

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, 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.

QFlu™ Combo Test for POC Use

1. Sample Collection
 Nasopharyngeal Swab or
 Throat Swab

2. Sample Elution

3. Reaction
 Sample Addition to Tubes A & B (0.25 mL each);
 Incubation for 15 min at RT

4. Signal Measurement
 Signal Detection Using Helios
 100 Luminometer (15 seconds)

5. Interpretation
 Tube A reading for Flu diagnosis (>30);
 A/B Ratio to indicate drug resistance status (<3.0).

Tier Selection			
Final tier assignment is based on overall product score.			
<input checked="" type="radio"/> Top Tier <input checked="" type="radio"/> Second Tier <input type="radio"/> Third Tier <input type="radio"/> Fourth Tier <input checked="" type="radio"/> Bottom Tier			
RANKINGS			
	Biological	Chemical	Radiological
FIELD USE System			
MOBILE Laboratory			
DIAGNOSTIC Laboratory			
ANALYTICAL Laboratory			

CONTACT INFORMATION
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COST

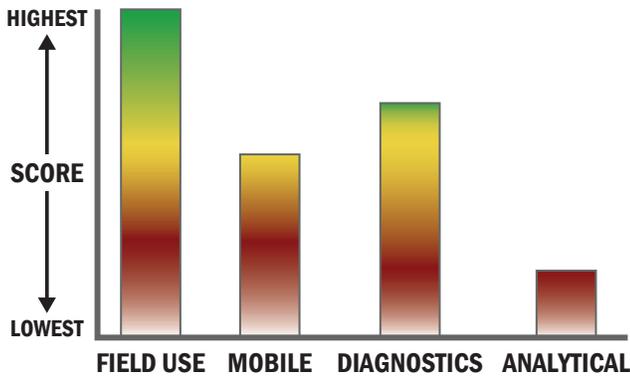
- \$500/product
- \$16.88/analysis

Survey Source
 Vendor Supplied Information



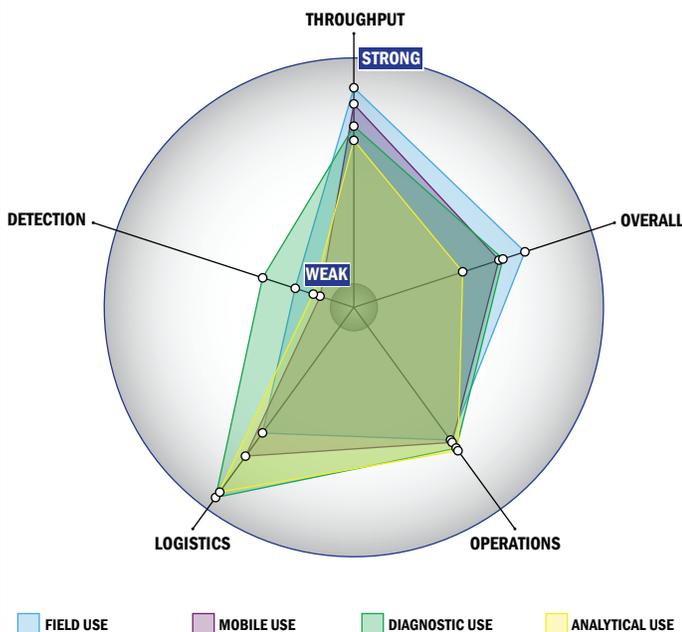
Scoring Analysis

System scores are compared across the four scenarios and ranked from highest to lowest.



Impact Chart

The Impact Chart is a spider graph representing specific categories and designed to give the reader a visual depiction of how a particular system is expected to operate across the four different scenarios. The score for each of the seven categories is presented as the percentage of the total possible score. Higher category scores extend the spokes of a graphic toward the outer edge of the chart. The area graphed for each of the four scenarios relates to how well the system performed in that scenario. Graphics for each of the four scenarios are super-imposed for ease of comparison.



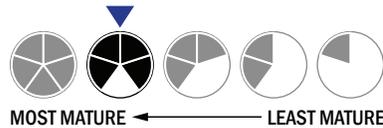
Evaluation Criteria

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