Infectious Diseases Point of Care Diagnostics

Products, Players and Outlook to 2017

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EXECUTIVE SUMMARY

- The point-of-care (POC) diagnostics market encompasses a wide range of products used outside the central laboratory, by either healthcare professionals, patients self-testing as supervised by a healthcare practitioner or by consumers. This includes products that test for blood glucose, fertility and pregnancy, infectious and cardiovascular disease, cancer, drugs of abuse, urinalysis, and hospital testing in areas such as critical care, surgical and emergency departments.

- POC infectious disease testing products can be used to screen for and diagnose a wide range of illnesses, including respiratory diseases such as influenza, common illnesses such as Strep A and H. pylori, HIV, hepatitis, tuberculosis (TB), sexually-transmitted infections (STIs) and tropical diseases such as malaria and dengue fever. Often, the tests can indicate if a disease may be present and follow-up lab tests may be required to confirm diagnosis.

- There are around 80 companies active in the POC infectious disease testing market, many of which are development-stage or have limited product portfolios and market share. The market leaders include Alere and Quidel for respiratory disease diagnostics and for other POC tests commonly used in physician’s offices. For HIV testing, Alere, Chembio Diagnostics, OraSure Technologies and Trinity Biotech hold strong market positions.

- The market for POC infectious disease testing can be broadly divided into testing in the developed world, and testing in emerging and developing countries. In the developed world, POC testing is most frequently conducted in doctor’s offices and other professional healthcare settings, where it can potentially facilitate faster diagnosis and treatment than lab-based testing. Demand in the developed world varies significantly, with the US a strong adopter of the technology and Japan also frequently using POC influenza testing products. However, infectious disease testing in Europe continues to be predominantly conducted in central labs and the POC market in this region is underpenetrated.

- In certain emerging markets and the developing world, access to central lab testing is often sparse or non-existent, particularly in remote areas. Therefore, POC testing can play a key role in broadening access to healthcare and reducing the prevalence of diseases such as HIV and malaria, which are commonly seen in such regions.

- Currently, the market for POC infectious disease testing is worth over US$900 million and it is estimated to have grown by 20% between 2010 and 2011. Growth in the market is challenging to predict, given the fact that POC respiratory disease testing comprises a large proportion of the market and growth in this area is largely dependent on the prevalence of respiratory diseases in a given year. For example, the market rose rapidly in 2009 as a result of increased demand brought about by the pandemic H1N1 virus, declined in 2010 when there was a weak influenza season and rose again in 2011 when rates of influenza were higher.

- As well as testing conducted by healthcare professionals, there is a move towards selling POC infectious disease products over-the-counter (OTC) directly to consumers, enabling them to test for a disease in the privacy of their own homes. In October 2012, OraSure launched the first rapid OTC HIV test to be FDA-approved in the US directly for use by consumers at home. The introduction of such products could present a significant growth opportunity for manufacturers.

- Other recent events that could help drive growth in the POC infectious disease testing market include moves in the US to broaden access to HIV and hepatitis C screening to a larger proportion of the population.

- Despite many positive aspects, there are several key challenges for the market to overcome. Concerns have been raised by laboratory professionals about the decentralisation of hospital testing and by doctors about patient and consumer self-testing. In both cases, there is concern that the use of POC products by lay users may lead to result misinterpretation, leading to a resistance to the changes needed for POC products to be more widely implemented.

- Concerns have also been raised about the accuracy of some POC tests used to diagnose conditions such as influenza and TB. For infectious disease testing, the ongoing development of POC PCR and DNA-based systems is expected to improve on the accuracy of currently-available products. The development of these new-generation products could also expand POC testing to new markets such as hospital-acquired infections such as MRSA and C. difficile. These devices could represent a significant market opportunity for manufacturers, should they be able to reduce the testing time and price point of the products to something suitable for and attractive to point-of-care users.
INTRODUCTION

The term ‘point-of-care (POC) diagnostics’ is generally defined as *in vitro* diagnostic (IVD) testing, meaning those that use bodily fluids extracted from the body such as blood, that is undertaken in the same location as the patient and that produces a result while the patient remains where the test was performed, facilitating faster diagnosis and treatment.

POC diagnostics is not recognised as a distinct product category by any regulatory body and its definition is therefore open to interpretation. There is debate as to the definition of where the “point-of-care” ends. For example, whether the test has to take place at the patient’s side or if it can be performed in the same hospital department the patient is in, but further away from the patient.

For the purpose of this report, Espicom has used the generally-accepted definition of POC diagnostics, which encompasses diagnostic testing that is not performed in a central laboratory. This area is often also referred to as decentralised or near-patient testing. It includes IVD testing undertaken in a doctor’s office, out-patient setting, emergency room, intensive or critical care unit, operating room (OR) or maternity unit, as well as by a patient or consumer. An important factor that distinguishes a POC technology is that it does not require interpretation by a trained laboratory professional, but is simple enough to be used by medical professionals or sometimes patients themselves.

Given these broad definitions, there are currently many types of POC diagnostic product on the market that can be used for various medical applications. These include tests that can diagnose and/or monitor cardiac events, cholesterol, blood coagulation, blood glucose, infectious diseases, pregnancy and fertility, liver and renal diseases.

The Role Of POC Testing in Infectious Disease Diagnostics and Surveillance

POC testing can offer clear benefits over the use of laboratory testing. As the test is conducted in the presence of or near the patient, the results are available much more quickly than laboratory test results. Some POC test results are available instantly, while others can take up to 90 minutes. In contrast, laboratory samples must be taken from the patient, sent to a laboratory, processed, analysed and then the results returned to the healthcare professional that requested the test. Laboratory results can therefore take several hours, days or even weeks to come back to the healthcare provider. This can mean losing valuable time in treating a patient, by which time the patient’s condition may have deteriorated, meaning they may require more lengthy or complex medical intervention.

