Cellex, Inc.

qFlu Dx Rapid Test

Key Symbols Use

	Catalogue Number
	Batch Code
	Expiration Date
	Temperature Limit
	Latex Free
	Caution
	Consult Instructions For Use
	In Vitro Diagnostic Medical Device
	Positive Control
	Contains Sufficient For <n> Tests
	Keep Away from Sunlight

qFlu Dx Rapid Test

For Diagnosis of Infection of Influenza Virus Type A & B

Cellex, Inc.

I. INTENDED USE

The qFlu Dx Rapid Test is intended for use as an aid in diagnosis of infection with influenza Types A and/or B virus.

II. SUMMARY

Influenza illness is classically characterized by sudden onset of fever, chills, headache, myalgias, and non-productive cough. Epidemics of influenza typically occur during winter months with an estimated 114,000 hospitalizations[1] and about 36,000 deaths[2] per year in the U.S. Globally, influenza epidemics lead to 3-5 million cases of severe illness and 300,000-500,000 deaths annually[3]. Periodically, a new strain or variant of human influenza virus appears, leading to an influenza pandemic and dramatically increased numbers of severe illnesses and deaths from influenza-related complications. The 1918 influenza pandemic, for example, led to infection of 20% of world's population and 50 million death[3].

Prompt diagnosis of influenza may aid timely treatment of the illness. Commonly used methods for influenza diagnosis include immunoassays, molecular assays and culture-based assays[4-9]. Various immunoassays often detect the presence of an influenza viral antigen in a sample using an antigen specific antibody whereas the molecular assays detect sequence-specific nucleic acids in a sample. The culture-based assays employ initial viral propagation in cell culture, followed by hemadsorption inhibition, immunofluorescence, or neutralization assays to confirm the presence of the influenza virus.

Among these assays, rapid immunoassays and molecular assays are most commonly used for influenza diagnosis for clinical purpose. However, both assay types are based on genetic sequences, directly or indirectly, of the influenza viral genome. The QFlu Dx Rapid Test is unique in that it detects the activity of influenza viral neuraminidase (NA), an essential enzyme for the life cycle of Type A and B influenza virus, and consequently is less susceptible to genetic changes of influenza virus.

Influenza viral NA is also the target of a new generation of antivirals known as neuraminidase inhibitors[10-12], which includes Tamiflu® and Relenza®. Patients with influenza may benefit from treatment of an antiviral, especially when the treatment is given within 48 hours of onset of the illness. It is thus important to promptly diagnose influenza.

III. PRINCIPLE OF DETECTION

Influenza viruses infect epithelial cells in the upper respiratory tract (nose and throat) and, in severe cases, may reach the lungs causing pneumonia. The neuraminidase (NA) of Type A and B flu virus enables the virus particles to reach the epithelial cell surface and the progeny virus particles to be released from the infected cells. Thus, NA is an essential enzyme for Type A and B virus and can be used as a target for detection of influenza virus or for pharmaceutical drugs.

The detection target of the qFlu Dx Rapid Test is the neuraminidase activity. The qFlu Dx Rapid Test uses a biochemiluminescence substrate that favors influenza viral neuraminidase, which can hydrolyze substrates that contain alpha-ketosidically linked N-acetylneuraminic acid (Neu5Ac). Other viruses such as parainfluenza and mumps viruses also possess surface enzymes with neuraminidase activity. However, unlike influenza viral neuraminidase, which primarily cleaves the alpha – 2, 6 bond, neuraminidase enzymes from these Paramyxovirus viruses favors alpha – 2, 3 linkage[13-18]. Thus, paramyxovirus may not be detected in the qFlu Dx Rapid Test. Although certain bacterial species, such as *clostridium perfringens*, possess neuraminidase that has alpha – 2, 6 activity[19-20], the substrate used in the qFlu Dx Rapid Test exhibits specificity towards influenza virus Types A and B neuraminidases, therefore minimizing potential interference from these bacterial species.

