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Lateral Flow Technology And The Future Of Point Of Care Diagnostics, 2nd Edition

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Abstracts

Lateral flow (LF) tests, also known as immunochromatographic strip (ICS) tests, are point of care tests that reduce the time spent waiting for test results from hours to minutes, require less training for operators, and reduce the cost of both device development and care. This report, Lateral Flow Technology and the Future of Point of Care Testing, 2nd Edition, takes an in depth look at the market, technologies, and trends in lateral flow point-of-care testing, looking at both self-testing by patients and at point-of-care testing by healthcare professionals.

Lateral flow devices and tests have been a popular platform for rapid immunoassays since their introduction in the mid-1980s, and since our last look at the market there has been continued interest and innovations. This report profiles over a hundred companies that currently market lateral flow tests. Many of these companies, plus more than ten additional companies, are developing innovations in lateral flow-based devices. Companies profiled in this report use lateral flow technology to develop and market a wide range of rapid tests for market segments of in vitro diagnostic (IVD) tests that can be performed in centralized laboratories.

Every critical aspect of the lateral flow test market is addressed, including the following key topics:

The current sales figures for LF productsand realistic projections for 2017

The core factors driving LF testing revenues up.

Breakout of LF-POC market by Self Test and Professional Breakout of LF-POC market by Key Test Segments (Fertility, Infectious Disease, Cardiac Markers,

Oncology, Drugs of Abuse, Other)

The trends to watch that could increase sales predictions.

Need-to-know companies in Lateral Flow Test devices.

Expected gains to be made by LF POC devices over lab-based immunoassays across categories.

Regional markets for lateral flow tests (US, Europe, Japan, ROW)

Obstacles that could trap new entrants.

Growth in lateral flow point-of-care testing is being fueled by many factors fueling growth of the point-of-care market as a whole. These include the globalization of infectious diseases and the associated public health issues, advances in therapies giving physicians more tools for treatment of patients if the doctor is able to rapidly diagnose the problem, the need to monitor an ever-growing group of people with chronic diseases such as cardiovascular diseases, cancer and other chronic conditions, and many other factors. Decentralized testing and the ability to get rapid test results is emerging as a tool for more efficient diagnosis and patient evaluation, and to improve the quality of patient care.

This report provides a realistic assessment acknowledging the reality of payors' emphasis on cost/benefit analysis for new technologies. Current sales and predictions for 2017 sales are provided for the diabetes, oncology, cardiac marker, pregnancy and other LF test markets.

Kalorama's unique and thorough research process provides an exhaustive analysis of this evolving market. Information was gathered using both primary and secondary research including comprehensive research of secondary sources such as company literature, databases, investment reports, and medical and business journals.

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About

Market leaders for traditional rapid infectious disease tests include the market leader Alere, Becton Dickinson (BD), Meridian, and Quidel. Other companies in this market include Acon Labs, Beckman, Polymedco, Princeton BioMediTech, and Trinity Diagnostics.

A number of people in companies in the POC industry have hoped that POC tests for H. pylori, Strep A, influenza, Lyme diseases and STDs (chlamydia and gonorrhea) would be more widely used. However, this has not happened to date. Many companies have developed POC tests for these and other infectious diseases, only to find that their markets have remained small.

One barrier has been the need to use serum samples for these tests. Also, these tests often take at least 30 minutes, and patients often did not want to sit around waiting for the test result. Another significant hurdle is that the POC tests for these infectious agents have not been as sensitive as the tests used in central laboratories. Many of the central lab tests for these infectious are based on molecular diagnostic platforms that detect DNA and RNA.

This market will change soon, as several companies are developing molecular diagnostic platforms that can detect the DNA or RNA of a pathogen in the near-patient or POC setting In addition, companies are making significant advances with urine and saliva-based assays. The resulting increased availability of noninvasive alternatives to blood testing is expected to provide a number of important public health implications. A system without needles or blood is inherently safer for healthcare workers than a test involving blood collection.

Research has shown that many people reluctant to undergo a blood test for HIV testing are willing to give an oral sample for this purpose. Non-invasive test systems are portable and simple to use, require minimal training, which means they can reduce health personnel costs and can be used outside of the traditional treatment setting.

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