

COVER STORY

DRIVING DIAGNOSTICS WITH AUTOMATION

Clinical laboratory automation is growing in India, however, its impact on patient care is yet to be felt as only a small percentage of laboratories are fully automated. How will automation shape-up in the coming years? Will automation be a key factor in the survival of clinical laboratories as they compete for their share of the diagnostics market? An analysis

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In the future, automation will increase in areas like microbiology lab and histopathological labs

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Dr Vandana Lal
Executive Director
Dr Lal Pathlabs

One of the major challenges faced by the new Indian government is to provide affordable healthcare to all. Healthcare in India, as elsewhere in the world, is facing unprecedented challenges, including the economic burdens associated with rising costs, chronic diseases, and caring for ageing populations. The need for efficient systems to deliver quality healthcare is much more intensified today and healthcare providers face the challenging mandate of doing more with less.

Medical diagnostics is at the centre of healthcare delivery and is facing its own challenges. With increasing demand for tests, focus on quality and accuracy by physicians as well as changing economic paradigm, laboratories are forced to think out-of-the-box to keep functioning.

An estimated 70 per cent of medical decisions are based on laboratory test results. However, diagnostic laboratories in India are limited by means and resources. The thought of investing in an automation system feels like a daunting task, let alone expanding a laboratory or replacing existing systems. But the need for quality and reproducibility as well as the increasing demand for tests with less turn-around-time have only fuelled the need for adoption and use of laboratory automation.

The key challenge for the diagnostic industry is to find

innovative and cost-effective ways to improve testing efficiency and eliminate errors. Given the variation of power supply in India, equipment manufacturers must have a clear vision of how to best enhance a laboratory's capability with their automated equipment. The question the industry is asking today is how do laboratories adopt automation and how do they positively impact patient care?

Market snapshot

According to a report published by RNCOS Industry Research Solutions in June 2012, the Indian diagnostic services market is estimated to have generated ₹97.3 billion in revenue during 2011 and is expected to grow at a compound annual growth rate (CAGR) of around 26 per cent to ₹235.8 billion by 2015.

The market in India is highly fragmented. It is not surprising given its healthcare delivery structure, but of the estimated one lakh laboratories in India many have just basic facilities and only three to four laboratories are state-of-the-art multidisciplinary core labs. The hierarchy has specialised laboratories on the top, followed by laboratories in hospitals and nursing homes, and finally by small testing centres. All specialised laboratories operate in the private sector. The government at the best has semi-automated laboratories.

Test volumes range from 50 to 100 samples per day for one laboratory located in a small town to several thousand samples per day for a major

laboratory. "Test samples processed per day in a laboratory attached to a tertiary care hospital ranges from 500-1000," informs Dr Arathi Prakash, Consultant, Clinical Bio Chemistry & Quality Manager, BGS Global Hospitals. The quality of services provided by these laboratories also varies widely. "The National Accreditation Board for Testing and Calibration Laboratories (NABL) was established to accredit the laboratories; however, the number of accredited laboratories remains low since accreditation, so far, is voluntary," informs Dr Vandana Lal, Executive Director, Dr Lal Pathlabs. Currently, only about 10 per cent of the market is organised and composed of laboratories with proper accreditation.

Scaling challenges

Today, diagnostic laboratories are facing many challenges in order to remain competitive but the most important consideration is error. "Mistakes occur primarily due to human error, but there are also chances of random error," says Dr Arathi Prakash, Consultant, Clinical Bio Chemistry and Quality Manager, BGS Global Hospitals. As a result, quality control has gained immense importance in a clinical laboratory. But maintaining a good team of quality managers is again a challenge. "A strong requirement for quality managers who are properly trained and have proper standard operating procedures in place is challenging," says Dr Suvarna Ravindranath, General Manager Karnataka, SRL Diagnostics.

In fact, it is necessary to train

and retain competent staff, which is equally challenging. Precision and accuracy are the mark of a good laboratory. Medical laboratories, through their systems, have to generate results that can be replicated or reproduced in different diagnostic centres. "The hallmark of a good medical laboratory is accurate analysis and reporting of diagnostic tests carried out by them thereby helping the medical fraternity to recommend proper dosages of medicines to cure the patient. A high degree of quality control in testing therefore instils trust and confidence in the patients. Challenges include, but are not restricted to trained and skilled manpower in proper analysis, and use of test equipment," explains V Ramakrishnan, Marketing Manager, Remi Elektrotechnik.

Automation gains

Since automation for clinical laboratories came into existence equipment manufacturers have been promoting the benefits of stand-alone and total laboratory automation systems. The crux of their marketing lies in the fact that these equipment save time, reduce manual steps and above all, remove the human element from testing to lower the risk of errors. So it does, but is automation really beneficial?

"Automation makes the process very easy, makes the process and manpower requirement less. Even with less manpower more tasks can be accomplished more efficiently," says Dr Ravindranath. "Even the turnaround time will scale up to significant improvements and the chances of

error is minimised to a large extent," she adds.

Talking about the benefits, Ramakrishnan says, "Lab automation ensures reduction of human errors in diagnosis and reporting of test results. It ensures consistent and reproducible results of same samples across different centres. It enhances the patients' and doctors' confidence on the test reports generated by the diagnostic centres."

