Life Technologies - StepOne 48 Well Real-Time Polymerase Chain Reaction System

GENERAL DESCRIPTION:

StepOne™ 48 well and StepOnePlus™ 96 well Real-Time Polymerase Chain Reaction (PCR) System. This is a cost effective real-time PCR system. This system in conjunction with Life Technologies large menu of consumables and reagents can be used on a variety of applications. There are detailed user guides that describe all aspects of the workflow. We also have world-class field application scientists and engineers to support and help. Basically, the system takes processed DNA or RNA as inputs and amplifies them via real-time PCR (which allows for real time data collection). The data gathered allows for analysis to provide quantitative and/or qualitative information. The StepOne™ and StepOnePlus™ systems support any real time PCR application. Life Technologies offers predesigned or custom assays that exist for the following applications: SNP genotyping, Gene Expression profiling, MicroRNA expression, Methylation, Translocation analysis, Gene Detection, Viral Load Analysis and mutation scanning. Other application areas include human identification, food safety, agricultural biology and others.

TECHNICAL DESCRIPTION:

These systems employ real-time (TaqMan®, SYBR® Green or other chemistries) polymerase chain reaction amplification of DNA/RNA samples on a peltier-based thermocycling apparatus using software to analyze data to offer quantitative and/or qualitative results.

CONTACT INFORMATION

Life Technologies
850 Lincoln Centre Drive
Foster City, CA 94404
POC: Roland Tan
650-554-3308

COST

- $14,900-$29,900/system
- N/A/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

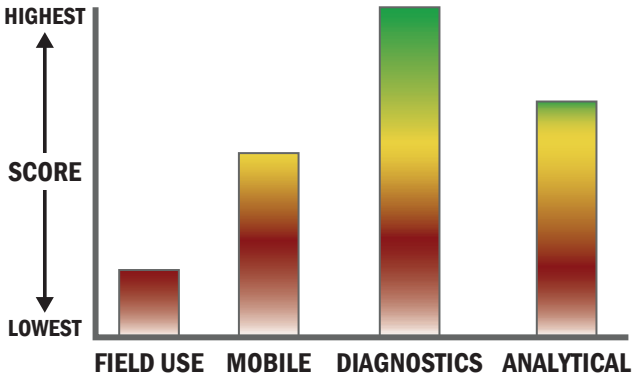
	Biological	Chemical	Radiological
FIELD USE System		N/A	N/A
MOBILE Laboratory		N/A	N/A
DIAGNOSTIC Laboratory		N/A	N/A
ANALYTICAL Laboratory		N/A	N/A

Survey Source

Vendor Supplied Information

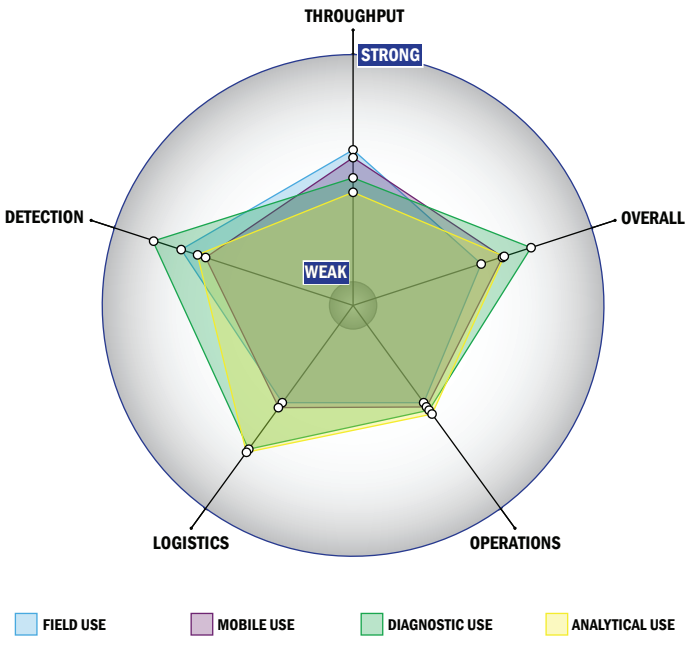
Scoring Analysis

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.



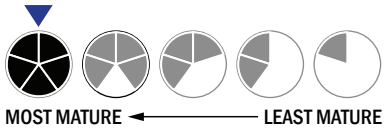
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- 349-96 samples every 2 hours
- The system could be adapted to a semi-automated system with some effort
- Device or system is intended for multiple detection assays
- 2 solutions, buffer, eluents, and/or reagents
- 2 components
- Less than 5 minutes is required for set-up
- 6-8 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Larger than a home dishwasher
- More than 50 kg
- 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)
- Between 1 to 3 years shelf life
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is closed and not 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 10 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Manual kit not integrated with the system handles spore lysis