

# CustomArray, Inc. - MX300



## GENERAL DESCRIPTION:

System for automating hybridization and reading of CustomArray DNA arrays, which can be used to detect organisms and genetic variants in laboratory settings. It is adaptable to any sample that has genetic material in it (either DNA or RNA).



## TECHNICAL DESCRIPTION:

Samples must be processed to extract nucleic acid material (using third-party kits), that material is then amplified (using a standard thermocycler), and the amplified material is put into the MX300 for hybridization to a DNA array and reading of results.

## CONTACT INFORMATION

CustomArray, Inc.  
6500 Harbour Hts Pkway, Suite 202  
Mukilteo, WA 98275

## COST

- \$40,000/system
- \$170/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
<b>FIELD USE System</b>			
<b>MOBILE Laboratory</b>			
<b>DIAGNOSTIC Laboratory</b>			
<b>ANALYTICAL Laboratory</b>			

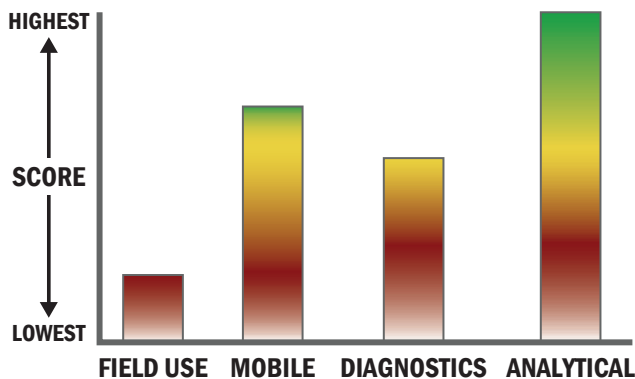
## Survey Source

Vendor Supplied Information



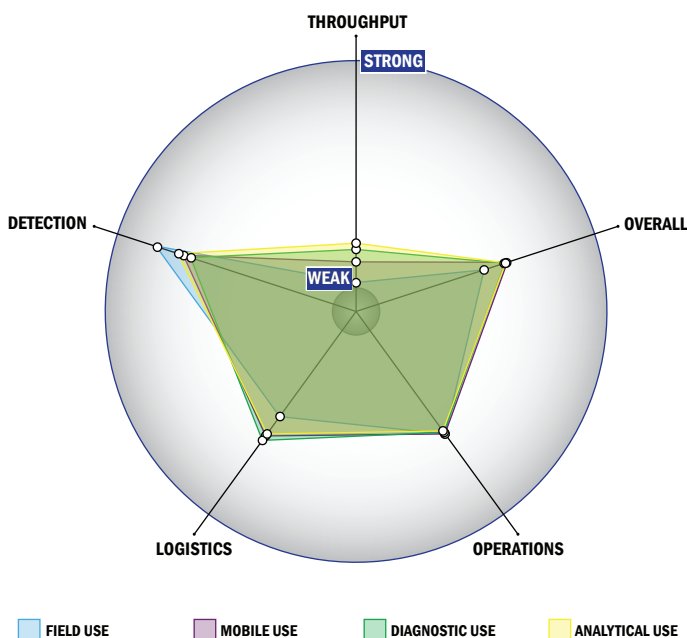
## Scoring Analysis

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.



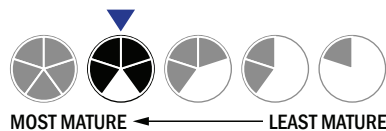
## Evaluation Criteria

### Throughput:

- Between 60 minutes and 8 hours for detection
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- 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
- Less than 5 minutes is required for set-up
- Greater than 12 steps are required for detection

### Logistics:

- More than a day of training and significant technical skills are required
- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Satellite, wireless and wired connections are available
- System or device has 110V electrical requirement



### Operations:

- Can be used from 4 °C to 41 °C
- Components must be frozen (-20 °C)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- 3-5 years expected life
- Results cannot be viewed in real-time
- The system could be adapted to a fully autonomous system with significant effort
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

### Detection:

- Possible the system could receive 510K clearance, no current efforts at this time
- Possible the system could receive FDA approval, no current efforts at this time
- Less than 10 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Less than 1 ng per mL
- Manual kit not integrated with the system handles spore lysis