HOWE SOUND RESEARCH

RESEARCH REPORT
MARCH 2019

SYNDROMIC MULTIPLEX DIAGNOSTIC MARKETS.

Strategies and Trends. Forecasts by Syndrome (Respiratory, Sepsis, GI etc.) by Country. With Market Analysis, Executive Guides and Customization.

2019 to 2023 - Global Version

HOWE SOUND RESEARCH
Call: 604 377 8604 Email: service@howesoundresearch.com

Howe Sound Research is a market research and consulting company based in Vancouver, British Columbia, Canada. In our spare time we like to sail in a large body of water nearby called Howe Sound. We publish market research reports that address scientific industries with an emphasis on Biotechnology and Clinical Diagnostic markets. We consider ourselves experts in these areas.

We approach market research differently than other companies. At any one time we have a limited number of reports and we update them frequently, sometimes several times a year. Our reports are prepared by people who understand the industry and have worked and studied in the area. This contrasts with the many research mills who produce canned reports on the Handbag market one day and the XRay market the next.

Our intellectual property is encryption protected. If you have issues with this or would like to upgrade to a corporate license that is not encrypted, please contact us at the email above.

Please feel free to contact us if you have any questions. We believe in customer service and are more than willing to provide after sales assistance and custom data.

Table of Contents

Table of Tables

Table of Figures

1.1 What are Syndromic Multiplex Tests?

Syndromic Multiplex tests identify many infectious diseases with a single test.

Syndromic Multiplex Testing (SMT) are single tests that report back on the presence, or not, of several infectious diseases at the same time. Today the pattern is for a doctor, when faced with a patient who has some kind of cold/flu for instance, (a respiratory syndrome) to make a preliminary diagnosis and then to order a limited number, or just one, test to see if the diagnosis is correct. This is the traditional approach that goes back to the days when not all infectious diseases were known and they were recognized instead by their symptoms. The laboratory was used to confirm, or not, the diagnosis and often the disease was treated, and still is today, before the laboratory results were in. Tests were considered to be expensive and were ordered only as needed and often not at all.

These tests are DNA based and consequently are more accurate and specific.

The revolution in genetic knowledge has created technologies that can recognize multiple pathogens using a single test. This is called a multiplex test. The technology is DNA based so these tests tend to be very much more accurate than traditional testing methods. And because of this DNA base the possibility exists of identifying specific classes of pathogens, e.g. those resistant to certain antibiotics.

A syndrome is a group of symptoms that are often seen together and suggest the presence of one or more infectious diseases. The GI-Enteric Syndrome for instance, might often just be referred to by its main symptom, diarrhea. So diagnostic tests are being developed that test for a wide range of pathogens, in a single test, that might cause this symptom. This Syndromic Multiplex testing approach costs more initially, sometimes a lot more, but despite that is proving very popular.

Suppliers are providing different tests for different syndromes with different pathogens identified. These can be performed on smaller proprietary instruments and sometimes on traditional laboratory

positive. The three-gene-product approach to western blot interpretation has not been adopted for public health or clinical practice. Tests in which less than the required number of viral bands are detected are reported as indeterminate: a person who has an indeterminate result should be retested, as later tests may be more conclusive. Almost all HIV-infected persons with indeterminate western blot results will develop a positive result when tested in one month; persistently indeterminate results over a period of six months suggests the results are not due to HIV infection. In a generally healthy low-risk population, indeterminate results on western blot occur on the order of 1 in 5,000 patients. However, for those individuals that have had high-risk exposures to individuals where HIV-2 is most prevalent, Western Africa, an inconclusive western blot test may prove infection with HIV-2.

The HIV proteins used in western blotting can be produced by recombinant DNA in a technique called recombinant immunoblot assay (RIBA).

2.1.3.2 Point of Care Tests (POCT)

Rapid antibody tests are qualitative immunoassays intended for use in point-of-care testing to aid in the diagnosis of HIV infection. These tests should be used in conjunction with the clinical status, history, and risk factors of the person being tested. The positive predictive value of Rapid Antibody Tests in low-risk populations has not been evaluated. These tests should be used in appropriate multi-test algorithms designed for statistical validation of rapid HIV test results.

