Cellex, Inc. - QFlu Combo Test for POC Flu Diagnosis and Drug Resistance Detection

GENERAL DESCRIPTION:
The QFlu Combo Test is designed for point-of-care use. It can simultaneously detect influenza virus in a sample and determine drug (e.g., Tamiflu) resistance within 15 minutes. The test uses a small, handheld detector that is powered with two AA batteries.

TECHNICAL DESCRIPTION:
The QFlu test detects influenza viral neuraminidase activity using a novel, biochemiluminescent substrate and a luciferin-neuraminic acid conjugate. In the presence of the influenza virus, the substrate is cleaved to release luciferin, which is immediately metabolized by luciferase in the reaction mix to generate detectable light. All reagents are formulated as a master mix. One only needs to add a sample (0.25 mL) into the reagent tube and, after 15 minute incubation, detect the light signal using a handheld luminometer. For detection of drug resistance, an additional reagent tube is used, which contains the drug (Tamiflu or Relenza). The signal difference between reagents with and without the drug is used to indicate drug resistance status. The instrument would be able to interpret the test results.

CONTACT INFORMATION
Cellex, Inc.
9700 Great Seneca Highway
Rockville, MD 20850
POC: X. James Li, Ph.D.
301-905-7269
lix@cellexinc.com
www.cellex.us

COST
• $500/product
• $16.88/analysis

Survey Source
Vendor Supplied Information
System scores are compared across the four scenarios and ranked from highest to lowest.

### Evaluation Criteria

**Throughput:**
- Between 2 and 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system could easily be adapted into a fully automated system
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- No set-up of the system is required for set-up
- Automatic detection

**Logistics:**
- Very brief (minutes-hours) training and minimal technical skills
- Less than 1 kg
- This system is not capable of transmitting data
- System or device uses batteries
- 4-8 hours battery life

**Operations:**
- Can be used from 25 °C to 37 °C
- Components must be stored at 4 °C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- 3-5 years expected life
- Results cannot be viewed in real-time
- The system is not capable of autonomy
- The system software is open and available for modification
- The system hardware is open and available for modification

**Detection:**
- Efforts are underway to achieve 510K clearance
- Efforts are underway to achieve FDA approval
- Less than 250 µL
- Fair specificity. System has a consistent level of false alarms (5-10%)
- 100-1,000 PFU per mL