Influenza A/B Rapid Test Device (Nasal/NP Swab and Nasal Washes/Aspirate)

FLU-S23

INTENDED USE

The Influenza A/B Rapid Test is an *in vitro* immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal/nasopharyngeal swabs and nasal washes/aspirates of humans. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. The test is not intended for the detection of influenza C viral antigens. Negative results do not preclude influenza A or B viral infections and should be confirmed via cell culture or molecular assay. The test is for professional use only.

INTRODUCTION

Influenza is a highly contagious, acute, epidemic to pandemic viral respiratory infection caused by three genera of the Orthomyxoviridaefamily[1]. Influenza virus can be distinguished into influenza virus A, B and C on the basis of antigenic differences between their nucleoprotein and matrix proteins. For types A and B, the antigenic variation of hemagglutinin and neuraminidase is responsible for the emergence of new strains, while type C is antigenically stable[1].Type A influenza viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B influenza infections are usually milder[2]. Influenza due to type C species is rare compared to types A or B[3].

Diagnostic tests of influenza available include rapid immunoassay, immunofluorescence assay, polymerase chain reaction (PCR), serology and viral culture. Immunofluorescence assays require staining of specimens immobilized on microscope slides using fluorescent-labeled antibodies for observation by fluorescence microscopy[4]. PCR can only be performed in well equipped laboratory facilities by trained personnel. Serological tests necessitate acute, convalescent blood specimens, and the diagnosis is only retrospective[5]. As the gold standard, traditional culture which employs virus isolation is time-consuming and requires considerable technical expertise[6].

Rapid immunoassay of influenza A and B has become more important due to the availability of effective antiviral therapy. Rapid diagnosis of influenza can lead to reduced hospital stays, antimicrobial use and cost of hospital care[7]. The Influenza A/B Rapid Test is a lateral flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza nucleoprotein antigens. The test is specific to influenza A and B antigens with no known cross-reactivity to normal flora or other respiratory pathogens.

PRINCIPLE

The Influenza A/B Rapid Test detects influenza A and B viral antigens through visual interpretation of color development. Anti-influenza A and B antibodies to the nucleoprotein antigens are immobilized on the test region A and B of the nitrocellulose membrane, respectively. A wash/aspirate or swab sample is added to the sample diluent buffer which is optimized to extract the influenza A or B nucleoprotein antigens from specimen. During testing, the extracted antigens bind to anti-influenza A and B antibodies conjugated to colored particles on the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by either anti-influenza A or anti-influenza B nucleoprotein monoclonal antibodies at the respective detection zone. Excess colored particles are captured at the internal control zone.

The presence of a red band in the A and/or B region indicates a positive result for the particular viral antigens, while its absence indicates a negative result. A red band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- **Test Device:** Each foil pouched device has two distinct test lines of monoclonal antibodies specific to influenza A and B viral antigens respectively, and a control line of anti-species antibody.
- **FLU Assay Buffer:** Detergent, tris, sodium chloride, blocking reagent and 0.1% sodium azide as preservative.
- **Extraction Tube:** Tubes for sample processing and sample delivery into devices.
- **Nozzle with Filter:** Tube tips to filter sample when delivered into devices.
- **Swab:** Swabs for sample collection.
- **Tube Stand:** Stand to support tubes in a stable upright position.
- **Package insert**

Materials Required but Not provided

- Clock, timer or stopwatch
- Transfer pipette

PRECAUTIONS

- For *in vitro* Diagnostic Use Only.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Sample Diluent Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Influenza virus antigens are relatively unstable. Care should be taken to store specimens as indicated in the document (refer to SPECIMEN COLLECTION AND STORAGE).
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin contact with all components containing sodium azide which is a skin irritant.
- 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[8].

STORAGE AND STABILITY

- Store the Influenza A/B Test Kit at 2~30℃when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

SPECIMEN COLLECTION AND STORAGE

Specimen Collection:

Acceptable specimens for testing with the Influenza A/B Rapid Test Kit include samples from nasal/nasopharyngeal swabs, nasal washes/aspirates. Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.Use freshly collected specimens for best test performance. Rapid tests will have more reliable clinical performance when performed early in the course of infection[9].

