RapidFor™

Influenza A/B Rapid Test Kit
Reference Number: VMD17
For professional use

IVD IFU CE

FOR IN VITRO DIAGNOSTIC USE

This instructions for use (IFU) must be read carefully prior to use. Instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

INTENDED USE

RapidFor™ Influenza A/B Rapid Test Kit is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens. The test is intended for healthcare professional use only. Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY

The Influenza infection is an acute feverish virus infection, which principally leads to an illness of the respiratory tract and appears as an epidemic or pandemic. The infection mostly results from a droplet infection. The virus spreads from the mucous membrane of the upper respiratory to the whole bronchial tract. There the virus and its toxin can lead to a serious inflammation of the bronchial mucosa and a damage of the vessels. The Types A, B and C were defined, from which many other variants are known. The distinction of the types will be possible by the different antigenicity of their nucleoproteins, which are coated by a matrix protein with type-specific antigenicity. The determination of the Influenza type (A, B or C) gives both the clinician and epidemiologist important indications for further actions. Influenza A often leads to a serious clinical course and an epidemic spread of the virus. Similarly, during Influenza A epidemic, the epidemiological importance and derived measures for the protection of the individual and population primarily stand in the foreground together with the severity of the clinical symptoms. Influenza B often leads to chills and fever. Body temperature be rise to 39~40°C in a few hours to 24 hours. In human, influenza B viruses evolve slower than A viruses and faster than C viruses. Influenza virus B mutates at a rate 2 to 3 times lower than type A. However, influenza B mutates enough that lasting immunity is not possible. It cannot course an epidemic spread of the virus.

PRINCIPLE OF THE PROCEDURE

The RapidFor™ Influenza A/B Rapid Test Kit is a colloidal gold enhanced immunoassay for the determination of influenza A and B virus in human swab sample. Anti-flu A antibody and Anti-flu B antibody are immobilized in the test region on nitrocellulose membrane. During the assay specimen is allowed to react with the colored conjugate (anti-flu A antibody and/or Anti-flu B antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. An flu A and/or flu B positive specimen produces a distinct color band in the test region, formed by the specific antibody antigen colored conjugate complex. Absence of this colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the test result.

REAGENTS AND MATERIALS SUPPLIED

CAT No	VMD17-SC01	VMD17-SC05	VMD17-SC25
COMPONENT	**1 Test/box**	**5 Test/box**	**25 Test/box**
Test Device	1 Test cassettes (1 Test/pouch x 1 pouch)	5 Test cassettes (1 Test/pouch x 5 pouches)	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer	1 single-use sealed tube with 500 µL extraction solution	5 single-use sealed tube with 500 µL extraction solution	25 single-use sealed tube with 500 µL extraction solution
Specimen Sampling swab	1 single-use, sterile nasopharyngeal swab	5 single-use, sterile nasopharyngeal swabs	25 single-use, sterile nasopharyngeal swabs
Dropper	1 single-use dropper	5 single-use droppers	25 single-use droppers
Packing Insert	1 instruction for use	1 instruction for use	1 instruction for use

STORAGE AND STABILITY

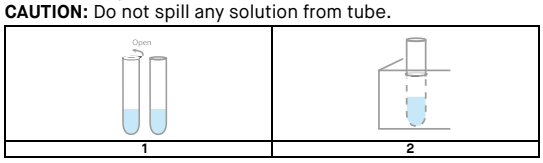
1.Store the test kit at 2°C - 30°C and 40-60% humidity. Do not store or freeze the kit below 2°C.
2.All components must be brought to room temperature before testing.
3.The test cassette must be used within 15 minutes after removal from the foil pouch.
4.The kit must not be used after the expiry date. The expiry date is stated on the label/packaging.

WARNINGS AND PRECAUTIONS

1.For in vitro diagnostic use only. Do not reuse the test device.
2.The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3.All positive results must be confirmed by an alternate method.
4.Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
5.Devices used for testing should be autoclaved before disposal.
6.Do not use kit materials beyond their expiration dates.
7.Do not interchange reagents from one kit lot to another.
8.Wear gloves during the entire testing process.
9.Do not pipette by mouth.
10.Do not eat or smoke while handling specimens.
11.Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant.
12.Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials as if they were infectious wastes, in a biohazard container.

TEST PROCEDURE

CAUTION: Read the instructions for use carefully before testing and carry out the following instructions as described.
CAUTION: Make sure that the test components are at room temperature when used.
The test procedure includes the following steps: sample collection, sample processing and test performance.
Before the Test:
1. Carefully open the sealed tube which include the extraction solution.
2.Place the open sealed tube to the holder.
CAUTION: Do not spill any solution from tube.



