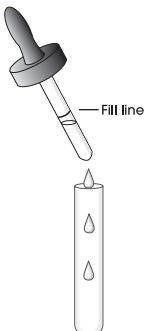
osom® Influenza A&B Test

QC inside®

1

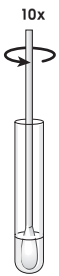


Add Extraction Buffer
Fill the dropper to the line marked on the barrel and expel entire contents into tube.

2

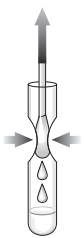
Add Swab in Buffer
Add swab to the tube with the extraction buffer.

3



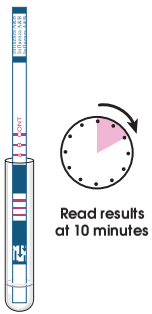
Mix
Vigorously rotate and twist the swab against the side of the tube at least 10 times.

4



Squeeze Liquid From Swab
Squeeze the sides of the tube to express as much liquid as possible. Dispose of swab properly.

5



Add Test Stick
Place test stick (arrows pointing downward) into the tube with buffer. Read results at 10 minutes.

SEKISUI DIAGNOSTICS

Rev. 3088-2, 12/12

Reading Test Results

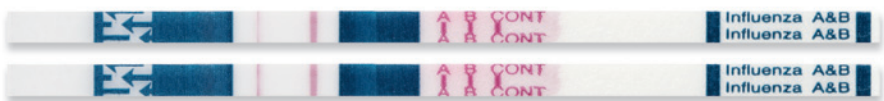
POSITIVE RESULTS

NOTE: A pink-to-purple line of *any intensity or thickness* in the A or B region is considered a positive result.

LINE PLACEMENT GUIDE

INFLUENZA A POSITIVE

One line in the control line position,
and one line in the "A" test line position.



INFLUENZA B POSITIVE

One line in the control line position,
and one line in the "B" test line position.

Note: It is possible to have 3 lines, which would indicate a positive test for Influenza A and Influenza B.

NEGATIVE RESULTS

One line in the control line position, and no lines
at either the "A" or the "B" test line positions.

INVALID RESULTS

No line appears at the control line position.
Repeat the test using a new sample
and a new test dipstick.

OSOM®

Influenza A&B Test

CLIA Complexity: Moderate

FOR LABORATORY AND PROFESSIONAL USE ONLY

INTENDED USE

The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. 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.[1]

SUMMARY AND EXPLANATION OF TEST

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches and fever. It affects 10%–20% of the United States population annually, resulting in more than 110,000 hospitalizations and 10,000 to 40,000 deaths.[2]

The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present more mild symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an appropriate antiviral therapy. Initiation of antiviral therapy within 48 hours of symptom onset is recommended for more rapid reduction of symptoms and to reduce viral shedding.[3] The OSOM influenza A&B Test can provide rapid detection of influenza A and/or B viral antigens from symptomatic patients.

PRINCIPLE OF THE TEST

The OSOM Influenza A&B Test consists of a test stick that separately detects influenza A and B. The test procedure requires the solubilization of the nucleoproteins from a swab by mixing the swab in Extraction Buffer. The test stick is then placed in the sample mixture, which then migrates along the membrane surface. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another mouse anti-influenza A and/or B antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the stick for results to be valid. The appearance of a second and possibly a third light pink to purple line will appear in the test line region indicating an A, B or A and B positive result.

REAGENTS AND MATERIALS PROVIDED

25 Test Sticks

25 Test Tubes

25 Foam Swabs

1 Extraction Buffer vial

- 12 mL (20mM phosphate buffered salt solution (pH 7.6), 0.25% protein stabilizer, 0.6% detergent and 0.09% sodium azide as a preservative)

1 Extraction Buffer dropper top

1 Influenza A Positive Control Swab (packaged with a desiccant tablet)

- Formalin inactivated Influenza A/Kitakyushu/159/93 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

1 Influenza B Positive Control Swab (packaged with a desiccant tablet)

- Formalin inactivated Influenza B/Lee/40 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

1 Directional Insert

1 Procedure/Result Interpretation Guide

1 Workstation

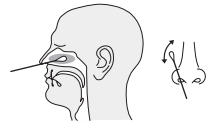
Note: Two extra test sticks have been included in the kit for external QC testing. In addition, extra components (swabs, tubes) have been provided for your convenience.