To ensure optimal performance, use the swabs supplied in the kit. Alternatively, sterile nylon, foam or rayon nasal swabs can be used for specimen collection. Do not use calcium alginate swabs.

- **Nasal Swab**

Insert the swab into the nostril that exhibits the most visible drainage, if secretion is not visible, into the nostril that is most congested. Gently push the swab until resistance is met at the level of turbinates (less than one inch into the nostril), rotate the swab a few times against nasal wall. Slowly withdraw the swab while continuing with a rotating motion.

Note: In patients whose nasal cavity is dry, wet the swab with a sterilized physiological saline solution (not supplied in the kit) in advance and then collect a sample with it.

- **Nasopharyngeal Swab**

Insert the swab carefully 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 several times.

- **Nasal Wash**

With the patient's head hyper-extended, instill sterile, normal saline into one nostril with a syringe. Use the minimal amount of saline that your procedure allows, as excessive volume will dilute the antigen in the specimen. To collect the nasal wash, place a clean, dry specimen container directly under the nose with slight pressure on the upper lip. Tilt the head forward allowing the fluid to run out of the nostril into the specimen container. Repeat for the other nostril and collect the wash into the same specimen container.

Note: The normal saline, syringe and specimen container is not supplier in the kit.

- **Nasal Aspirate**

Insert one aspirating tube with a trap up to the depth of the nasal cavity. Connect another tube to the aspiration device making it a negative pressure. Aspirate a nasal fluid to the trap. Soak the nasal aspirate obtained to a sterile swab.

Note: The aspirating device is not supplied in the kit.

For nasal wash/aspirate, sample volumes of 1~3 ml are recommended. If transport medium is used, minimal dilution of specimens (1 ml) is recommended.

Specimen Transport and Storage:

Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test:

Brain Heart Infusion Broth	Hank's Balanced Salt Solution
M5 Media	Saline or Phosphate Buffer Solution

Alternatively, samples may be stored at refrigerated (2~8℃), or at room temperature (15~30℃), in a clean, dry, closed container for up to 8 hours prior to testing. Nasal wash or aspirate specimens may also be stored frozen (-70℃ or colder) for up to one month.

TEST PROCEDURE

Bring devices, reagents and specimens and/or controls to room temperature (15~30℃) before use.

1. For each specimen swab, open the foil pouch just before testing and remove the test device, and put it on a clean, level surface. Label the tube with the patient identification. For best results, the assay should be performed within one hour.
2. Gently mix sample diluent buffer. Add 8 drops into the extraction tube.
3. **For Nasal/ Nasopharyngeal Swabs**
   a. Insert the swab into the extraction tube. Mix well and squeeze the swab several times by compressing the walls of the tube against the swab.
   b. Roll the swab head against the inside of the tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

   For Nasal Wash/Aspirate Specimens
   a. Vortex or thoroughly mix specimen. Do not centrifuge, as the removal of cellular material may adversely affect test sensitivity.
   b. Transfer 300 uL of specimen into the extraction tube using transfer pipette.
4. Insert filtered nozzle into sample extraction tube. Invert the tube and add 2 drops (approximately 100uL) of test sample into the sample well by gently squeezing the tube.
5. Read results at 15 minutes and disregard after 30 minutes. Do not handle or move the test device until the 15 minutes are up. Do not interpret the result after 20 minutes.

RESULT INTERPRETATION

Influenza A Positive: One red band appears in the control region (C), and another red band in the A region (A).

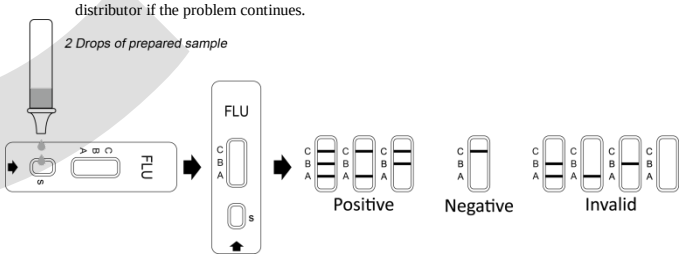
Influenza B Positive: One red band appears in the control region (C), and another red band in the B region (B).

Influenza A+B Positive: One red band appears in the control region (C), and two other red bands appear in both A region (A) and B region (B).