If no antibodies to HIV are detected, this does not mean the person has not been infected with HIV. It may take several months after HIV infection for the antibody response to reach detectable levels, during which time rapid testing for antibodies to HIV will not be indicative of true infection status. For most people, HIV antibodies reach a detectable level after two to six weeks. Although these tests have high specificity, false positives do occur. Any positive test result should be confirmed by a lab using the western blot.

Interpreting antibody tests

of anti-HBs is called the window period. A person negative for HBsAg but positive for anti-HBs either has cleared an infection or has been vaccinated previously.

Individuals who remain HBsAg positive for at least six months are considered to be hepatitis B carriers. Carriers of the virus may have chronic hepatitis B, which would be reflected by elevated serum alanine aminotransferase (ALT) levels and inflammation of the liver, if they are in the immune clearance phase of chronic infection. Carriers who have seroconverted to HBeAg negative status, in particular those who acquired the infection as adults, have very little viral multiplication and hence may be at little risk of long-term complications or of transmitting infection to others.

PCR tests have been developed to detect and measure the amount of HBV DNA, called the viral load, in clinical specimens. These tests are used to assess a person's infection status and to monitor treatment. Individuals with high viral loads, characteristically have ground glass hepatocytes on biopsy.

2.2.4 Market Opportunity Analysis

The market opportunity in HBV molecular diagnostics can be characterized broadly as

- Decreased window (zero) testing
- Point of care testing – nucleic acid based
- Genotyping

The traditional tests for HBV rely on detection of the antigen. These tests are limited by the time it takes for the full infection to develop and thereby produce the antigen in quantity. More sensitive nucleic acid based tests can reduce this "window" and have the opportunity to set a new detection standard.

Molecular Diagnostics (nucleic acid based testing) is moving into the Point of Care (eg. Emergency Ward) sphere. HBV with its relationship to drug use and sexual transmission is an important area for POC testing.

4.4.1 Comparing Syndrome and Targeted Testing

Syndromic testing, and its popularity, represent a shift in thinking about diagnosis. Traditionally diagnosis is done by a doctor with the lab tests confirming (or not) the diagnosis. In the syndromic testing paradigm, *the diagnosis shifts to the lab*. The doctor, recognizing the limits of their craft, lets the lab do the real work, and often saves physician time in the process. It is no wonder that time pressed Emergency Room physicians are enthusiastic adopters. Working against this is a very traditional view, control costs by stopping physicians from ordering unnecessary and expensive tests. This narrow view ignores the broader cost picture and the goal of the medical system, better care.

