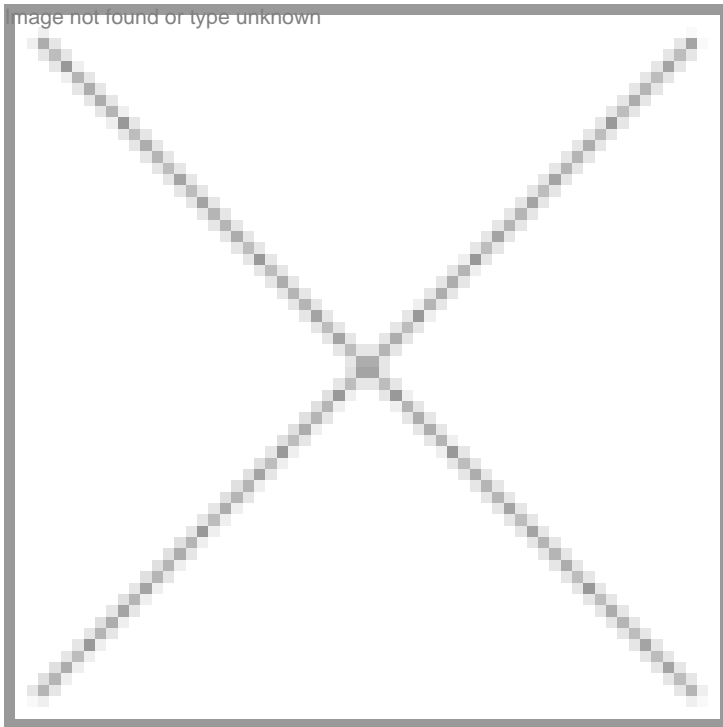


IVD market on fast track

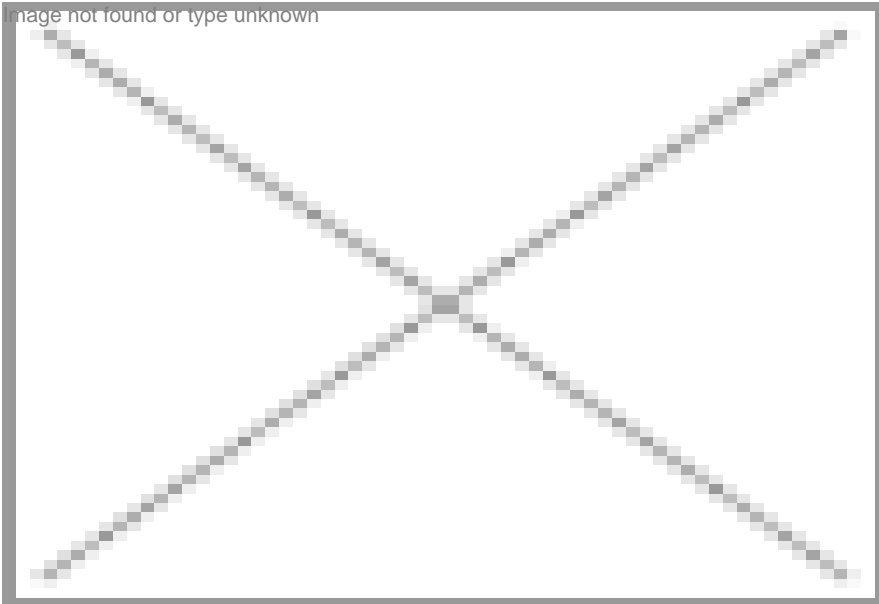
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IVD market on fast track

Fuelled by strong double-digit growth rates of segments such as molecular diagnostics and diabetes care, the in vitro diagnostic segment is set to take off in a big way, with worldwide sales expected to surpass \$44.5 billion by 2010.

Advances in human genomics, bioinformatics, miniaturization, and microelectronics-often blended with information technology and computer technology-have led to a growth spurt in the market for in vitro diagnostic (IVD) tests, with worldwide sales expected to surpass \$44.5 billion by 2010, according to a 2006 study from Kalorama Information.



The global market for IVD, in 2004, stood at \$28.5 billion. It is witnessing a good growth fuelled by strong double-digit growth rates of segments such as molecular diagnostics and diabetes care. The molecular diagnostic segment is expected to grow at over 15 percent in the next five years much higher than other sectors.

The IVD market accounts for about 38 percent of the total global medical devices and diagnostic market. The other two segments include diagnostic imaging equipment market with a share of 41 percent and the rest accounts for electro-medical devices, according to IntelLab Corporation.