The qFlu Dx Rapid Test contains one key reagent, the qFlu Reagent, for detection of influenza viral neuraminidase activity. The qFlu Dx Rapid Test is simple and rapid. The assay involves 1) sample collection, 2) addition of the sample to the qFlu Reagent Tube, 3) incubation at room temperature for 15 minutes, and 4) detection of the signal and automated interpretation with an analyzer. When used with the Analyzer, the only manual steps are sample collection and sample addition to the reagent vial. The analyzer performs signal detection and result interpretation. The entire process can be completed within 20 minutes.

Although designed as a qualitative assay, the signal from the qFlu Dx Rapid Test reagent is correlated to virus titer in the sample.

IV. REAGENTS AND SUPPLIES

A. KIT COMPONENTS

The qFlu Dx Rapid Test kit contains the following components:

	Catalog No.	5000
	Number of Tests / Kit	**40**
Kit Component	qFlu Dx Reagent Pouch (20 Tests/Pouch)	2
	Q-Sample Buffer Tube	40
	Disposable Pipette (0.25 mL)	40
	Positive Control (PC-1)	1

Note: Use Q-Sample Buffer as the negative control.

B. STORAGE CONDITIONS

The Reagent Pouch and positive control pouch or the entire kit should be stored at 2-8℃.

C. SUPPLIES NOT PROVIDED (PURCHASED SEPARATELY)

- Helios Analyzer
- Q-Sample Buffer
- Sample Collection Swabs (may be purchased from other suppliers)
- Heat Block (optional)

V. SAMPLE COLLECTION, TRANSPORT AND STORAGE

A. SAMPLE COLLECTION

Sample collection from patients is critical for accurate diagnoses. Influenza viruses infect the epithelial cells in the upper respiratory tract, *i.e.,* nose and throat. Nasopharyngeal (NP) and throat swab samples can be used with the qFlu Dx Rapid Test.

Collect a nasopharyngeal (NP) sample using a NP swab (not provided as part of the test kit) as follows:

1. Remove any mucus that is blocking the nasal passage.
2. Estimate the distance from the base of the nose to the front of the ear and insert the swab only ½ this distance.
3. Tilt the patient's head back.
4. Gently insert the swabs along the medial part of the septum (coughing may occur), rotate the swab and remove it;
5. Insert the swab into Q-Sample Buffer Tube and tightly close the cap; label with patient ID.
6. The sample with the swab can be kept at 2-8°C for up to 96 hours

Collect a throat swab using a throat swab (not provided as part of the test kit) as follows:

1. Use a tongue suppressor to suppress the tongue;
2. Rub the swab against the patient's tonsillar mucosae and posterior orpharynx multiple times;
3. Insert the swab into Q-Sample Buffer Tube;
4. Vigorously rub the swab against the tube wall;
5. Dispose the swab; the sample can be stored the sample at 2-8°C for up to 96 hours;

B. SAMPLE TRANSPORT

Specimens in Q-Sample Buffer may be transported on ice. Refer to supplier's instruction for samples collected in other media.

C. SAMPLE STORAGE

Specimens in Q-Sample Buffer can be stored at 2-8°C for up to 96 hours. Follow supplier's instruction for samples collected in other media.

VI. DETECTION PROTOCOL

A. DETECTION PROTOCOL FOR SAMPLES COLLECTED IN Q-Sample Buffer

Step 1 – Add 250 µL of the sample in Q-Sample Buffer to qFlu Dx Rapid Test Reagent Tube.

Step 2 – Incubate at room temperate for 15 minutes.

Step 3 – Place the reagent tubes in Helios Analyzer to measure the signal. Refer to Section VIII for an instruction to operate Helios Analyzer.

Step 4 – The analyzer automatically interprets the test result. Record sample information and test results for permanent record. See next section for result interpretation guide.

B. PREPARATION OF SAMPLES COLLECTED IN OTHER SAMPLE MEDIA (VTM, Hank's Salts, and M4)

1. Mix a sample with an equal volume of 2X Q-Sample Buffer, e.g., mix 0.5 mL of sample with 0.5 mL of 2X Q-Sample Buffer. Save the remaining sample in the medium for culture use if necessary.

