

Tetracore, Inc. - T-COR 4 Handheld Real-Time PCR Thermocycler



GENERAL DESCRIPTION:

Tetracore's T-COR 4 Handheld Real-Time PCR Thermocycler can process four independent samples and is capable of analyzing two targets per sample. The T-COR 4 has a footprint of 9" x 7.5" x 3", weighs 6 pounds, and runs continuously off battery power for 8 hours. The system is capable of running both standard TaqMan® real-time PCR and Isothermal real-time fluorescence based amplification. Isothermal real-time fluorescence based amplification allows for confirmatory analysis in 10 minutes. The user can choose to run the device in either stand-alone mode or connected to a PC. Intuitive software allows the user to set up, run, and analyze an experiment. Easy to learn and simple to use, the T-COR 4 is designed for use by both first responders in the field and biologists in the laboratory. We have demonstrated the identification of agents in powder samples, agents in environmental samples, bacteria, and viruses. Tetracore produces 18 dry real-time PCR and 4 dry Isothermal Assays for the T-COR 4. Dry assays developed for the system are subject to accelerated stability testing at 55 degrees Celsius and 45 degrees Celsius, and to real-time stability testing at room temperature. We have data supporting a shelf life of more than 18 months at room temperature. The T-COR 4 is an open system capable of running any customer's assay, in either a wet or dry formulation. A handheld, battery powered centrifuge is included with the system.



TECHNICAL DESCRIPTION:

A handheld, battery powered, peltier-based thermocycler designed for use with TaqMan® real-time PCR amplification and Isothermal real-time fluorescence based amplification. Isothermal real-time fluorescence based amplification allows for confirmatory analysis in 10 minutes. Tetracore has designed a proprietary, modular optical system such that the instrument can be modified to suit future end users requirements. The developed optical technology enables Tetracore to support the fields of biotechnology, such as nucleic acid detection, polypeptide detection, and environmental sensing.

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	●	N/A	N/A
MOBILE Laboratory	●	N/A	N/A
DIAGNOSTIC Laboratory	●	N/A	N/A
ANALYTICAL Laboratory	●	N/A	N/A

CONTACT INFORMATION

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Survey Source

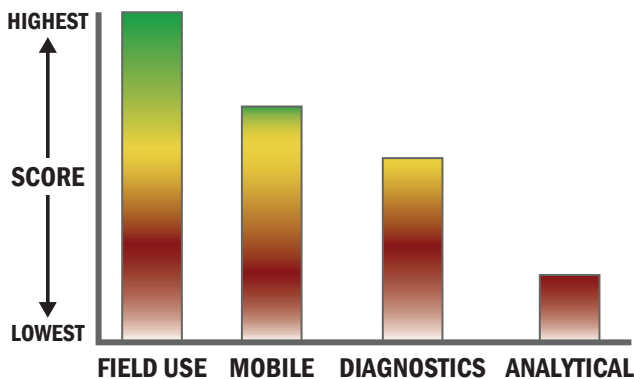
Vendor Supplied Information

COST

- \$16,000/system
- \$12/analysis

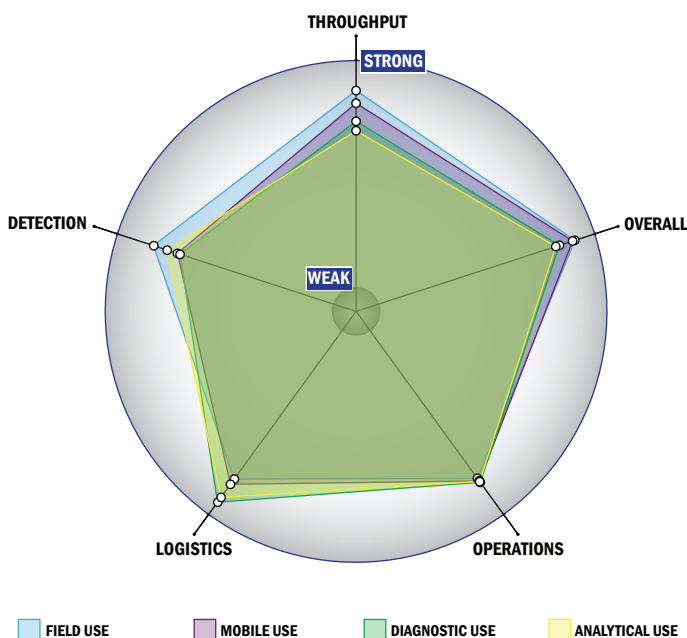
Scoring Analysis

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.



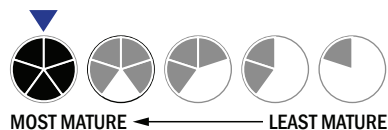
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- 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
- 1 component
- No set-up of the system is required
- 3-5 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
- 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 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:

- 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