MATERIALS REQUIRED BUT NOT PROVIDED
A timer or watch

WARNINGS AND PRECAUTIONS
- For *in vitro* diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.[4]
- Swabs, tubes and test sticks are for single use only.
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not interchange or mix components from different kit lots.
- 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.[1]

STORAGE CONDITIONS
- Store test sticks and extraction buffer tightly capped at room temperature (15˚–30˚C/59˚–86˚F).
- Do not freeze any of the test kit components.
- Do not use test sticks and reagents after expiration date.
- Recap the desiccated container immediately after removing a test stick.
- Test sticks that have been outside of the desiccated container for more than 1 hour should be discarded.

SPECIMEN COLLECTION AND PREPARATION
- Only nasal swabs can be used with this test. Use of nasal washes or aspirates has not been validated.
- Insert the swab into the nostril that appears to have the most secretion. Using a gentle rotation, push the swab until resistance is met at the level of the turbinates (at least one inch into the nostril). Rotate the swab a few times against the nasal wall.



- Use only the swabs supplied in the OSOM Influenza A&B Test kit. Swabs from other suppliers have not been validated. Do not use swabs that have cotton,rayon or polyester tips or wooden shafts.
- Test the swab as soon as possible after collecting the specimen. If swabs cannot be processed immediately, specimens may be held at room temperature for no longer than 8 hours. Swabs may also be stored at 2˚–8˚C (36˚–46˚F) for up to 24 hours. Extracted samples may be held at room temperature or refrigerated (2˚–8˚C/36˚–46˚F) for up to 24 hours.
- To transport patient samples place swab in a clean, dry container such as a plastic or glass tube.
- **If a culture result is desired, a separate swab must be collected for the culture.**
- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate specimen collection and/or handling. Training in specimen collection is recommended because of the importance of specimen quality.

QUALITY CONTROL (QC)
The OSOM Influenza A&B Test provides two types of controls: procedural internal controls to aid in determining test validity, and two external positive and negative controls for influenza A and influenza B. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

Internal Procedural Controls
Several controls are incorporated into each test stick for routine quality checks.

1. The appearance of the control line in the results window is an internal procedural control:

   Test System: The appearance of the control line assures that adequate Extraction Buffer volume was present and that adequate capillary migration of the extracted sample has occurred. It also verifies proper assembly of the Test Stick.

   Operator: The appearance of the control line indicates that adequate Extraction Buffer volume was present for capillary flow to occur. If the control line does not appear at the read time, the test is invalid.

2. The clearing of the background in the results area may also be documented as an internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid. Call Sekisui Diagnostics Technical Service at (800)332-1042 if you experience a problem.

External Quality Control Testing
The OSOM Influenza A&B Test kit includes one Influenza A Positive Control Swab and one Influenza B Positive Control Swab, each of which contains inactivated virus, for external quality control testing. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

Use the Controls to help ensure that the test sticks are functioning properly and to demonstrate proper performance by the test operator.

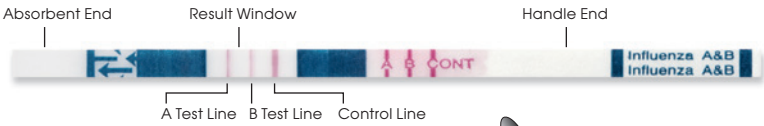
- The presence of a light pink to purple line at the "A" test line position and at the "Control" line position when the Influenza A positive control swab is tested, indicates that the influenza antigen binding property of the test stick is functional.
- The presence of a light pink to purple line at the "B" test line position and at the "Control" line position when the Influenza B positive control swab is tested, indicates that the influenza antigen binding property of the test stick is functional.

External controls are intended to monitor substantial reagent failure. The positive controls will not challenge the assay at the cutoff.

Quality Control requirements should be established in accordance with local, state and federal regulators or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received and with each new operator. Additional controls may be purchased separately (OSOM Influenza A&B Control Kit #191).

QC Testing Procedures
The Positive Control Swabs are impregnated with sufficient influenza A or B antigen to produce a visible positive test result. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen.

TEST PROCEDURE.



When opening kit for the first time, unscrew the cap from the Extraction Buffer bottle and replace it with the dropper top included in the kit. Discard the original Sample Buffer cap.

