

Overview

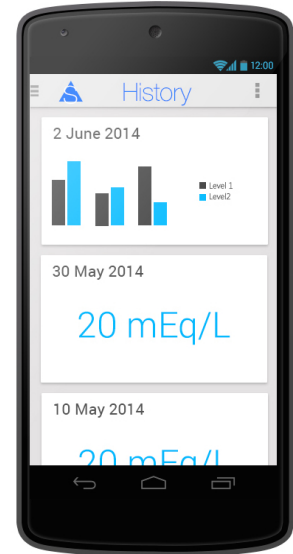
SALT (Sodium Analyte Level Test) is a revolutionary point of care medical device that rapidly and reliably measures salt levels in urine using 2 urine strips and a mobile app. No laboratory needed!

Problem

For 157 million Americans with hypertension and prehypertension, monitoring salt intake is crucial for a healthy heart. Despite the importance of salt intake, few doctors monitor it because there is no technology on the market or in the lab capable of performing a one-time measure of 24-hour urine salt levels.

How It Works

2 disposable urine strips measure 2 urine analytes, one from dietary salt and one, a metabolic constant. After a picture is taken of each test strip, vision processing software decodes the strip. The patented SALT algorithm, developed by researchers at Cornell, gives salt levels.



Clinical Value

- **Physicians** can use information from SALT to assess and optimize response to hypertension drug therapies.
- **Dieticians** can use patient salt level data to recommend dietary changes
- **Patients** can self-monitor salt levels to increase awareness and compliance to low salt diets, which have been shown to lower blood pressure and eliminate medication use.

Competitive Advantage

A one-time test capable of measuring 24-hour salt levels in urine does not currently exist on the market or in the lab, substantially limiting competitors. However, key competitors are:

- **24 hour urine collection test**
 - Ordered by a physician, a patient collects urine in a jug over the course of a day. Results analyzed in hospital lab. Cumbersome & rarely performed.
 - SALT can be analyzed at home or on the go with a small urine sample, no doctor or lab required
- **American Heart Association recommended Manual Sodium Tracker & Mobile Apps**
 - Patients manually track food intake & salt content. Inefficient, inaccurate.
 - Because 77% of daily salt intake is from processed and prepared foods, patients may not know exact nutritional content. SALT gives more accurate results in a one-time reading.

Regulatory Strategy

FDA 510K De Novo Pathway

- Submit a PDS (Pre De Novo Submission) to the FDA,
 - Provide feedback via an in-person meeting or teleconference within 75 days
- Design a validation study based on FDA feedback
- Submit a 510K document



Pricing

- Pricing Strategy:
 - SALT will be priced at \$39.99 for a 50 count bottle of strips, consisting of 25 pairs
 - The mobile app will be downloaded for free from GooglePlay & the Apple App Store
- Manufacturing:
 - Creatinine test paper by Teco Diagnostics
 - Creatinine strips by PortaScience
 - Chloride strips by Hach Inc.
 - PortaScience will package strips together as a kit, with proper bottle and labeling
 - Total cost of manufacturing is \$24.97/bottle, with a profit of \$15.02/bottle

Market Opportunity

- Total US Market is 157 Million Patients
- Hypertension/Heart Failure Market under 60
 - 78 Million with hypertension
 - 79 Million with pre-hypertension
 - Market penetration conservatively based on 22 Million Americans with hypertension and heart failure currently under treatment & under the age of 60
Under age 60 assumes capable of using a mobile app

Stage of Development

- Published clinical validation of scientific method in leading journals
- Intellectual Property patient claims allowed, final patent to be issued in 3-4 months
- Beta version of app under development
- \$10,000 raised from Family & Friends Round
 - For incorporation, website, app development, product samples, packaging samples

Investment Opportunity

- \$100,000 Seed Round. Deliverables in 1 Year:
 - FDA Pre-Novo Submission
 - Clinical Validation Study
 - FDA De Novo 510 K Clearance

Management Team

Fon Powell, Founder

- Cornell Biomedical PhD Candidate
- Duke (B.S.) in Neuroscience & Biology, US Amgen Scholar

Dr. Ladan Golestaneh

- Nephrologist, Montefiore Medical Center
- Associate Professor of Clinical Medicine, Albert Einstein College of Medicine

Eliot Kim, Advisor

- Founder of Pepper5, an NYC-based gastrointestinal medical device company
- Over 15 years of experience in medical device startups
- Led the development of a hypertension surgical system at Maya Medical, acquired for \$230M by Covidien in 2012