

Patented Disposable Test Cartridge

## **QL Care: A Point-of-Care Analyzer that Fulfills All**

### **Point-of-Care Requirements**

- **Proprietary and Innovative Core Technology**
- **Superior Sensitivity – Bioluminescence**
- **Superior Accuracy and Precision**
- **Quantitative Results in 15 Minutes**
- **Applicable to any Immunoassay**
- **Fully Automated and User Friendly**
- **Robust Software and Hardware**
- **Fully Portable (Dual Power, Li)**
- **Addresses Current Market Needs**

CardioGenics has developed a state-of-the-art point-of-care (POC) analyzer and is in the process of adapting 4 test products to the whole-blood cartridge format. CardioGenics has integrated its proprietary core technology into the heart of the QL Care analyzer.

The QL Care analyzer is a compact analyzer that meets all POC testing requirements and delivers accurate results of complex testing at the patient's bedside. The QL Care analyzer is fully portable (measuring 8" x 9" x 5" and weighing about 7 pounds) and has dual power with 8- to 10-hour rechargeable battery life. The QL Care analyzer has the ability to internally store over 5,000 patient test results, integrate with any network for data transfer, and print results using its integral printer.

**The QL Care analyzer value proposition:**

- **To patients** – improved medical care through more timely and accurate diagnosis.
- **To medical practitioners** – improved diagnosis, monitoring and reduced liability.
- **To the medical institution/practice** – potential for cost savings and additional revenue-generating potential.

**The QL Care analyzer main features:**

- A POC platform designed for use without specific laboratory training;
- A POC platform with superior testing sensitivity and earlier detection of disease;
- A POC platform that employs bar-coded disposable test cartridges;
- Operation that requires only the addition of a sample to the pre-loaded cartridge;
- Faster diagnosis with 15 minutes or less to results;
- Design that facilitates “walk-away testing” with no extra steps required by operator;
- Testing results that are viewable on the touch LCD, printable by the integral printer, or downloadable to any data network;
- Highly portable and compact enough for use in critical care units, hospital ERs, physicians' offices and ambulances; and
- Provides substantial healthcare cost savings due to reduced testing costs, earlier detection and improved patient management.

**The Company believes that its QL Care analyzer is positioned to become the new industry standard in POC immunoassay testing. Given the current demands for providing better healthcare at reduced cost, the QL Care analyzer is poised to fulfill fundamental needs.**

**The QL Care analyzer has achieved exclusive standing amongst POC Immunoassay analyzers based on the following key features:**

- First automated, patent-protected testing platform with no moving parts, which are the leading cause of failure in all diagnostic equipment;
- First platform to accelerate the testing results using electromagnetic fields, which also increases test sensitivity and reliability; and
- First fully automated platform designed to work with whole blood as the testing medium and measure light emission; no sample preparation or membrane separation required.

**The QL Care analyzer has achieved exclusive standing amongst POC Immunoassay analyzers based on the following key features:**

- First POC analyzer to employ chemiluminescence – the same technology used in central lab analyzers – ensuring highest sensitivity of testing,;
- First POC analyzer to use a photon-multiplying device to measure light released, which maximizes testing sensitivity; and
- First POC analyzer to eliminate membrane-binding (membranes are a major cause of testing inaccuracy).

**The QL Care analyzer has achieved exclusive standing sharing the following key features of POC testing:**

- Walk-away testing with no other steps required besides adding the sample;
- No sample metering: volumes are controlled by cartridge design and sensors;
- An intuitive graphical user interface that facilitates operation by non-technical personnel via on-board user tutorial;
- Disposable cartridges pre-packaged with all necessary reagents – no preparation or handling is required - and pre-coded self-identification;
- Fast turnaround time with 15 minutes from sample application to results;
- Unlimited testing menu; open architecture allows the development of tests for various disease markers, with no machine alteration needed; and
- Full automation, with an integral computer that controls all testing and machine functions with self-diagnostics

