Vstrip®

Vstrip Flu A & B Rapid Test

For *in vitro* diagnostic use

REF IG01020S IVD 20 TESTS KIT 15℃ 30℃ IVD USE 2021/04 V01

Vstrip Flu A & B Rapid Test

Vstrip Flu A&B Rapid Test is an immunochromatographic assay for the rapid detection of Influenza type A and type B viral antigens in the nasal secretions.

INTENDED USE

Vstrip Flu A&B Rapid Test is a rapid in vitro immunochromatographic assay for the qualitative detection of influenza type A and type B virus from the nasopharyngeal swab of symptomatic patients. The influenza type A and type B virus can be detected by this test in the infection when symptoms have appeared. The test is intended for professional and laboratory use as an aid in the rapid diagnosis of influenza type A and type B viral infections. The test doesn't detect Influenza type C. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

SUMMARY

Influenza viruses are single-strand RNA viruses and include type A, type B and type C. Type A viruses are classically more prevalent and are associated with the most serious influenza epidemics, while type B viruses are generally milder than type A. Type C viruses have not been previously associated with any serious epidemic diseases in history. Both types A and B viruses can prevalent simultaneously, but usually one type is dominant during a given season. [1] Influenza is a highly contagious, acute, viral infection of the upper respiratory tract. Typical symptoms of the influenza infection are an abrupt onset of fever, headache, myalgia, malaise, nonproductive cough, sore throat and rhinitis. The infection usually continues for about a week and most people recover within 1 to 2 weeks. If it occurs to the young, the elderly and people suffering from medical conditions such as lung diseases, diabetes, cancer, kidney or heart problems, influenza poses a serious threat. Under normal circumstances, the infection may lead to severe complications of underlying diseases, pneumonia and death.

Vstrip Flu A&B Rapid Test is an immunochromatographic test that using monoclonal antibody-coated latex to detect the presence of Influenza type A and type B viral antigens 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 Flu A&B Rapid Test is a rapid immunochromatographic assay that utilizes specific monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasopharyngeal swab specimens. To perform the test, insert the test dipstick into the extraction buffer. If the extracted specimen contains influenza A or B antigens, a blue test line or red test line will appear on the dipstick indicating a positive result and along with a purple control line. A purple control line will always appear in the result window to indicate that it confirms correct assay procedure and active kit components. If influenza antigen is not present, or is present at very low levels in the specimen, only the control line will be visible. Whenever the purple 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 (20 dipsticks):
   Each test houses a strip incorporated with a pair of anti-influenza A and anti-influenza B specific mouse monoclonal antibodies and packed in individual foil pouch.
2. Extraction Buffer (20 tubes):
   Tube vials with detergent, protein and salt.
3. Sterile Nasopharyngeal Swabs (20 pieces)
4. Flu A Positive Control (1 piece):
   Inactivated Influenza A viruses are the main component of the positive control swab. (Influenza A Antigen: Cultured in chicken egg, had been inactivated with Gamma radiation and should contain no infectious material)
5. Flu B Positive Control (1 piece):
   Inactivated Influenza B viruses are the main component of the positive control swab. (Influenza B Antigen: Cultured in MDCK Cells, had been inactivated with Gamma radiation and should contain no infectious material)
6. Package Insert

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer
3. Disposable gloves

PRECAUTIONS

Read the package insert carefully prior to testing the kit and follow the instruction to obtain accurate results.

1. For in vitro diagnostic use.
2. Directions should be read and followed carefully.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Do not interchange or mix different lots of Vstrip Flu A&B Rapid Test.
5. Do not insert the test dipstick directly into the sampling area (mouth, nasal).
6. Disregard test results beyond specified time (10 min).
7. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[2]
8. Use of Nitrile or Latex gloves is recommended when handling patient samples.[2]
9. Dispose of containers and used contents in accordance with Federal, State and Local requirements.
10. Do not reuse kit components.
11. The test dipsticks must remain sealed in the protective foil pouch until use.
12. To obtain accurate results, you must follow the Package Insert. Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
13. Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
14. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[3,4]
15. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza type A viruses in circulation. When other influenza type A viruses are emerging, performance characteristics may vary.
16. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL $_3$, facility is available to receive and culture specimens.

