

IN VITRO DIAGNOSTICS

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The *In Vitro* Diagnostic (IVD) market place is currently witnessing radical change fuelled by an increased demand for testing, continued technological advancements, better diagnostic tools, improved treatment monitoring, faster response times and increased availability of over-the-counter tests.

GLOBAL IVD MARKET

The IVD industry responded to the global financial crisis by developing innovative technologies and approaches; digital pathology, multiplex assays, automation and test service commercialization. Trends to the increased use of biomarkers and molecular approaches to testing have been seen, with the latest estimate of the size of the global IVD market in terms of revenues is \$44.3 billion and is estimated to continue to grow at a rate of 6% for the next 5 years with certain segments and territories estimated to grow significantly faster.

DRIVERS OF IVD MARKET

Globally, several factors are driving demand for IVDs, including high population growth, increased affluence, aging populations. Diseases that were once fatal are now chronic, and The World Health Organisation's Global Burden of Disease data show aging and generations of children facing costly chronic disease is cited as a key driver of health spending. Neurological diseases, such as Alzheimer's, show the fastest growth rate in Australia

In the USA, demand is predicted to increase due to the recent passage of President Obama's healthcare reform bill in the USA is predicted to increase the demand for IVD and high-volume testing at lower costs. In the Asia Pacific region the fastest growth was recorded by the molecular biology segment followed by coagulation and point of care (POC); which supported a compound annual growth rate of almost 9% for the overall IVD market between 2007 and 2008, and even more interesting predictions for the future.

AUSTRALIAN IVD MARKET

The Australian market represents less than 2% of the global market however it has become an influential world market because of its well developed clinical laboratory accreditation system, will be the first Jurisdiction to introduce a GHTF based regulatory scheme for IVDs, most IVD companies across the world are represented in Australia, which also support much of the New Zealand market directly from Australia.

EMERGING MARKETS

Emerging markets with special IVD needs (difficult environments with unregulated infrastructure) are driving new technology initiatives; however they have little or no infrastructure and large capital investment makes them unattractive or not feasible. The ability to gain market share in the emerging markets is fraught with many logistical and competitive barriers

REGULATORY AFFAIRS

The US FDA has made significant efforts to improve its responsiveness to IVD product submissions and approvals. For example, the FDA Modernization Act of 1997 and Project BioShield Act of 2004, which allows the FDA to grant Emergency Use Authorisation (EUA), in order to strengthen public health protection.

European IVD Directive. The European Union's In Vitro Diagnostic Directive 98/79/EC was released on December 7 1998, and broke down the need to gain approvals in multiple sovereign states; however, regulations continue to grow stronger. As a result, the IVD industry has seen and should continue to see, a more rapid introduction of new technologies and innovations. In Australia, the revised regulatory framework will now see all IVDs undergo pre-market regulatory assessment in accordance with their level

of risk and all IVDs are required to be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

A FOCUS ON DISEASES

Diagnostic trends for respiratory infections such as Tuberculosis and avian flu are moving away from culturing to a molecular diagnostic approach that delivers faster and more sensitive results. The challenge is to bring rapid diagnostics to large populations in remote locations. Tests with sensitivity issues, in some cases related to their cyclical nature include HIV and malaria. Cardiovascular disease is the leading cause of death in industrialized countries. Cancer in its various forms accounted for around 13% of all deaths and there is now evidence from research that many types of cancers (i.e., lung, breast, ovarian, and colon cancers) may be detected via a blood test that looks for reduced immune responses in patients. HPV diagnostics is booming, with many other disparate families of disease being considered including the autoimmune diseases, which lead to many common debilitating disorders. More than eighty illnesses are caused by autoimmunity.

POINT OF CARE DIAGNOSTICS

Many IVD companies still believe in the huge potential for simple, rapid assays in the point-of-care (POC) market but the major challenge - and opportunity - is to improve penetration in primary and secondary care settings in the professional care market. The POC market grew by 11% in 2008 and was valued at US\$12.6 billion. Growth has been driven by the wider adoption of POC technologies and new products. In Europe, the market varies greatly from country to country. However, the physician's office testing market is still very much in its infancy and tests continue to be undertaken by a central laboratory. The three fastest growing sectors of the POC diagnostic market are infectious diseases, cancer and cardiovascular conditions.

PERSONALISED MEDICINE – MOLECULAR DIAGNOSTICS

The area of personalised medicine is on the verge of major expansion and will rely on improved personal diagnostics coupled with personalised treatments. Although many companion diagnostic (CDx) deals have been announced, the financial terms are not always disclosed. It is likely that any diagnostic would be developed only after the drug is on the market. An evolving platform is DNA microarray, which is already being used for multiplex coverage of key biomarkers associated with drug metabolism.

Several genetic biomarkers involving Epidermal Growth Factor Receptor (EGFR) and associated gene mutations are validated for cancer treatment as FDA approved test/treatment regimens for Herceptin, Gleevec, Erbitux, Iressa and Tarceva. Also notable is the growing use of protein biomarkers in clinical trials for cancer drugs, which was expected to be more than \$1B in 2010. However, biomarkers have not achieved the level of significance in the IVD industry that many people expected; this may be due to the lack of specificity.