2. Follow Steps 1-4 of the detection protocol.

Note: Q-Sample Buffer contains a detergent, which inactivates the virus. Consequently, the virus in Q-Sample Buffer can no longer be recovered for culture.

C. TESTING THE POSITIVE CONTROLS

1. Add a PC reagent bead into a Q-Sample Buffer Tube and mix to dissolve the reagent.
2. Follow Steps 1-4 of the detection protocol.
3. Expected signal on Helios Analyzer: >1000 RLU

Use Q-Sample Buffer as a negative control.

VII. CUTOFF VALUE

When Helios Analyzer is used, the cutoff value is 220K. A sample is considered when the RLU is equal to or greater than 220K.

VIII. OPERATION OF HELIOS ANALYZER

An abbreviated operation instruction for Helios is provided in this section. Refer to Operation Manual of Helios Analyzer for detailed and up-to-date instruction.

1. Calibrate the Analyzer
   When the Analyzer is first turned on, it automatically undergoes self-calibration.

2. Select Run Tests and then qFlu Dx Rapid Test

3. Select the number of samples to be tested.

   Helios Analyzer has 18 samples chambers – and can simultaneously detect 18 samples. It is important to identify which of the sample chamber is used for detection of which sample.

4. Input Sample ID when necessary

5. Perform a Measurement

   Follow the instruction on the screen:
   - Open the cap;
   - Insert qFlu Dx Reagent Tube to a sample Chamber;
   - Record which sample is placed to which sample chamber;
   - Close the cap firmly;
   - Touch the "Start" to begin measurement;

6. Record the Test Results
   - Record the test results;
   - Helios Analyzer can temporarily store up to 5000 sample testing data.

IX. PERFORMANCE CHARACTERISTICS

A. REACTION KINETICS

Three levels of two influenza virus strains were tested (**Table 1**). Both strains of virus were 2009 H1N1 Pandemic strains. In the presence of influenza virus, signal intensity from QFlu Dx Reagent of the qFlu Dx Rapid Test increased rapidly in the first

5 to 10 minutes, followed by a plateau period that lasted at least 120 minutes (**Fig 1**). During the plateau period (10-120 min), the sign intensity was constant with a coefficient of variation of less than 7% (**Table 1**).

Table 1 | Sample Panel Used in Kinetics Study

Panel Member	Virus Strain	Virus Level	Mean	%CV
1	A/CA/07/2009	H	11,666	2.46
2	A/NC/39/2009	H	11,565	2.31
3	A/CA/07/2009	M	3,860	1.71
4	A/NC/39/2009	M	2,960	2.45
5	A/CA/07/2009	L	561	6.65
6	A/NC/39/2009	L	416	6.24
7	Negative	N/A	N/A	N/A

B. PRECISION

1. Site-to-Site Reproducibility

A study panel comprising samples with two virus strains at low to medium levels of titers were tested along with a negative sample in three sites over a period of five days. Two operators were involved in the study in each site. Each operator tested three replicates each day.

Presence or absence of influenza virus was correctly determined for all samples and replicates (**Table 2**). OC resistance status was correctly determined for at least 98.89% of the replicates (95% CI: 94.03% - 99.73%) for a sample with mean Reagent I readings above the equivocal zone (**Table 2**). The coefficients of variation of RLU for all influenza virus positive samples were less than 30% (**Table 2**). As expected, higher variability was observed for those samples with lower RLU such as the negative sample.

Table 2 | Site-to-Site Reproducibility

		A/CA/07/2009			A/NC/39/2009		NC
Sample		1	2	3	4	5	6
Replicates		90	90	90	89	90	90
Signal (RLU)	Mean	371	1276	5402	687	2976	58
	SD	78	197	1006	199	642	45
	%CV	20.99	15.26	18.63	29.02	21.56	78.88
% Flu Positive		100	100	100	100	100	0

2. Within Site Repeatability

A study panel comprising samples with two virus strains at low to medium levels of titers were tested along with a negative sample was used for this study. The samples were tested over a period of 12 days. Two runs and two replicates per run were performed daily.