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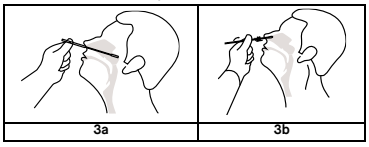
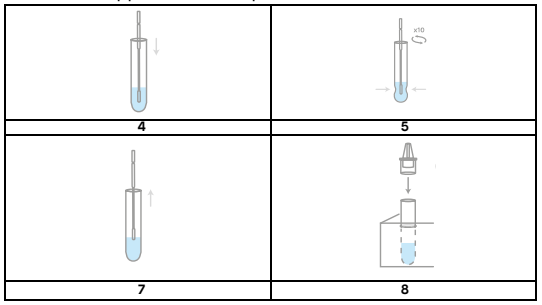
Sample Collection:
CAUTION: The sample collection procedure differs between the individual swab samples. Please perform only one of the indicated swab samples (3a – 3b).
3a. Nasopharyngeal swab: Ask the patient to place the head slightly in the neck. Then slowly insert the sterile swab headfirst trans nasally into the nasopharynx until you feel a slight resistance. Turn the swab 3 times close to the inner wall of the nasal cavity and carefully remove the swab from the nose. Avoid contact with the nasal mucosa when inserting and removing.
or 3b. Anterior nasal swab: Insert the sterile swab into the anterior nasal section and rotate the swab 3 times along the inner wall of the nasal cavity. Then remove the swab.


3a 3b

Sample Processing:
4.Insert the used swab with the swab headfirst into the extraction tube.
5.Rotate the swab in the extraction buffer 10 times along the inner wall of the extraction tube. Then push the swab head out along the inner wall to ensure that the sample on the swab is completely eluted into the buffer.
6.Squeeze the swab head along the inner wall to ensure that the sample is completely eluted from the swab.
7.Take off the swab from the extraction buffer.
8.Put the dropper to the sample-extraction solution mixture.



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Test Operation
9.Take the required reagents and test cassette to equilibrate to room temperature.
CAUTION: Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 15 minutes.
10.Unpack the aluminum foil bag and remove the test cassette.
11. Add 3 drops from the extraction tube with the processed sample into the sample well and start a timer.


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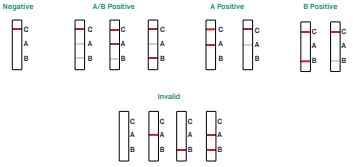
12.Read the test result after 15 minutes. After 20 minutes, the test result is no longer valid, and the test must be repeated.
13.Dispose of all samples and materials used in the test as biohazardous waste. Laboratory chemicals and biohazardous waste must be disposed of in accordance with local regulations.

INTERPRETATION OF TEST RESULTS

Positive: Both purplish test band and purplish control band appear on the membrane.
Negative: Only the purplish control band appears on the membrane. The absence of a test band indicates a negative result.
Invalid: There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test card.



PERFORMANCE CHARACTERIST

1.Clinical result
The Influenza A/B Rapid Test Kit have tested with positive and negative clinical samples tested by a leading commercial test. The result shows that the Influenza A/B Rapid Test Kit is very accurate to commercial kit.

Influenza A:

Influenza A/B Rapid Test	RT-PCR comparative test result		
	Positive (+)	Negative (-)	Total
Positive	152	2	154
Negative	4	373	377
Total	156	375	531
Sensitivity: 152/156 x 100% = 97.44%, (95% CI: 93.57-99.30)			
Specificity: 373/375 x 100% = 99.47%, (95% CI:98.09-99.94)			
Accuracy: 525/531 x 100% = 98.87%, (95% CI: 97.56-99.58)			

Influenza B:

Influenza A/B Rapid Test	RT-PCR comparative test result		
	Positive (+)	Negative (-)	Total
Positive	160	3	163
Negative	5	376	381
Total	165	379	544
Sensitivity: 160/165 x 100% = 96.97%, (95% CI: 93.07-99.01)			
Specificity: 376/379 x100% = 99.21%, (95% CI: 97.70-99.84)			
Accuracy: 536/544 x 100% = 98.53% (95% CI: 97.12-99.36)			

2. Limit of Detection (LOD):
The analytical sensitivity (limit of detection or LOD) of the test was determined using quantified ($TCID_{50}$/mL) cultures of three influenza A strains and two influenza B strains, serially diluted in negative nasopharyngeal matrix. Each dilution was run as 20 replicates in the test. Analytical sensitivity (LOD) is defined as the lowest concentration at which at least 95% of all replicates tested positive. The demonstrated LOD for each strain tested is shown below:

