

Illumina, Inc. - BeadXpress Reader



GENERAL DESCRIPTION:

The BeadXpress Reader is the optimal solution for both small and high-throughput laboratories conducting molecular testing that benefit from robust, multiplexed-based assays. It employs a dual-color laser detection system that identifies the unique holographic codes embedded in VeraCode microbeads, and detects the signal intensity associated with each bead. This system supports the development of both single- and two-color assays, across genotyping, methylation, and protein-based assays. The BeadXpress System comes with VeraScan software, which provides a user-friendly graphical interface to control the BeadXpress Reader, enabling users to load assays, perform real-time scans, and view scan data for up to 96 samples per run. The software features administrator control of setting user specific accounts and rights, configuration of default file locations, and security options, including alerts via email. It also offers customization of scanning protocols, enables acquisition and viewing of intensity data, and report generation.



TECHNICAL DESCRIPTION:

VeraCode glass microbeads provide an ideal surface for numerous bioassays including genotyping, gene expression, and protein-based assays. Illumina's proprietary technology precisely embeds digital holographic elements within glass microbeads to create unique bead types. Each microbead can easily carry high-density codes (24-bit), for virtually unlimited development of bead types. When excited by a laser, each VeraCode bead emits a unique code image, allowing for quick and specific detection by Illumina's BeadXpress Reader System.

CONTACT INFORMATION

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COST

- \$98,500/system
- \$10.50/analysis

Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- Second Tier
- Third Tier
- ◐ Fourth Tier
- Bottom Tier

RANKINGS

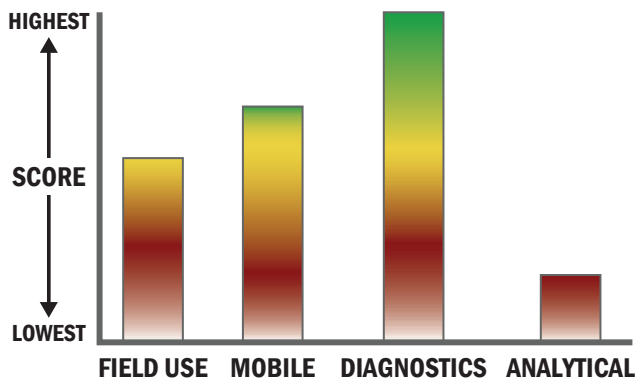
	Biological	Chemical	Radiological
FIELD USE System	● Bottom Tier	○ N/A	○ N/A
MOBILE Laboratory	● Bottom Tier	○ N/A	○ N/A
DIAGNOSTIC Laboratory	◐ Fourth Tier	○ N/A	○ N/A
ANALYTICAL Laboratory	● Bottom Tier	○ N/A	○ N/A

Survey Source

Internet Supplied Information

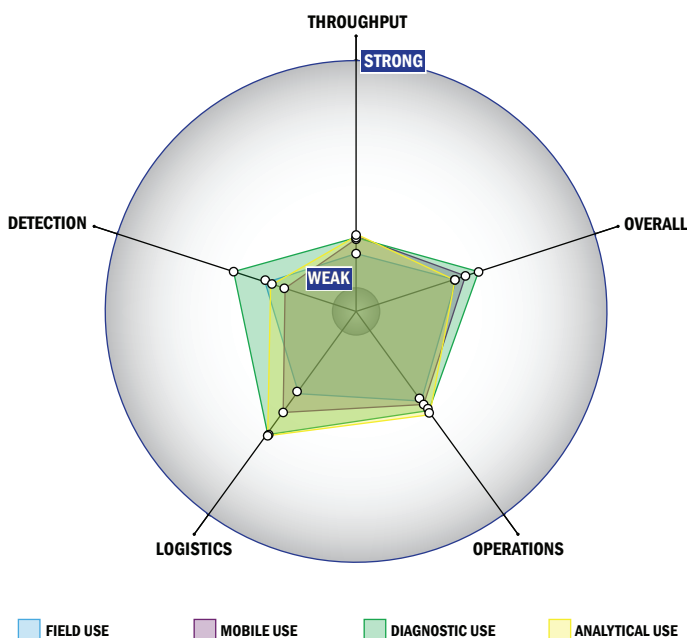
Scoring Analysis

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.



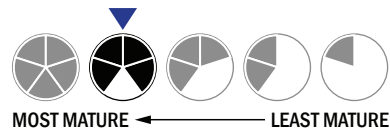
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system could be adapted to a fully automated system with some effort
- Device or system is intended for multiple detection assays
- 5 or more solutions, buffer, eluents, and/or reagents
- 5 or more components
- Less than 5 minutes is required for set-up
- Greater than 12 steps are required for detection

Logistics:

- A day of training and technical skills are required
- Approximately the size of a home dishwasher
- More than 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



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 6 months shelf life
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system could be adapted to a fully autonomous system with significant effort
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Detection:

- System currently has 510k clearance
- System currently has FDA approval
- Greater than 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- Less than 1 ng per mL
- Manual kit not integrated with the system handles spore lysis.

