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EXPRESS DIAGNOSTICS

INDIA'S FOREMOST DIAGNOSTICS MAGAZINE

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Leader's Corner

Dr Sushil Shah
Founder and Chairman,
Metropolis Healthcare

TISSUE DIAGNOSTICS WIDENING THE HORIZON IN ONCO CARE

Having evolved over the last two decades, the tissue diagnostics sector is going to gain new heights backed by rising incidence of cancer

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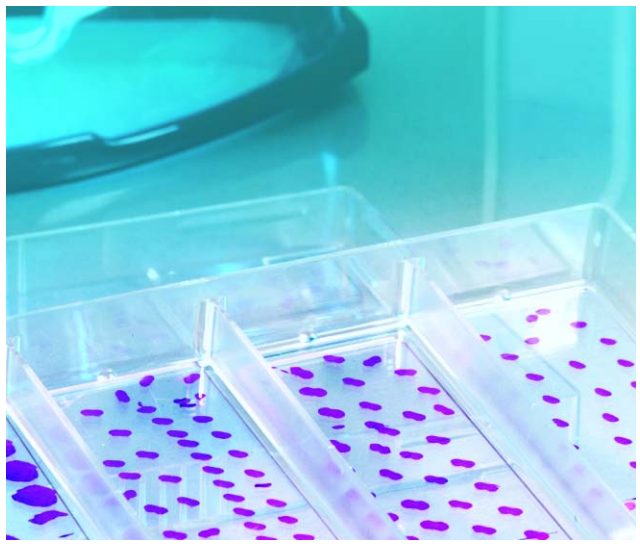

LAB TECH

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LEADER'S CORNER

LAB IN FOCUS

EDITOR'S NOTE

Diagnostics labs strategise to beat the blues

Unlike the hospital and pharma segments, diagnostics labs had fairly good Q1 res ults. These positive sentiments come inspite of increased competition leading to price wars as well as regulatory concerns like the essential list of diagnostics and price caps from the government. However each company has deployed counter strategies and it looks like these are now yeilding results.

A Prabhudas Lilladher note analyses that for Dr Lal Path Labs, rationalisation of clinical labs and re-routing many tests from regional labs to the central labs in Delhi and Kolkata has lead to improved margins. Secondly, patient volumes increased due to aggressive contribution from expanded bundle-offer packages.

The flip side is that Dr Lal Path Labs' overall realisations declined marginally as moderate growth in high-end tests (test per patient in Q1FY20 improved to 2.4 vs 2.3 from Q1FY19) was offset by lower realisations of bundle-test business. Thus revenues/patient declined marginally to Rs684 in Q1FY20 vs. Rs691 in Q1FY19 due to price rationalisation. Looking ahead, the company's market expansion plans are set to make up the loss. The focus will be to penetrate further in West Bengal and volume growth in FY20E and FY21E could possibly come from the stabilisation of the central lab in Kolkata.

Thyrocare Technologies' strategy is increased focus on its B2B business as well as exploring new opportunity in pregnancy tests. Like Dr Lal Path Labs, the focus is on volumes growth. While Thyrocare will keep up the spend on advertisements (at 4-5 per cent of sales) for growth in the B2C segment, it will increase focus on B2B with higher incentives and revenues per franchisee as it eliminates layers of middlemen and channels benefits of rationalised price to end consumers, according to a note from Prabhudas Lilladher.

Thyrocare's second strategy was to launch pre-natal and neonatal tests in May FY20 as the segment is expected to gain volume and premium pricing. With disruptive pricing, the management plans to target molecular biology testing (child deformity) in neonatal segment as 50 per cent of these tests are imported from China. There has reportedly been good uptake in this segment in the first three months since commercialisation of the neo-natal tests.

Metropolis Healthcare also showed good growth. Their strategy to expand retail contribution in focus cities showed results, with Q1FY20 revenue from retail contribution at 56 per cent (51 per cent in Q1FY19). Total patient visits and total tests performed registered an excellent growth of 17.7 per cent and 20.9 per cent YoY. The second strategy was the launch of a new wellness initiative in February 2019 across 36 cities, which clocked a 40 per cent growth in the first quarter.

Further growth could come if all diagnostics companies look at participating in the Ayushman Bharat (AB) Yojana. The first anniversary milestone of AB is due on September 23 and will hopefully see both celebrations as well as introspection by both the government and private sector.

Each company has deployed counter strategies which are now yeilding results

Dubbed Modicare and central to Prime Minister Modi's re-election, the scheme is a first step towards universal healthcare coverage but it has its fair share of detractors.

