SARS-CoV-2/Flu A/Flu B Ag Rapid Package Insert

REF VLD01-03-13-011/ VLD01-03-13-013	English

PRINCIPLE AND INTENDED USE

VivaDiag™ SARS-CoV-2/Flu A/Flu B Ag Rapid Test is for the rapid, qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen, the influenza A and influenza B virus antigens in human nasal swab, oropharyngeal swab or nasopharyngeal swab specimen. The test is for in vitro diagnostic use only. For professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.

VivaDiag™ SARS-CoV-2/Flu A/Flu B Ag Rapid Test is based on immunochromatography technology. Each test device has one line of anti-SARS coronavirus antibody on the detection line (Cov line), one line of anti-influenza A antibody on the detection line (A line), one line of anti-influenza B antibody on the detection line (B line) and one line of anti-mouse IgG antibody on the quality control line (C line). When extracted specimen is added to each 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 coronavirus antibody, anti-influenza A antibody and anti-influenza B antibody on the detection line. If the specimen contains SARS-CoV-2, influenza A or influenza B antigen, the detection line will appear red indicating the SARS-CoV-2, influenza A or influenza B 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

Each test kit contains test devices, extraction solution (in the sealed tube), tube tips, tube stand, sterile swabs and package insert.

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.
- 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.
- Positive results may be due to present infection with SARS-coronavirus strains, influenza A or influenza B, see “cross-reactivity” for details. Follow-up testing with a molecular diagnostic and / or CT should be considered to confirm the testing result.
- For *in vitro* diagnostic use only.
- Not for at-home testing.
- Performance of the test has not been established for monitoring antiviral treatment of SARS-CoV-2, influenza A or influenza B infection.
- 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.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.
- Only use nasal swab or throat swab as specimen. Follow the package insert to obtain accurate results.
- Wear protective gears such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Wash hands thoroughly after handling.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits.

SPECIMEN COLLECTION AND HANDLING

1) Specimen collection

- Nasal swab specimen (recommended)

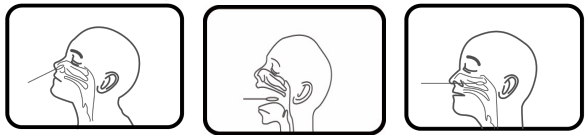
It is important to obtain as much secretion as possible. Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

- Oropharyngeal swab specimen (optional)

It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when remove the swab.

- Nasopharyngeal swab specimen (optional)

It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.



Nasal swab | Oropharyngeal swab | Nasopharyngeal swab

2) Specimen handling

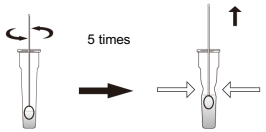
Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

TEST PROCEDURE

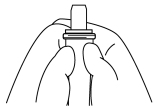
Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

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

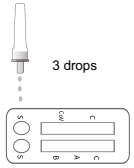
2. Collect specimen refer to **Specimen Collection.**
3. Insert the swab with collected specimen into the tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the tube. Remove the swab while squeezing the sides of the tube to extract the liquid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



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 each 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.*
- *Please follow local regulations to handle the used materials.*

INTERPRETATION OF TEST RESULTS

For SARS-CoV-2 Ag:

Positive Result:

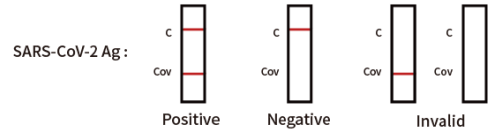
Both the quality control line C and the detection line CoV appear.

Negative Result:

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

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.



For Flu A/Flu B Ag:

Positive Results:

Positive influenza A antigen:

Both the quality control line C and the influenza A detection line appear, while the influenza B detection line does not appear.

Positive influenza B antigen:

Both the quality control line C and the influenza B detection line appear, while the influenza A detection line does not appear.

Positive influenza A and B antigen:

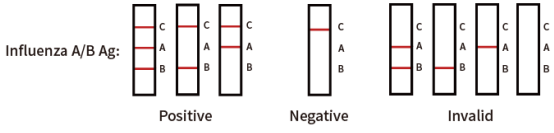
All 3 lines appear, including the quality control line C and the influenza A and influenza B detection lines.

Negative Result:

Only the quality control line C appears, with no other line appearing on the influenza A or influenza B detection line. It indicates the test result is negative for both influenza A and influenza B antigens.

Invalid Result:

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



QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE

1. Limit of Detection

Virus Type/Subtype	Concentration
SARS-CoV-2	75.5 $TCID_{50}$ /mL
Influenza A (H1N1)	1303 $TCID_{50}$ /mL
Influenza A (H3N2)	1260 $TCID_{50}$ /mL
Influenza B (Yamagata lineage)	10000 $TCID_{50}$ /mL
Influenza B (Victoria lineage)	1600 $TCID_{50}$ /mL

2. Clinical Sensitivity/Clinical Specificity

A total of 415 **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 for nasal swab specimens.

VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test	SARS-CoV-2 PCR		
	Positive	Negative	Total
SARS-CoV-2 Positive	163	1	164
SARS-CoV-2 Negative	9	242	251
Total	172	243	415
Sensitivity	94.77% (163/172, 95%CI, 90.36%~97.22%)		
Specificity	99.59% (242/243, 95%CI, 97.71%~99.93%)		
Accuracy	97.84% (725/741, 95%CI, 96.52%~98.67%)		

The VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for SARS-CoV-2 showed: a clinical sensitivity of 94.77%, a clinical specificity of 99.59%, and a clinical accuracy of 97.84%.

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	2	55	98	3	101
Negative	2	358	360	3	311	314
Total	55	360	415	101	314	415
Sensitivity	96.36% (53/55, 95%CI, 87.68%~99.00%)			97.03% (98/101, 95%CI, 91.63%~98.98%)		
Specificity	99.44% (358/360, 95%CI, 98.00%~99.85%)			99.04% (311/314, 95%CI, 97.23%~99.67%)		
Accuracy	99.04% (411/415, 95%CI, 97.55%~99.62%)			98.55% (409/415, 95%CI, 96.88%~99.34%)		

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 99.44% and a clinical accuracy of 99.04%.

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 99.04%, and a clinical accuracy of 98.55%.

A total of 415 **oropharyngeal 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 for oropharyngeal swab specimens.

VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test	SARS-CoV-2 PCR		
	Positive	Negative	Total
SARS-CoV-2 Positive	165	2	167
SARS-CoV-2 Negative	7	241	248
Total	172	243	415
Sensitivity	95.93% (165/172, 95%CI, 91.84%~98.01%)		
Specificity	99.18% (241/243, 95%CI, 97.05%~99.77%)		
Accuracy	97.83% (406/415, 95%CI, 95.93%~98.85%)		

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 99.18%, and a clinical accuracy of 97.83%.

VivaDiag™ SARS-CoV -2/ Flu A/ Flu B Ag Rapid Test	Flu A PCR			Flu B PCR		
	Positive	Negative	Total	Positive	Negative	Total
Positive	52	2	54	98	3	101
Negative	3	358	361	3	311	314
Total	55	360	415	101	314	415
Sensitivity	94.55% (52/55, 95%CI, 85.15%~98.13%)			97.03% (98/101, 95%CI, 91.63%~98.98%)		
Specificity	99.44% (358/360, 95%CI, 98.00%~99.85%)			99.04% (311/314, 95%CI, 97.23%~99.67%)		
Accuracy	98.80% (410/415, 95%CI, 97.21%~99.48%)			98.55% (409/415, 95%CI, 96.88%~99.34%)		

The VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for Flu A showed: a clinical sensitivity of 94.55%, a clinical specificity of 99.44% and a clinical accuracy of 98.80%.

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 99.04%, and a clinical accuracy of 98.55%.

A total of 415 **nasopharyngeal 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 for nasopharyngeal swab specimens.

VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test	SARS-CoV-2 PCR		
	Positive	Negative	Total
SARS-CoV-2 Positive	166	1	167
SARS-CoV-2 Negative	6	242	248
Total	172	243	415
Sensitivity	96.51% (166/172, 95%CI, 92.60%~98.39%)		
Specificity	99.59% (242/243, 95%CI, 97.71%~99.93%)		
Accuracy	98.31% (408/415, 95%CI, 96.56%~99.18%)		

The VivaDiag™ SARS-CoV-2/ Flu A/ Flu B Ag Rapid Test for SARS-CoV-2 showed: a clinical sensitivity of 96.51%, a clinical specificity of 99.59%, and a clinical accuracy of 98.31%.

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	2	55	98	2	100
Negative	2	358	360	3	312	315
Total	55	360	415	101	314	415
Sensitivity	96.36% (53/55, 95%CI, 87.68%~99.00%)			97.03% (98/101, 95%CI, 91.63%~98.98%)		
Specificity	99.44% (358/360, 95%CI, 98.00%~99.85%)			99.36% (312/314, 95%CI, 97.71%~99.83%)		
Accuracy	99.04% (411/415, 95%CI, 97.55%~99.62%)			98.80% (410/415, 95%CI, 97.21%~99.48%)		

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 99.44% and a clinical accuracy of 99.04%.

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 99.36%, and a clinical accuracy of 98.80%.

CROSS-REACTIVITY AND INTERFERENCE

1. Cross-Reactivity

There was no cross-reaction 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.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		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

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