Note: Co-infection with influenza A and B is very rare. A clinical specimen that generates positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.

Negative: Only one red band appears in the control region (C), and no band appears either in the A region (A) or B region (B).

Invalid: No red band appears in the control region (C), whether a test band(s) is present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues.



REPORTING RESULTS

Positive for Influenza A and/or B: Positive for Influenza A and/or B virus antigen. The result does not identify a specific Influenza A or B virus subtype or rule out co-infections with other pathogens.

Negative: Negative for Influenza A and B virus antigens. Infection due to influenza A or B cannot be ruled out, as the virus antigen in the specimen may be below the detection limit of the test. Virus culture or molecular assay is recommended.

Invalid: Test result is inconclusive. Do not report results. Collect another specimen and repeat the test.

QUALITY CONTROL

Internal Procedural Controls

The Influenza A/B Rapid Test Device has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the RED color located at the "C" line is present before reading the result.

External Positive and Negative Controls

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

LIMITATIONS OF THE TEST

1. The Influenza A/B Rapid Test Kit is for professional in vitro diagnostic use, and should only be used for the qualitative detection of influenza A and/or B. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Additional testing is required to differentiate any specific influenza A and B subtypes or strains, in consultation with state or local public health departments.
3. Both viable and nonviable influenza A and B viruses are detectable with the Influenza A/B Rapid Test Kit.
4. The performance characteristics of the Influenza A/B Rapid Test have not been established for use in monitoring antiviral treatment or for cell culture identification methods.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
6. Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that

have undergone minor amino acid changes in the target epitope region.

7. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
8. Individuals who received nasally administered influenza A vaccine may have positive test results for up to three days after vaccination.
9. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
10. The etiology of respiratory infection caused by microorganisms other than influenza A or B virus will not be established with this test.
11. Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will often yield lower sensitivity than testing specimens from children.
12. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
13. A high dose "hook effect" may occur where the color intensity of test band decreases as the concentration of antigen increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the test band.

PERFORMANCE CHARACTERISTICS

Specimen Correlations

Of the 280 total nasal swabs from influenza A viral infection patients, 108 were found to be positive by cell culture and 172 were found to be negative by cell culture. These swabs were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 1.

Table 1: Nasal Swab Specimen Correlation Summary of Influenza A

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza A+	96	9	105
	Influenza A-	12	163	175
	Total	108	172	280

Positive agreement with Cell Culture: 96/108=88.9%
Negative agreement with Cell Culture: 163/172=94.8%
Total agreement with Cell Culture: (96+163)/280=92.5%

Of the 280 total nasal swabs from influenza B viral infection patients, 89 were found to be positive by cell culture and 191 were found to be positive by cell culture. These swabs were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 2.

Table 2: Nasal Swab Specimen Correlation Summary of Influenza B

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza B+	73	7	80
	Influenza B-	16	184	200
	Total	89	191	280

Positive agreement with Cell Culture: 73/89=82.0%
Negative agreement with Cell Culture: 184/191=96.3%
Total agreement with Cell Culture: (73+184)/280=91.8%

Of the 190 total nasopharyngeal swabs from influenza A viral infection patients,78 were found to be positive by cell culture and 112 were found to be positive by cell culture. These swabs were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 3.

Table 3: Nasopharyngeal Swab Specimen Correlation Summary of Influenza A

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza A+	65	9	74
	Influenza A-	13	103	116
	Total	78	112	190

Positive agreement with Cell Culture: 65/78=83.3%
Negative agreement with Cell Culture: 103/112=92.0%
Total agreement with Cell Culture: (65+103)/190=88.4%

Of the 190 total nasopharyngeal swabs from influenza B viral infection patients,85 were found to be positive by cell culture and 105 were found to be positive by cell culture. These swabs were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 4.

Table 4: Nasopharyngeal Swab Specimen Correlation Summary of Influenza B

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza B+	70	6	76
	Influenza B-	15	99	114
	Total	85	105	190

Positive agreement with Cell Culture: 70/85=82.4%
Negative agreement with Cell Culture: 99/105=94.3%
Total agreement with Cell Culture: (70+99)/190=88.9%

Of the 300 total nasal washes from influenza A viral infection patients,113 were found to be positive by cell culture and 187 were found to be positive by cell culture. These washes were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 5.

