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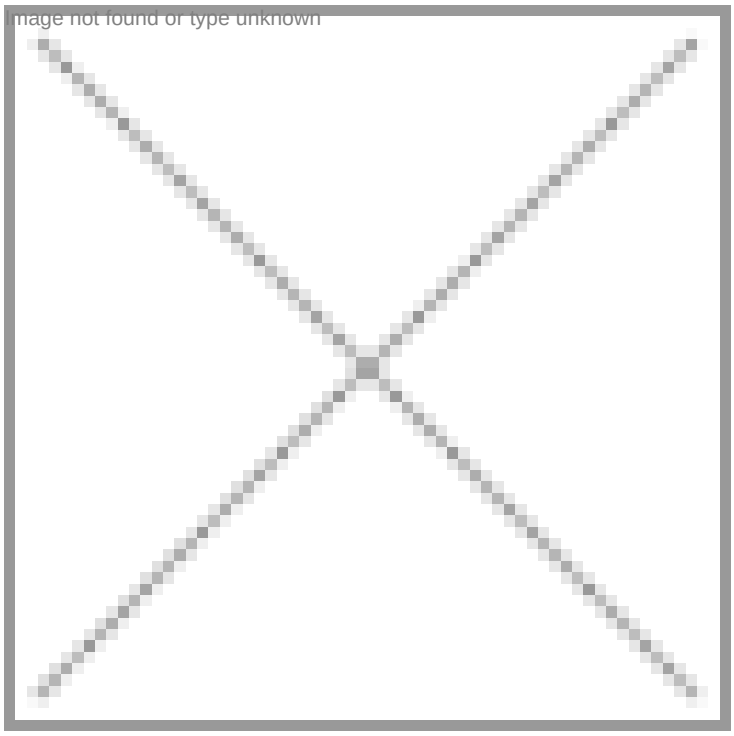
Molecular diagnostics enables tailor-made treatments

06 May 2009 | News



Molecular diagnostics enables tailor-made treatments

Molecular diagnostics has grown by leaps and bounds in the last decade with molecular diagnostic tools being used to test patient samples for a wide range of diseases.

In the future, molecular diagnostics is expected to lead the tailor-made or personalized medical treatments, customized according to the patients' genetic make-up and exact characterization of the disease. Thus molecular diagnostics will play a key role in boosting the effectiveness of medical therapies and expected to reduce the adverse drug reactions. This will lead to a modern healthcare system that is more affordable and efficient.

The field of molecular diagnostic is rapidly growing, particularly in the US and European biotech hubs. It plays an important role in detecting and treating diseases. In 2007, the global molecular diagnostics market was estimated at Rs 13,116 crore and is projected to grow by 17 percent annually until 2010. The market can be divided into infectious disease, blood screening, oncology, genetic testing, companion diagnostics and applied testing. Molecular diagnostics has paved the way for more efficient drug development. For example, human papilloma virus (HPV) is a major cause of cervical cancer in women, the HPV Subtypes like HPV16 and HPV18 account for about 70 percent of all cervical cancer cases. During the development of a vaccine against HPV (Gardasil), Merck & Co. used molecular diagnostics to identify and classify the strains of HPV in women who participated in the clinical trials of the drug. This allowed the study to more clearly show the efficacy of Gardasil against the relevant strains of HPV that are known to cause cervical cancer and the results became an integral part of the company's regulatory submission to the Food and Drug Administration (FDA).

At present, polymerase chain reaction (PCR) based testing predominates; however, alternative technologies aimed at reducing genome complexity without PCR are anticipated to gain momentum in the coming years. Furthermore, development of integrated chip devices (lab-on-a-chip) should allow point-of-care testing and facilitate genetic readouts from single cells and molecules. Together with proteomics-based testing, these advances will improve molecular diagnostic testing and will

present additional challenges for implementing such testing in healthcare settings.

Focusing on infectious diseases

Abbott is a global healthcare company focused on discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. Abbott Molecular's instruments and reagents detect pathogens and key changes in patients' genes and chromosomes, which permit earlier diagnosis and selection of appropriate therapies and improved monitoring of disease progression.