Presence or absence of influenza virus was correctly identified for 100% of the replicates for all samples (95% CI: 92.75% - 99.95%) (**Table 3**). The CV ranged from 10.48% to 33.59%.

Table 3 | Within Site Repeatability

		A/CA/07/2009			A/NC/39/2009		NC
Sample		1	2	3	4	5	6
N		48	48	48	48	48	48
Signal (RLU)	Mean	373	1009	3933	724	3357	101
	SD	82	198	1003	228	352	34
	%CV	21.91	19.68	25.50	31.49	10.48	33.59
% Flu Positive		100	100	100	100	100	0

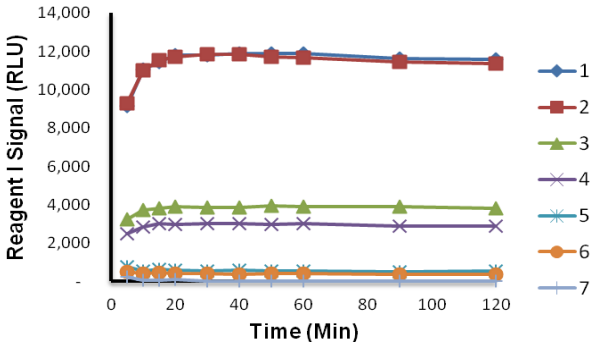

Fig 1 | Reaction Kinetics
Reactions were initiated by adding influenza virus to the detection mix.

C. LINEARITY

Samples containing 2.83 to 5.06 log $TCID_{50}$ units/mL of influenza virus (A/CA/07/2009) were tested. The correlation coefficient (R^2) over this virus concentration range (2.23 log units) was 0.9967 (95% CI: 0.9690-1.0; **Fig 2**). Similar linear range and linearity were observed for influenza virus strains.

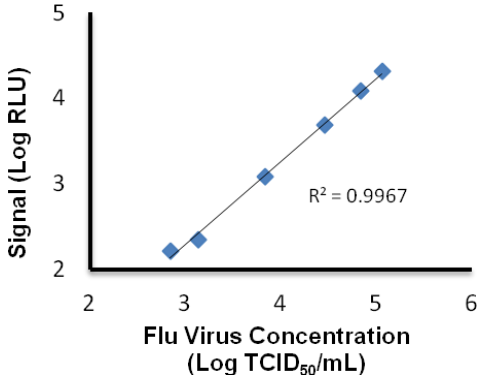

Fig 2 | Linearity
A scattering plot between signal (relative light units, RLU) and influenza virus concentrations.

D. LIMITS OF DETECTION (LOD)

Samples of two influenza virus strains (A/CA/07/2009 and A/NC/37/2009) approaching the limit of detection were tested in 20 replicates. LOD is defined as the lowest concentration tested, which gave a positivity rate of at least 95%. The LOD for influenza virus detection was 995 and 953 $TCID_{50}$/mL for A/CA/07/2009 and A/NC/39/2009, respectively (**Table 4**).

Table 4 | Limits of Detection

Panel Member		**1**	**2**	**3**	**4**	**5**
Virus Strain		A/CA/07/2009			A/NC/39/2009	
Virus Concentration ($TCID_{50}$/mL)		663	995	1,326	953	1,271
S/CO	Mean	0.98	1.58	1.96	1.15	1.87

	%CV	13.81	7.98	6.59	8.36	3.45
Percent Flu Positive		45%	100%	100%	100%	100%

E. COMPARATIVE ANALYTICAL SENSITIVITY

To compare the analytical sensitivity of the qFlu Test with an FDA-approved rapid antigen test, a Type A and a Type B virus strains were sequentially diluted and tested with both tests. This study showed that the qFlu Test is approximately 100 and 5 times as sensitive as the FDA approved rapid influenza antigen test for A/CA/07/2009 and B/NC/82/2009, respectively (**Table 5**).