The National Health Authority (NHA) is well aware that there are many loop holes. It's website has two working papers with preliminary analyses of some aspects. While the first paper deals with the patterns of utilisation for hysterectomy, the second focusses on neo-natal care packages. Though a longer and deeper review will be necessary, there are already some worrying trends which can be corrected. For instance, the researchers flagged data on a few male hysterectomy cases as well as a few among women under 15 years and more than 90 years of age. This could indicate issues in SECC data quality and also the need for improved monitoring of both data and claims usage.

Both papers point to the need for greater involvement of the private sector. Revised package rates are due to be released on the first anniversary and it is hoped that these will encourage more private sector enterprises to participate on AB.

The case to aim for a part of the AB pie is logical. A recent white paper by SKP, titled India's National Health Protection Scheme: Ayushman Bharat – Growing Opportunities in Affordable Healthcare, outlines why the scheme could unlock huge opportunities for different healthcare stakeholders

Diagnostic labs bag the third largest share (10 per cent) of the total healthcare out of pocket expenditure (OoPE) in India, after medicines (52 per cent) and private hospitals (22 per cent). Since free diagnostics and medicines for maternal health, child health and NCD's will be provided for citizens eligible to be covered by AB, this segment is bound to see a volume increase as the scheme increases its coverage over the next few years. The same goes for the other segments as well. Over the next three years, the medical equipment and furniture segment is expected to post a 33-45 per cent CAGR, while the medical consumables and disposables will touch 23-33 per cent CAGR. The expected impact on the pharma industry (post NHPS) is expected to be 15-16 per cent CAGR over the next three years.

Thus the case for diagnostic companies to be part of AB seems very clear. For one, it would expand their market share into the rural areas, while assuring volume growth.

The challenge would be to ensure timely payments and prevent frauds. But one year down the line, the NHA is putting in systems to ensure that the loopholes are plugged. Given this evolution, will diagnostic labs bite the bait?

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Roche receives UD FDA approval for cobas pro® integrated solutions

With integrated solutions, laboratories can run tests faster on less equipment, automate manual tasks, deliver results quickly to aid in treatment decisions

Roche Diagnostics announced that the US Food and Drug Administration (FDA) has cleared its cobas pro® integrated solutions, a new generation of Serum Work Area (clinical chemistry and immunochemistry) laboratory solution, designed to optimise lab operations. With the cobas pro integrated solutions, laboratories are now able to run tests faster on less equipment, automate manual tasks and deliver results more quickly to aid in treatment decisions.

"We are excited about the accelerated FDA clearance of the cobas pro integrated solutions, our new generation of Serum Work Area solutions inspired by our mission to help improve speed and reliability of treatment decisions for patients and their families," said Thomas Schinecker, CEO, Roche Diagnostics. "Reliable, fast and sustainable diagnostic solutions are vital for optimal clinical care delivery for patients, and a key element in the evolution of general healthcare quality."

The latest innovation from Roche allows for up to 2,200 tests per hour with three modules working in parallel and synchronized to improve efficiency.[1] Additionally, the cobas pro integrated solutions can boast up to 3¼ hours less operating time for a daily routine workload compared to cobas 6000,[2,3] while 93 per cent of Roche Immunoassays have reaction times of 18 minutes or less.[4,5] Reducing the time in delivering results to physicians and patients across a number of therapeutic areas is vital to clinical decision making.

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1. Roche Diagnostics, Medical and Scientific Affairs (MSA); EAC / based on 2013 EAC interviews with cardiologists and oncologists in Germany and the US (N=40).

2. European Diagnostic Manufacturers Association (EDMA), 2009; based on: The Lewin Group, commissioned by Advamed, "The Value of Diagnostics", 2005.

3. cobas® pro integrated solutions product specifications. Data on file.

4. For a daily routine workload, as compared to cobas® 6000. Data on file.

5. Based on calculations with value calculation tool. Data on file.

Neuberg Diagnostics announces merger of Healyst Laboratory

The merger will bring all collection centres of Healyst Laboratory under Neuberg brand

Neuberg Diagnostics recently announced a merger of Healyst Laboratory with Neuberg Ehrlich laboratory for an undisclosed sum. The merger will bring all seven collection centres of Healyst Laboratory under the Neuberg brand, also integrating its clinical processing lab with the merged entity.

"Through this merger, we have integrated 82 years of Ehrlich's legacy and Srinivasan's sound knowledge in the diagnostics business with a young organisation like Neuberg," said GSK Velu, Chairman, Neuberg Diagnostics.