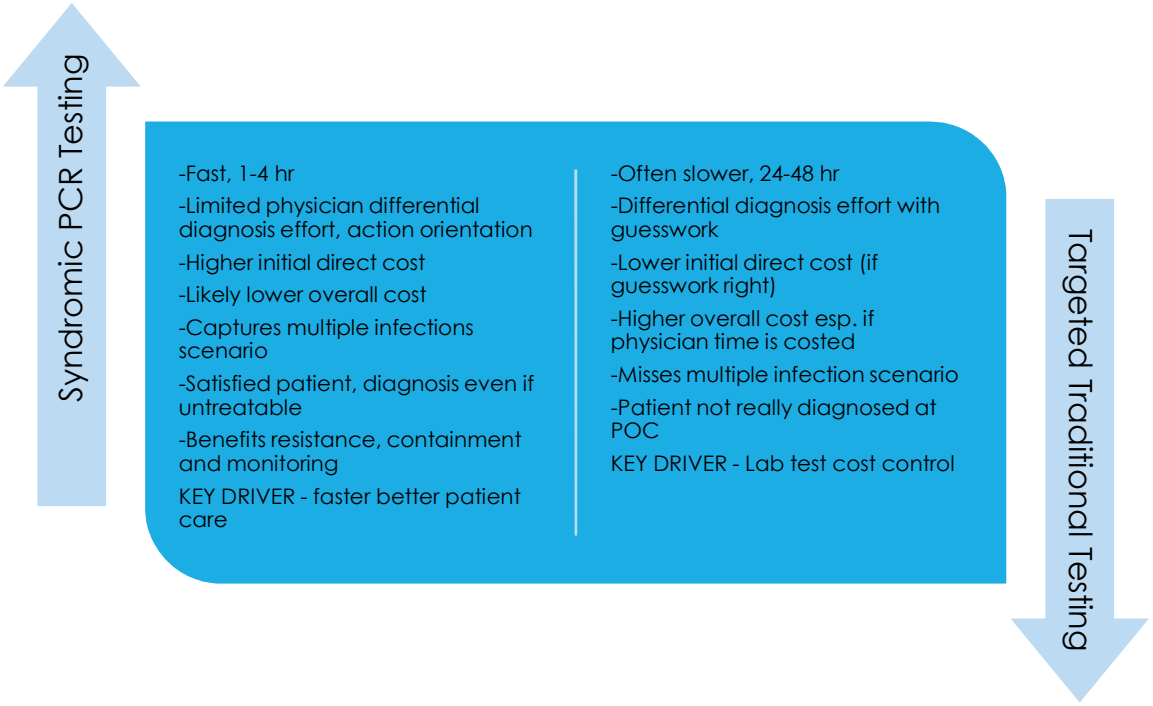

FIGURE 12 COMPARING SYNDROMIC AND TARGETED TESTING

Recent Developments – Importance and How to Use This Section

Importance of These Developments

Many users, especially those in the financial community, have noted that this section of the report can be extremely valuable in helping to understand industry current events and the evolution of key market players. These items are not chosen at random. They have been selected by the authour(s) as significant and worth reading about, i.e. important. Please keep this in mind in reviewing them.

How to Use This Section

These items are NOT in date order. They are in the order in which they have been added to the report. This report is updated regularly, and new items are incorporated, and others removed. Numbering of items may not be sequential. Generally newer items are in the lower part of this section and have the highest numbers. Please refer to the date of an item to understand its currency. Reading this entire section is recommended for those not familiar with the industry. Many of the trends and issues noted elsewhere are illustrated in these actual events.

Akonni Biosystems Submits Multiplex Diagnostics System to FDA

Jan 04, 2019

Akonni Biosystems announced today it has submitted a molecular diagnostics system to the US Food and Drug Administration for 510(k) clearance. The system can perform multiplex testing using on-slide PCR and microarray technologies.

The system, called TruDiagnosis, consists of the TruDx imager, TruArray consumable test kit, and TruSpot software. The firm did not disclose whether a specific diagnostic assay was submitted along with the TruDiagnosis system.

The submission marks "a significant milestone" for the company, CEO and Founder Charles Daitch said in a statement, representing a critical next step in realizing Akonni's mission "to develop, manufacture, and sell molecular diagnostic tools for rapid, affordable, and

Aus Diagnostics

AusDiagnostics Pty. Ltd.
290-292 Coward Street
Mascot NSW 2020, Australia
ABN 84 612 059 686

http://www.ausdiagnostics.com

TEL. +61 2 9698 8030

Revenue: ~$7.5M

Description:

This privately held company was founded in 2006 by the current Managing Director. The company offers a wide range of syndromic multiplexing kits using a distributor strategy with offices in the UK and New Zealand. The company is active in a wide range of markets beyond human medical syndromic multiples testing, including veterinary and environmental assay markets.

The company offers a robust kit product line with several panel options in each of the following Syndrome categories

Respiratory	GI Enteric
Meningitis	Sepsis
Sexually Transmitted Disease	Bacterial Resistance
Parasites	HPV

The instrument lineup consists of:

A High-Plex System with two main parts: the Sample Processor and a Real-time PCR analyser. This can be supplemented by a nucleic acid extracton machine

Sample Processor. It performs sample handling, runs up to 24 (High-Plex) or up to 48 (Ultra-Plex) reactions and sets up 96-well or 384-well Real-