Routine test segments-chemistry/immunoassay workstations, hematology, and routine microbiology-currently make up about 70 percent of the market test-wise. But intensive price pressure and automation continuously erode the market value of these segments and more expensive nucleic acid, pharmacogenomic tests and immunoassays for cancer, cardiovascular diseases and infectious diseases will begin to overshadow these mature segments by 2010.

According to a report from Business Insights, the global IVD market is dominated by a handful of large players with several hundred smaller players competing for market share. Further consolidation within the sector can be expected as pharmaceutical companies seek acquisitions in the diagnostic field to complement their drug development programs in the emerging personalized medicine era. Leading IVD companies Roche and Abbott illustrate the synergies between diagnostics and pharmaceuticals. Both companies have development projects for new biomarkers in the fields of oncology and infectious diseases.

Underlining the growing significance of molecular technologies, leading medical technology company Becton Dickinson has increased its participation in the molecular diagnostics sector with the acquisition of GeneOhm, which specializes in healthcare-associated infections, such as MRSA.

Companies specializing in diagnostics, such as Gen-Probe, Inverness Medical Innovations and Tm Bioscience, are targeting niche markets. While small companies remain vulnerable to competition from larger players, they have established their market presence through differentiated technology.

The innovative technology companies represent a valuable source for larger companies and laboratories. Affymetrix' GeneChip technology is licensed to several top players, including Roche and Johnson & Johnson. Nanogen's NanoChip electronic microarray platform and PCR reagents enable laboratories to develop multiple assays with universal parameters.

Consolidation of the IVD industry is highlighted by the dominance of the leading 15 companies, which account for almost 90 percent of the global IVD market. Roche is the major player with a 20 percent market share. The other leading companies include LifeScan of Johnson & Johnson, Bayer, Beckman Coulter, Dade Behring, BD, bioMerieux and Bio-Rad.

The acquisition of one of largest IVD companies, Diagnostic Product Corporation (DPC), by Siemens Medical Solutions heralds a trend towards the emergence of new players in the market as in vivo and in vitro diagnostic technologies converge.

With the acquisition of DPC, Siemens holds the unique position of being the first company to bring in vitro diagnostics, in vivo diagnostics and healthcare IT under one roof, but faces constant competitive threats from other companies looking to enter the market. However, according to market analysts at Frost & Sullivan, the IVD market holds enough potential to continue attracting such companies to participate and invest either through partnerships or acquisitions.

Opportunities to enhance diagnostic management are ample and such alliances and collaborations are beneficial to both companies and patients. Recent acquisitions have also set off a new trend to combine early diagnosis with information technology to create a new "early health" model of care focused on swift diagnosis, pre-symptomatic disease detection and prevention.

Asia outlook

With the presence of rich pool of innovation and intellectual property, manufacturing capacity, emerging industry players and maturing market-Asia is beginning to experience the surge in IVD market. At present, Asia Pacific accounts for only two percent of the IVD global sales. Over the past few years, the Asian IVD market has been the only region experiencing close to a double-digit growth rate. While an ageing population and widening health insurance penetration are advancing growth opportunities in this high potential market, divergent country-specific social, economic, political and healthcare issues threaten to impede overall market development.

The Kalorama Information report predicts that emerging markets, such as South America and Southeast Asia, where rising standards of living have sparked the growing demands for quality medical care, will experience 10-20 percent annual growth. While Japan, EU, and the US markets, accounting for 85 percent of the total IVD market, will begin to lose market share, with their portion of the market decreasing to 80 percent by 2010.

Asia's ageing population is expected to double by 2025, increasing the number of people likely to require medical treatment. Rising average life expectancies coupled with more affluence are expected to boost expenditure on healthcare treatments, including IVD. For instance, Japan-with the world's third largest aged population-accounts for 90 percent of IVD market revenues in Asia. In other countries, governments are being confronted with the dilemma of reducing healthcare outlays even while expanding healthcare coverage to all. However, the growing realization of their tremendous financial and therapeutic benefits is furthering the popularity of IVD tests. From being under-utilized and undervalued, IVD tests are now increasingly being regarded as key to improving overall cost efficiency and patient outcomes.

Lack of proper health insurance and constrained personal finances has resulted in low levels of consumer spending. In the absence of a strong medical insurance sector, most of the healthcare expenditure is borne by the individuals themselves. It is estimated that 82 percent and 63 percent of total healthcare spending in India and China, two major countries in the region respectively, is "out-of-pocket." This is expected to slowly change with private insurance companies increasing their penetration and introducing some kind of healthcare coverage.