STEP 1: ADD EXTRACTION BUFFER
Using the supplied dropper top, add 0.3 mL of Extraction Buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube. **Note: Add Extraction Buffer to the tube before putting in the specimen swab to prevent contaminating the Extraction Buffer vial.**

STEP 2: MIX SWAB IN BUFFER
Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.

STEP 3: SQUEEZE LIQUID FROM SWAB
Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. Discard the swab in a suitable biohazardous waste container.

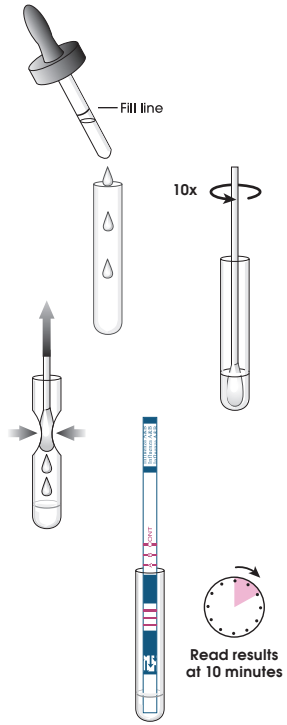
STEP 4: ADD TEST STICK
Remove a Test Stick from the canister. Recap the canister immediately. Place the test stick (arrows pointing downward) into the tube with the extraction buffer solution.

Set a timer for 10 minutes.

STEP 5: READ RESULTS
At 10 minutes remove the test stick from the tube and read the results (some positive results may be seen earlier).

For help in reading the test stick or for correct line placement refer to the Result Interpretation Guide or stick diagram above

Discard used test tubes and Test Sticks in suitable biohazardous waste container.



READING TEST RESULTS

INFLUENZA A POSITIVE

One line in the control line position, and one line in the "A" test line position.

INFLUENZA B POSITIVE

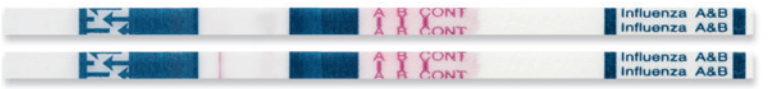
One line in the control line position, and one line in the "B" test line position.

Note: It is possible to have 3 lines, which would indicate a positive test for Influenza A and Influenza B.

NEGATIVE RESULTS

One line in the control line position, and no lines at either the "A" or the "B" test line positions.

INVALID RESULTS



No line appears at the control line position. Repeat the test using a new sample and a new test dipstick.

REPORTING RESULTS[1]

- Report negative test results as influenza A (or B) virus antigen not detected. Infection due to influenza cannot be ruled out since the antigen may be present in the specimen below the detection limit of the test. Negative tests are presumptive and should be confirmed by culture.
- Report positive test results as positive for influenza A (or B) virus antigen. This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
- If result is considered invalid, repeat the test using a new sample and a new test dipstick.

LIMITATIONS

- Additional testing is required to differentiate any specific influenza A subtypes or strains, in consultation with state or local public health departments.[1]
- The OSOM Influenza A&B Test is for the qualitative detection of influenza A and B viral antigens. The test performance depends on antigen load and may not correlate with cell culture performed on the same specimen. Negative test results are not intended to rule out other non-influenza viral infections.
- Sensitivity can differ with various strains of influenza due to difference in antigen expression. Specimens might contain new, non-identified strains of influenza that express varying amounts of antigen.
- This test detects both viable and non-viable influenza A and B, and may yield a positive result in the absence of living organisms.
- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate specimen collection and/or handling.
- As with all diagnostic assays, the results obtained with this test kit yield data that must be used only as an adjunct to other information available to the physician.
- Use of nasal wash or aspirate has not been validated.
- *Staphylococcus aureus* in specimens at concentrations greater than $9x10^8$ cfu/mL may interfere with the test results. Bacterial levels in sinonasal infections have been reported at levels that are much less than those that affect the assay; typically ranging between 10^5 and 10^7 cfu/mL.[5]
- High levels of blood on specimen swabs might cause an intense red background on the test strip that could interfere with the test interpretation. Avoid samples that have been heavily contaminated with whole blood.
- It is well-recognized that testing done with children will appear more sensitive because children shed virus more abundantly and longer than adults.[6]
- Positive and negative predictive values of these diagnostic assays are highly dependent on prevalence or current level of influenza activity.[6] During peak influenza activity in a season, positive predictive values are higher, with false positives less likely; and negative predictive values are lower, with false negatives more likely. Conversely, during low influenza activity (e.g., off-season or beginning of a season), negative predictive values are higher and positive predictive values lower, with false positive test results more likely.