The Neuberg consortium currently has around 60 diagnostic labs and 500 collection centres in India, South Africa and Dubai. The consortium members include Anand Diagnostic Laboratory (Bangalore), Supratech Micropath (Gujarat), Ehrlich Laboratory (Chennai), Global Labs (South Africa) and Minerva Diagnostics (Dubai).

"Our primary focus will be to grow Neuberg Ehrlich to a strong position in the region and to model the desired changes for further growth and expansion," said P Srinivasan, Technical Director, Neuberg Ehrlich Laboratory.

Neuberg Ehrlich laboratory is equipped to perform a range of pathological investigations including new generation technologies like genomics, metabolomics and proteomics. It currently has 10 clinical labs and 50 collection centres in Tamil Nadu and will add 50 more collection points in the next 3 months.

The diagnostics company also announced the launch of 'Anywhere, Anytime', a new service that offers diagnostics tests (blood, urine, ECG) to individuals at their preferred timing and location, subject to basic standards of hygiene and privacy.

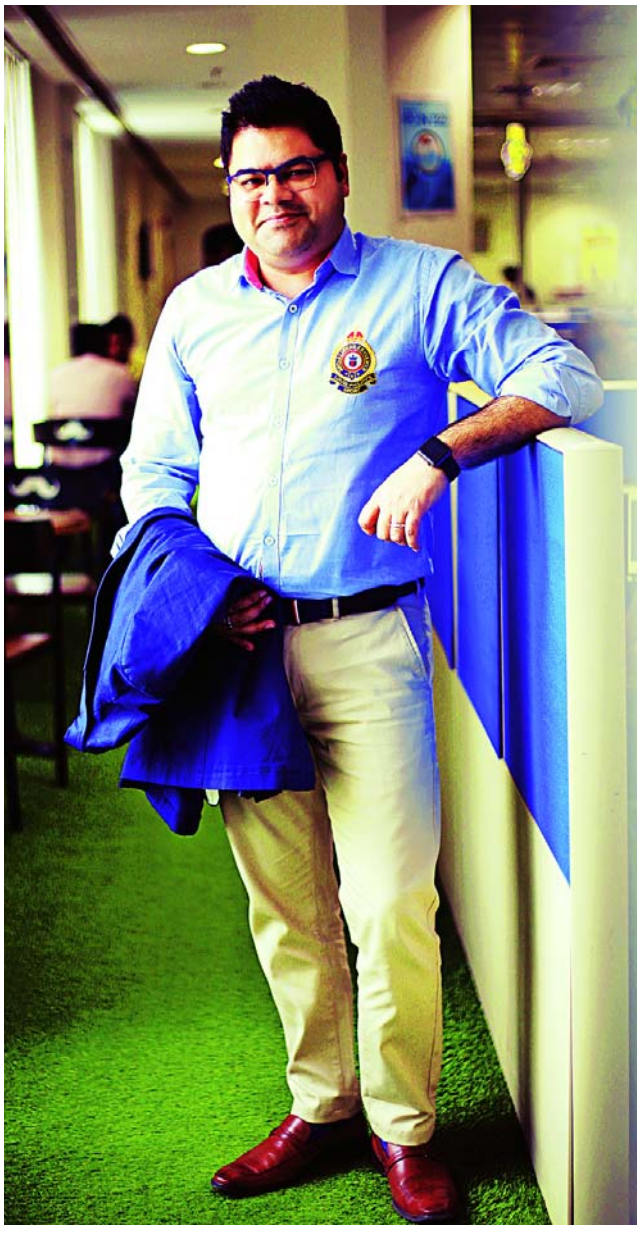
"We are in the fourth generation of diagnostics. From a 'healthcare less' phase, now evolved to a 'personalised healthcare' phase, where the diagnostics needs of one person need not be the same with the other," Velu said.

"The service was launched on a trial basis in Bengaluru and today we are introducing it in Chennai. Individuals can call us to collect their blood samples from any place of their convenience and at any time," he added.

INTERVIEW

‘We aim to enable every Indian in pursuing wellness from their homes’

Technology-driven and well-being focussed, we make sure to offer highly-trained phlebotomists and precision-driven labs to ensure accuracy and perfection in tests, informs **Deepak Sahni**, Founder and CEO, Healthians, to **Akanki Sharma**



DEEPAK SAHNI
Founder and CEO, Healthians

What led to the formation of Healthians? What was the idea/reason behind coming up with it?
The idea of starting a diagnostic and wellness company took root when I encountered a gap between what the industry was offering as a diagnostic service and what the consumers needed. I realised that the entire health ecosystem of India is based on a reactive approach, rather than a proactive one. The diagnostic space of the country was traditionally B2B and dependent upon franchise and doctor’s network to reach customers, which again means that we only target people who are already ill.

