



A New Class of
Point-of-Care Devices
for Critical Care and in Home
Stat measurements



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Chronic Diseases Escalating: Disease Management is Critical

- **Congestive Heart Failure (CHF)** affects 5.1 million Americans
- **Incidence of Congestive Heart Failure in the US:** 670,000 new cases last year, 55,833 per month, 12,884 per week, 1,840 per day, 76 per hour
- **End Stage Renal Disease** affects 400,000 Americans

Point of Care Diagnostics

Need for Increase speed of therapeutic intervention

Applying the Diabetes model to other conditions:

- ◆ Diagnosing & Monitoring Patients with Potassium problems, including,
 - ◆ [Hypokalemic Periodic Paralysis](#)
 - ◆ [Gitelman's Syndrome](#)
 - ◆ [Bartter's Syndrome](#)
 - ◆ [Andersen-Tawil Syndrome](#)
- ◆ Congestive heart failure
- ◆ End-stage renal disease
- ◆ Rapid 'Stat' testing of patients
- ◆ Results at the bedside, delivered by primary care worker
- ◆ Eliminate delays due to processing of samples in central labs and the costs of maintaining specialized technicians in acute units
- ◆ Routine screening into the home to reduce out patient visits
- ◆ \$10B market, a major growth segment of total *In Vitro* Diagnostics market (36% of total)

Stat K Point of Care System

First Product Approved for Rapid Testing of K⁺

1. Remove Cartridge from package



2. Insert cartridge into analyzer.
Analyzer calibrates.
Draw and apply 2 drops of blood



3. After 30 seconds or less, read results



Total time: < 90 seconds

StatPath Advantage

- ◆ Instant Market
 - We have estimated the number of people in North America needing to check their potassium levels at greater than 5,000.
 - There are at least 1,500 people who need to check their potassium levels on a regular basis
 - Estimated sales are 500 cartridges per day
- ◆ Very Low cost
 - ◆ Analyzer only \$400 vs. \$5,000 to \$100,000 for equipment from other companies
- ◆ High Portability
- ◆ Ease of use, enabling access to home test market
- ◆ No technician needed to run test
 - ◆ Cartridges are Solid state and supplied Pre-calibrated
- ◆ Room temperature storage of consumables
 - ◆ No lengthy calibration before testing can start
 - ◆ Available instantly in the home, doctors office, medical ward or emergency vehicle
- ◆ Proprietary Chemistry IP on device and application

Patented Technology

- **Pre-calibrated Disposable Medical Devices**, US Patent No. 5,098, 545, Issued on March 24, 1992.
- **Information Storage and Transmittal for Medical Diagnostic Devices**, Patent was issued on November 29, 2000, Patent Number 6,153,085
- Proprietary Manufacturing methods for the production of the active measurement membranes

Stat K is the only true POC Device in the Market

- Abbott i-Stat – Handheld Mini Lab “Near Patient Testing”
- Very Expensive
- Cartridges must be refrigerated prior to use



Financing Objectives

- ◆ Raise funds of \$150,000
 - ◆ Update existing manufacturing hardware. Estimated \$82K USD
- ◆ Purpose:
 - ◆ Convert from analog to digital analyzer and incorporate the smartphone technology. Estimated cost: \$48K USD Includes 100-120 Analyzer Boards
 - ◆ Create smartphone software. Estimated cost \$20K USD
 - ◆ Upgrade to compatible digital manufacturing equipment
 - ◆ Streamline the membrane manufacturing and assembly process
- ◆ Update of FDA 510(k) for Stat K product with the new technology
- ◆ Establish Clinical Evaluation sites
- ◆ Ready to market 4th Quarter-2016 to the first target market of Periodic Paralysis Patients
- ◆ Then roll-out to Dialysis patient management market

Take A Look At Where We're Up To With This Project

View a 90 second demonstration of the Stat K device.



StatPath Platform Targets Multiple Indications

Additional Membranes Ready for Production

- ◇ Sodium
- ◇ Calcium
- ◇ Chloride
- ◇ Lithium
- ◇ PH and Bicarbonate
- ◇ Sodium Chloride
- ◇ Carbon Dioxide

First Product is the Potassium K+ Test for:

- ◆ Diagnosing & Monitoring Patients with Potassium problems. Check out the Facebook pages for the conditions below and you will see how important our blood analyzer is, both to individuals and their families..
 - ◆ [Hypokalemic Periodic Paralysis](#)
 - ◆ [Gitelman's Syndrome](#)
 - ◆ [Bartter's Syndrome](#)
 - ◆ [Andersen-Tawil](#)
- ◆ End Stage Renal Disease
- ◆ Acute monitoring of Congestive Heart Failure patients
- ◆ Home use Stat K for routine screening of congestive heart failure patients and home dialysis

StatPath Opportunity Summary

- StatPath, a Proprietary point of care system
- 1st product Stat K FDA (510K) approved and target launch Q4 2016, a new class of POC test
- Pipeline family of products
- Cost effective tests for Institutions, Professionals and Individual users
- Products Address large & growing markets
- Experienced management team
- Manufacturing plan in place
- Strong distribution partners
- High net profit opportunity enhanced by extremely low operating costs.

Impression of what the StatPath Technologies Blood Analyzer will look like.