## *Operation Steps*

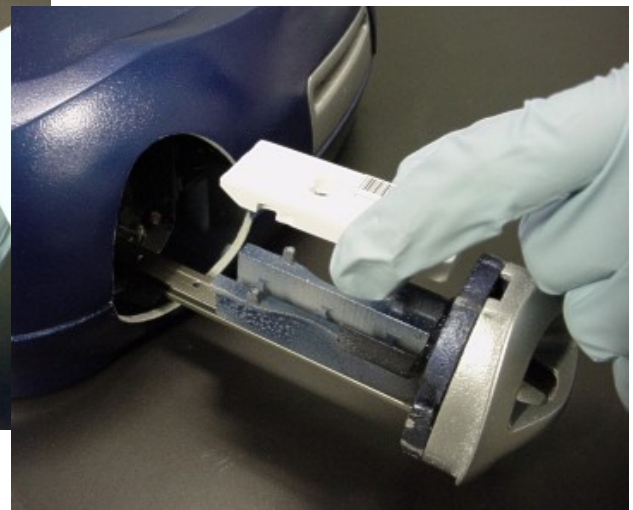
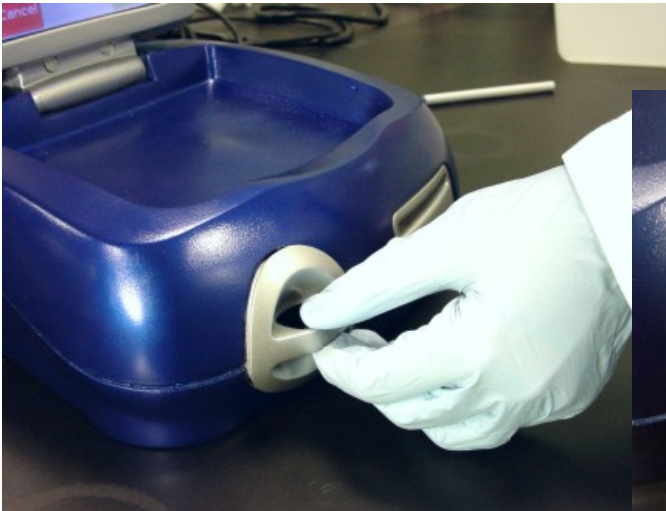
### **Step 1: User Interface**

The user initiates the operation of the machine by opening and tapping an intuitive user-interface touch screen.



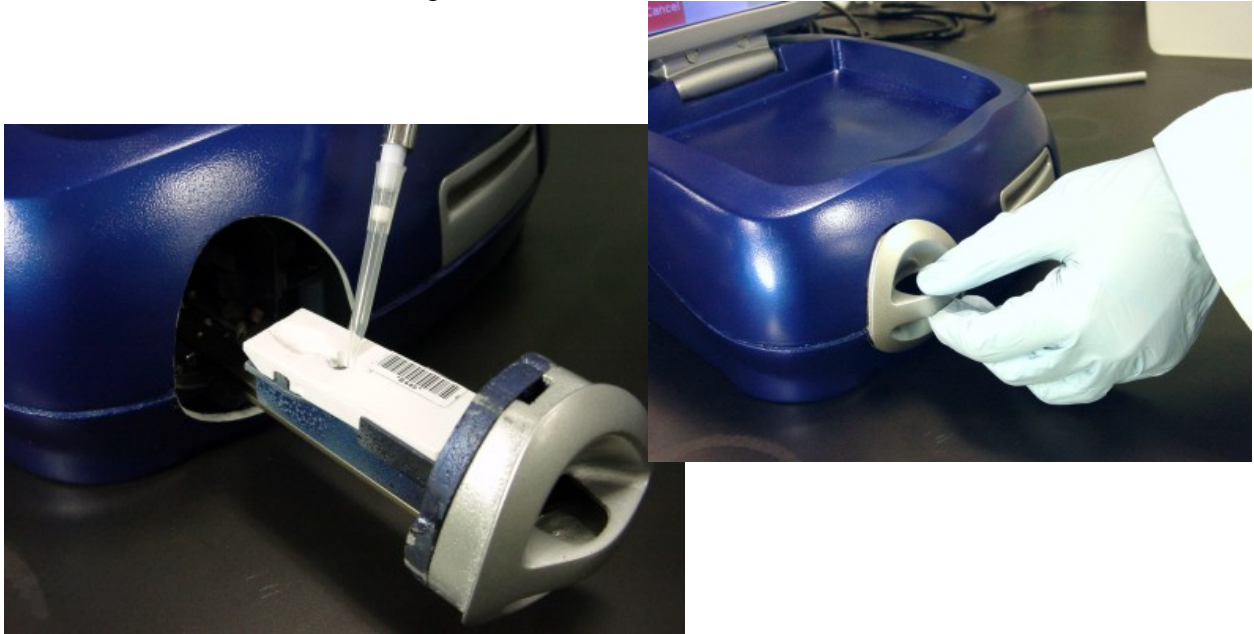
### **Step 2: Test Preparation**

The user opens the cartridge door and inserts the cartridge for the desired test.



