Vstrip COVID-19 Antigen Rapid Test

IVD CE REF IG10020S02 IG10050S02 15℃ 30℃ IVD USE 2020/11 V01 Vstrip COVID-19 Antigen Rapid Test

For prescription use only

For in vitro diagnostic use only

INTENDED USE

Vstrip COVID-19 Antigen Rapid Test is a rapid in vitro immunochromatographic assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The Vstrip COVID-19 Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

SUMMARY

SARS-CoV-2 is positive-sense single-stranded RNA virus with envelope, the virion is approximately 50–200 nanometres in diameter[1]. It has four structural proteins, known as the spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins; the N protein holds the RNA genome, and the S, E, and M proteins together create the viral envelope[2]. The gene sequence is similar to Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) and Middle East Respiratory Syndrome Coronavirus (MERS-CoV) but belong to different species.

The incubation period for COVID-19 is typically range from 2 to 14 days. Those infected with the virus may be asymptomatic or develop common respiratory symptoms, including fever, cough and fatigue (other symptoms may include muscle pain, diarrhea, sore throat, loss of smell, and abdominal pain). Severe patients may progress to acute respiratory distress syndrome (ARDS), septic shock, diffuse alveolar damage (DAD) and death[3].

Vstrip COVID-19 Antigen Rapid Test is an immunochromatographic test that using antibody-coated latex to detect the presence of SARS-CoV-2 virus in the nasal secretions. The test is easy to perform and test results can be visually interpreted in 10 minutes.

PRINCIPLE OF THE TEST

Vstrip COVID-19 Antigen Rapid Test is a rapid immunochromatographic assay that utilizes specific antibodies to detect nucleocapsid protein of SARS-CoV-2 virus in nasopharyngeal swab specimens. The Vstrip COVID-19 Antigen Rapid Test is designed to detect antigen from the SARS-CoV-2 in nasopharyngeal swab from patients who are suspected of COVID-19 by their healthcare provider.

To perform the test, insert the test dipstick into the extraction buffer. If the extracted specimen contains SARS-CoV-2 viral antigen, a red test line will appear on the dipstick indicating a positive result and along with a purple black control line. A purple black control line will always appear in the result window to indicate that it confirms correct assay procedure and active kit components. If SARS-CoV-2 viral antigen is not present, or is present at very low levels in the specimen, only the control line will be visible. Whenever the purple black control line does not develop within 10 minutes, the test is considered invalid.

MATERIALS PROVIDED

All provided materials should be stored and handled at 15-30℃.

1. Test Dipsticks:
   Each test houses a strip incorporated with a pair of anti-SARS-CoV-2 specific antibodies and packed in individual foil pouch.
2. Extraction Buffer:
   Tube vials with detergent, protein and salt.
3. Nasopharyngeal Swabs
4. Package Insert

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer
3. Goggle
4. Protective tools

WARNINGS AND PRECAUTIONS

1. For prescription and in vitro diagnostic use only.
2. This test has been authorized only for the detection of proteins from SARSCoV-2, not for any other viruses or pathogens.
3. Directions should be read and followed carefully.
4. Do not use if the test device package is damaged.
5. The test dipsticks must remain sealed in the protective foil pouch until use.
6. Do not use the kit contents beyond the expiration date printed on the outside of the box.
7. Do not interchange or mix different lots of Vstrip COVID-19 Antigen Rapid Test.
8. Do not reuse kit components.
9. To obtain accurate results, you must follow the Package Insert.
10. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[4]
11. Use of protective tools are recommended when handling patient samples.[4]
12. Do not insert the test dipstick directly into the sampling area (mouth, nasal).
13. When collecting a nasopharyngeal swab sample, use the nasopharyngeal swab supplied in the kit. Use of alternative swabs may result in incorrect results.
14. Inadequate or inappropriate sample collection, storage, and transport may yield false test results. Negative results do not rule out SARS-CoV-2 infection.
15. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[5,6]
16. If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
17. Disregard test results beyond specified time (20 min).
18. Test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.
19. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
20. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
21. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
22. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
23. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
24. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Material Safety Data Sheet (MSDS) located at Vstip com.

STORAGE AND STABILITY

Kits may be stored at 15–30 °C. DO NOT FREEZE. Reagents and devices must be at room temperature (15–30 °C) when used for testing.

SPECIMEN COLLECTION AND HANDLING

Specimen Preparation

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use the swabs supplied in the kit.

Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after seven days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

Specimen Storage

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed.

Nasopharyngeal Swab Specimen Collection

It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, carefully insert the sterile swab into the nostril that presents the most secretions 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 several times.

ASSAY PROCEDURE

All specimens and assay procedures must be handled at room temperature.