In a country where more than 50 per cent of the population is below 30 years of age, a reactive approach to healthcare will cost us $4.5 trillion for management of diseases. This sort of in-depth analysis of the market helped us determine that our value proposition would be a cost-effective, standardised and accurate diagnostic service that would enable them to lead healthier lives.

> We have our own sample collection team which is highly trained and the complete process from sample collection to delivery of reports is controlled by technology. With our mobile application, this process becomes seamless for customers, guaranteeing quality and backed with money-back guarantee on accuracy to each of our customers

How and where does Healthians function? Is it a pan-India organisation? Who are your customers?
We work on a B2C and customer-centric approach, which makes it unique from existing B2B and franchise model businesses. The model not just offers a better price, convenience and experience apart from quality results, but it also promotes wellness by offering free doctor and diet consultation with every report. Our diagnostic and chronic management plans have proven to be instrumental in effective disease management.

Technology-driven and well-being focussed, we make sure to offer highly-trained phlebotomists and precision-driven labs to ensure accuracy and perfection in tests. The mission is to enable every Indian in pursuing wellness from the comfort of their homes and seamlessly avail reliable testing services.

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INTERVIEW

Our one test can find more resistant superbugs than all our competitors

More than three decade old molecular biology company XCyton Diagnostics has already carved its presence in the Indian market and are offering solutions at a competitive range. **Dr BV Ravikumar**, Founder and Managing Director, XCyton Diagnostics shares the company's plans with **Usha Sharma**

DR BV RAVIKUMAR
Founder and Managing Director, XCyton Diagnostics

> We offer our solutions to critical care doctors, a single-test diagnostic for about 20 types of complex clinical conditions, that they see regularly such as sepsis, meningitis, pneumonia, encephalitis etc. In each test, we look comprehensively for all pathogens which cause 95 per cent of each illness in India

Since the 90's you have been in the molecular diagnostic business and have seen the different diameters of it, tell us about key findings/learnings?
In the last three decades there has been a significant shift in the molecular diagnostic business. Molecular biological methods for the detection and characterisation of microorganisms have revolutionised diagnostic microbiology and are now part of routine specimen processing. One of the foremost development was the commoditisation of ELISA kits for various infections. Because of this a strategic major decision was taken to address unmet diagnostic need of life-threatening infections. We had foreseen in 2004 that Anti-Microbial-Resistance and complex syndromic infections would be the future of diagnostics. Sadly, we are proven right.

Give us a brief understanding of the company's ongoing activities and how are you scaling up your research capabilities?
Strategic discovery and development are directed towards design of diagnostics for maximised clinical relevance. We already have proprietary signatures for 69 pathogens and in coming 12 months we will add 18 more pathogens to our list.

How big is the molecular diagnostic market in India and what percentage is it growing annually?
The market potential as calculated by computing all the diseases that necessarily require molecular diagnostics for preventing mortality and morbidity is $1 billion which is a Rs 7000 crore market in India.

The company was involved in manufacturing immuno-diagnostic kits for the detection of infections, tell us more about it.
We had only one product in the immuno-diagnostic category named ELISA. We have stopped it from 2011.

Why did you stop manufacturing immuno-diagnostic kits?
Our kits were marketed by Qualigens (Subsidiary of GSK) which was later acquired by Thermo-Fisher. Due to commoditisation of ELISA kits and the resultant price wars they were not interested in blood banking and other urology market in India. Due to the drug licensing policy, we were classified as a pharmaceutical company and in order to get some investments from international funds we gave up the licenses.

Though the infectious disease diagnostics market is growing significantly globally, there is an absence of compiled regulatory guidelines and

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Our one test can find...

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lack of centralised laboratory facilities, how do you address this issue?
Many countries have clear cut guidelines. Yes, India is modifying and amending the IVD (in-vitro diagnostics) guidelines. Central labs are mainly responsible for diagnostic delivery in all countries - advanced or developing. Even very small countries have central labs but no access to point-of-care diagnostics. Developing nations have vast regions of country with poor connectivity to avail central lab tests. Our plans are to make Syndrome Evaluation System (SES) a POC device. We are in process of raising necessary resources.

