The QL Care Analyzer: A Leap Forward in POC Diagnostics

In an effort to ensure more timely and accurate diagnoses for a wide array of medical conditions, cutting-edge technology is being harnessed to set a new standard in point-of-care (POC) immunoassay testing. The use of chemiluminescence and disposable test cartridges are among the advances being incorporated into the next generation of portable POC devices.

Immunoassays are testing procedures that employ specific antibody binding for measuring an analyte in a test sample. The lack of a quantitative immunodiagnostic point-of-care (POC) platform that offers lab-quality results has led to reluctance of medical practitioners to adopt POC on a large scale. However, after many years of slow growth, the professional POC immunoassay test market is beginning to come alive; with 14% growth, this market segment is projected to reach $2.77 billion in 2012.

Considerable pressure to ensure more timely and accurate diagnoses for a wide array of medical conditions, from heart attacks to cancer, is serving as an incentive for diagnostics companies to develop innovative testing technologies. The QL Care Analyzer, a device currently being developed by Cardiogenics Inc., incorporates many of the advances that will mark the next generation of POC immunoassay testing.

The QL Care Analyzer (QLCA) is a fully portable, fully automated, compact analyzer that can deliver accurate results of complex medical tests anywhere, including in emergency rooms, doctor's offices, and EMS vehicles. The device measures 8 × 9 × 5 in., weighs approximately seven pounds, and is powered by a rechargeable lithium-ion battery that can operate for eight to 10 hours between charges. A standard memory processor has the storage capacity to hold up to 5,000 patient records.

Designed to be operated by personnel who lack specific laboratory training as well as by testing specialists, the QLCA can deliver the results of a specific test within 15 minutes. (This interval can be contrasted, for example, with the 2.8 hours that lab-based immunodiagnostics currently require to deliver results of testing). Once test results have been obtained, the data can be transferred from the QLCA to any

network via RS323 and USB ports (Bluetooth capability is still in development). A touch LCD screen incorporates an intuitive graphical user interface that facilitates operation; the testing results are viewable on-screen and can also be printed out via an internal printer. Quality control software assesses the operation status of the hardware before testing commences.

The analyzer incorporates two standout features: its use of patent-protected disposable test cartridges and its use of chemiluminescence to derive test results. The single-use cartridges, which can be loaded into the analyzer, come prepackaged with all necessary reagents to perform a specific test when a patient's whole blood sample is added to it. A barcode on each cartridge contains a set of data, including the type of test, lot number, expiration date, and calibration curve that allows the machine to assess test results. There are in excess of 200 immunoassay tests used in human clinical diagnostics; the analyzer's "open architecture" means that adding a new test to its capabilities would require only the creation of a new cartridge with the appropriate biological reagents. CardioGenics intends to partner with a multinational company to handle the manufacturing of the cartridges.

The analyzer is the first POC device to employ chemiluminescence to ensure the highest test sensitivity. The light emitted by the chemical reaction resulting from the combination of the patient's blood and a specific reagent can be measured and a diagnosis rendered. (CardioGenics has pioneered a class of reagents for this task–a series of solutions that harbor tiny paramagnetic beads that have been coated with specific proteins that define a target marker). Laboratory machines that employ chemiluminescence typically use mechanical means, including pipette injectors, pumps, and valves, to deliver the final trigger compound that is required to initiate light generation. In place of moving components, the analyzer employs an electronic signal that is manipulated via a novel and patent-protected technique. In contrast to traditional methods, the analyzer's electron trigger allows the delivery of reagents with precise timing. Subsequently, a photomultiplier and photocounter inside the analyzer measure and analyze the light that is released when the paramagnetic beads are separated from the solution–a process that takes less than one millisecond.

To support the use of the analyzer, CardioGenics is developing a series of tests. A troponin I (TNI) test will detect the presence and quantity of this specific heart muscle protein, which is released in the bloodstream shortly after a heart attack; a plasminogen activator inhibitor type-1 (PAI-1) test will help optimize the performance of a heart drug prescribed for heart attack patients; a heart failure risk stratification test will assess the risk of death in heart failure patients; and a heart failure genomics risk test will predict the response of heart failure patients to routinely administered drugs. A prostate-specific antigen (PSA) test and cancer tests

are among those currently in the planning stage.

In practice, a simple set of steps are involved in the operation of the analyzer. First, the user initiates the operation of the machine by opening and tapping the user-interface LCD touchscreen. Next, the cartridge door is opened and the cartridge for the desired test is inserted. Then, a non-metered blood sample is applied to the cartridge and the door closed to secure the cartridge within the machine. The machine automatically identifies the type of test from the barcode on the cartridge, loads the required calibration software, and runs the appropriate test. The operator enters patient data as the test runs. Finally, results are displayed on the LCD and electronically stored in the machine; they can be forwarded to a desired network or printed out.

The QL Care Analyzer represents a highly innovative approach to satisfying the need for faster and more accurate diagnoses for a wide range of medical conditions where immunoassay testing plays a role. Going forward, CardioGenics anticipates achieving a series of milestones–negotiating a marketing and distribution agreement with a global IVD partner and completing the FDA submission process–that might offer patients the potential of a brighter future.

Yahia Gawad *is the founder, CEO, and director of CardioGenics Inc. He has worked extensively on cardiac diagnostic test products that he has taken from concept and bench development to commercialization through regulatory approval processes. Dr. Gawad can be reached at 905-673-8501 or info@cardiogenics.com* [1].

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