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Market

The molecular sleuths

*Indian players are entering all sections of the diagnostics market, but molecular diagnostics offers the highest growth. After all, clues to future cures lie hidden in our genes. **Viveka Roychowdhury** analyses*

Who would not want to know the future? Parents would love to know the kind of individual their newborn child will grow up to be. Do they have a budding Picasso or an eccentric Einstein, a Barkha Dutt or a Medha Patkar in their family? Personality profiles are not yet possible, but the emerging field of molecular diagnosis can certainly yield fairly comprehensive disease profiles by analysing DNA samples. The medical fraternity/researcher, using various diagnostic tools, takes on the garb of a detective, searching for evidence at the crime scene.



These reliable and versatile diagnosis tools are already changing healthcare delivery systems, given that approximately 70 percent of treatment decisions are based on results of pathology tests. This shift from 'opinion based' to 'evidence based' medicine has made it possible for healthcare professionals to actually prevent disease, rather than merely cure patients.

The beginning of molecular diagnostics had to wait for the decoding of the human genome and path-breaking technologies like Polymerase Chain Reaction (PCR—a technique used to multiply DNA amounts in samples to aid accurate detection) which took disease diagnosis down to the gene level. The basic desk-top pathology tests have evolved into super-specialty laboratory divisions like molecular genetics and molecular pathology. The integration of IT in laboratory medicine has also made a great difference.

Diagnostics tests are broadly divided into two types—in vitro diagnostic (IVD) tests, which do not require the patient to be present and involve analysis of patient samples; and in vivo diagnostic tests which are done on the patient and are basically imaging techniques like X-rays, CTs, MRIs and nuclear imaging.



Explaining the concept of molecular diagnostics, Vivek Trikha, Head-Diagnostics, Dabur OncQuest, says that it borrows from two new disciplines—genomics and proteomics—and categorises cancer using technology, such as mass spectrometry and gene chips. Determining how genes and proteins interact in a cell, it focuses on gene and protein activity patterns, in different types of cancerous or precancerous cells. "Molecular diagnostics uncovers these sets of changes and captures this information as expression patterns. Also called 'molecular signatures', these expression patterns are improving the clinicians' ability to diagnose cancer. Soon all cancers may be diagnosed this way," predicts Trikha.

Today, molecular diagnostics makes up just five percent of the IVD market, but it is the fastest growing segment. Giving the figures, Dr Bhibhu R Das, Executive Director-R&D, SRL Ranbaxy, says, "Globally the molecular diagnostic segment is projected to outperform the overall diagnostics market, growing from \$13.8 billion in 2005 to \$22.7 billion in 2010 (AGR of 10.4 percent), in contrast to the overall forecasted increase from \$36.5 billion in 2005 to \$53.6 billion in 2010 (AGR of eight percent) for the entire IVD market. In particular, the Nucleic Acid Testing (NAT) segment is currently very dynamic and is expected to grow from \$1.1 billion in 2005 to \$3.3 billion in 2010, an overall AGR of 24.2 percent."

These aggressive projections are based on solid reasons. Consider the evolving DNA diagnosis arena. "Due to their relative simplicity, fair rapidity, solid reliability, universal workability and remarkable sensitivity, DNA diagnostics hold a distinct position in the area of molecular diagnostics," says Girish Mehta, President and Business Head, Wellspring/NPIL Laboratories and Diagnostic Services Private Limited (name of company proposed to be changed to Piramal Diagnostic Services Private Limited, subject to approval by the company's shareholders and Central Government).