Table 5: Nasal Wash Specimen Correlation Summary of Influenza A

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza A+	96	8	104
	Influenza A-	17	179	196
	Total	113	187	300

Positive agreement with Cell Culture: 96/113=85.0%
Negative agreement with Cell Culture: 179/187=95.7%
Total agreement with Cell Culture: (96+179)/300=91.7%

Of the 300 total nasal washes from influenza B viral infection patients, 94 were found to be positive by cell culture and 206 were found to be positive by cell culture. These washes were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 6.

Table 6: Nasal Aspirate Specimen Correlation Summary of Influenza B

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza B+	82	9	91
	Influenza B-	12	197	209
	Total	94	206	300

Positive agreement with Cell Culture: 82/94=87.2%
Negative agreement with Cell Culture: 197/206=95.6%
Total agreement with Cell Culture: (82+197)/300=93.0%

Of the 180 total nasal aspirates from influenza A viral infection patients, 71 were found to be positive by cell culture and 109 were found to be positive by cell culture. These washes were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 7.

Table 7: Nasal Aspirate Specimen Correlation Summary of Influenza A

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza B+	59	5	64
	Influenza B-	12	104	156
	Total	71	109	180

Positive agreement with Cell Culture: 59/71=83.1%
Negative agreement with Cell Culture: 104/109=95.4%
Total agreement with Cell Culture: (59+104)/180=90.6%

Of the 180 total nasal aspirates from influenza B viral infection patients, 71 were found to be positive by cell culture and 109 were found to be positive by cell culture. These washes were tested with the Influenza A/B Rapid Test Device. The results are shown in Table 8.

Table 8: Nasal Wash Specimen Correlation Summary of Influenza B

		Cell Culture +	Cell Culture -	Total
Influenza A/B Rapid Test	Influenza B+	41	5	46
	Influenza B-	7	127	134
	Total	48	132	180

Positive agreement with Cell Culture: 41/48=85.4%
Negative agreement with Cell Culture: 127/132=96.2%
Total agreement with Cell Culture: (41+127)/180=93.3%

Analytical Sensitivity/LOD

The limit of detection (LOD) was identified by evaluating different concentrations of one subtype of influenza A virus and one strain of influenza B virus in the Influenza A/B Rapid Test. Multiple operators tested each concentration of the two influenza strains for multiple times. The concentrations identified as the LOD levels for each strain tested are listed below.

Influenza A: A2/Aichi/2/68(H3N2), 2.3×10^3 *$CEID_{50}$/test
Influenza B: Hong Kong 5/72, $3.5\times10^3 CEID_{50}$/test
*$CEID_{50}$: Chicken Embryo Infectious Dose

Analytical Reactivity

The influenza A and B strains listed below showed positive reaction in the Influenza A/B Rapid Test.30 strains of human, avian or animal-derived influenza A virus had been tested. Although the specific influenza strains causing infection in humans can vary year to year, they all contain the conserved nucleoproteins targeted by the Influenza A/B Rapid Test.

Influenza Virus Strain	
A/Narita/1/2009（H1N1）	A/Chicken/Yamaguchi/7/04 (H5N1)
A/NWS/33 10（H1N1）	A/Chicken/Italy/99 (H7N1)
A/Hong Kong/8/68（H3N2）	A/Chicken/Netherlands/03 (H7N7)
A2/Aichi/2/68(H3N2)	A/Swine/Hokkaido/2/81 (H1N1)
A/WS/33（H1N1）	A/Duck/Tottori/723/80 (H1N1)
A/New Jersey/8/76（HswN1）	A/Duck/Hokkaido/17/01 (H2N3)
A/Mal/302/54（H1N1）	A/Duck/Mongolia/4/03 (H3N8)
A/Anhui/1/2013 (H7N9)	A/Duck/Czech/56 (H4N6)
A/Shanghai/1/2013 (H7N9)	A/Duck/Pennsylvania/10128/84 (H5N2)
A/Hong Kong/156/97（H5N1）	A/Turkey/Massachusetts/3740/65 (H6N2)
A/Hong Kong/483/97（H5N1）	A/Seal/Massachusetts/1/80 (H7N7)
A/Duck/Mongolia/119/2008 (H7N9)	B/Hong Kong 5/72
A/Duck/Mongolia/128/2008 (H7N9)	B/R5
A/Duck/Mongolia/147/2008 (H7N9)	B/Russia/69
A/Duck/Mongolia/129/2008 (H7N9)	B/Lee/40

