Mobile Diagnostics Without Compromise

- Central lab quality results in minutes versus hours — within or outside of a lab environment
- Facilitates rapid decision making, enabling faster therapeutic intervention
- Measures multiple biomarkers at once from a single patient sample
- Handheld platform and integrated, mobile connectivity enable use in any healthcare setting
- Automated and easily used by non-technical personnel

Nanōmix is the leader in the development of mobile point-of-care diagnostics, with a platform and assays that provide rapid, accurate, quantitative information for use in settings where time is critical to clinical decision-making and improved patient care. Our company aims to broadly improve healthcare delivery by bringing central lab-quality diagnostic testing to the point of initial patient interaction, whether in the hospital, pre-hospital, or remote settings, enabling faster decision-making and potentially treatment-in-place. We are developing a broad pipeline of assays across all diagnostic categories, initially targeting a $1B market with a multiplex test panel to screen patients for serious infections including sepsis. This panel was CE Marked in late 2019 and the first filing with the FDA is in process.

Mobile Healthcare and the Nanōmix eLab Solution

The healthcare market is rapidly evolving to incorporate a decentralized system of care delivery within a broad spectrum of environments: the emergency department, skilled nursing facilities, elderly homes, urgent care centers, ambulances, or remote locations.

Thus, while hospital central labs currently are the gold standard of clinical testing, mobile diagnostic platforms offering high-quality testing results at affordable prices are needed to serve this decentralized system. Based on this evolving demand for high-quality, mobile diagnostics, experts expect the worldwide point-of-care market to grow from US $20B to more than US $38B in 2022.

ED & EMS POC Testing

The Nanōmix eLab® System is specifically designed to meet this evolving market need. It includes a durable, handheld, rechargeable battery powered instrument and a disposable multiplex, microfluidic test cartridge.

Proprietary biosensors deliver laboratory-quality performance wherever the patient needs it, including a wide range of testing environments outside the hospital. The Nanōmix eLab System is well suited for markets that include pre-hospital assessment, chronic medical care, and post-hospital disease management, as well as use in remote locations far from traditional centers of health care delivery. Whether on the ambulance, in a skilled nursing facility or in the clinic, the Nanōmix eLab System will help mobile health providers to quickly triage patients to a higher level of care when necessary.


Results in 10 min

Initial Products Address Large Markets, Unmet Clinical Needs

Nanōmix initial commercial development programs target a significant unmet need: a test to screen and assess patients with serious infections including sepsis. This application requires the accuracy of laboratory-quality assay performance and the rapid time-to-results that the eLab System provides.

The eLab S1 Assay Panel will be the first comprehensive sepsis screening test available at the POC. Early intervention is critical for the survival of sepsis patients. During the first six hours from onset of symptoms, each hour of delay in initiating treatment is associated with a mean decrease in survival of 8%. Current screening approaches insufficiently identify patients with early sepsis and poorly differentiate patients with other disorders. Single biomarker tests often require hours to generate results, meaning that they are not useful for the urgent need to assess and treat septic patients. The Nanōmix eLab System's multiplex design employs three analytes indicative of the patient's condition, enhancing the performance of initial screening. The eLab System's mobility allows the identification of likely septic patients in the pre- or post-hospital setting, where currently such diagnoses are often delayed and lead to poor patient outcomes.

Other products were spurred by the rise of SARS-CoV-2. As the COVID-19 pandemic began, Nanomix scientists quickly developed two 10-minute point-of-care assays — one for antibodies and one for antigens — that are being validated internally and at independent clinical facilities. We anticipate that the antibody test will be available in mid-June 2020 and the antigen

test will be available in July 2020. With this dual test availability, the Nanomix eLab platform will enable testing subjects for early evidence of infection (antigen) and for active or past infection (IgG/IgM antibodies).

Nanomix has also recently completed feasibility testing of a rapid POC diagnostic for acute kidney injury. Designed to help reduce the time to diagnosis, the assay may also be useful in assessing the state of transplanted kidneys. Future tests on the eLab System will address critical care areas requiring rapid diagnosis as well as infectious disease applications.

Proprietary Technology

The eLab System utilizes a proprietary nano-biosensor to generate multiple electrochemical assay results from a single patient sample. Specificity is generated by functionalizing each of the electrodes on the sensor for particular biomarkers. The sensor is incorporated into a single-use consumable microfluidics cartridge that processes the biological sample and reports its results through the handheld eLab System. Nanōmix has more than 30 issued patents protecting its intellectual property.

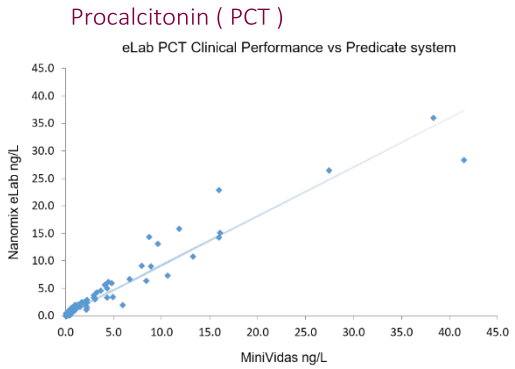
- A wide variety of biomolecules with varying chemistries can be tested on a single device in one operation
- The electrochemical detection system eliminates the need for ongoing calibration and maintenance commonly associated with optical systems
- Wireless connectivity provides for flexible transmission of patient results to other devices for data sharing, management, and EMR integration.

CE Mark and FDA Submission

Nanomix has completed clinical trials of the S1 multiplex assay for serious infections including sepsis. The S1 assay provides quantitative results for three analytes: CRP, lactate, and PCT. The assay and the eLab Analyzer were tested against FDA cleared predicate systems in clinical trials conducted at multiple hospital sites in the U.S. Nanomix has received CE Mark and the initial FDA 510(k) filing is in process for plasma samples from venous whole blood. Commercialization will be done through experienced distribution partners and initial sales of the CE Mark product are expected in 2020.

Laboratory Quality Results

Clinical testing demonstrates that the Nanomix eLab System provides laboratory quality results for all three analytes in the S1 Assay Panel.



Clinical Results for PCT

Performance of the eLab system is strongly correlated with the performance of central laboratory analyzers. Clinical testing of 180 subjects shows a strong correlation with an approved lab device testing for PCT. The linear regression R2 was .935.

Corporate Partners

Nanōmix has formed a strategic partnership with the leader in the EMS space to lead worldwide sales into the pre-hospital market. An equity investment and business collaboration with a Hong Kong life science group accelerates our entry to China and expands our product reach to veterinary markets.

Team

Nanōmix's seasoned leadership team has the requisite experience for success. The team has backgrounds that include technology, microfluidics, assay development, software, manufacturing operations, clinical development, and sales and marketing.

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