Table 5 | Comparative Analytical Sensitivity

		Dilution				
		$1:10^2$	$1:10^3$	$1:10^{3.7}$	$1:10^4$	$1:10^5$
A/CA/07/09	RLU	25,973	2,786	459	238	0
	S/CO	117.00	12.55	2.07	1.07	0.00
	Pos/Neg	Pos	Pos	Pos	Pos	Neg
	Comparison Test	Pos	Neg	Neg	Neg	NT
B/NC/82/09	RLU	13,044	1,409	267	151	0
	S/CO	58.76	6.35	1.20	0.68	0.00
	Pos/Neg	Pos	Pos	Pos	Neg	Neg
	Comparison Test	Pos	Pos	Neg	Neg	NT

Pos – Positive
Neg – Negative
NT – Not tested

F. ANALYTICAL REACTIVITY (INCLUSIVITY)

Various strains of influenza virus collected from previous years were tested in triplicates at concentrations approaching the limit of detection (**Table 6**). All signals were above the cutoff. As the signals were within the equivocal zone for drug susceptibility detection, the R-Factor values for some of the samples were above the drug resistance cutoff. These samples were retested at a higher concentration, which resulted in R-Factor values below resistance cutoff indicative of drug susceptibility of these virus strains (**Table 6**). The data is consistent with the expected susceptibility to oseltamivir of these viruses.

Table 6 | Analytical Reactivity

Virus Strain	$TCID_{50}$/mL or $CEID_{50}$/mL	Signal (RLU)	Mean S/CO
A/PR/8/34	0.8	284.00	1.29
A/FM/1/47	0.07	283.33	1.29
A/NWS/33	5,330	244.67	1.11
A/Denver/1/57	53,300	270.67	1.23
A/New Jersey/8/76	741	284.67	1.29
A/Port Chalmers/1/73	6,846	265.00	1.20
A/Hong Kong/8/68	2,330	384.00	1.75
A/Aichi/2/68	13	282.33	1.28
A/Victoria/3/75	158	290.33	1.31
B/Lee/40	2.50	287.67	1.30
B/Allen/45	1.98	280.67	1.28
B/GL/1739/54	0.11	285.00	1.30
B/Taiwan/2/62	8.90	259.67	1.18
B/Hong Kong/5/72	528	312.67	1.42
B/Maryland/1/59	1.48	305.00	1.39

G. ASSAY SPECIFICITY AND CROSS-REACTIVITY

1. Potentially Interfering Substances

The following substances were tested and found no interference with the qFlu Dx Rapid test: Whole blood with EDTA as anti-coagulant (0.25%), Mucin (0.25%), Phenylephrine (0.1%), Oxymetazoline (0.005%), Sodium chloride with preservative (10%), Dexamethasome (0.5 mg/mL), Flunisolide (0.5 mg/mL), Beclomethasone (0.5 mg/mL), Triamcinolone (0.5 mg/mL), Fluticasone (0.5 mg/mL), Menthol (0.5 mg/mL), Tobramycin (0.5 mg/mL), Nasal Gel (10%), and Benzocaine (0.05 mg/mL).

2. Other Viruses

The following viruses were tested and found no interference with the QFlu test: Human Adenovirus Type 1 ($5x10^{5.5}$ $TCID_{50}$/mL), Human Adenovirus Type 7 ($5x10^{4.75}$ $TCID_{50}$/mL), Human Coronavirus ($1.6x10^5$ $TCID_{50}$/mL), Human Herpesvirus Type 4 ($5x10^{3.5}$ $TCID_{50}$/mL), Human Herpesvirus Type 5 ($5x10^{3.5}$ $TCID_{50}$/mL), Human Enterovirus ($1.6x10^7$ $TCID_{50}$/mL), Human Parainfluenza Type 2 ($1x10^7$ $TCID_{50}$/mL), Measles ($3.4x10^3$ $TCID_{50}$/mL), Human Syncytial Virus (RSV) and Rhinovirus ($5x10^{5.5}$ $TCID_{50}$/mL).