Influenza Type	Strain	TCID $_{50}$/mL
A	A/California/7/2009 (H1N1)	2.4×10^2
A	A/Victoria/361/11(H3N2)	4.0×10^2
A	A/Wisconsin/588/2019 (H1N1pdm09)	2.0×10^2
A	A/Victoria/2570/2019 (H1N1pdm09)	4.0×10^2
A	A/Darwin/9/2021 (H3N2)	3.5×10^2
A	A/Darwin/6/2021 (H3N2)	3.5×10^2
B	B/Austria/1359417/2021	8.0×10^2
B	B/Phuket/3073/2013	5.0×10^2

3. Cross-reactivity:
The potential cross-reactivity of the respiratory pathogens and other microorganisms with which the majority of the population may be infected was tested using the Influenza A/B Rapid Test Kit t at medically relevant levels, bacteria and viruses are given in the following tables. None of the organisms or viruses listed in the table below gave a positive result with the Test at the tested concentration.

Viruses Tested

Virus Type	Concentration
Adenovirus Type 3	1.0 x10^5 $TCID_{50}$/mL
Adenovirus Type 5	1.8 x10^5 $TCID_{50}$/mL
Adenovirus Type 7	1.8 x10^5 $TCID_{50}$/mL
Human Parainfluenza Type 1	1.8 x10^5 $TCID_{50}$/mL
Human Parainfluenza Type 2	4.3 x10^5 $TCID_{50}$/mL
Human Parainfluenza Type 3	1.6 x10^5 $TCID_{50}$/mL
Human Parainfluenza Type 4	1.3 x10^5 $TCID_{50}$/mL
Human coronavirus OC43	1.8 x10^5 $TCID_{50}$/mL
Human coronavirus NL63	1.8 x10^5 $TCID_{50}$/mL
Human coronavirus 229E	2.5 x10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type A	1.2 x10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type B	2.4 x10^5 $TCID_{50}$/mL
Rhinovirus Type 1	1.0 x10^5 $TCID_{50}$/mL
Rhinovirus Type 14	1.0 x10^5 $TCID_{50}$/mL
Rhinovirus B70	1.0 x10^5 $TCID_{50}$/mL
Enterovirus CA16	1.0 x10^5 $TCID_{50}$/mL
Enterovirus 70	3.1 x10^5 $TCID_{50}$/mL
Avian influenza virus H7N9	1.0 x10^5 $TCID_{50}$/mL
Avian influenza virus H5N1	1.0 x10^5 $TCID_{50}$/mL
Human para-flu virus Type 1	1.0 x10^5 $TCID_{50}$/mL
Human para-flu virus Type 2	1.0 x10^5 $TCID_{50}$/mL
Human para-flu virus Type 3	1.0 x10^5 $TCID_{50}$/mL
Human para-flu virus Type 4	1.0 x10^5 $TCID_{50}$/mL
Cytomegalovirus	1.0 x10^5 $TCID_{50}$/mL
Measles virus	1.8 x10^5 $TCID_{50}$/mL
Boca virus	1.0 x10^5 $TCID_{50}$/mL
Mumps virus	3.2 x10^5 $TCID_{50}$/mL
Epstein Barr Virus	1.0 x10^7 $TCID_{50}$/mL
Herpes simplex virus (HSV-1)	1.0 x10^5 $TCID_{50}$/mL
Varicella-zoster virus	1.0 x10^5 $TCID_{50}$/mL
Human metapneumovirus	2.4 x10^5 $TCID_{50}$/mL
MERS coronavirus	8.9 x10^5 $TCID_{50}$/mL
SARS-coronavirus	2.5 x10^5 PFU/mL
Human coronavirus (HKU1)	10^6 $TCID_{50}$/mL (In-silico)

Bacteria Tested

Bacteria Type	Concentration
Bordetella pertussis	5.8 ×10^6 CFU/mL
Bordetella parapertussia	1.0 ×10^5 CFU/mL
Staphylococcus epidermidis	1.2 ×10^7 CFU/mL
Staphylococcus aureus	3.0 ×10^6 CFU/mL
Staphylococcus pneumoniae	1.0 ×10^5 CFU/mL
Streptococcus pyogenes	1.6 ×10^6 CFU/mL
Streptococcus pneumoniae	1.8 ×10^6 CFU/mL
Streptococcus salivarus	1.0 ×10^5 CFU/mL
Escherichia coli	1.0 ×10^5 CFU/mL
Candida albicans	1.3 ×10^6 CFU/mL
Mycobacterium tuberculosis	10^6 CFU/mL (In-silico)
Paramyxovirus parotitis	1.0 x10^5 $TCID_{50}$/mL
Pneumocystis jirovecii	10^6 CFU/mL (In-silico)
Moraxella catarrhalis	1.0 ×10^5 CFU/mL
Pseudomonas aeruginosa	1.0 ×10^5 CFU/mL
Pneumocystis	1.0 ×10^5 CFU/mL
Legionella pneumophila	2.0 ×10^6 CFU/mL
Corynebacterium pneumophila	1.0 ×10^5 CFU/mL
Lactobacillus pneumophila	1.0 ×10^5 CFU/mL
Klebsiella pneumoniae	1.0 ×10^5 CFU/mL
Mycoplasma pneumoniae	1.3 ×10^7 CFU/mL
Chlamydia pneumoniae	1.0 x10^5 $TCID_{50}$/mL
Neisseria pneumophila	1.0 ×10^5 CFU/mL
Neisseria meningitides	1.0 ×10^5 CFU/mL
Haemophilus influenza	2.7 ×10^6 CFU/mL