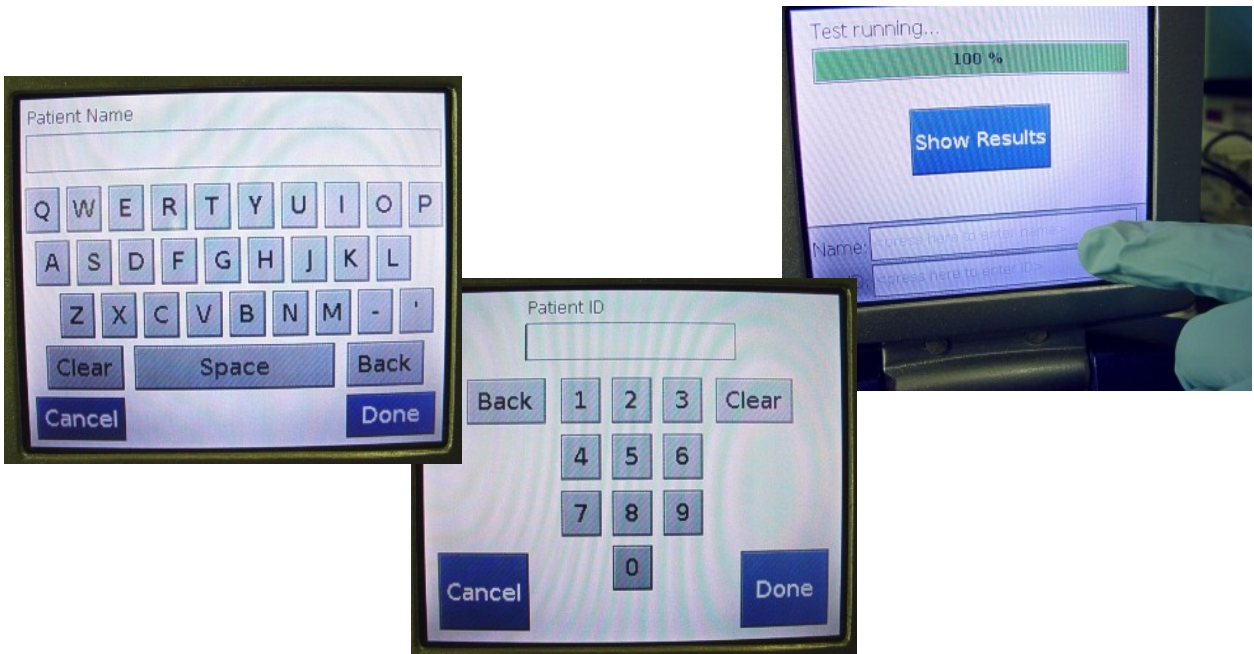
### Step 3: Test Initiation

The user adds the sample to the cartridge and closes the door to secure the cartridge within the machine, thus initiating the test.



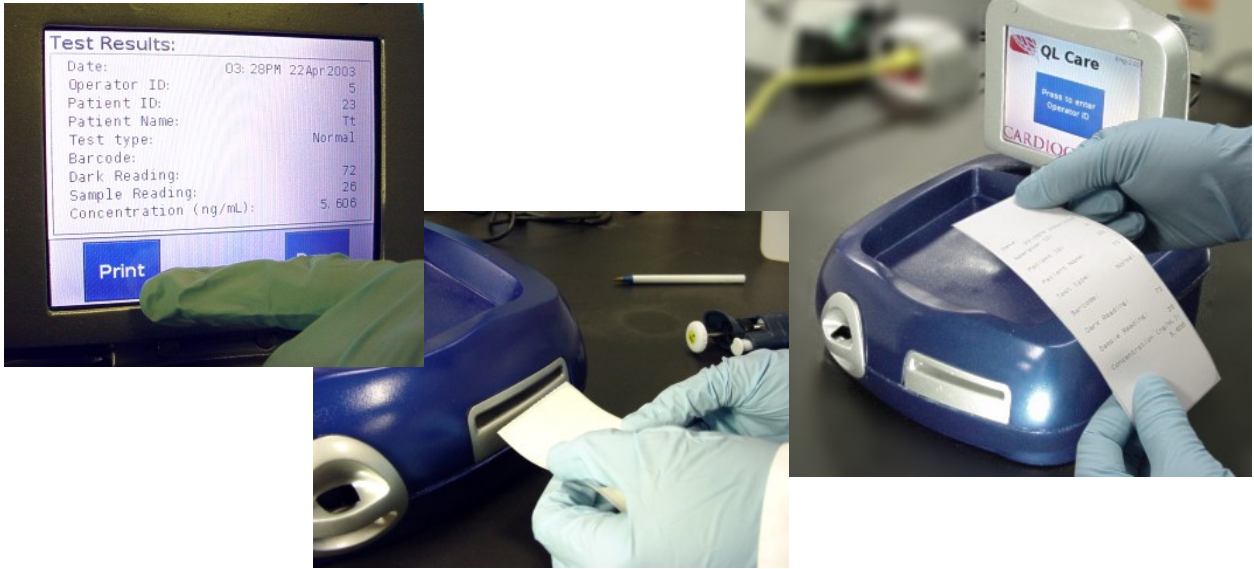
### Step 4: Automatic Calibration

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.