"The current scenario in India is not healthcare but 'sickcare', the concept of preventive healthcare is at a very nascent stage"



- Vivek Trikha
Head-Diagnostics
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- Girish Mehta
President and Business Head
Wellspring / NPIL Laboratories and
Diagnostic Services

Market evolution

According to Ameera Patel, Executive Director, Metropolis Health Services, molecular diagnostics is a 15 year old concept in India. The evolution of the MD market went through three distinct

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phases. Molecular diagnostic tools were first used for detection of infectious diseases like HIV, (H1N1) Haemophilus influenzae type B, Hepatitis C (HCV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), Human papillomavirus (HPV), tubercle bacillus (TB), etc. Blood banking [NAT testing to screen blood for HIV, HBV, HCV, West Nile virus (WNV)] was the next phase, while the current generation of tools, which was kick-started by PCR technology, encompasses pharmacogenomic testing, predictive testing, genetic testing and companion diagnostics. Mehta points out that in 1992 Roche Diagnostics Division was the first to launch PCR-based diagnostic tests under the Amplicor trademark for HIV, HBV, and HCV.

These phases are visible in Indian companies as well. As Das says, molecular diagnostics at SRL Ranbaxy was initiated with the extensive infectious disease range, followed by molecular oncology markers, genetic disorder tests and more recent ones have been pharmacogenomics and preventive genetic markers.

"Screening tools involving antibody detection by the ELISA method (Enzyme-Linked ImmunoSorbent Assay) will be replaced by confirmatory molecular tools wherein direct nucleic acid detection is done. Diagnosis will not only be quicker but also will be accurate"



- Ameer Patel
Executive Director
Metropolis Health Services

"More than 1,000 Single Nucleotide Polymorphisms (SNPs) have been identified with established link-up with appearance of specific disease/ disorder. The most interesting aspect of these discoveries is the pace with which these tests are getting applied for paediatric groups, young adults as well as prospective parents"



- Dr Bhibhu R Das
Executive Director-R&D
SRL Ranbaxy

"The current molecular diagnostics products consist mainly of tests designed around a single biomarker associated with a disease state. Though today it extensively covers the entire infectious disease segment along with certain division of oncology and genetic disorders, the next-generation molecular diagnostics will employ multiplexing platforms, such as DNA or protein microarrays, to perform parallel biomarker analysis which will enable to effectively diagnose and manage complex metabolic disorders such as cardiovascular disorders and diabetes," reveals Das. He adds that internationally the trend is changing, with more focus on determination of genetic pre-disposition, pre-symptomatic disease, and prediction of individual drug response.

This trend also offers a glimmer of hope to the pharmaceutical industry, as pharma companies are using molecular diagnostics to identify biomarkers, and then screening drug candidates which respond to these biomarkers during the R&D process. This translational research approach to drug discovery in effect ploughs clinical knowledge back into the discovery process. This

'personalised' approach to medicine throws up the possibility of 'customised' medicine for specific populations. The fact that the US Food and Drug Agency (US FDA) is also advocating personalised medicine as part of its 'Critical Path Initiative' will also cause globally, pharma companies to align with smaller molecular diagnostic providers to develop tests that can be used to guide prescribing and give inputs to their drug discovery process. This emerging approach is being dubbed 'theranostics', i.e. the closer links between diagnostics and therapeutics, which will add value to diagnostics, currently undervalued by both healthcare payers (patients) and providers.

Today, SRL Ranbaxy offers more than 50 molecular tests to national and international clients. "The prime motivation is the strong commitment and focus towards translational research and knowledge intensity driven by R&D of SRL Ranbaxy. Together, these factors augur well for the future growth of molecular diagnostics in India with the accompanying prospect of greater affordability down the road," avers Das.

In fact, Indian diagnostics providers like SRL Ranbaxy, Metropolis, Wellspring and Dabur OncQuest could well do to diagnostics what the Indian generic pharma industry did for the pharma industry—provide affordable and high quality diagnostic solutions. "Indian companies can now use the molecular diagnostic platform to develop any number of molecular diagnostic kits. Diagnostic manufacturers are already entering into this newly emerging market, which used to be a monopoly of foreign multinational firms on the basis of scientific expertise and clinical excellence of Indian experts to develop such diagnostic kits for all diseases. Thus, India can become a low-cost manufacturing base for such products. The current Indian market for diagnostic services is expected to be over Rs 3,000 crores," points out Trikha.