In non-urgent cases where a result is returned from a laboratory in days or weeks, the patient is no longer with the healthcare professional. The healthcare provider has to contact the patient, who may or may not return for treatment. This delay could lead to a patient’s condition worsening, the patient spreading infectious diseases within their community or them never returning to receive treatment. It also often makes two visits to the healthcare provider necessary, taking up more of the doctor’s time that could be spent with other patients.

By increasing the speed of diagnosis, POC diagnostics can offer healthcare providers an opportunity to improve the quality of patient care. It also saves healthcare providers time and reduces costs. A faster diagnosis can mean a faster medical intervention, potentially avoiding the need to admit a patient into hospital and the costs incurred as a result, while also freeing up that hospital bed. For general practitioners, having a test result immediately available means they do not have to contact the patient and arrange an additional appointment for treatment, which is also more convenient for the patient.

POC diagnostics can also enable diagnosis and treatment to be undertaken away from a healthcare facility. In developed countries, it can enable healthcare providers to undertake screening programmes in rural areas, community centres, schools or religious buildings, helping to reach sections of the community that have little access to or do not access traditional healthcare centres. In developing regions of the world, POC diagnostics can also improve healthcare provision where there is a lack of infrastructure such as central laboratories or in rural areas. POC diagnostics is playing an important role in improving the health of the developing world, enabling screening and testing for infectious diseases such as HIV, hepatitis, malaria and tropical diseases.
POC Infectious Disease Testing Products

Currently, POC infectious disease diagnostic products can be used for the detection and diagnosis of respiratory diseases, common illnesses such as Strep A and H. pylori, viral hepatitis, tuberculosis (TB), HIV, sexually-transmitted infections (STIs) and tropical diseases such as malaria and dengue fever.

A key to reducing the spread of infectious diseases is to quickly identify patients that have them and provide treatment as soon as possible, improving the health of the patient and also preventing them from transmitting the disease to other people. Therefore, POC tests that can quickly diagnose infectious diseases are a key focus of healthcare strategy.

Infectious disease testing has historically been conducted in a laboratory, meaning patients have to wait for results to come back, during which time their condition could have worsened or they could have infected additional people. In addition, with traditional tests in typical populations, a large proportion of people tested never return to get their results, so treatment is delayed or never begins. POC testing provides results while the patient is still with the healthcare provider, eliminating the chance of them not follow-up with their test results.

In addition to benefits in developed nations, rapid infectious disease testing is particularly important in developing countries, many of which have been hard-hit by diseases such HIV and malaria. In these areas, POC diagnostics can assist healthcare workers in obtaining test results for people in remote areas or where there is no access to central labs. Tests that can diagnose a patient at the POC can therefore speed the detection of disease and increase the accessibility of diagnosis and detection.

However, there are some issues about the accuracy of some current POC infectious disease tests, particularly in the case of influenza tests, which has come to light since the 2009 H1N1 flu pandemic. Some of the POC products on the market may produce false positive or negative results, meaning patients may be treated for a condition they do not have, or may not be treated when they are infected. In addition, most tests just provide a yes or no answer, and patients often require further lab testing to accurately confirm diagnosis.

Despite the limitations of current products, POC tests can be useful in disease outbreaks that need to be quickly contained, providing a tool for detecting cases faster than lab testing. They are particularly useful in developing countries or for outreach work, where there is no access to lab testing.

Customers of POC Infectious Disease Tests

POC infectious disease diagnostic tests can be used by medical professionals in hospitals, out-patient departments, doctor’s offices and in the community; and by consumers who can purchase some tests over-the-counter (OTC).

Most infectious disease tests are used by medical professionals. Therefore, more complex tests can be made available than those used by consumers or patient self-testers. Such tests may require more interpretation as healthcare professionals understand the significance of the tests being conducted, and can be provided with more training and ongoing support in the products’ use. However, unlike laboratory staff, most healthcare professionals do not have experience of performing IVD tests and are rarely trained in best practice laboratory techniques for sample handling and preparation. In order to maintain patient and staff safety when transferring testing from the laboratory to the physician’s office, POC products are designed to minimise the need for sample handling and preparation, offering features such as automated processing and operation without the need to add reagents or manual handling steps.

The consumer POC market has very different dynamics and priorities than the professional-use market. While much of the market is unregulated and consumers can purchase many different tests via the internet and other sources, properly approved tests have to demonstrate accuracy and be simple enough for totally untrained people to use safely and without misinterpretation. An example would be a pregnancy test, which provides a simple yes or no answer.

There is concern among some healthcare professionals about some OTC tests on the market. Results can sometimes be complex to interpret, and accuracy is dependent on how well the test is performed or at what time after testing users read the results. Some doctors are concerned that a false negative result for such a test may give patients false reassurance they are well and they may ignore the symptoms of potentially life-threatening medical conditions, where treatment success and a reduction in complications depend on prompt diagnosis. Alternatively, patients may face unnecessary medical tests to rule out a false positive result, as well as the associated anxiety. Both situations can actually lead to increased healthcare costs, either for unnecessary tests to rule out conditions or for more extensive treatment if patients fail to address serious illnesses promptly. There have been calls for more regulation of the OTC market, as well as clearer product labelling that explains to users how to test and the limitations of testing.