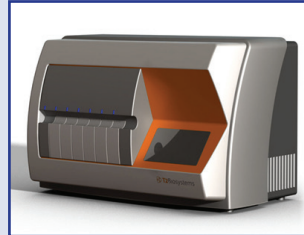


# T2 Biosystems - T2Dx



## GENERAL DESCRIPTION:

T2's revolutionary new technology is based on clinically-proven magnetic resonance MR technology, and uses nanoparticles coupled with reagents to quickly detect—within minutes—the presence of specific substances in solution using a miniaturized, portable MRI instrument. Detection of the high level magnetic resonance signal from the solution enables the detection of low concentrations of target agents or substances. Unlike most existing diagnostic detection techniques which are based on optical detection methods that require pure samples and multiple processing steps, T2's technology is not optical and therefore does not require purification of biological samples. This significant advantage allows the T2 system to perform single-step processing and rapid turnaround times without the need for trained technicians. Furthermore, the technology can accurately identify almost any specimen, including proteins, nucleic acids, or enzymes; bacterial, cancer or other cells; viruses; or small molecule drug compounds within almost any sample, including whole blood, plasma, serum and urine. T2's system is faster, more reliable, more portable and more readily accessible than any diagnostic testing system now on the market.



## TECHNICAL DESCRIPTION:

Compact, rugged, non-optical detection of immunoassay and nucleic acid assay targets, directly in unprocessed samples.

## CONTACT INFORMATION

T2 Biosystems  
101 Hartwell Avenue  
Lexington, MA 02421

## COST

- \$5,000 - \$50,000/system
- \$5/analysis

## Tier Selection

Final tier assignment is based on overall product score.

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

### RANKINGS

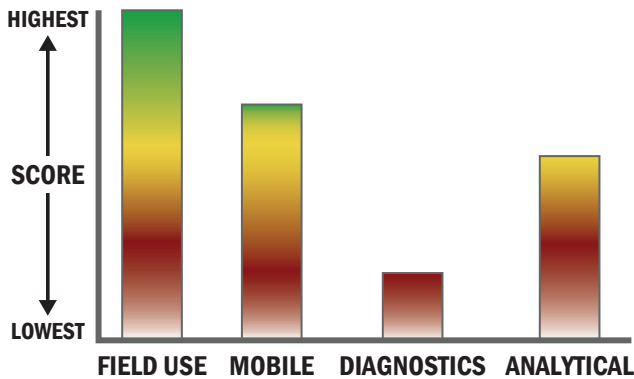
|                              | Biological                           | Chemical                             | Radiological |
|------------------------------|--------------------------------------|--------------------------------------|--------------|
| <b>FIELD USE System</b>      | <span style="color: green;">●</span> | <span style="color: green;">◐</span> | N/A          |
| <b>MOBILE Laboratory</b>     | <span style="color: green;">●</span> | <span style="color: green;">●</span> | N/A          |
| <b>DIAGNOSTIC Laboratory</b> | <span style="color: green;">◐</span> | <span style="color: green;">◐</span> | N/A          |
| <b>ANALYTICAL Laboratory</b> | <span style="color: green;">●</span> | <span style="color: green;">◐</span> | N/A          |

## Survey Source

Vendor and Internet Supplied Information

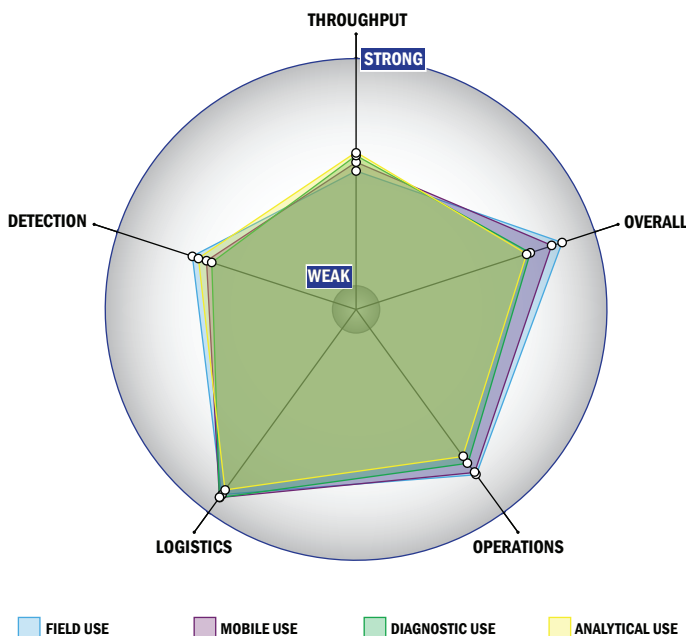
## Scoring Analysis

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.



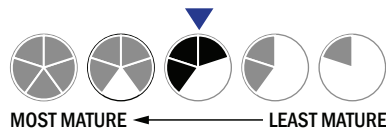
## Evaluation Criteria

### Throughput:

- Between 2 and 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 4 solutions, buffer, eluents, and/or reagents
- 1 component
- Greater than 20 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
- Satellite, wireless and wired connections are available
- System or device has 110V electrical requirement
- 4-8 hours battery life



### Operations:

- Can be used from  $-21^{\circ}\text{C}$  to  $42^{\circ}\text{C}$  (All temperatures)
- Components must be stored at room temperature ( $27^{\circ}\text{C}$ )
- 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 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  $10\ \mu\text{L}$
- 1-100 CFU per mL
- 1-100 PFU per mL
- Less than  $1\ \text{ng per mL}$
- Fully automated spore lysis
- $< 1 \times 10^{-6}\ \text{mg/m}^3$
- $< 1\ \text{ppb}$