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of the Influenza A/B Test, 69 commensal or pathogenic microorganisms (24 viruses, 45bacteria) that may be present in the upper respiratory tract were tested. Positive and negative specimens were spiked with these microbes. Bacterial or yeast isolates were evaluated at a concentration of 10^7~ 10^8 org/ml. Viral isolates were inoculated at a concentration of 10^4~10^8 $TCID_{50}$/ml. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/ml. None of the microorganisms tested yielded a positive result with the influenza-negative samples or interfered with detection of the influenza A or B positive samples. Both the negative and positive respiratory specimens were positive when spiked with influenza A strain A2/Aichi/2/68(H3N2)or influenza B strain Hong Kong 5/72.

Virus other than Influenza A/B viruses

Human adenovirus B, C	Adenovirus type 10, 18	Human coronavirus OC43
Coxsackievirus A9, B5	Human herpesvirus 2, 5	Echovirus 2, 3, 6
Herpes simplex virus 1	Human rhinovirus 2, 14, 16	Measles
Mumps	Sendai virus	Parainfluenza virus 2, 3
Respiratory syncytial virus	Rubella	Varicella-Zoster

Bacteria

Acinetobactercalcoaceticus	*Bacteroidesfragilis*	*Bordetella pertussis*
Bacillus cereus	*Bacillus subtilis*	*Bordetellaparapertussis*
Branhamellacatarrhalis	*Chlamydia pneumoniae*	*Corynebacterium diphtheria*
Citrobacterfreundii	*Enterobacter cloacae*	*Enterococcus faecalis*
Escherichia coli	*Gardnerellavaginails*	*Haemophilusinfluenzae*
Klebsiellaoxytoca	*Klebsiellapneumoniae*	*Lactobacillus casei*
Lactobacillus plantarum	*Legionella pneumophila*	*Listeria monocytogenes*
Moraxella catarrhalis	*Mycobacterium avium*	*Mycobacterium intracellulare*
Mycobacterium tuberculosis	*Mycoplasma pneumoniae*	*Neisseria meningitides*
Neisseria sicca	*Neisseria subflava*	*Nocardia asteroids*
Proteus vulgaris	*Pseudomonas aeruginosa*	*Serratialiquifaciens*
Staphylococcus aureus	*Staphylococcus epidermidis*	*Streptococcus Groups A, B, C, F, G*
Streptococcus mutants	*Streptococcus pneumoniae*	*Streptococcus salivaris*
Streptococcus sanguis	*Yersinia enterocolitica*	

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal or nasopharynx cavity, were evaluated at the concentrations listed below. None of them were found to affect test performance of the Influenza A/B Rapid Test Kit.

Substance	Concentration	Substance	Concentration
3 OTC nasal sprays	10%	Guaiacol glycerol ether	20 mg/ml
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Mupirocin	250 μg/ml
4-acetamidophenol	10 mg/ml	Oxymetazoline	10 mg/ml
Acetylsalicylic acid	20 mg/ml	Phenylephrine	10 mg/ml
Albuterol	20 mg/ml	Phenylpropanolamine	20 mg/ml
Chlorpheniramine	5 mg/ml	Relenza ® (zanamivir)	20 mg/ml
Dexamethasone	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu ® (oseltamivir)	100 mg/ml
Diphenhydramine	5 mg/ml	Tobramycin	40 mg/ml
Doxylamine succinate	1 mg/ml	Triamcinolone	14 mg/ml
Flunisolide	3 mg/ml		

Reproducibility Study

A blind study of the Influenza A/B Rapid Test was conducted at three separate clinical sites. Panels of blind-coded specimens containing negative, high-negative, low positive (at the LOD), and moderate positive (above the LOD) influenza A and B viral samples were used by three non-professional users per site to evaluate the reproducibility of Influenza A/B Rapid Test. Participants tested each sample multiple times on three different days. 96% of the samples tested produced the expected result.

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		