Diagnostic tools and their effect on healthcare delivery

TOOLS	APPLICATIONS
Novel in vitro molecular tests (molecular diagnostics)	Improved detection and classification of existing diseases, identity testing, forensic testing, histocompatibility testing,
Novel probes for imaging cell functions, (dynamic imaging)	Monitoring cell functions and in turn new effective drug discovery
Genotyping tests (pharmacogenetic tests)	Predicting the effect of patient's genetic uniqueness on drug efficacy and safety, monitoring response to therapy
Predisposition diagnostic tests	Profiling the future risk of an individual (or their progeny) of developing diseases of monogenetic or multigenetic origins, screening apparently healthy populations

From sickcare to healthcare

The unravelling of the human genome has opened up a treasure trove of information. As Das points out, "More than 1,000 Single Nucleotide Polymorphisms (SNPs) have been identified with established link-up with appearance of specific disease/disorder. The most interesting aspect of these discoveries is the pace with which these tests are getting applied for paediatric groups, young adults as well as prospective parents. Currently, prenatal tests for certain genetic disorders such as Down's Syndrome and cystic fibrosis are commonly available with necessary regulation of patient consent and counselling aspects for prenatal care only." SNPs are pivotal in correlating genetic information with diseases, because an SNP is basically a change in the DNA strand in which a single base differs from the usual base sequence at that position.

Patel predicts that screening tools involving antibody detection by the ELISA method (Enzyme-Linked ImmunoSorbent Assay) will be replaced by confirmatory molecular tools wherein direct nucleic acid detection is done. Diagnosis will not only be quicker, but also will be accurate, which will provide a good therapy monitoring tool to evaluate outcome of the treatment regimen chosen. In addition, genotyping tools will also help in choosing therapy.

The main benefit of these predictive tests is that it offers the chance of earlier detection and treatment and the hope of postponing or preventing disease. For example, once a person has been identified as having a predisposition to cancer, heart disease or other lifestyle disorders, he can reduce disease risk by making lifestyle changes, or phasing out responsible environmental factors. For instance, if researchers could sequence and compare the DNA samples (at the genome level) of an individual before and after the diagnosis of a disease, say cancer, then they have more clues as to which regions of the human genome are involved in and control onset of the disease.

As Trikha points out, "The current scenario in India is not healthcare but 'Sickcare', the concept of preventive healthcare is at a very nascent stage. With individualised therapeutics the newest buzzword, these tests at genetic level shall monitor patient's individual response to the molecular targeted therapies and shall give the clinician a larger and clearer picture for better patient management." However, often new technologies throw up new dilemmas. Trikha lists some of these barriers like reimbursement issues, education and awareness of the clinical utility of a test, the inability to fully interpret test data, and the fact that gene patents are preventing widespread adoption of the tests by routine clinical laboratories.

As Das emphasises, this patient-specific care paradigm (to be effected by molecular diagnostics) is intended to deliver more personalised care earlier in the disease process, in order to pre-

empt/avoid complications and cost. The most significant impact expected in near future is the ability to prescribe the medication or treatment choices for specific patient groups, with negligible side-effects and improved results. According to him, the future holds even more promise for these areas, as the delivery of care focuses on management and prevention of disease, rather than only treatment. Enabling early diagnosis and more targeted therapies (e.g. closely observed by drug response monitoring), coupled with the improved management of patient information will not only help improve the quality, but also decrease the cost of care, Das points out.

Market watchers caution that as with any new technology, users will have to systematically evaluate the clinical effectiveness of these applications and tests. While market forces may make a strong case for using these tests, the patient/lay public will have to be counselled and advised so they can make an informed decision. Until then, while pharma companies may adopt a wait and watch policy, diagnostic companies are going full steam ahead. z

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