Clinical Performance Much higher

Nasopharyngeal(NG) swab samples were tested with a RT-PCR method, Lateral Flow Test and with qFLU Dx Test, the results are presented in

		QFlu Dx Test		Lateral Flow Test (FDA approved)	
		Positive	Negative	Positive	Negative
RT-PCR	Positive	38	4	13	29
	Negative	0	55	0	55
	Subtotal	38	59	13	84
Sensitivity		90.48%		30.95%	
Specificity		100%		100%	

Table 1 Comparison Chart --- RT-PCR vs. qFLU Dx Test vs. Lateral Flow Test

Similar Detection Rate for All Subtypes of Flu A/B

The qFlu Dx Rapid Test can detect all subtypes of Flu A/B, including H1N1, H3N2, H7N9 (Table 2). The test had similar setection rate for all subtypes

		PCR	Qflu Dx Test	
		Positive	Positive	% Detected
Type B		91	74	81.32%
Type A	H1N1	173	142	82.08%
	pH1N1 (New）	89	73	82.02%
	H3N2	305	257	84.26%
	H7N9	20	14	70.00%
Subtotal		678	560	82.60%

Table 2 Detection Efficiency of Various Influenza Virus
PS. Slightly lower detection rate for H7N9 was probably due to much lower sample size.

Simultaneously diagnose influenza and detectresistance to Tamiflu

A study using a cohort of 203 isolates (104 Tamiflu® resistant and 99 susceptible virus) and an IC50 assay as the Lateral Flow Test (Cutoff: 50 nM). The qFlu Mx Rapid Test (R-Factor>2.4, resistant virus) correctly identified 100% of resistant virus (IC50 50 nM) and 100% susceptible virus (IC50<50 nM) (Table 3).

			Resistant Virus	Suscept ble Virus		
Strain			08/09 H1N1	07/08 H1N1	08/09 H3N2	Type B
qFlu Mx Rapid Test	R-Factor (Oseltamivir)	N	104	9	35	54
		Mean	4.29	0.23	0.31	0.74
		SD	0.39	0.11	0.30	0.24
		Range	3.75-6.02	0.05-0.38	0.83-1.29	0.42-1.67
		% Susceptible	0	100	100	100
	Sensitivity		100% (95% CI: 96.55% - 99.98%)			
	Specificity		100% (95% CI: 96.34% - 99.98%)			

For orders and inquiries, please contact

Cellex Inc.,
76 TW Alexander Drive
Resarch Triangle Park NC 27709
www.Cellex.us
info@cellex.us

CE

Cellex®

qFlu Dx Rapid Test
qFlu Mx Rapid Test

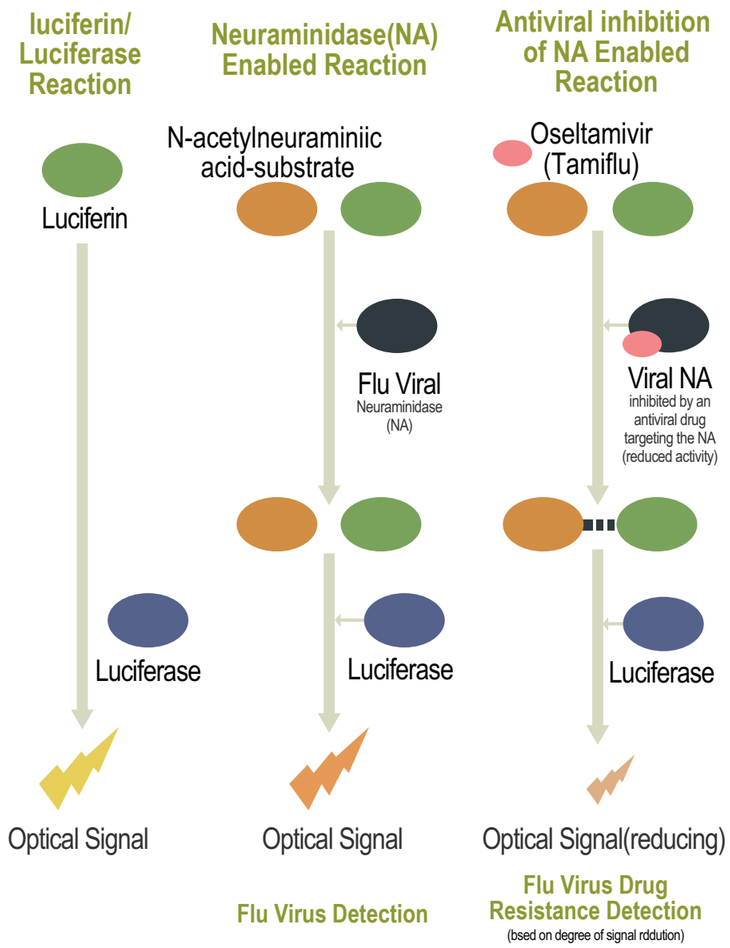
Influenza screening and drug resistance detection