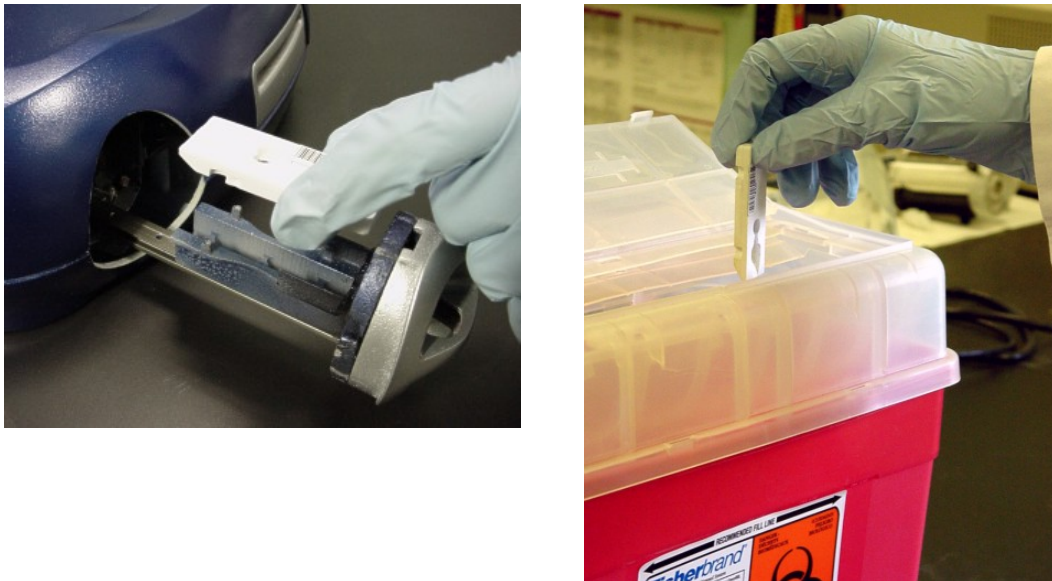
## Step 5: Presentation of Results

Results are displayed on the LCD, electronically stored in the machine and/or forwarded to a desired network. They can also be printed on the internal printer.



## Step 6: Completion of Test

The single-use cartridge is removed and disposed, readying the machine for the next test.



## THE QL CARE ANALYZER

### QL Care Analyzer Architecture

The operational specifications of the QL Care analyzer were determined at the outset: to deliver testing results that match laboratory testing with the advantages of POC testing. The QL Care analyzer was developed to address the shortfalls of commercial technologies.

At the heart of the QL Care analyzer is a superior patent-protected detection technology that was developed specifically for this analyzer. The patent-protected core technology allows all necessary compounds to be pre-deposited in the single-use disposable cartridge, thus eliminating complex mechanical design.

Laboratory machines that employ chemiluminescence (CL) use mechanical means, including injectors and valves, to deliver the final trigger compound needed to initiate light generation. The QL Care analyzer employs an electronic signal for this delivery involving no moving components. This novel and patent-protected method employs an electronic signal that is controlled and manipulated with high precision, resulting in improved light collection. This allows highly sensitive testing based on the complex immunoassay reactions, but employing a much-simplified mechanical design.

Using electronic-triggering core technology allows a simplified process that eliminates several key technical and mechanical complexities from the platform's design. The reliance on mechanical or physical means for compound delivery is prone to failure and also may interfere with collecting emitted light when applied to luminescent reactions.

The QL Care analyzer's electron trigger opened the way to the development of a POC platform that employs CL, the most sensitive testing process currently available. Unlike the use of valves, pumps or injectors to deliver reagents, chemical entrapment with electronic release allows the delivery of reagents with precise timing.

### Strategic Advantages of Core Technology

CardioGenics is the only company to successfully deploy CL in a compact, fully automated POC platform. The core technology has the following major advantages:

- **Versatility** – applicable to all five families of CL compounds. CGI has filed three patent applications protecting the core technology;
- **High efficiency light collection (solution-phase light emission)** – the technology can be used in POC test machines and large laboratory analyzers;
- **No restriction to a specific solid phase** – ELISA plates, latex and paramagnetic particles, etc., all could be used as the solid phase; and
- **No moving parts for trigger** – no pipette injectors and no tanks required to trigger the light generation.