According to Frost & Sullivan, clinical chemistry (38 percent) and immunoassay (29 percent) followed by haematology and microbiology are driving the growth of the IVD market in Asia. The fastest growth was, however, recorded by the molecular biology segment followed by coagulation and point of care (POC). Increased adoption of nucleic acid testing (NAT) based infectious diseases and viral assays (molecular diagnostics), blood glucose testing (POC), cardiac markers and glucose (clinical chemistry), coagulation self-monitoring and bacteriology culture (microbiology) is set to support a compound annual growth rate of almost nine percent for the overall IVD market between 2003 and 2010.

A prominent trend has been that of cancer overtaking infectious diseases as the leading killer in Asia. This has increased the potential for premium-priced tests for cancer detection. Although the region has traditionally been more of a follower rather than leader in developing and adapting to newer tests, novel, premium-priced assays are poised to replace more conventional testing options. Therefore Asian countries offer a great market potential for IVDs, considering that they account for a small percentage of total healthcare costs. In particular, the development of molecular diagnostic assays used to test newly identified disease targets is fueling excitement over the promise of personalized medicine and theranostics.

Global IVD market evolves

From being primarily driven by bench top instruments with innovative assays, the global IVD market has continuously evolved over the last decade and is now more focused on larger systems that are integrated with different software and automation components and on developing screening and disease confirmation tests.

Innovative technologies are expanding the capabilities of diagnostics, particularly molecular diagnostics which enable earlier and more precise diagnosis. Molecular diagnostic tools are enabling personalized healthcare through patient selection for specific treatment and monitoring of disease progression. Although realizing the potential of new technologies will depend on overcoming challenges such as regulatory and reimbursement hurdles, new diagnostic opportunities will expand the IVD market to over \$40 billion by 2010.

There are several changes taking place in healthcare provision that are influencing the market for diagnostic products and the dynamics of industry as a whole. IVD companies' abilities to anticipate and react in a timely manner to these changes will, to a great extent, determine the success or failure of new technologies. The fact that patients are taking greater responsibility for their healthcare decisions, and have wider access to information on new technologies, has empowered consumers who are playing a key role in driving demand. Healthcare demand is also fuelled by a rapidly ageing population and the availability of new and advanced technologies. Combined, these factors are placing considerable pressure on healthcare budgets.

Faced with rising healthcare costs, private and public payers will require compelling evidence in the form of cost-benefit analysis to support the reimbursement of diagnostic and therapeutic products. In this regard, the development of technologies that enable pre-symptomatic screening and individual patient risk profiles are likely to make a difference by establishing closer links between diagnostics and therapeutics. The resulting "theranostics" will bring more value to diagnostic tests, which are undervalued by healthcare payers and providers.

Faced with demands for multiplexing, rapid turn-around time, sensitivity and specificity, while still remaining cost-effective, the challenge for IVD manufacturers will be to strike a balance between the various components of diagnostics systems - chemistry, detection instrumentation technology and software.

As technical breakthroughs continue to drive the IVD market, the healthcare industry is becoming aware of their increasingly important impact on the way medicine is practiced. By focusing on predicting patient outcomes, targeted medicine, earlier disease detection and more advanced automation, diagnostics has secured considerable market growth potential. This promises to contribute to significant healthcare cost savings in the near future.

The IVD industry is rapidly evolving and is presently more dynamic than in over a decade. Diagnostics currently possess tremendous potential for growth, but harnessing this opportunity requires that market-participants concentrate on efforts to raise awareness regarding the importance and benefits of optimizing patient diagnosis.

Understanding individual markets and clinical needs is becoming increasingly important to overcoming obstacles and promoting the adoption of new technologies.

Despite several challenges, the IVD market expects to see a great deal of growth, especially as a result of developments in molecular diagnostics and point of care testing. As systems are becoming smaller, more integrated, and increasingly automated, the industry is also beginning to see a shift in priorities toward enhanced customer service efforts and more optimal data management solutions.

For a long time, the IVD industry has been fairly stagnant however, recent discoveries have ignited a great deal of excitement over potential medical applications. Consequently, many companies have been boosting investments in research and development, focusing on pharmacogenomics and theranostics. In the near future, innovative technologies will enable physicians to identify disease, choose the ideal treatment, and monitor the patient's response to therapy. This concept of personalized medicine is still in its infancy but is expected to create great opportunities for both the pharmaceutical and diagnostic industries.

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