-CoV-2/Flu A/Flu B Ag Rapid Test is intended for the simultaneous qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, influenza A and influenza B in anterior nasal swab specimens from individuals suspected of respiratory viral infection within the first 4 or 7 days of the onset of symptoms. Influenza within 4 days of symptom onset and SARS-CoV-2 within 7 days of symptom onset. This is used to aid for diagnosis of COVID-19, Influenza A and B infection. A usability study has been performed with self-collected nasal swab samples in individuals aged 18-69, sampling and testing from anyone the age of 2-17 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 colour vision impairment) should be assisted in the test. The Rapid Test is a presumptive test only.

VivaDiag SARS-CoV-2/Flu A/Flu B Ag Rapid Test is based on immunochromatography technology. Each test device contains one SARS-CoV-2 Rapid Test and one Influenza A/B Rapid Test. For SARS-CoV-2 Rapid Test, the extracted specimen will react with the coated anti-SARS-CoV-2 antibody on the detection line (T line). It indicates a positive result if the detection line appears red. Otherwise, the test result will be negative. For Influenza A/B Rapid Test, the extracted specimen will react with the coated anti-Influenza A antibody and anti-Influenza B antibody on the detection lines (A/B line). It indicates a positive result if 1 or 2 detection lines appear red. Otherwise, the test result will be negative. For each test device, the two quality control lines containing anti-mouse IgG antibodies should appear red for all valid tests. If the quality control lines doe not appear, the test result will be invalid even if the detection line appear.

COMPOSITION

REF No.	VCD24-10-011	VCD24-10-012	VCD24-10-013
Components	1 test/box	5 tests/box	25 tests/box
Test Device	1	5	25
Extraction Solution (500 µL)	1	5	25
Sterile Swab	1	5	25
Biohazard Bag	1	5	25
Package Insert	1	5	25
Tube Stand	1	1	1

Materials required but may not provided: timer.

STORAGE AND HANDLING

- Store the test kit in a cool, 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 or refrigerate. 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 June18,2022.*

WARNINGS, PRECAUTIONS AND LIMITATIONS

- Results from SARS-CoV-2, influenza A or influenza B antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2, influenza A or influenza B infection or to inform infection status.
- Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- Negative results do not rule out SARS-CoV-2, influenza A or influenza B infection, particularly in those who have been in contact with the virus. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- Inaccurate results may occur if the level of SARS-CoV-2 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.
- False negative results are more likely to occur (for antigen tests) if a test is performed outside the window of highest viral shedding of the influenza virus (which is usually within the first 4 days of onset of symptoms).
- Test swab specimens immediately, and no more than one hour after collection.
- Do not use swabs that are damaged or already used.
- 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.
- Individuals with colour-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 the reach of children and pets.
- 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 use any damaged test device or material.
- Do not reuse the test device or use test kit beyond the expiration date.
- Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Please take the necessary safety measures (e.g., face mask, gloves) when testing for other people.
- Only use anterior nasal swab as specimen, Follow the package insert to obtain accurate results.
- Wash hands thoroughly before and after sampling and testing. Wash hands thoroughly after handling.
- 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.
- Test can only be used once only.
- Individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
- This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2, influenza A or influenza B 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.
- Dispose of the used device in biohazard bag.
- Extraction solution should only be used as directed, do not ingest.
- Do not dip the swab into provided solution or other liquid before inserting the swab into the nose.
- Avoid contact with skin and eyes.
- If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water.

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

Virus Type/Subtype	Concentration
SARS-CoV-2	75.5 $TCID_{50}$ /mL
SARS-CoV-2 Delta	75 $TCID_{50}$/mL
SARS-CoV-2 Omicron	75 $TCID_{50}$/mL
Influenza A (H1N1)	1405 $TCID_{50}$ /mL
Influenza A (H3N2)	1170 $TCID_{50}$ /mL
Influenza B (Yamagata lineage)	10500 $TCID_{50}$ /mL
Influenza B (Victoria lineage)	1043 $TCID_{50}$ /mL

2. Clinical Sensitivity/Clinical Specificity

A total of 871 anterior nasal swab specimens from symptomatic subjects were tested using the VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test. The performance of the VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test was compared to a commercialized molecular assay.

Summary of sensitivity/specificity of the VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test compared to PCR.

VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test	SARS-CoV-2 PCR		
	Positive	Negative	Total
SARS-CoV-2 Positive	377	3	380
SARS-CoV-2 Negative	16	475	491
Total	393	478	871
Sensitivity	95.93% (377/393, 95%CI, 93.49%~97.48%)		
Specificity	99.37% (475/478, 95%CI, 98.17%~99.79%)		
Accuracy	97.82% (852/871, 95%CI, 96.62%~98.60%)		

VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test	Flu A PCR			Flu B PCR		
	Positive	Negative	Total	Positive	Negative	Total
Positive	53	3	56	98	4	102
Negative	2	813	815	3	766	769
Total	55	816	871	101	770	871
Sensitivity	96.36% (53/55, 95%CI, 87.68%~99.00%)			97.03% (98/101, 95%CI, 91.63%~98.98%)		
Specificity	99.63% (813/816, 95%CI, 98.92%~99.87%)			99.48% (766/770, 95%CI, 98.67%~99.80%)		
Accuracy	99.43% (866/871, 95%CI, 98.66%~99.75%)			99.20% (864/871, 95%CI, 99.35%~99.61%)		

The VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for SARS-CoV-2 showed: a clinical sensitivity of 95.93%, a clinical specificity of 99.37%, and a clinical accuracy of 97.82%.

The VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for Flu A showed: a clinical sensitivity of 96.36%, a clinical specificity of 99.63% and a clinical accuracy of 99.43%.

The VivaDiag SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for Flu B showed: a clinical sensitivity of 97.03%, a clinical specificity of 99.48%, and a clinical accuracy of 99.20%.

3. Usability Study

A usability study was performed by lay person, 150 participants were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 100.00% (30/30) for detection of SARS-CoV-2 virus, 100.00% (30/30) for detection of Influenza A virus, 100.00% (30/30) for detection of Influenza B virus, relative specificity was 100.00% (60/60). 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.

4. Variant Study

It can detect SARS-CoV-2 variants: Alpha, Beta, Gamma, Delta, Omicron, Lambda, Mu, Epsilon; Influenza A variants: H1N1, H3N2, H5N1, H7N9; Influenza B variants: Yamagata lineage, Victoria lineage.

CROSS-REACTIVITY AND INTERFERENCE

1. Cross-Reactivity

There was no cross-reaction and microbial interference with potential cross-reactive substances except SARS-coronavirus for SARS-CoV-2 Test.

Influenza A, Influenza B, Adenovirus, Respiratory syncytial virus, Coronavirus, MERS-Coronavirus, Parainfluenza virus, Rhinovirus A16, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumonia, Streptococcus pyrogens, Mycoplasma pneumoniae, Chlamydia Pneumoniae, Staphylococcus aureus, Human Metapneumovirus, Enterovirus, Haemophilus influenza, Candida albicans, Bordetella pertussis, Staphylococcus epidermidis, Pneumocystis jirovecii, Pooled human nasal wash.

2. Interference Substances

There was no interference for the substances listed below.

Anti-viral drugs: Zanamivir, Oseltamivir, Artemether-lumefantrine, Doxycycline 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. If I get a positive result, how can I determine which virus I have tested positive for?

SARS-CoV-2: Both the quality control line C and the detection line CoV appear.
Flu A :Both the quality control line C and the influenza A detection line appear, while the influenza B detection line does not appear.
Flu B: Both the quality control line C and the influenza B detection line appear, while the influenza A detection line does not appear.
Flu A/Flu B: All 3 lines appear, including the quality control line C and the influenza A and influenza B detection lines.

Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary. Individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care. 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. **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. For further advice or to get a PCR test for coronavirus (SARS-CoV-2) you can contact your state or territory health authority, please see your local contact numbers below.

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

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

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

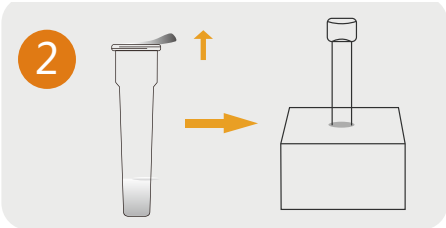
Number: 1624019501
Effective date: 2023-07-20

SARS-CoV-2/Flu A/Flu B Ag Rapid Test

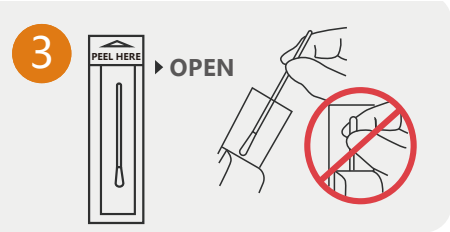
(SELF-TEST Quick Reference Guide)

Test Procedure

1. Wash your hands.

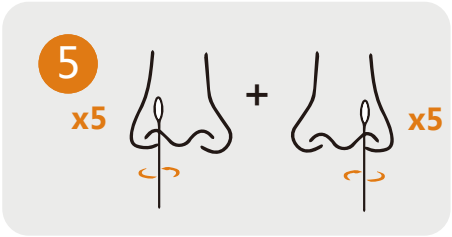


2. Open the extraction solution, place the tube on the tube stand.

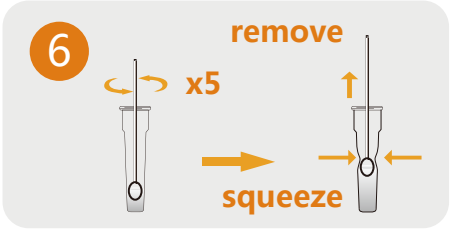


3. Open the swab.
DO NOT TOUCH the sterile swab tip.

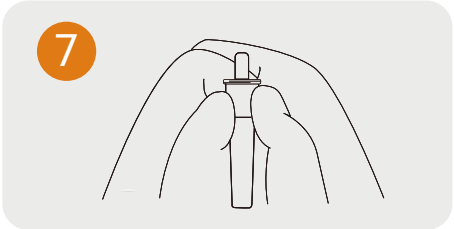
4. Insert the swab is into one nostril **(about 1.5 cm)**.



