

## MetastaticPrecision - Rapid Cancer Diagnostic

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**The Problem:** Cancer is a global epidemic that has impacted most Americans in some way. The National Cancer Institute projects 580,000 deaths in the United States this year due to cancer<sup>1</sup>. To fight cancer and increase survival, we must develop faster and more accurate diagnostic tests. The incidence of diagnostic error, including failure to diagnose existing cancer or delayed diagnosis, is 28%<sup>2</sup>. This disturbing statistic indicates a need for more reliable, faster, and accurate diagnostic tests. The standard techniques for diagnosis involve an invasive procedure to obtain tissue biopsy and histological analysis to identify biomarkers. However, due to their limited specificity and inability to distinguish cancer cells of varying metastatic potential, biomarkers tests are not adequate and fail to detect or completely capture the heterogeneity of the cancer.

**The Invention:** We have developed a low-cost, rapid, and more accurate *in vitro* diagnostic (IVD) technology that can distinguish and isolate cancerous cells of varying aggressiveness from noninvasive liquid biopsy samples. MetastaticPrecision IVD is a proprietary bi-component device that uses modified wicking fibers, novel non-circular cross-sectioned fibers that enhance fluid transport, and a novel capture device to isolate metastatic cells. To date, the technology has been used to separate and isolate cancerous cells, MCF-7s, from a cellular mixture also containing benign cells, MCF-10As. The device can distinguish cancer cells within minutes, and isolate cancerous cells efficiently (>90%). Further results have shown the IVD can distinguish and isolate more aggressive cancer cells (MDA-231) from less aggressive cancer cells (MCF-7). Current technologies, such as Food and Drug Administration (FDA)-approved CellSearch (Veridex), have low isolation efficiency and purity of cancer cells from liquid biopsies and fail to capture multiple subpopulations of cancer cells with varying metastatic properties. Our technology can identify subpopulations of cancer cells and isolate aggressive cancerous cells with high efficiency and purity. MetastaticPrecision IVD exclusively provides the ability to distinguish subpopulations of cancer cells based on their metastatic capabilities. This ability allows this IVD to objectively capture the heterogeneity of the cancer, provide more accurate prognosis, and help develop more efficient therapeutics.

**The Opportunity:** Cancer is commonly called the aging disease. With the rise of the baby boomer generation the incidence rate of cancer is projected to significantly increase<sup>3</sup>. The worldwide market for IVDs is expected to reach 7 billion dollars this year<sup>4</sup>. According to a 2008 market report by Frost and Sullivan, the biomarkers segment of the IVD market is expected to grow rapidly,

especially from easy-to-access fluids<sup>5</sup>. In addition, the need for an accurate and rapid early detection test has yet to be achieved. MetastaticPrecision has the potential to analyze liquid biopsy and provide accurate and comprehensive information regarding the heterogeneity of the cancer. This device has potential in the pharmaceutical industry by aiding in the development of highly specific therapeutics and reducing the overuse of cancer treatments. The current \$44 billion dollar global pharmaceutical market is highly competitive but still growing<sup>6</sup>. Globally, 50% of cancer deaths occur in areas of the world with limited resources<sup>7</sup>. MetastaticPrecision can eventually target these countries, proving them a simple, affordable, and available point-of-care approach for early detection of cancer. The point-of-care *in vitro* testing market is estimated to reach \$72.3 billion by 2018<sup>8</sup>.

**Market Strategy:** MetastaticPrecision technology will initially allow the development and validation of an IVD assay for the early detection of breast cancer. The technology is currently being tested to validate and optimize the device to capture heterogeneous populations of breast cancer cells. Standards will be developed to objectively and rapidly identify the cancer cells of varying metastatic potential within a sample, without the need of multiple pathologists or trained personnel to analyze data. To further show analytical and clinical validity, the company will apply for a National Institutes of Health Small Business Innovation Research grant to fund retrospective validation studies for this IVD. MetastaticPrecision will then pursue venture capital and grants from cancer foundations to fund a testing facility, product development, and regulatory approval. MetastaticPrecision IVD is not considered a multivariate assay and may only require the company to obtain Clinical Laboratory Improvement Amendments certification, which is significantly less expensive than FDA approval. However, due to the novelty of the device the FDA may require approval through the 510(k) pathway for a Class II medical device. To accelerate clinical adoption through clinical trials and more extensive validation testing, MetastaticPrecision will partner with a pharmaceutical company. FDA approval and clinical adoption is expected to take a maximum of 5 years and cost approximately \$15 million. MetastaticPrecision will establish pricing with Current Procedural Terminology (CPT) codes to identify the IVD test with insurance providers and begin reimbursement. The CPT code is established against current standard of care. The pricing for this IVD test for hospitals, based on existing CPT codes, is expected between \$50-\$500. The IVD test requires significantly less reagents, lab supplies, and trained personnel, greatly reducing the overall cost.

MetastaticPrecision will begin as a platform or service company performing diagnostic testing of samples in house. After clinical adoption, MetastaticPrecision will manufacture IVDs and sell to hospitals and clinical labs for on-site use. MetastaticPrecision will also target academic research centers and pharmaceutical companies, and finally target developing countries around the world lacking inexpensive, simple, and rapid diagnostic tools. Once MetastaticPrecision IVD has shown to improve patient outcome and contribute therapeutic success for breast cancer cases, the company will expand into optimizing the IVD for other cancer types and point-of-care applications.

#### **References:**

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