3. Microbes

The following microbial species were tested and found no interference with the QFlu Dx Rapid Test: *Chlamydia pneumoniae* ($5x10^{4.5}$ $TCID_{50}$/mL), *E. coli* ($1x10^6$ CFU/mL), *Mycoplasma pneumoniae* ($2x10^5$ CFU/mL), *Streptococcus aureus* ($1x10^6$ CFU/mL), *Streptococcus epidermidis* ($1x10^6$ CFU/mL), *Streptococcus pyogenes* ($1.7x10^6$ CFU/mL), *Haemophilus influenza* ($1.2x10^6$ CFU/mL), *Neisseria spp*. ($1.5x10^6$ CFU/mL), *Streptococcus salivarius* ($2.5x10^6$ CFU/mL), *Neisseria meningitidis* ($3.7x10^6$ CFU/mL), Moraxella catarrhalis ($3.8x10^6$ CFU/mL), and *Streptococcus pneumoniae* ($1.4x10^4$ CFU/mL). *Corynebacterium sp* (1.3 $x10^6$ CFU/mL), *Lactobacillus sp* ($1.8x10^6$ CFU/mL), *Pseudomonas aeruginosa* ($5.6x10^6$ CFU/mL). When tested at higher concentration, *e.g.*, 10^6 CFU/mL, *Streptococcus pneumoniae* resulted in noticeable increase in non-specific signal.

H. SAMPLE MATRICES AND STORAGE CONDITIONS

1. Sample Matrices

Samples collected in virus transport media were tested after dilution into 5X Q-Sample Buffer. Compared to samples directly eluted in Q-Sample Buffer, which requires no dilution, at least 89% of the neuraminidase activity was detected for samples in UTM or M4 medium. However, only 59% activity was detected in samples collected in virus transport medium (VTM) containing DMEM/F12 (1:1) and 1% BSA.

2. Storage Conditions

More than 80% and 71% neuraminidase activity was retained after storage for up to 96 hours (4 days) at 2-8°C or room

temperature, respectively, in Q-Sample Buffer, VTM with BSA, UTM or M4 medium (**Table 7**).

Table 7 | Stability of Samples in Various Sample Matrices

Time (Hr)	Temp	Q-Sample Buffer	VTM with BSA	UTM	M4
0	N/A	100	100	100	100
24	2-8°C	88.70	91.83	83.66	102.32
	RT	90.12	78.19	76.11	83.82
48	2-8°C	88.07	87.07	88.97	99.12
	RT	87.03	77.08	82.75	88.57
72	2-8°C	84.30	82.87	82.30	100.45
	RT	87.69	78.91	78.10	82.87
96	2-8°C	80.64	87.41	87.66	95.97
	RT	87.95	75.86	71.59	82.89

3. Freeze/Thaw Cycles

Samples were stored at -70°C and tested after each freeze/thaw cycle. The retained activity of a sample is expressed as a percentage of that before freezing. Freezing of samples in Q-Sample Buffer caused significant loss of neuraminidase activity (**Table 8**). At least 77.06% activity could be retained after three freeze/thaw cycles when stored in VGM (Virus Growth Medium), UTM or M4 (**Table 8**).

Table 8 | Stability of Samples after Freeze/Thaw

Matrices	Virus	Number of Freeze/Thaw Cycles			
		0	1	2	3
Q-Sample Buffer	A/CA/07/09	100	29.67	31.58	31.34
	A/NC/39/09	100	58.96	64.68	64.43
VGM	A/CA/07/09	100	85.43	89.80	82.15
	A/NC/39/09	100	77.06	82.03	81.64
UTM	A/CA/07/09	100	90.17	94.71	100.19
	A/NC/39/09	100	88.96	88.96	93.60
M4	A/CA/07/09	100	91.67	90.28	102.08
	A/NC/39/09	100	96.24	90.23	95.49

I. CLINICAL PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity and Specificity

A total of 1974 throat swabs were collected from patients exhibiting symptoms of upper respiratory infection. All samples were tested with RT-PCR (reverse transcription polymerase chain reaction). Of these samples, 678 were RT-PCR positive and 1,296 were RT-PCR negative.