## **Strategic Advantages of the QL Care Analyzer**

The QL Care analyzer fulfills current clinical and market needs. The lack of a quantitative immunodiagnostic POC platform that offers lab-quality results has resulted in medical practitioners' reluctance to adopt POC on a large scale. Qualitative immunodiagnostic tests, such as pregnancy tests and drugs of abuse, have had significant impact on patient management. Yet few quantitative POC immunoassay test products and test platforms are commercially available even though their benefits are clear.

The QL Care analyzer was developed in response to the critical needs of the industry. Introducing immunodiagnostic POC tests that offer the same results as lab-quality analyzers represents a significant improvement of the state of current POC testing, and it will have a significant clinical benefit and a very high commercial value. The benefits it is expected to provide for patient management and healthcare cost savings leads us to believe that the QL Care analyzer has the potential to become the small analyzer of choice in a global market.

Currently available POC platforms employ detection processes adapted from laboratory methods of the last decade (such as spectroscopy and fluorimetry) and applied to the testing of a single cartridge. Spectroscopy (color measurements) and fluorimetry (light emission induced by shining light on a chemical) were gradually eliminated from the clinical laboratory over the last decade.

The QL Care analyzer is the world's first platform that employs CL technology and is designed specifically for the POC environment. It could be deployed in any location where fast turnaround time combined with lab-quality results adds significant value. It will also supplement and complement the use of larger lab-based testing machines in hospitals and large central labs.

With its open architecture, CardioGenics believes that its QL Care analyzer could be employed to test for the current immunoassays that are commercially available (there are in excess of 200 tests used in the field of human clinical diagnostics). Adding a new test requires only a change of the biological reagents in the cartridge with no alteration to the QL Care analyzer itself.



## **ROAD MAP TO COMMERCIALIZATION**

### **QL CARE ANALYZER DEVELOPMENT**

After several years of development, building up prototype models and testing all chemical, electrical, digital and mechanical aspects, the QL Care analyzer is ready for adapting test products to its cartridge format. The core technology was validated by third-party testing.

All the electronic, chemical and electrical modules were developed, tested and optimized. The analyzer software was also developed and tested. The quality control software assesses the operation and performance of all the hardware before any testing.

### **TEST ADAPTATION**

Currently, CardioGenics is adapting several test products for the QL Care analyzer. Once test adaptation is achieved, CardioGenics will initiate B-site testing. Four hospitals in Canada and the US are already lined up for testing. Once the company is satisfied with the B-Site testing results, FDA clinical testing and data collection will be initiated.

CardioGenics expects to initiate FDA submission of the QL Care analyzer and Troponin I test within 14 to 16 months. FDA approval for this type of product averages 96 days.

### **PRODUCT MANUFACTURING AND COST CONTROL**

In order to minimize capital costs and maintain focus on core competencies, CGI initially will not establish its own manufacturing facilities. The QL Care analyzer will be assembled and manufactured under agreements with original equipment manufacturing (OEM) partners that possess the necessary expertise and economies of scale. Further, OEM sources with relevant expertise will contract out for the production of commercial lots of test cartridges. Currently, CardioGenics is in discussions with several candidates to finalize long-term supply and assembly agreements.

### **STEPS TO COMMERCIAL LAUNCH**

The following testing steps are required within 14 to 18 months:

- **Optimize the cartridge design for handling non-metered sample;**
- **Import developed test products to the POC cartridge format;**
- **B-site testing of the developed POC platform and test product; and**
- **Obtain FDA and other necessary regulatory approvals for commercialization.**

The following strategic steps would be required to commercialize the products:

- **Utilize the existing infrastructure of IVD distributors by negotiating a marketing agreement with a global IVD partner;**
- **Build up and expand an operating team with expertise in product development and commercialization; and**
- **Extend protection of the Company's increasing intellectual property through additional patent filing.**

## **FUTURE MILESTONES**

The Company anticipates achieving the following milestones:

- Finalize all patent applications;
- OEM agreements for manufacturing of platforms and disposable cartridges;
- Negotiate marketing license with a global IVD partner;
- Negotiate several POC license agreements with owners and marketers of niche immunoassay test products;
- Creation of performance testing data for the first test/platform;
- FDA submission for the QL Care analyzer and the first test product;
- Commercial launch of the first test product and platform; and
- Continuation and expansion of the protection of the intellectual property rights.