SPECIMEN COLLECTION AND 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 (or stored at 2-8℃ no more than 48 hours). 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.

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.

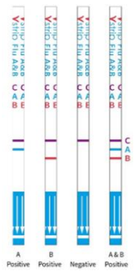
1. Check the expiration date on each component's package or outer box before use. Do not use any test material beyond the labelled expiration date.
2. Place the swab with sample into the extraction tube. Roll the swab three-five (3-5) times. Leave the swab in the extraction buffer for 1 minute.
3. Roll 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 10 minutes.

INTERPRETATION OF RESULTS

Positive result:

At 10 minutes, the appearance of ANY shade of a blue and/or red Test Line below the purple Control Line, and the appearance of a purple procedural Control Line indicates a positive result for the presence of influenza A and/or B viral antigen.

1. If only a BLUE line appears below the purple procedural Control Line (C), the test results are positive for type A (A).
2. If only a RED line appears below the purple procedural Control Line (C), the test results are positive for type B (B).
3. If both a BLUE and RED line appear below the purple procedural Control Line (C), the test results are positive for both type A (A) and type B (B) .



Report positive test results as 'Positive for influenza A (or B) virus antigen'. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

Negative result:

At 10 minutes, the appearance of ONLY the purple procedural Control Line indicates influenza A and B 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 Influenza A (or B) virus antigen not detected. A negative result does not exclude influenza viral infection and should be confirmed by cell culture.

Invalid result:

If at 10 minutes, the purple procedural Control Line does not appear, even if a Blue or Red Test Line (A or B) 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 line appearing in the "Control Line" (next to the letter C) 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.

External Controls

External control may also be used to demonstrate that the kit components and assay procedure perform properly. Positive control be run once for each untrained operator, once for each new shipment of kits- provide that each different lot received in the shipment is tested- and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State regulations or accreditation requirement.

Both influenza A and influenza B positive controls are supplied in the kit and should be tested using the following procedure:

1. Place the positive control swab into the extraction tube. Roll the swab five (5) times. Leave the swab in the extraction buffer for 1 minute.
2. 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.
3. 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.
4. Read result at 10 minutes. Do not read the result after 10 minutes.

With the Flu A Positive Control, the test result should show two distinct colored lines (blue & purple) appear in the strip. In Flu B Positive Control, the test result should show two distinct colored line (red & purple) appear in the strip.

If the controls do not perform as expected, repeat the test or contact Vstrip Technical Support before testing patient specimens.

EXPECTED VALUES

There are two main types of influenza virus: Types A and B. The influenza A and B viruses that routinely spread in people are responsible for seasonal flu epidemics each year. Influenza A viruses can be broken down into sub-types depending on the genes that make up the surface proteins. Over the course of a flu season, different types (A & B) and subtypes (influenza A) of influenza circulate and cause illness.

While seasonal influenza viruses can be detected year-round, flu viruses are most common during the fall and winter. The exact timing and duration of flu seasons can vary, but influenza activity often begins to increase in October. Most of the time flu activity peaks between December and February, although activity can last as late as May.

Anyone can get the flu. Most people who get the flu will have mild illness, will not need medical care or antiviral drugs and will recover in less than two weeks. Some people are more likely to get flu complications that can result in hospitalization and sometimes death. These people include people 65 years and older, people with certain chronic medical conditions (such as asthma, diabetes, or heart disease), pregnant women, and young children.

LIMITATIONS OF THE PROCEDURE

1. The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from the Nasopharyngeal swab.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. Failure to follow the Test Procedure and interpretations of Test Results may adversely affect test performance and/or invalidate the Test Results.
4. Test Results must be evaluated in conjunction with other clinical data available to the physician.
5. Negative test results do not rule out other potential non-influenza viral infections. Negative results should be confirmed by cell culture.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not identify specific influenza A or B virus subtypes.
8. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when the prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
9. Do not use this test within 3 days that Individuals who received nasally administered influenza vaccine, may have false positive results.
10. Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
11. If differentiation of specific influenza A or B subtypes and strains is needed, additional testing, in consultation with the state or local public health department, is required.
12. Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will have lower sensitivity than testing specimens from children.