These samples were tested using the qFlu Dx Rapid Test. Of the 678 RT-PCR-positive samples, 560 were tested positive with the qFlu test whereas 1,241 of the RT-PCR negative samples (N=1296) were tested negative with the qFlu Dx Rapid test (**Table 9**). The sensitivity and specificity of the qFlu Dx Rapid Test are 82.60% (95% CI: 80.01-84.80%) and 95.76% (95% CI: 95.30-96.30%), respectively.

Table 9 | Clinical Sensitivity and Specificity of qFlu Dx Rapid Test

		qFlu Dx Rapid Test		**N**
		Positive	Negative	
RT-PCR	Positive	560	118	678
	Negative	55	1241	1296
N		615	1359	**1974**
Sensitivity: 82.60% (95% CI: 80.01-84.80%)				
Specificity: 95.76% (95% CI: 95.30-96.30%)				

The 615 PCR-positive samples consist of 91 Type B virus, 173 seasonal A/H1N1, 89 pandemic A/H1N1 (A/pH1N1), 305 seasonal A/H3N2 and 20 A/H7N9. Except for H7N9, which had only 20 samples, all flu virus types/subtypes showed similar detection rate by the qFlu Dx Rapid Test (**Table 10**).

Table 10 | Composition of Flu Positive Samples

Virus Type/Subtype	**RT-PCR**	**qFlu Dx Rapid Test**	
	Positive (N)	**Positive (N)**	**% Detected**
Type B	91	74	81.32
A/H1N1	173	142	82.08
A/pH1N1	89	73	82.02
A/H3N2	305	257	84.26
A/H7N9	20	14	70.00
Subtotal (N)	**678**	**560**	**82.60**

2. Comparison with a Lateral Flow-Based Test

To compare the performance characteristics of qFlu Dx Rapid Test with those of a lateral flow test, 97 throat swab samples were randomly selected and tested with RT-PCR, qFlu Dx Rapid Test and a lateral flow based test. In comparison with RT-PCR, the qFlu Dx Rapid Test detected 90.48% of the positive samples whereas the lateral flow-based test detected 30.95% (**Table 11**). No false positive samples were detected by either test (**Table 11**).

Table 11 | Comparison with Lateral Flow-Based Flu Test

		qFlu Dx Rapid Test		**Lateral Flow Test**	
		Pos	Neg	Pos	Neg
RT-PCR	Pos (N=42)	38	4	13	29
	Neg (N=55)	0	55	0	55
Sensitivity		90.48%		30.95%	
Specificity		100%		100%	

X. WARNING AND PRECAUTIONS

1. Specimens in Q-Sample Buffer should NOT be frozen prior to testing; they should be stored at 2-8℃.
2. Specimens should not be transported under extreme adverse temperature conditions. Transport should be carried out within a temperature range of 0℃ (32℉) to 30℃ (86℉).
3. Reagents should not be used past their expiration dates.
4. All clinical specimens and materials used to collect these specimens should be considered potentially infectious and handled accordingly. Dispose of all materials by placing in 0.5% sodium hypochlorite (1:10 dilution of household bleach).
5. The assay should be performed at 20℃ to 37℃.
6. Samples collected in Q-Sample buffer cannot be used for culture as the Q-Sample Buffer inactivates the virus.

XI. LIMITATIONS

Influenza C is not detected with the qFlu Dx Rapid Test because it does not possess a neuraminidase enzyme. Identification of Influenza C must be determined by an alternative method such as cell culture followed by confirmation with monoclonal antibodies.

XII. REFERENCES

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XIII. ORDER INFORMATION

Item	Catalog No.
qFlu Dx Rapid Test Kit (40 Tests/Kit)	5000

XIV. CONTACT INFORMATION

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	Consult instructions for use		For in vitro diagnostic use only		Use by
	Catalog #		Lot Number		Tests per kit
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