- Individuals who received nasally administered influenza vaccine may have positive test results for up to three days after vaccination.[1]
- 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.[1]

EXPECTED RESULTS

Influenza viruses can cause epidemics which typically occur during the winter months and can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically worldwide. Influenza viruses cause disease among all age groups. Rates of infection are highest among children, but rates of serious illness and death are highest among persons aged ≥ 65 years and persons of any age who have medical conditions that place them at increased risk for complications from influenza.

During the 2004–2005 clinical study, the observed results by age with culture are:

	n	Influenza A (95% CI)		Influenza B (95% CI)	
		Sensitivity	Specificity	Sensitivity	Specificity
Ages 2–19	132	73.0%	96.8%	65.2%	92.7%
		(55.9%–86.2%)	(91.0%–99.3%)	(42.7%–83.6%)	(86.0–96.8%)
Ages 20–79	251	74.3%	96.1%	55.6%	98.2%
		(62.4%–84.0%)	(92.2%–98.4%)	(35.3%–74.5%)	(95.5%–99.5%)

PERFORMANCE CHARACTERISTICS

A clinical trial was conducted during the 2004–2005 flu season in the United States at 12 sites located in the east, central and west regions to establish the clinical sensitivity and clinical specificity of the OSOM Influenza A&B Test in detecting influenza A and influenza B antigens in nasal swab specimens. Sites included family practice and pediatric offices, emergency departments and clinics. All clinical samples were collected from patients with flu-like symptoms including fever, dry cough and myalgia.

Nasal swab specimens were collected from a total of 383 subjects enrolled in the study. Of the 383 samples, 132 samples were from pediatric subjects (2–19 years) and 251 samples were from adults (≥ 20 years). The OSOM Influenza A&B Test was compared to cell culture to determine the comparative clinical sensitivity and clinical specificity for detection of influenza A and influenza B in nasal swab specimens.

COMPARISON OF OSOM INFLUENZA A&B TEST TO CELL CULTURE: NASAL SWAB

FLU A

OSOM Influenza A&B	Culture A+	Culture Negative	Total
A+	79	9[1]	88
A+B+	0	1[2]	1
Negative	28[3]	266	294
Total	107	276	383

Clinical Sensitivity: 73.8% (79/107) (95% CI 64.4%–81.9%)

Clinical Specificity: 96.4% (266/276) (95% CI 93.4%–98.2%)

Polymerase Chain Reaction (PCR) was performed on specimens that gave inconsistent results. This assay is not FDA approved or cleared. These results are provided for information only.

PCR Results:
[1] 5 Positive, 4 Negative
[2] 1 Negative
[3] 24 Positive, 2 Negative, 1 B Positive, 1 Quantity Not Sufficient (QNS)

FLU B

OSOM Influenza A&B	Culture B+	Culture Negative	Total
B+	30	11[4]	41
A+B+	0	1[5]	1
Negative	20[6]	321	341
Total	50	333	383

Clinical Sensitivity: 60.0% (30/50) (95% CI 45.2%–73.6%)

Clinical Specificity: 96.4% (321/333) (95% CI 93.8%–98.1%)

Polymerase Chain Reaction (PCR) was performed on specimens that gave inconsistent results. This assay is not FDA approved or cleared. These results are provided for information only.

PCR Results:
[4] 10 Positive, 1 Negative
[5] 1 Negative
[6] 19 Positive, 1 Negative

Performance characteristics for influenza A were established when influenza A (H3N2) was the predominant influenza viruses in circulation.[7] When other influenza A viruses are emerging, performance characteristics may vary. The detection of influenza A/H5N1 virus, or any other specific novel influenza A virus, from human specimens have not been established.[1]

Assay Reproducibility
A reproducibility proficiency study was conducted to demonstrate that the OSOM Influenza A&B Test will perform acceptably in the hands of nurses, nurse practitioners and physicians' office personnel. A panel of swabs including negative (no virus), strong negative (below the limit of detection), low (near the limit of detection) and mid viral levels for influenza A and B were coded and masked to the operators. This study was conducted with three operators at three health centers in the eastern United States (2 physician's offices and 1 clinic site) and at Sekisui Diagnostics. Two invalid tests were considered as incorrect results in each analysis.