1. Check the expiration date on each component's package or outer box before use. Do not use any test material beyond the labelled expiration date.
2. Place the swab with sample into the extraction tube. Roll the swab three-five (3-5) times. Leave the swab in the extraction buffer for 1 minute.
3. Roll the swab head against the side of the extraction tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Place the test dipstick into the extraction buffer with the arrows on the test dipstick pointing down. Do not handle or move the test dipstick until the test is completed and ready for interpretation.
5. Read result at 10 minutes. Some positive results may appear sooner. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Positive result:

At 10 minutes, the appearance of any shade of a **RED** Test Line below the **PURPLE BLACK** Control Line, and the appearance of a purple black procedural Control Line indicates a positive result for the presence of SARS-CoV-2 viral antigen. Report positive test results as 'Positive for SARS-CoV-2 viral antigen'. A positive result does not rule out co-infections with other pathogens.

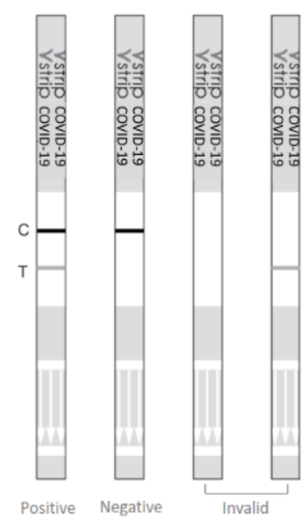
Negative result:

At 10 minutes, the appearance of ONLY the **PURPLE BLACK** Control Line indicates SARS-CoV-2 viral antigen were not detected. A negative result indicates that the sample is negative for antigen or the antigen level is below the detection limit.

Report negative test results as SARS-CoV-2 viral antigen not detected. A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostics.

Invalid result:

If at 10 minutes, the purple black procedural Control Line does not appear, even if a Red Test Line appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test dipstick.



INTERNAL CONTROLS

1. A purple black line appearing in the "Control Line" is an internal control. It confirms correct assay procedure and active kit components. If not, the test result is invalid.
2. A clear background is served as the internal negative control. The background color should be white and should not interfere with the reading of the test result. If the background color interfere the reading, it is recommended to repeat the test.

LIMITATIONS OF THE PROCEDURE

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 viral antigen from the nasopharyngeal swab.
2. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
3. Users should test specimens as quickly as possible after specimen collection.
4. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
5. Results from the Vstrip COVID-19 Antigen Rapid Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
6. Positive test results do not rule out co-infections with other pathogens.
7. Negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
8. Negative test result do not rule out SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnostics.
9. Antibodies may fail to detect, or detect with less sensitivity, when SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

CLINICAL PERFORMANCE

The performance of the Vstrip COVID-19 Antigen Rapid Test for detection of SARS-CoV-2 was established with 79 individual symptomatic patients who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases.

Nasopharyngeal swabs were collected and handled as described in the package insert. All specimens were not frozen and tested with Vstrip COVID-19 Antigen Rapid Test by blinded operator on the same collection day.

The performance of the Vstrip COVID-19 Antigen Rapid Test was compared to results with an FDA Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

		Reference PCR Results		
		+	-	Total
Vstrip COVID-19 Antigen Rapid Test	+	21	1	22
	-	2	55	57
	Total	23	56	79

Sensitivity: 91.30% (95%CI: 71.96% - 98.93%)

Specificity: 98.21% (95%CI: 90.45% - 99.95%)

Accuracy: 96.20% (95%CI: 89.30% - 99.21%)

Positive predictive value: 95.45% (95%CI: 74.99% - 99.32%)

Negative predictive value: 96.49% (95%CI: 87.97% - 99.04%)

ANALTICAL SENSITIVITY (LIMIT OF DETECTION)

The limit of detection (LOD) for direct swab was established using inactivated SARS-CoV-2 isolate USA- WA1/2020 (NR-52287) and SARS-CoV-2 recombinant nucleocapsid protein. The materials were spiked into the pooled human clinical nasal matrix (CNM) obtained from multiple healthy volunteers and confirmed as SARS-CoV-2 negative.

An initial range finding study was performed in triplicate using a 2-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested by the Vstrip COVID-19 Antigen Rapid Test. The estimated LoD found from the initial 2-fold serial dilution test was confirmed by additional testing 1-20 replicates.

The confirmed LoD for Vstrip COVID-19 Antigen Rapid Test show as below Table.

No.	Type	Strain	Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
1	Inactivated SARS-CoV-2, gamma-Irradiated	USA-WA1/2020	2.8 x 10^5 $TCID_{50}$/mL	3.13x10^2 $TICD_{50}$/mL	20/20	100
2	SARS-CoV-2 recombinant nucleocapsid protein	-	0.29 mg/mL	30 ng/ml	20/20	100

CROSS REACTIVITY

The cross-reactivity of Vstrip COVID-19 Antigen Rapid Test was performed on the positive and negative clinical nasal matrix containing high levels of non-target microorganisms. A total of 12 bacteria were tested at a target concentration between 10^6 and 10^{10} cfu/mL and the 15 viruses were tested at concentrations between 10^5 and 10^9 $TCID_{50}$/mL (or pfu/mL). Each organism and virus were tested in triplicate in the absence or presence of 2xLoD ($TCID_{50}$/mL: 6.25x10^2) of gamma inactivated SARS-CoV-2. No cross-reactivity or interference was seen when tested at the potentially interfering concentrations. The organisms and viruses are documented in the below Table.

