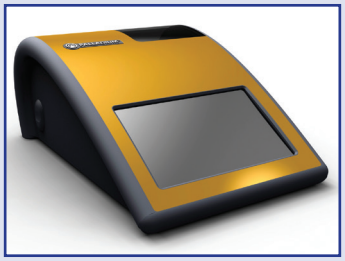
Integrated Nano-Technologies, LLC - Palladium

GENERAL DESCRIPTION:



INT's Palladium System is an automated field deployable DNA based diagnostic and biological identification system. The unit can be used by first responders or as a point of care diagnostic system. The system utilizes a novel electronic array which allows for identification of multiple nucleic acid sequences within a sample. The current system incorporates sample preparation. It uses PCR to amplify target sequences which provides a high degree of sensitivity and specificity. The system is designed for field use. It is less than nine pounds and is battery powered. Reagents do not need refrigeration. The sample preparation process is versatile and has been used to prepare target material from biological samples, such as blood, tissue, and whole insects, or environmental samples such as air filter washes or soil. Target materials evaluated on the system include DNA and RNA targets from bacteria and viruses. The system integrates all steps from sample preparation to result into a single disposable cartridge which includes all reagents. The unit has GPS and communications capability in order to record time, and location and report results.

TECHNICAL DESCRIPTION:

INT's Palladium System utilizes a novel electronic nucleic acid sensor. Target nucleic acids bind to sensors forming a bridge between electrodes. The presence of a target is determined electrically. This approach allows for a multiplexed array of sensors, for simultaneous testing for a number of targets. The system also incorporates a sample preparation process which uses nano- magnetic particles to separate and concentrate target molecules. The sample preparation process works with a wide variety of sample matrixes and with high yields using nucleic acid concentrations from femto-moles to milli-moles. Finally, the system uses a unique revolver disposable cartridge which is low cost and easy to manufacture. The revolver design allows for valving of multiple reagents with only one valve. The design of the cartridge provides flexibility to modify processing steps without the need to rework the cartridge.

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

CONTACT INFORMATION

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COST

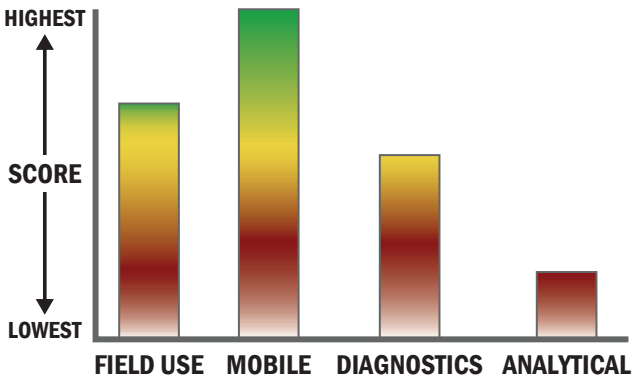
- $10,000-$35,000/system
- $15/analysis

Survey Source

Vendor Supplied Information

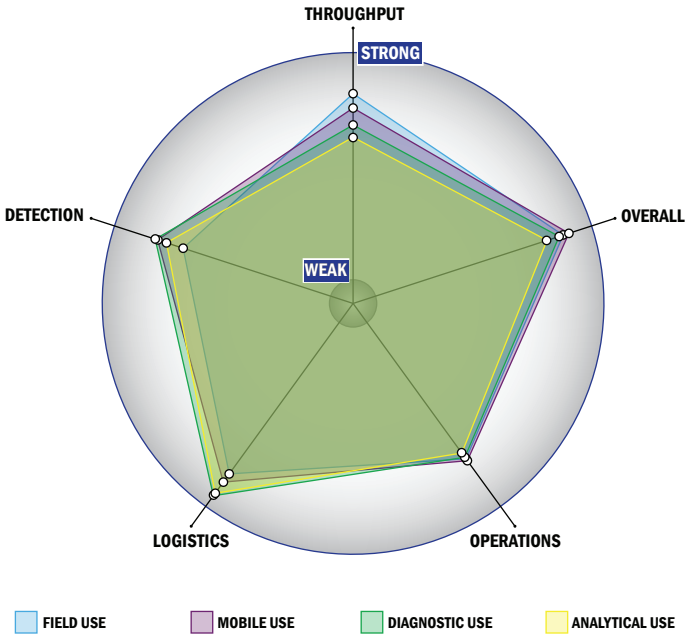
Scoring Analysis

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.



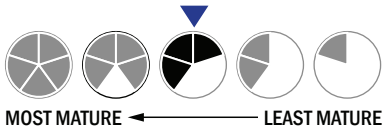
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- Multiple samples, multiple tests/sample per run
- 95-32 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
- 1 component
- Less than 5 minutes is required for set-up
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 1 and 5 kg
- Wireless and wired connections are available
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- 5-10 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 closed and not available for modification

Detection:

- Efforts are underway to achieve 510K clearance
- Efforts are underway to achieve FDA approval
- 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
- Fully automated spore lysis