	Correct Response for Flu A		Lower 95% Confidence Interval	Upper 95% Confidence Interval
A - Strong Neg	12/12	100.0%	73.0%	100.0%
A - Low	23/24*	95.8%	78.9%	99.9%
A - Med	11/12*	91.7%	61.5%	99.8%
B - Strong Neg	12/12	100.0%	73.0%	100.0%
B - Low	23/24	95.8%	78.9%	99.9%
B - Med	11/12	91.7%	61.5%	99.8%
AB - Med	12/12	100.0%	73.0%	100.0%
Negative	48/48	100.0%	92.5%	100.0%
Total Agreement	152/156*	97.4%	93.6%	99.3%

	Correct Response for Flu B		Lower 95% Confidence Interval	Upper 95% Confidence Interval
A - Strong Neg	12/12	100.0%	73.0%	100.0%
A - Low	23/24*	95.8%	78.9%	99.9%
A - Med	11/12*	91.7%	61.5%	99.8%
B - Strong Neg	11/12	91.7%	61.5%	99.8%
B - Low	21/24	87.5%	67.6%	97.3%
B - Med	11/12	91.7%	61.5%	99.8%
AB - Med	12/12	100.0%	73.0%	100.0%
Negative	46/48	95.8%	85.7%	99.5%
Total Agreement	147/156*	94.2%	89.3%	97.3%

*invalids due to insufficient volume or no control line

Analytical Sensitivity
Dilutions of influenza A/Kitakyushyu/159/93 (H3N2) and for influenza B/Lee/40 virus were run in triplicate on three lots of the OSOM Influenza A&B Test. The approximate detection limits of the OSOM Influenza A&B Test are 3.3 x 10^5 $TCID_{50}$/mL for influenza A and 1.07 x 10^6 $TCID_{50}$/mL for influenza B.

Analytical Specificity and Cross-reactivity
The OSOM Influenza A&B Test was evaluated with 44 bacterial and viral isolates. Cross-reactivity testing was performed with materials obtained from ATCC. Bacterial isolates were tested at a concentration of approximately >10^8 cfu/mL. Very high levels of Staphylococcus aureus (>9x10^8 cfu/mL) produced a positive result for influenza A. All other bacteria listed gave negative responses. Viral isolates were tested at approximately 1.1 x 10^6 – 1.7 x 10^9 $TCID_{50}$/mL.

All viruses listed produced negative responses.

Bacterial Panel

Acinetobacter calcoaceticus
Bordetella pertussis
Candida albicans
Corynebacterium diphteriae
Enterococcus faecalis
Enterococcus gallinarum
Escherichia coli
Haemophilus influenza
Klebsiella pneumoniae
Legionella pneumophilia
Moraxella catarrhalis
Mycobacterium avium
Mycobacterium tuberculosis
Neisseria meningitidis
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus Group A
Streptococcus Group B
Streptococcus mutans
Streptococcus pneumoniae
Torulopsis glabrata

Viral Panel

Adenovirus Type 1
Adenovirus Type 2
Adenovirus Type 3
Adenovirus Type 6
Coxsackievirus B2
Coxsackievirus B3
Coxsackievirus B4
Coxsackievirus B5
Echovirus 6
Echovirus 11 (Gregory)
Echovirus 30
Measles
Mumps (Enders strain)
Parainfluenza Type 1
Parainfluenza Type 2
Parainfluenza Type 3
Parainfluenza Type 4B
Rhinovirus 3
Rhinovirus 4
Rhinovirus 7
RSV (Long strain)

Influenza A/B Panel testing

A total of 46 human and animal influenza strains were tested with the OSOM Influenza A&B test. Viral titers ($TCID_{50}$) for A/Kitakyushu/159/93 (H3N2) and B/Lee/40 were determined by inoculating MDCK cells, followed by standard procedures for cell culture viral assays. Aliquots of these controls with known $TCID_{50}$ were then used to establish a standard curve in an ELISA assay. The concentrations of other influenza viruses were determined indirectly using the ELISA assay after the viruses had been inactivated. Influenza viruses were tested at an ELISA estimated $TCID_{50}$ as listed in the table below.

All influenza virus isolates gave positive results with the test line at the expected location for the A, B and animal (positive for influenza A) isolates.