Abbott also offers genomic tests for chromosome changes associated with congenital disorders and cancer, including the PathVysion HER-2 DNA Probe kit to identify women with metastatic breast cancer who could benefit from Herceptin therapy, and UroVysion, which detects genetic changes in bladder cells for use in monitoring bladder cancer recurrence and for use as an aid in the initial diagnosis of bladder cancer in patients with hematuria (blood in urine) suspected of having bladder cancer. In the infectious diseases segment, there is the Abbott RealTime HIV-1 assay, an in-vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of human immunodeficiency virus type 1 (HIV-1), and the ViroSeq HIV-1 Genotyping System to detect HIV genomic mutations that confer resistance to specific types of antiretroviral drugs, as an aid in monitoring and treating HIV infection. In January 2009, Abbott introduced a real-time PCR-based diagnostic test for HPV in Europe for identifying patients infected with specific viral genotypes known to pose the highest risk for progression of cervical cancer.

In December 2008, Abbott Molecular acquired Ibis Biosciences, a subsidiary of Isis Pharmaceuticals. The move was to acquire Ibis' technological lead in biodefense applications, microbial forensics and infectious disease detection. The detection and surveillance of infectious diseases in hospital and clinical setting are considered as the powerful tools for screening diseases. In 2002, Abbott formed an alliance with Celera Diagnostics focused on developing and marketing a broad menu of next-generation molecular diagnostics products for unmet medical and laboratory needs. Celera delivers personalized disease management through a combination of products and services incorporating proprietary discoveries. Celera also commercializes a wide range of molecular diagnostic products through Abbott and has licensed other relevant diagnostic technologies developed to provide personalized disease management for cancer and liver diseases.

Abbott has also been working on a global surveillance program since last three decades (early 1970s on hepatitis and mid 1980s on HIV) to tackle the issue of continuous challenge faced by physicians and laboratories to overcome the diversification and global redistribution of groups, subtypes and recombinant strains of such viruses. Abbott has received a 2007 Chicago Innovation Award for its m2000 molecular diagnostic instrument and the Abbott RealTime HIV-1 viral load test, the most sensitive test of its kind capable of detecting and precisely measuring all known strains of HIV. The test approved for use in the US since May 2007, and run on the m2000 system, can detect and measure all group M, group N and group O strains of HIV-1 as well as non-B subtypes of the virus.

The reason for the high healthcare cost stems from the fact that majority of laboratory-based conventional testing needs to use more than one method that lacks precision and involves crude methodology that indirectly concludes presence or absence of a disease condition. Even with norms of revalidation in place, patients may erroneously be treated for a condition that does not exist, pushing the cost for an ineffective treatment and subsequently corrective procedure, leading to low quality of life or maybe worse. The molecular diagnostics technologies are appropriately positioned to address these gaps. The initial cost of any such product may look high but it turns out to be significantly cheaper in the long run considering high diagnostic reliability, speed of diagnosis, quality of life for patient and swiftness of recovery.

Molecular diagnostics—a global overview

The infectious disease testing dominates the molecular diagnostics market. This is due to the fact that infectious diseases provide a major market opportunity and it is expected to grow at an average annual rate of 3.69 percent and reach almost Rs 62,485 crore in 2016.

Pharmacogenetic testing has the second largest market in the molecular diagnostics segment. The pharmacogenetic testing is projected to sustain an explosive average annual growth rate of 184 percent. Such a growth rate is based on new discoveries in the field of mental health and the relationship between genetic signatures of neuropsychiatric disorders and optimal treatment procedures. Pharmacogenetic testing is expected to generate revenues of Rs 3.06 lakh crore by 2016.

The second fastest growing molecular diagnostics segment is oncology testing, which currently represents the smallest market segment in molecular diagnostics. Oncology testing is projected to grow at an average annual rate of 68 percent, bringing its size to over Rs 49,381 crore by 2016. Molecular diagnostics is capable of enhancing the diagnosis and management of cancer. Development in functional genomic studies is fueling the growth of molecular diagnostics.

Gene and chromosome testing is the third-largest molecular diagnostics segment. At this point in time, genetic tests are conducted as prenatal test for clinically assessing newborns for various chromosomal abnormalities. Gene and chromosome testing is expected to grow at an average annual rate of 11.2 percent and reach Rs 26,757 crore by 2016.

Source: Report from Kalorama Information (New York), entitled "Molecular Diagnostics:

Major World Markets".

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