Bacteria panel	
Bordetella pertussis	*Mycoplasma pneumoniae*
Candida albicans	*Pseudomonas aeruginosa*
Chlamydia pneumoniae	*Staphylococcus aureus*
Escherichia coli	*Staphylococcus epidermidis*
Haemophilus influenzae	*Streptococcus pneumoniae*
Legionella pneumophila	*Streptococcus pyogenes*
Viral panel	
Adenovirus type 7	Human Parainfluenza Virus (HPIV)
Adenovirus type 41	Influenza A -H1N1
Enterovirus Type 68	Influenza A -H3N2
Enterovirus (EV71)	Influenza B -Vic
Human coronavirus 229E*	Influenza B -Yam
Human coronavirus NL63	Respiratory syncytial virus*
Human coronavirus OC43*	Rhinovirus
Human Metapneumovirus (hMPV 3 type B1)*	

*Unit: pfu/ml

ENDOGENOUS INTERFERING SUBSTANCES

Nasal spray product and common chemicals were evaluated and did not interfere with the Vstrip COVID-19 Antigen Rapid Test in clinical nasal matrix at the levels tested below.

Interference substances	Testing Concentration	Interference substances	Testing Concentration
Afrin (Oxymetazoline)	15% v/v	Nasal Washing Salt	20 mg/ml
Aspirin	20 mg/ml	Naso GEL (NeilMed)	5% v/v
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Nasal Gel (Oxymetazoline)	10% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v	NASONEX Aqueous Nasal Spray	10%
CVS Saline Nasal Spray	15% v/v	Oxymetazoline HCl	10 mg/ml
Dextromethorphan	10 mg/ml	Phenylephrine HCl	100 mg/ml
Diphenhydramine HCl	5 mg/ml	Ponstan	20 mg/ml
Fisherman's Friend	1.5 mg/mL	Ricola (Menthol)	1.5 mg/mL
Hemoglobin	20 mg/ml	Sore Throat Phenol Spray	15% v/v
Homeopathic (Alkalol)	1:10 dilution	Swinin nasal sprays	10%
Hosoon Troches (ROOT)	20 mg/ml	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Ibuprofen	20 mg/ml	Tobramycin	4 µg/mL
Mucin	0.50%	Whole Blood	4%
Mupirocin	10 mg/mL	Zicam	5% v/v
Nasal Ointment	10%		

HIGH-DOSE HOOK EFFECT

The Vstrip COVID-19 Antigen Rapid Test was tested up to 2.8x10^5 $TCID_{50}$/ml of gamma-inactivated SARS-CoV-2 strain and no high-dose hook effect was observed.

REPRODUCIBILITY

An evaluation of the Vstrip COVID-19 Antigen Rapid Test was conducted at three laboratories using 48 coded samples, were prepared using the SARS-CoV-2 recombinant nucleocapsid protein spiked into simulated respiratory secretion. Testing was performed by training personnel with educational background at three different locations. The study panel contained negative, high negative, low positive and moderate positive samples. Each sample level was tested at each site by two operators.

The results obtained at each site agreed >99% with the expected. The data analyses support the hypothesis that Vstrip COVID-19 Antigen Rapid Test is easily reproducible by different operators and can be performed with little to no difficulty.

STORAGE INSTRUCTION

1. The product should be stored at 15-30 °C, away from direct sunlight. Reagents and devices must be at room temperature (15–30 °C) when used for testing.
2. Kit contents are stable until the expiration date printed on the outer box.
3. The test dipsticks must be kept in the sealed pouch until use.
4. Do not freeze or overheat the test kit or kit reagents.

ORDERING INFORMATION/ PACKAGING

1. IG10020S02……20 Tests/Kit
2. IG10050S02……50 Tests/Kit

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at +886-2-2691-9895. If outside Taiwan, contact your local distributor or xizhi@pbf.com.tw.

REFERENCES

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6. The Clinical Virology Laboratory, Department of Laboratory Medicine at Yale: http://info.med.yale.edu/labmed/virology/booklet.html.

SYMBOL LEGEND

REF	Catalog number	LOT	Batch Code	Σ	Contains sufficient for < n > tests
IVD	In vitro diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use		Manufacturer		Temperature Limit
EC REP	Authorized Representative in the European Community	CE	CE Marking		

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