Influenza A Strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Beijing/262/95	H1N1	8.25E+07
Brazil/11/78	H1N1	NA
Chile/1/83	H1N1	NA
New Jersey/8/76	H1N1	2.78E+08
Taiwan/1/86	H1N1	3.47E+07
Guizhou/54/89	H3N2	7.54E+07
OMS/5389/88	H3N2	NA
Beijing/32/92	H3N2	3.97E+06
England/427/88	H3N2	4.73E+07
Johannesburg/33/94	H3N2	1.61E+07
Leningrad/360/86	H3N2	2.50E+06
Mississippi/1/85	H3N2	NA
Philippines/2/82	H3N2	9.75E+07
Shangdong/9/93	H3N2	1.67E+08
Shanghai/16/89	H3N2	3.49E+08
Shanghai/24/90	H3N2	NA
Sichuan/2/87	H3N2	NA
Kitakyushyu/159/93	H3N2	3.19E+08
Akita/1/94	H3N2	2.90E+08
Beijing/262/95	H1N1	1.71E+08
Yamagata/32/89	H1N1	7.28E+07
New Caledonia/20/99	H1N1	6.86E+07
Panama/2007/99	H3N2	1.40E+08
Wyoming/03/03	H3N2	7.40E+06
Fujian/411/02	H3N2	6.12E+07
*Mexico/4108/2009***	H1N1	7.91E+06 EID_{50}/mL*
*Kansas/13/2009***	H3N2v	1.00E+05*
*Pennsylvania/14/2010***	H3N2v	1.00E+08 EID_{50}/mL*
*Minnesota/11/2011***	H3N2v	1.00E+08 EID_{50}/mL*
*Indiana/08/2011***	H3N2v	1.00E+06*
*Indiana/10/2011***	H3N2v	1.00E+09 EID_{50}/mL*
*West Virginia/06/2011***	H3N2v	1.00E+05*

* The estimated detectable limit for the Mexico/4108/2009 strain and these H3N2v strains were based on the EID_{50} /mL or $TCID_{50}$/mL stock concentration value provided by the CDC.

** Although this test has been shown to detect these 2009 H1N1 and H3N2v viruses, cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for these 2009 H1N1 and H3N2v influenza viruses have not been established. The OSOM Influenza A&B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

Influenza B Strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Ann Arbor/1/86		NA
Beijing1/87		1.04E+07
Guangdong/120/2000		6.44E+07
Hong Kong/8/73		1.74E+07
Panama/45/90		3.79E+07
Singapore/222/79		4.84E+07
Yamagata/16/88		1.78E+07
Lee/40		2.13E+08
Mie/1/93		4.84E+07
Guangdong/05/94		1.27E+07
Johannesburg/5/99		5.87E+07
Shandong/7/97		4.41E+07
Shanghai/361/2002		NA

Animal Influenza Strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
A/Duck/Singapore-Q/F119-3/97	H5N3	1.65E+08
A/Equine/Prague/56	H7N7	5.37E+06
A/Duck/Wisconsin/1120/82	H5N3	2.30E+08
A/Hong Kong/483/97	H5N1	1.06E+08
A/Hong Kong/213/2003	H5N1	1.84E+08
A/Turkey/Ontario/71	H7N3	8.12E+07
A/Mallard/Wisconsin/479/79	H7N3	2.08E+08
A/Mallard/Saskatchewan/38/81	H7N3	2.46E+08

Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.

INTERFERING SUBSTANCES
The following potential interferents were tested and were found to have no affect on the performance of the OSOM Influenza A&B Test.

Potential Interferent	Concentration
Acetyl Salicylic Acid	20 mg/mL
Acetamidophenol	10 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dextromethorphan HBr	20 mg/mL
Diphenhydramine HCl	5 mg/mL
Ephedrine HCl	20 mg/mL
Guiacol Glyceryl Ether	20 mg/mL
Oxymetazoline HCl	10 mg/mL
Phenylephrine HCl	100 mg/mL
Phenylpropanolamine	20 mg/mL
Whole Blood	2%

OTC Throat Drops	Concentration
Throat Drop (Halls)	25%
Throat Drop (Zinc)	25%
Throat Drop (Ricola)	25%

OTC Nasal Sprays	Concentration
Nasal Spray (Zicam)	10%
Nasal Spray (Afrin)	10%
Nasal Spray (Vicks Sinex)	10%

Note: A very high hemoglobin concentration could interfere with the interpretation of the test result.

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ASSISTANCE
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