- Self-owned Patent: Homogeneous Biochemiluminescence Assay (HBA) Technology
- Able to detect all Subtypes of Flu A/B
- Less Susceptible to Genetic Changes of Flu Viruses
- Simultaneous Detection of Resistance to Tamiflu
- Significantly Higher Sensitivity than Traditional POC Method

Homogeneous

biochemiluminescence assay (HBA) technology

A luciferin derivatized substrate is used for sensitive and specific detection of influenza viral neuraminidase, which is present in both Type A and Type B Flu virus. In the presence of viral neuraminidase, the derivatized luciferin is free and immediately oxidized by luciferase in the reaction mix to generate detectable light signal.



qFlu Dx Rapid Test Kit

40 Tests / Kit Consisting of

- Two Pouches, each containing 20 qFlu Dx Reagent Vials
- 40 Q-Sample-Sample Buffer Vials
- 40 Disposable Pipettes (0.25 mL)
- 1 Positive Control Pouch with one PC-1 vial and one PC-2 vial. PC contains lyophilized recombinant flu neuraminidase (NA). PC-1 and PC-2 contain NA derived from different flu strains

qFlu Mx Rapid Test Kit

20 Tests / Kit Consisting of

- 20 qFlu Reagent I Vials in one pouch
- 20 qFlu Reagent II Vials in one pouch
- 20 Q-Sample-Sample Buffer Vials
- 20 Disposable Pipettes (0.25 mL)
- 1 Positive Control Pouch with

  One PC-1 Vial containing recombinant flu neuraminidase susceptible to Tamiflu

  One PC-2 Vial containing recombinant flu neuraminidase resistant to Tamiflu

Helios Analyzer 201

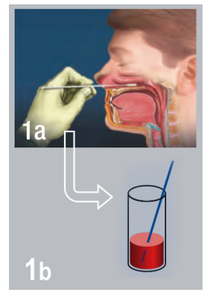
A Point of Care Hand-held Analyzer Designed for qFlu Dx and qFlu Mx Rapid Tests

Smart and easy-to-use analyzer
Dimensions (L*W*H): 200mm×83.5mm×66.5mm
Weight: 0.7kg
External Input/Output: USB, Bluetooth,WIFI
Test loading: QR Scanner
Memory: up to 10000 test records

Simple steps

Step1 Sample Collection

- Collect a NG Swab
- Elute the sample



Step2 Reaction

- To Reagent I & II of qFLU Mx Test (or to Reagent I only of qFLU Dx Test)
- Incubate for 15 min at Room Temperature (15℃-30℃)

Step3 Measument

- Signal Measurenment and Result Interpretation

Ordering Information

Helios Analyzer 201 Order No.9201
qFlu Dx Rapid Test (40 Tests) Order No.5000
qFlu Mx Rapid Test (20 Tests) Order No.5100

Other Helios Test (Under development, coming soon)

qBV Rapid Test (Bacterial Vaginosis Test) Order No.5200
qAR Rapid Test (Antibiotic resistance Test) Order No.5300
qUTI Rapid Test (Urinary Tract Infection Test) Order No.5500
qHP Rapid Test (H. pylori Infection Test) Order No.5600