"Automation provide laboratories the ability to establish sustainable processes," says Dr Lal. Giving an example, she says that if a mid-level laboratory wants to increase productivity and deliver faster testing results they can consider installing a new automation system. While automation decreases turn-around time from five days to less than two days it also helps the lab slash material cost since the test uses less sample and hence the number of tubes collected from each patient gets cut in half. It also helps to decrease water use, and produces less waste. As a result, overall lab costs reduce by 30 per cent. Thus, it creates a sustainable process for the lab.

Although automation seems highly beneficial it also comes with considerable expense. "The cost of automation is huge. Be it a hospital or stand-alone laboratory, investments are considerable and so there should be much thought given to the type of automation to opt for," says Dr Prakash.

"Test assays are constantly evolving. The flexibility and adaptability of an automation system needs a lot of considera-



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tion. The system should have the ability to meet current testing needs and also be easily reconfigured to handle future demands," she explains.

Automation and quality

Leveraging the full capability of automation to drive quality and productivity improvement is the aim of all laboratories.

"Laboratory automation primarily is a means to improve efficiency and reduce human errors in all steps of testing. There is also an enhanced use of informatics continuum where there is a continuous recording of diagnostic test information. The electronic validation and authentication ensures better accuracy and consistent quality test results," says Dr Th. Dhahali Singh, MD, BABINA Diagnostics, Imphal. Reiterating this view, Dr Lal says, "Automation leads to greater levels of quality. In our laboratory we use state-of-the-art laboratory automation with new-generation automation systems that tie together multiple analysers, pre-analytical and post-analytical automation devices, and software. "This helps us to process greater volumes of tests and improve turnaround times, while reducing errors, enhancing productivity, and lowering costs," she adds.

While many believe that automation provides consistent quality, there are many who don't buy this theory. "Lab automation alone will not ensure quality," says Dr Ravindranath. "It will provide reproducibility only to a certain extent. There is a difference between quality and reproducibility. Reproducibility is something like precision but accuracy will come only if you



Automation in clinical laboratory is gaining pace in India

practice quality. Quality procedures and standards need to be in place," she further adds.

Routine quality control (QC) and maintenance of laboratory automation plays an important part in the upkeep and performance of instruments. "Quality management comprehensively includes controlling the quality of procedures at each and every step, including pre-analytical (specimen collection and transport), analytical (specimen processing in the lab) and post-analytical (reporting and interpretation of results). Concept of total quality management (TQM) is closely interlinked with good laboratory practices and goes far beyond the widely practiced conventional QC procedures. TQM includes technical accuracy and precision, equipment and supplies, staff training and skill, financial management (cost-effectiveness), lab safety, communication etc," says Dr Prakash.

Prohibitive cost of automation

Manual labour is readily avail-

able and less expensive in India, however in a clinical laboratory automation supersedes manual labour. It requires a huge initial investment compared to the unit cost of the product. In India, automated laboratory equipment are expensive. Dr Singh informs, "The capital investment for automation is relatively huge. However, an advantage of automation is that it allows for a reduction in the manpower requirement and cost because of a leaner system." He adds, "The best innovation that has come up is the development of customisable automation configurations that allow the flexibility of phased implementation." "The cost of automation varies. If an analysis is needed to be interfaced with computers, this will not cost much. However if robotics is taken into consideration then alongwith automation it will definitely cost quite a lot," says Dr Ravindranath.

So, it is understandable then that not many laboratories in India are fully automated. "Only five per cent of labs in India are

automated," reveals Dr Lal. "Most labs are semi-automated and some have a few automated equipment," she adds. "It's very difficult to analyse the labs in the public sector but as per my knowledge there are no fully automated clinical laboratories in the public sector," she says.

Downtime in clinical laboratory automation is another hassle that needs to be addressed. Prompt service and annual maintenance is most desired in automated systems. Failure to maintain the automation system ultimately result in lost time and faulty results; both of which are detrimental to good patient care. "In India, it's seen that a rental automated machine is better serviced and maintained than a purchased machine," says Dr Prakash. "Manufacturers should ensure good maintenance and service despite the way in which the equipment is acquired," she adds.

Looking to the future

Automation in clinical laboratory is gaining pace in India. In future, smaller laboratories will

consolidate and feed samples to larger automated laboratories. "In the future, this market is expected to become more organised and consolidated as small and independent laboratories become franchisees in the hub-and-spoke model of the larger players. By 2015, 30 per cent of the market is predicted to be organised," says Dr Lal. "This will lead to more automated labs in India," she adds.

"Automation will extend beyond traditional robotics to include more mobile systems. Pre-analytical process will get more customised and efficient," says Dr Ravindranath.

"Taking the human element out of the equation and utilising robotic automation only for clinical laboratory is the next step," feels Dr Lal.

However, there are still some disciplines like histopathology and microbiology that are not fully automated. "In the future, automation will increase in the areas like the microbiology lab and the histopathological labs," says Dr Prakash.

Clinical laboratory automation involves the integration or interfacing of automated or robotic transport systems, analytical instruments, and pre- or post-analytical process equipment such as automated centrifuges and aliquoters, decappers, recappers, sorters, and specimen storage and retrieval systems. In addition to the electrical and mechanical interfaces of these various components, the computers that control these devices or instruments must also be interfaced to each other and/or the laboratory information system.

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