4. Interference:
The performance of Influenza A/B Rapid Test was evaluated with potentially interfering substances that may be present in nasopharyngeal specimens. The potentially interfering substances were evaluated with influenza A (A/Taiwan/42/06) and influenza B (B/Taiwan/2/62) at concentrations of 2x LOD. There was no evidence of interference caused by the substances tested at the concentrations shown below.

Substances	Concentration
Whole Blood	4%
Mucin	1 mg/ml
Benzocaine	5 mg/ml
Menthol	10 mg/ml
Zanamivir	5 mg/ml
Mupirocin	1 mg/ml
Tobramycin	1 mg/ml
Fluticasone	1 mg/ml
Beclomethasone	1 mg/ml
Dexamethasone	5 mg/ml
Flunisolide	1 mg/ml
Triamcinolone	10 mg/ml
Mometasone	1 mg/ml
Sodium Chloride with preservative	20%
Phenylephrine	10 mg/ml
Afrin (Oxymetazoline)	10 mg/ml
Ibuprofen	1 mg/ml
Tetracycline	3 µg/ml
Chloramphenicol	3 µg/ml
Erythromycin	3 µg/ml
Arbidol	5 mg/ml
Ribavirin	5 mg/ml
Histamine dihydrochloride	10 mg/ml
Throat spray (Menthol)	15%
Mupirocine	10 mg/ml
Ice throat candy (Menthol)	1.5 mg/ml
Tamiflu (Oseltamivir)	10 mg/ml
Naphthoxoline hydrochloride nasal drops	15%
Fisherman's Friend	1.5 mg/ml
Cromoglycate	15%
Sinex (Phenylephrine Hydrochloride)	15%
Fluticasone propionate spray	15%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/ml
Naso Gel (NeilMed)	5%
CVS Nasal Spray (Cromolyn)	15%
Saline Nasal Spray	15%
Zicam Cold Remedy	5%
Homeopathic (Alkalol)	10%
Sodium Cromolyn Eye Drops	15%
Alkalol Nasal Wash	10%
Throat Lozenge	1.5 mg/ml
Sore throat phenol throat spray	15%

5) Hook Effect
For Influenza A:
The highest concentration without Hook Effect was 2.5 x 10^7 $TCID_{50}$/mL.

For Influenza B:
The highest concentration without Hook Effect was 2.0 x 10^7 $TCID_{50}$/mL.

LIMITATIONS
1.The result of the product must not be considered as a confirmed diagnosis. The evaluation of the test results must be done together with RT-PCR results, clinical symptoms, epidemiological information, and further clinical data.
2.The contents of this kit are to be used for the qualitative detection of influenza A and influenza B antigens from nasopharyngeal and nasal swabs. Other specimen types may not be used.
3.The Influenza A/B Rapid Antigen Test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes
4.Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
5.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
6.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7.React less than 10 minutes may lead a false negative result; React more than 20 minutes may lead a false positive result.
8.Individuals who received nasally administered influenza A vaccine may produce positive test results for up to three days after vaccination.
9. This test cannot rule out diseases caused by other bacterial or viral pathogens.
10. Performance of the Test has not been established for monitoring antiviral treatment of influenza.

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SYMBOLS USED

COMPONENT	Materials Included	TUBE	Tube
TEST CARD	Test Card	IFU	Instruction for Use
	Consult Instructions for Use		Expiration Date
2°C 30°C 36°F 86°F	Store at 2℃ ~ 30℃		Manufacturer
	Keep Dry		Date of Manufacture
LOT	Lot Number		Do Not Reuse
DILUENT	Sample Diluent	REF	Reference Number
	Keep away from sunlight	Σ	Tests per Kit
IVD	In Vitro Diagnostic Device		Do not use if the package is damaged
90% 40%	Store at 40-60% humidity	SWAB	Swab
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device		

Vitrosens Biyoteknoloji A.Ş.
Address: Şerifali Mah., Şehit Sokak, No:17/A, 34775, Ümraniye/İstanbul
Telephone:0(216) 784 41 01
E-mail : info@vitrosens.com
Web: www.vitrosens.com

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