PERFORMANCE CHARACTERISTICS

The evaluation was conducted comparing the nasopharyngeal swab sample results obtained using Vstrip Flu A&B Rapid Test to FDA-cleared commercial kit.

Influenza A		Commercial kit	
		+	-
Vstrip®	+	36	2
	-	2	92

Influenza A Sensitivity: 94.7%
Influenza A Specificity: 97.9%
Influenza A Accuracy: 97.0%
Positive Predictive Value (PPV): 94.7%
Negative Predictive Value (NPV): 97.9%

Influenza B		Commercial kit	
		+	+
Vstrip®	+	21	0
	-	2	109

Influenza B Sensitivity: 91.3%
Influenza B Specificity: 100.0%
Influenza B Accuracy: 98.5%
Positive Predictive Value (PPV): 100.0%
Negative Predictive Value (NPV): 98.2%

Differences in performance are expected when this test is used on specimens from adults versus from children, but specific differences are not known.

ANALTICAL SENSITIVITY

The limit of detection (LoD) for the Vstrip Flu A&B Rapid Test was established in an analytical sensitivity study performed with influenza A strain and influenza B strain in clinical nasal matrix. The LoD was confirmed by testing total 20 replicates at the target concentration to demonstrate detection at least 95% of the time. The approximate LoD concentrations identified for each strain tested are listed in the table below.

No.	Name	Serotype	Subtype /Lineage	Clinical Matrix	Test
1	A/TW/1121/2017	Flu A	H1N1	$1X10^3$ $TCID_{50}$/mL	$1X10^2$ $TCID_{50}$/mL
2	B/TW/2872/17	Flu B	Vic	$1X10^4$ $TCID_{50}$/mL	$1X10^3$ $TCID_{50}$/mL

$TCID_{50}$/mL = 50% tissue culture infectious dose

Note 1: The data of other influenza A virus subtypes from patient specimens have not been established yet.

Note 2: Clinical Matrix: establish the concentration of virus strains in real clinical nasopharyngeal specimens.

Note 3: Test: The final test virus strain concentration in the sample extract.

Inclusivity

A total of 21 influenza A and B strains were tested in clinical nasal matrix using the Vstrip Flu A&B Rapid Test. All influenza A virus isolates gave positive A and negative B results. All influenza B virus isolates gave negative A and positive B results.

No.	Name	Serotype	Subtype/Lineage	Concentration ($TICD_{50}$/ml)
1	A/TW/344/2019	Flu A	H1N1	$1.7x10^4$
2	A/PR/8/1934	Flu A	H1N1	$1.96x10^4$
3	A/WSN/1933	Flu A	H1N1	$1.58x10^5$
4	A/TW/141/2002	Flu A	H1N1	$1.19x10^5$
5	A/TW/2235/2009	Flu A	H1N1	$5x10^4$
6	A/TW/2651/2010	Flu A	H1N1	$8.89x10^4$
7	A/TW/12/2011	Flu A	H1N1	$1.58x10^5$
8	A/TW/2030/2014	Flu A	H1N1	$1.19x10^4$
9	A/TW/1608/2019	Flu A	H3N2	$1.8x10^4$
10	A/TW/3890/2017	Flu A	H3N2	$3.8x10^4$
11	A/TW/3277/2011	Flu A	H3N2	$8.89x10^4$
12	A/TW/2195/2014	Flu A	H3N2	$6.67x10^3$
13	A/TW/2722/2012	Flu A	H3N2	$8.89x10^3$
14	A/TW/2109/2013	Flu A	H3N2	$2.81x10^4$
15	A/TW/595/2015	Flu A	H3N2	$1.19x10^4$
16	B/TW/2668/2019	Flu B	Yam	$4x10^5$
17	B/TW/1050/2014	Flu B	Vic	$6.67x10^5$
18	B/TW/2578/2014	Flu B	Yam	$6.67x10^5$
19	B/TW/3859/2014	Flu B	Yam	$2.81x10^5$
20	B/TW/2129/2019	Flu B	Vic	$9.2x10^5$
21	B/TW/2092/2017	Flu B	Yam	$4.8x10^5$

$TCID_{50}$/mL = 50% tissue culture infectious dose

CROSS REACTIVITY

The cross reactivity of the Vstrip Flu A&B Rapid Test was evaluated with a total of 15 bacteria, 7 viruses. Bacteria were evaluated at a concentration over 10^7 org/ml. Viruses were evaluated at a concentration of over 10^5 $TCID_{50}$ /mL. None of the microorganisms tested in the following table gave a positive result.