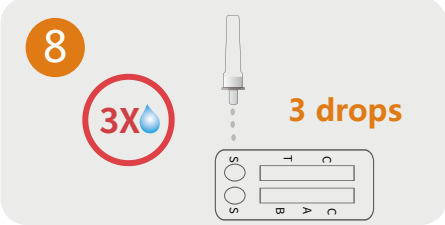
5. Roll the swab **5 times** along the mucous. **Repeat** this process for the other nostril.



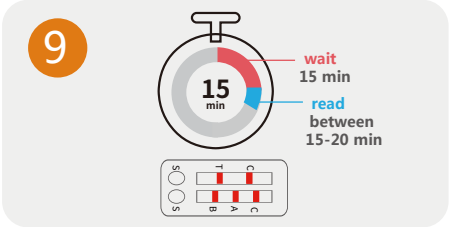
6. Insert and roll the swab **5 times** in the extraction tube. Remove the swab while **squeezing** the sides of the tube.



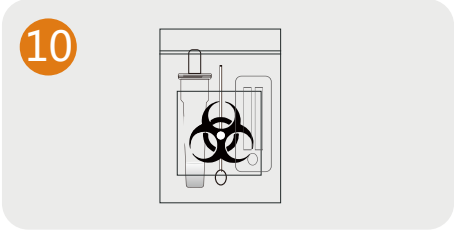
7. Put on the tube tip firmly.



8. Remove the device from foil pounch. Apply **3 drops** of the extracted specimen into **each** 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.

VivaChek

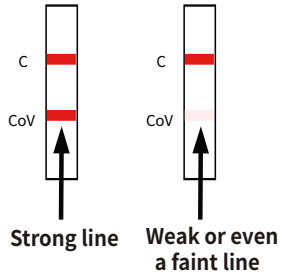
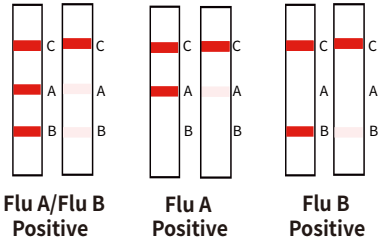
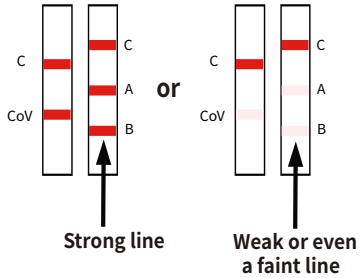
CUSTOMER SUPPORT HELP LINE (Customer Service Hours: 24 hours, 7 days) 1800 726 696

SARS-CoV-2/Flu A/Flu B Ag Rapid Test

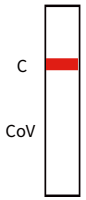
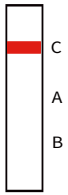
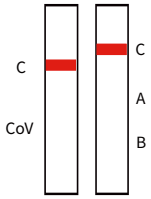
(SELF-TEST Quick Reference Guide)

Test Result

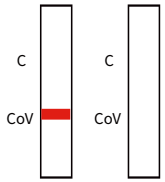
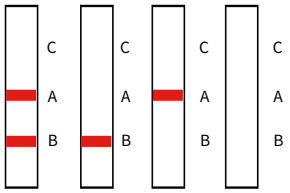
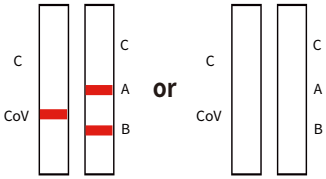
Positive

SARS-CoV-2 Positive	Flu A/Flu B Positive	SARS-CoV-2 +Flu A/Flu B Positive	What to do ?
			For positive COVID-19 results: 'Follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if necessary. If unwell, please consult a medical practitioner for follow up clinical care.' For positive Influenza A/B results: 'If you have a positive result, please consult a medical practitioner for follow up clinical care' .

Negative

SARS-CoV-2 Negative	Flu A/Flu B Negative	SARS-CoV-2 +Flu A/Flu B Negative	What to do ?
			That means that you are negative or that the viral load is too low to be detected by the test. If you have symptoms such as headache, migraine, fever, loss of the smell or taste senses, it is recommended testing be repeated within 1 – 3 days, and if unwell seek medical assistance.

Invalid

SARS-CoV-2 Invalid	Flu A/Flu B Invalid	SARS-CoV-2 +Flu A/Flu B Invalid	What to do ?
			It is possibly caused by incorrect test operation. Repeat the test with a new test cassette and fresh sample. If the same problem still exists, please stop using the batch number of the product immediately and call 1800 726 696 for further assistance.

ViVaChek

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