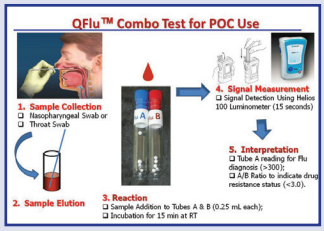
Cellex, Inc. - QFlu Combo Test for Rapid and Simultaneous Flu Diagnosis and Drug Resistance Detection

GENERAL DESCRIPTION:



The QFlu Combo Test is intended to be used in point-of-care setting (initial response) for simultaneous diagnosis of influenza and drug resistance. There is only one key reagent, the master mix, and a handheld device for detection of the light signal. The assay is essentially a one-step assay (sample addition), which can be completed in 17 minutes with approximately 2 minute manual time. Analytical studies show that the test is at least 100,000 as sensitive as the lateral flow based flu test.

TECHNICAL DESCRIPTION:

The QFlu Combo Test uses a specific substrate for detection of influenza viral neuraminidase activity (hence diagnosis of influenza) and inhibition of this enzyme (hence determination of resistance to Tamiflu and Relenza). The substrate is a conjugate between luciferin and modified neuraminic acid. In the presence of flu virus, the substrate is cleaved to liberate luciferin, which is immediately oxidized by luciferase to generate light signal. The reagents are formulated as a master mix. Sample testing involves sample addition and signal detection using a handheld luminometer.

CONTACT INFORMATION

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COST

- $500/product
- $5/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

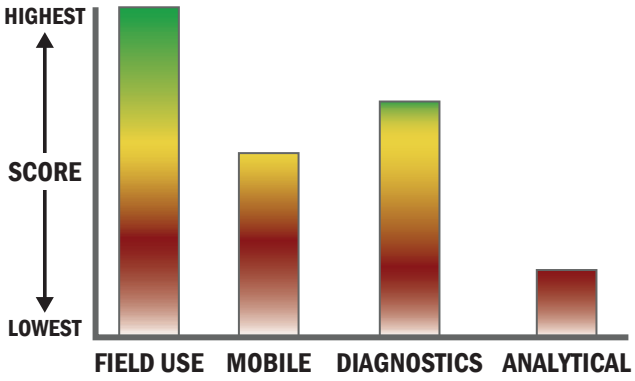
	Biological	Chemical	Radiological
FIELD USE System		N/A	N/A
MOBILE Laboratory		N/A	N/A
DIAGNOSTIC Laboratory		N/A	N/A
ANALYTICAL Laboratory		N/A	N/A

Survey Source

Vendor Supplied Information

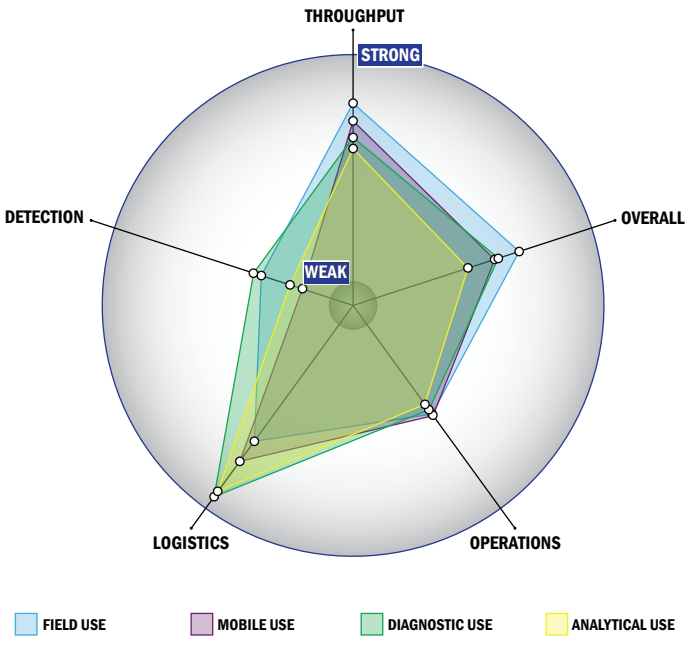
Scoring Analysis

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.



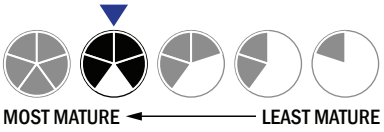
Evaluation Criteria

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
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 1 kg
- Wired connections are available
- 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
- 1-3 years expected life
- Results cannot be viewed in real-time
- The system could be adapted to a fully autonomous system with some effort
- 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
- Fair specificity. System has a consistent level of false alarms (5-10%)
- 100-1,000 PFU per mL of original sample
- 1-10 ng per mL