EQM Research, Inc. - Test-mate ChE Cholinesterase Test System

GENERAL DESCRIPTION:

The Test-mate ChE is a complete, self-contained and portable cholinesterase testing system. The system requires only 10µL for each blood test, which may be conveniently obtained from a fingerstick sample. The entire assay may be completed in less than 4 minutes, facilitating the rapid evaluation of poisoning status. The small size (11" x 7" x 10") and weight (10 pounds) allows the unit to be easily transported between test sites.

TECHNICAL DESCRIPTION:

The Test-mate ChE reagents are based on the Ellman method. Acetylthiocholine (AcTC) or butyrylthiocholine (BuTC) is hydrolyzed by AChE or PChE, respectively, producing carboxylic acid and thiocholine which reacts with the Ellman reagent (DTNB, dithionitrobenzoic acid) to form a yellow color which is measured spectrophotometrically at 450nm. The rate of color formation is proportional to the amount of either AChE or PChE.

CONTACT INFORMATION

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COST

- $2,480/system
- $6/analysis

Tier Selection

Final tier assignment is based on overall product score.

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

RANKINGS

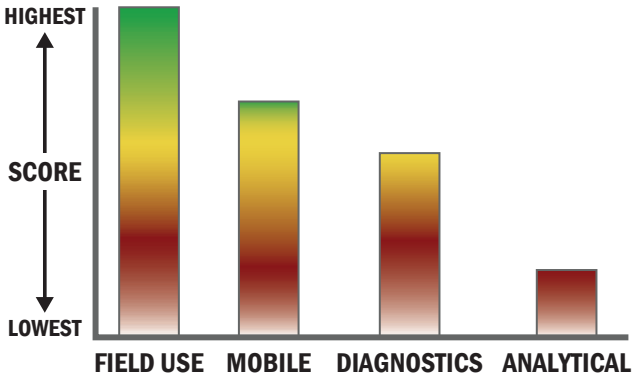
	Biological	Chemical	Radiological
FIELD USE System	N/A	Fourth Tier	N/A
MOBILE Laboratory	N/A	Bottom Tier	N/A
DIAGNOSTIC Laboratory	N/A	Bottom Tier	N/A
ANALYTICAL Laboratory	N/A	Bottom Tier	N/A

Survey Source

Vendor Supplied Information

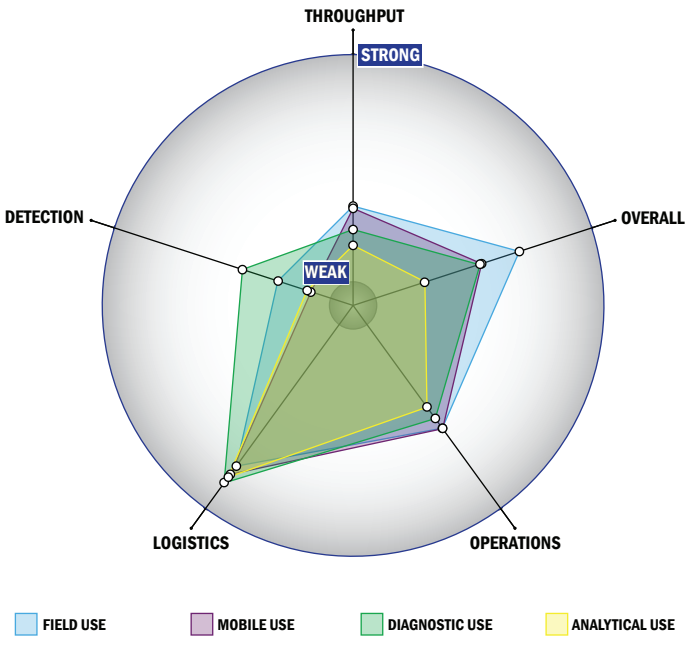
Scoring Analysis

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.



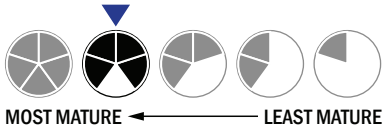
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- 1 sample, single test/sample per run
- Less than 32 samples every 2 hours
- The system or approach is not amenable to full or semi-automation
- Device or system is intended for multiple detection assays
- 3 solutions, buffer, eluents, and/or reagents
- 4 components
- Less than 5 minutes is required for set-up
- 9-12 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a toaster
- Between 1 and 5 kg
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 37 °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 cannot 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:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 50 µL
- Good specificity. System has a consistently low level of false alarms (2-5%)