

# OsteoTest: At Home Osteoporosis Test

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## Executive Summary

Osteoporosis is a widespread problem with increasing cases as baby boomers increase in age. Injuries due to falling have costs in excess of \$17 billion associated with them and cause significant quality of life issues for elderly patients. Having a more convenient method of testing for osteoporosis will increase early detection and decrease associated costs of the disease. Our device will use a small blood sample to detect alkaline phosphatase levels, which will be correlated to bone turnover rates in patients. An immunoassay with magnetic beads will be encapsulated in a disposable device that will be cheap, portable and easy to use for elderly patients. Current methods, such as DEXA scans, are expensive, must occur in a doctor's office and are time consuming. Our device will improve upon all of these areas.

## Problem and Clinical Need

- Osteoporosis is the loss of bone density by which the bones lose optimal mass and strength.
- Can occur due to excessive bone reabsorption and inadequate response to increased bone reabsorption
- Diagnosis of the disease allows preventative treatment to save money and increase quality of life.
- While osteoporosis cannot be cured, it can be retarded by: exercise, diet and medicine.
- Design Requirements:** Affordable, Accurate, Portable, Ease of Use and Clear Readout

## Market Analysis

- Currently affects over 14 million Americans, another 47 million are at high risk and 5 million have fractures due to Osteoporosis.
- Affects 1 in 3 women and 1 in 5 men.
- This number will only continue to grow as the generation of baby boomers becomes older.
  - Estimated that by 2020, bone loss will affect 60 million citizens over 50<sup>[1]</sup>
- Total costs including prevalent fractures are more than \$19 billion.
- Current Standards: DEXA scan and an X-Ray.
  - X-Ray scans are not as precise
  - DEXA scans are expensive and time consuming

## Description of Design



Figure 1: CAD model of casing design

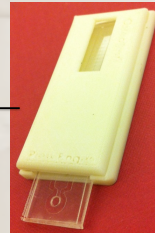


Figure 2: Actual casing with device and magnet (inside casing)

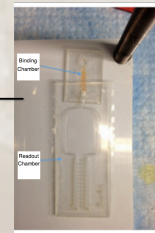


Figure 3: Working prototype with coated binding chamber and readout chamber

### Casing Design (Figure 1 & 2)

- Casing designed using CAD
- Casing constructed via Rapid 3D Prototyping
- Top locks into bottom using a snapping mechanism
- Magnet is housed internally in the casing

### Sandwich ELISA

- Binding chamber is coating in BALP antibody
- ALP enters binding chamber
- ALP is captured by BALP antibody and remains within binding chamber
- Magnetic beads coated with another form of BALP antibody enter binding chamber
- Magnetic beads bind to ALP
- Excess beads are washed through binding chamber to readout chamber

### Device Design (Figure 3)

- Device is made of two parts: binding chamber and readout chamber
- Both chambers are laser cut from polyethylene glycol (PEG)
- Readout chamber is laminated to seal
- Binding chamber is coated and covered with a thin PEG cover sheet with inlet and outlet ports



Figure 4: Un-used coated binding chamber



Figure 5: ALP captured in binding chamber

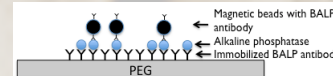


Figure 6: Completed sandwich ELISA in binding chamber using magnetic beads

## What is Novel About the Device?

- Measures bone turnover rate using Alkaline Phosphatase biomarker.
- Small and portable hand-held at-home test.
- Ease-of-use in terms of self pricking and magnified readout.
- Disposable.
- Affordable and available to a large population

## Estimation of Product Costs

- OsteoTest is estimated to cost \$2.67 per device (without Cost of Machinery)
- Cost of Machinery is \$10,000 (one time purchase)
- Cost of Unit at Bulk
  - 10,000 Units - \$3.70 per device
  - 100,000 Units - \$2.77 per device
- Profit
  - Product Selling Base Price- \$10 per device
  - Profit per 10,000 Units- \$63,000
  - Profit per 100,000 Units- \$723,000

## Anticipated Regulatory Pathway

- Class II medical device
- Novel device; no predicate device exists in market
- Require Premarket Approval (PMA)
- Needs valid scientific evidence; target post-menopausal women
- Must be reviewed by CBER
- Blood samples from human clinical studies determines accuracy
- Blood samples from animal studies proves functionality

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