Genomics and personalized medicine is a long-term theme supported by explosive scientific developments and a compelling need in drug development. In the future, Leroy Hood, founder of the Institute for Systems Biology sees a strong move to personalized medicine which he defines as P4 medicine - Predictive, Personalized, Preventative (shifting focus to wellness) and Participatory. In his vision, nanotechnology approaches will be required to develop individual Patient Based Assays to interrogate wellness and track the pathways to disease. Not only will this require great leaps in technology, equipment, data analysis and management, it will also demand that doctors are educated to understand and communicate the results of this testing.

TRENDS IN INSTRUMENTATION

Decentralisation continues even though POC and physician office laboratory (POL) tests are still significantly more expensive than central lab tests on a per-test basis. Microbiology is on the crest of the molecular diagnostics wave, in **Emerging Markets**, there is demand for reduced overall test costs, rapid results and simplified operations in which the ideal IVD process from whole blood sample to result requires no operator intervention. **Microfluidics** has made significant progress; new fluidic drivers obviate the need for pumps and valves, and appear to offer many advantages for lab card-based POL and POC applications.

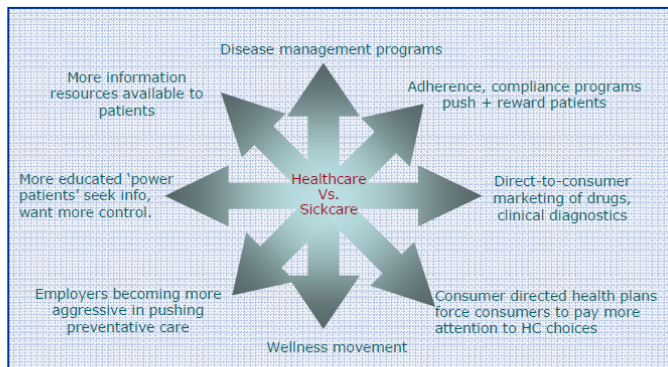
Detection Technologies. While optical detection technologies have become customary (ranging from absorbance to various means of fluorometry to chemiluminescence), they inevitably become more expensive as sensitivity increases. Alternative detection technologies such as impedance measurement and electromagnetic detection of binding events using magnetic beads are emerging, which appear to offer much promise at reduced costs, and **Mass spectrometry** is poised to make its clinical lab entry in microbiology applications, aimed at reducing turnaround times on tests. The trend toward automated processing in closed systems protects lab workers from having to directly handle or manipulate biohazardous procedures.

WHAT DOES THE FUTURE HOLD

The IVD industry will follow the general trend of the overall Healthcare industry from Therapeutic to Preventative medicine. This is summarized in the diagram below (from Frost & Sullivan Asia 2009 Diagnostics Market Report):

- Rise of the Consumer
- New era of proactive medicine and empowerment of the consumer. Patients demand more information from healthcare providers
- Evidence based Healthcare
- Increase in evidence-based healthcare or the illustration (providing evidence) of the effectiveness of a test in order to justify its use, e.g. cardiac risk markers.
- Personalized Medicines
- In particular, advances in genomics, proteomics, pharmacogenetics and theranostics are anticipated to result in the optimization of diagnosis and therapy tailored to the individual
- Integrated Solution
- From bench top instruments with innovative assays to larger systems, which are integrated with different software and automation components
- Expanding capabilities- Alliances
- By investing in R&D and Collaboration & partnership with smaller companies across the world to overcome the vast gap of different geographical differences
- Upsurge in IVD Tests
- Key role in improving patient outcomes and cost-savings due to earlier and more precise diagnoses and patient monitoring

Figure below illustrate various dimensions and market trends shaping the direction of Healthcare industry form Therapeutic to Preventative medication era. This paradigm shift highlights equal contribution of patients together with clinicians & suppliers. The outlook based on this shift will bring noticeable changes to the way Healthcare providers deliver their services.



Source: Frost & Sullivan Growth Consulting Practice Healthcare APAC Copyright @2009

CONCLUSION

The IVD industry faces challenges from growing public health issues in the developed world (e.g. diabetes and flu epidemics) and from epidemics in developing nations (e.g. tuberculosis, HIV, the re-emergence of drug-resistant malaria). Technologies are available to address such challenges, coming from advances in information technology, microfluidics, molecular diagnostics, nanotechnology, and most recently proteomics-based mass spectrometry. The opportunities lie in matching progress in the development of biomarkers of disease with technologies and identifiable improvements in therapeutic outcomes. With regulatory bodies increasingly aware of the need for swift and flexible responses and for developing procedures and information technology infrastructure to speed up product approvals, the landscape ahead for IVD manufacturers continues to present significant challenges and correspondingly large opportunities.

If you would like to obtain a copy of the full report or discuss the IVD industry, please contact:

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