Bacteria (Concentration:org/ml)

No	Name	ATCC	Con.	No	Name	ATCC	Con.
1	*Pseudomonas aeruginosa*	14207	$3X10^7$	9	*Streptococcus Group G*	43492	$6X10^7$
2	*Serratia marcescens*	21074	$6X10^7$	10	*Streptococcus mutans*	25175	$5x10^7$
3	*Staphylococcus aureus*	12715	$7X10^7$	11	*Streptococcus pneumoniae*	6301	$7x10^7$
4	*Staphylococcus epidermidis*	12228	$6X10^7$	12	*Streptococcus sanguis*	49295	$6x10^7$
5	*Streptococcus Group A*	19615	$6X10^7$	13	*Salmonella typhi*	6539	$3x10^7$
6	*Streptococcus Group B*	12386	$6X10^7$	14	*Salmonella enteriditis*	13076	$3x10^7$
7	*Streptococcus Group C*	12388	$6X10^7$	15	*Vibrio cholerae*	14035	$6x10^7$
8	*Streptococcus Group F*	12392	$6X10^7$				

Virus (Concentration: $TCID_{50}$/mL = 50% tissue culture infectious dose)

No	Name	Con.	No	Name	Con.
1	Adeno virus type 7	$2.81x10^7$	5	Herpes simplex virus type 2	$2.8x10^6$
2	Corona virus (HCoV-229E)	6×10^5	6	Human parainfluenza virus Type 2	$1.19x10^6$
3	Echovirus type 11	2.11×10^6	7	Respiratory syncytial virus 2958/14	1×10^5
4	Enterovirus Type 71	$2.11x10^6$			

Reproducibility

An evaluation of the Vstrip Flu A&B Rapid Test was conducted at three laboratories using 144 coded samples. The samples spiked with clinical nasal matrix were performed by training personnel with educational background at three different locations. The study panel contained negative, low positive (with Flu A or B antigen) and moderate positive (with Flu A or B antigen) samples. Each sample level was tested at each site in replicates of 3 days. The results obtained at each site agreed >99% with the expected. The data analyses support the hypothesis that Vstrip Flu A & B Rapid Test is easily reproducible by different operators and can be performed with little to no difficulty.

INTERFERING SUBSTANCES

Nasal spray product and common chemicals were evaluated in clinical nasal matrix, and did not interfere with the Vstrip Flu A&B Rapid Test at the levels tested below.

Interference substances	Concentration	Interference substances	Concentration
Aspirin	20 mg/ml	NASONEX Aqueous Nasal Spray	10%
Dextromethorphan	10 mg/ml	Oxymetazoline HCl	10 mg/ml
Diphenhydramine HCl	5 mg/ml	Phenylephrine HCl	100 mg/ml
Hemoglobin	20 mg/ml	Ponstan	20 mg/ml
Hosoon Troches (ROOT)	20 mg/ml	Swinin nasal sprays	10%
Mucin	4%	Whole blood	5%
Nasal Washing Salt	20 mg/ml	Ibuprofen	20 mg/ml
Nasal Ointment	10%		

STORAGE INSTRUCTION

1. The product should be stored at 15-30℃, away from direct sunlight.
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.

PACKAGING

Vstrip Flu A&B Rapid Test .....20 Tests/Kit

ORDERING INFORMATION

Product No. : IG01020S

REFERENCES

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2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
4. 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	CONTROL +	Positive Control
	Temperature Limit				

PIC/S GMP 藥廠

PBF

Panion & BF Biotech Inc.

16F., No.3, Park St., Nangang Dist., Taipei City 115, Taiwan
Manufactured by: Panion & BF Biotech Inc. Xizhi Factory
Manufacturer Address: 6F.-3, No.306, Sec. 1, Datong Rd., Xizhi Dist., New Taipei City 22146 Taiwan
Technical Support: +886-2-2691-9895
Email: xizhi@pbf.com.tw
www.pbf.com.tw
www.vstriptech.com