Holomic, LLC - Rapid Diagnostic Reader



GENERAL DESCRIPTION:

The Holomic Rapid Diagnostic Reader (HRDR) is an economical handheld reader on a smartphone platform, enabling more reliable lateral flow immunoassay tests. HRDR is a portable, handheld, light-weight and universal reader that is optically and mechanically robust as well as highly accurate. Furthermore, the HRDR is integrated into wireless communication networks allowing for the real-time spatiotemporal



mapping of warfare threats and other global epidemics that can be diagnosed using state-of-the-art rapid diagnostic tests (RDTs).

The HRDR is also designed for laboratory testing providing quantitative, accurate and fast readouts not subject to human error or lighting conditions. The reader is universal and can read RDTs of varying formats. The reader can be used standalone or connected to cellular or Wi-Fi networks featuring printout of results to a Bluetooth portable printer or Wi-Fi-connected printers.

TECHNICAL DESCRIPTION:

The HRDR digitally images and reads immunochromatographic rapid diagnostics tests (RDTs) for the quantitative interpretation, wireless transmission and digital storage of the test results. This universal reader employs an opto-mechanic attachment to the cell-phone devices that accommodates various RDTs and encloses a custom-designed optical reflection-mode imaging interface. This interface includes multiple narrowband color LEDs with a lithium-ion battery as well as its recharging USB port which are located on a single PCB (printed circuit board). In order to wirelessly communicate between the cell-phone and the reader attachment, this PCB board also utilizes a photo-sensor as a switch to control the illumination LEDs by generating light pulses using the cell-phone camera flash.

The hardware attachment is complimented by the cell-phone reader application to acquire, analyze and digitally transfer the test results to the cloud. Running custom-developed image processing algorithms, this application provides a user-friendly interface to interpret various RDTs.

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 **MOBILE** Laboratory **DIAGNOSTIC** Laboratory **ANALYTICAL** Laboratory

Survey Source

Vendor Supplied Information

CONTACT INFORMATION

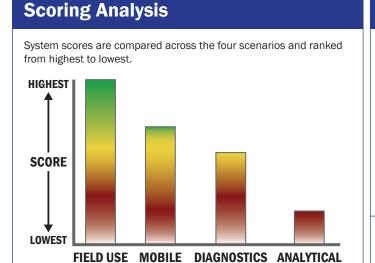
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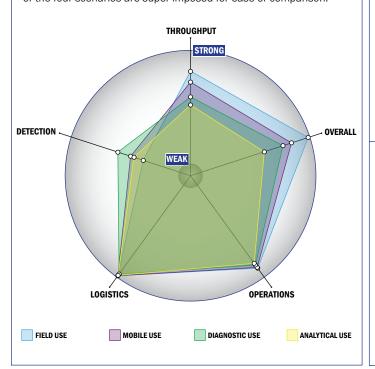
COST

- \$1,400/system
- \$3.00-\$30.00/analysis



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.



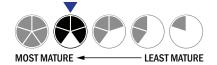
Evaluation Criteria

Throughput:

- 2 minutes or less for detection
- 1 sample, single test/sample per run
- 95-32 samples every 2 hours
- The system could easily be adapted into a fully automated system
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- Less than 5 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 soda can
- Less than 1 kg
- · Satellite, wireless and wired connections are available
- · System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from < -21°C to > 42°C (All temperatures)
- 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 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 50 μL
- \bullet Superior specificity. System has a false alarm rate approaching zero (~0%)
- Spore lysis not necessary for detection by system