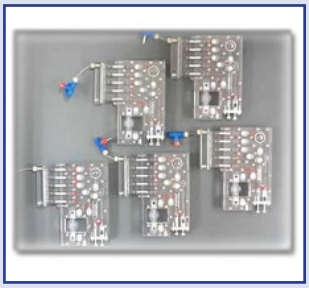
Microfluidic Systems - The Dragonfly System

GENERAL DESCRIPTION:

The Dragonfly System platform offers the precision of molecular diagnostics in an easy to use format that can deliver confirmatory results in 30 minutes or less. The Dragonfly platform is being designed to be a Role 1 CLIA-waived diagnostic device that is highly multiplexed and designed for diagnostic/confirmatory field use by a medically trained operator in a "primary care" setting (Point of Care or Point of Need settings).



TECHNICAL DESCRIPTION:

The assay format of the Dragonfly platform is TaqMan probe-based chemistry in a single-use disposable cartridge. The Dragonfly platform cartridge system is able to process clinical samples such as blood, urine, saliva, buccal and nasopharyngeal swabs. It is also anticipated that the system will have the ability to process stool samples in subsequent generations of the device. All sample preparation necessary post-collection is performed within the disposable cartridge of the Dragonfly platform system. The Dragonfly platform uses ultrasonic lysis for the rupture of tough cell membranes that are then microfluidically passed through a purification column preferentially binding the nucleic acid in the presence of chaotropic agents. The nucleic acid is washed with multiple steps prior to being eluted into the detection chamber of the instrument. The current time-to-result for the Dragonfly platform is thirty (30) minutes or less, depending on which assay panel is being performed. We anticipate a further reduction in time-to-result in subsequent generations of the system. The Dragonfly platform will be fully automated with radio frequency identification (RFID) chips embedded in each cartridge allowing for efficient, automated, error-free protocol determination by the Platform programming. Required training for the Dragonfly platform will be minimal taking less than 1 hour and utilizing easy to understand simple visual aids. The Dragonfly platform requires no human interpretation and is capable of reporting data out-put (positive/negative) to a local, on-screen digital readout and or electronic data output to a remotely located server.

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	Second Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Top Tier	N/A	N/A
ANALYTICAL Laboratory	Second Tier	N/A	N/A

CONTACT INFORMATION

Microfluidic Systems
1252 Quarry Ln. Suite A
Pleasanton, CA 94566

COST

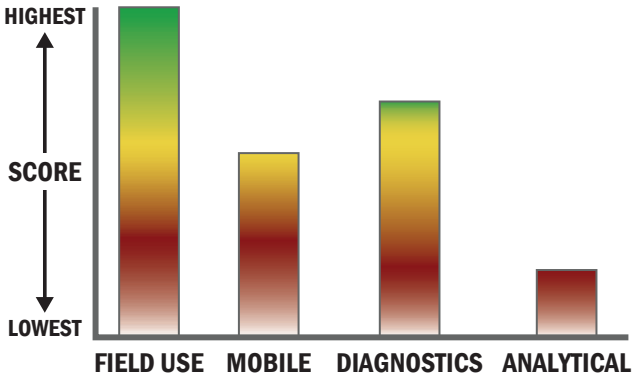
- $15,000-$20,000/system
- $10-$15/analysis

Survey Source

Vendor Supplied Information

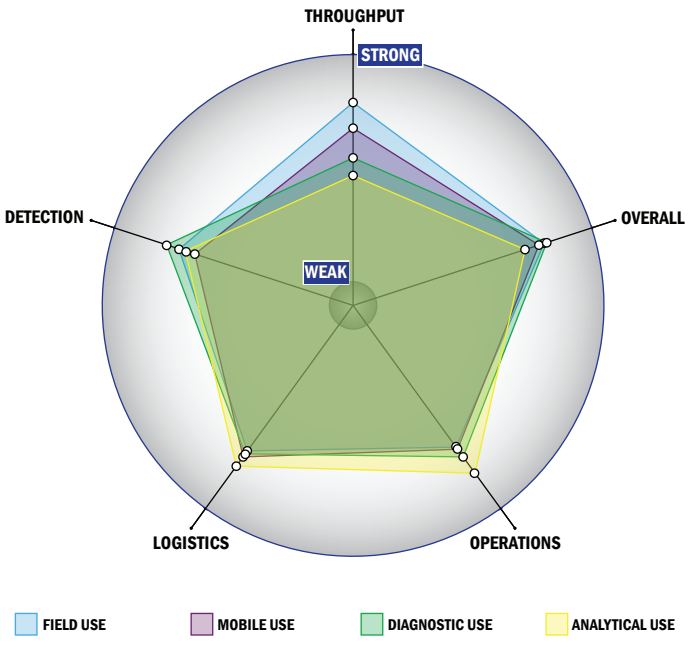
Scoring Analysis

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.



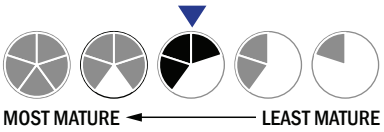
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, <10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 0 components
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 5 and 25 kg
- Satellite, wireless and wired connections are available
- System or device uses batteries
- 1-2 hours battery life



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at room temperature (27 °C)
- Between 1 to 3 years shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Detection:

- Efforts are underway to achieve 510K clearance
- Possible the system could receive FDA approval, no current efforts at this time
- Less than 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- 1-10 ng per mL
- Fully automated spore lysis