Tell us more about XCyton's Syndrome Evaluation System (SES) and how it is different from other available products in the market?
When a doctor sees a patient with a life-threatening infection, SES tells them the exact pathogen and whether it is resistant (a superbug) in a few hours. Everyone else takes a few days. Plus, we can do things others cannot:

1. Doctors already use our SES to stop unnecessary antibiotics or change therapy to the right one.

2. If we report zero infection doctors look for non-infectious causes for the disease.

What solutions do you offer for critical care management and how it helps physicians to assess, diagnose for treatment?
We offer our solutions to critical care doctors, a single-test diagnostic for about 20 types of complex clinical conditions, that they see regularly such as sepsis, meningitis, pneumonia, encephalitis etc. In each test, we look comprehensively for all pathogens which cause 95 per cent of each illness in India. Others look for far less number of pathogens. We diagnose more pathogens important to India and worldwide, not just those in North America or Europe. From one test, we can find more resistant superbugs than all our competitors.

Tell us about your business strategies and how are you expanding your presence globally?
We have tied up with MedGenome Labs in the domestic market for infectious disease genetic test to leverage their strong presence even in tier 2- tier 3 cities. We are moving to expand our lab services internationally with ongoing studies in Singapore and soon to start in the US and EU. Later, we plan to develop a point-of-care devices to be used, at the ICU patient's bedside.

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STRATEGIC DISCOVERY AND DEVELOPMENT ARE DIRECTED TOWARDS DESIGN OF DIAGNOSTICS FOR MAXIMISED CLINICAL RELEVANCE

'We aim to enable every Indian...

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Covering all major metros, we are now present in over 30 cities across India.

What is the current scale of your business in Delhi and in neighbouring states (if any)? Have you received any funding from the government?
Healthians was in incubation stage during the end of 2014.

WITH SEED FUNDING FROM YOUWECAN OPERATIONS STARTED IN 2015 IN DELHI

With seed funding from YouWeCan operations started in 2015 in Delhi, our idea was to start from the most competitive and largest market in North India, so that we would get all the learnings necessary to establish and expand our business later. By the end of 2016, we had penetrated deep into the Delhi market and built the technology and processes needed to expand. We entered tier II cities like Lucknow and Kanpur in September 2017; from there, expansion to every city has been a bit easier than the earlier cities. Healthians collects over 3,500 samples daily and 60 per cent of it is from Delhi NCR region. Talking about the government funding, we haven't received any from the government.

As a startup, what challenges did you face while entering into the market and how did you overcome those?
There have been several challenges along the way. We started as an aggregator of diagnostic labs but within a few months, we changed it from an aggregation to a self-logistics model. The problem with the aggregation model was that while we were generating business for the labs, the collection of samples was under the control of labs. Many a times, the phlebotomist would not reach on time or would not offer a great experience, which was hurting the credibility of the brand. Once we were able to solve this by organising the fragmented phlebotomist handling and monitoring using technology, another challenge on hand was to ensure 100 per cent accurate on-time reports. We took another six to eight months to take control of the labs under our own management and putting technology and process in place for over 150 checkpoints to ensure the best experience for our customers.

How can a patient be assured trust and satisfaction at Healthians?
We have our own sample collection team which is highly trained and the complete process from sample collection to delivery of reports is controlled by technology. With our mobile application, this process becomes seamless for customers, guaranteeing quality and backed with money-back guarantee on accuracy to each of our customers. Apart from this, Healthians is deeply integrated with machines at labs and has robust quality control system. All of our labs are NABL-compliant and we have our quality audit teams and processes that are of international standards.

Kindly elaborate your vision "Adding 10 healthy years to every Indian's life." How do you plan to do so?
We offer the benefits of tech intuitiveness helping our customers in living a healthy and better life through our proprietary concepts like CoolSure, Health Karma, SmartPrik, Health Tracker and AI-based reports. Beyond tests, we inform our customers of future health trends, along with medical recommendations, dietary and lifestyle advice on the basis of test reports, medical history and lifestyle inputs. Our AI-based tools help customers improve their lifestyle conditions and timely reminders make them aware about repeating the tests on time. Hence, each step that they take today adds healthy years to their life tomorrow.

Your growth strategy for the next five years?
We plan to grow exponentially both in terms of our customer base and geography in this year. In addition, we expect to cross Rs 100 crore revenue mark and have at least 40 labs under our brand by next year. As we establish ourselves across the country, we are aiming to add over 200 labs and 3,000 phlebotomists across 150 cities over the next 18-24 months.

Healthians team is driven by serving the mandate of helping a billion Indians by improving their lifespan with quality 10 years. We already have over 700,000 households on the platform and hope to double our customer base by 2020.

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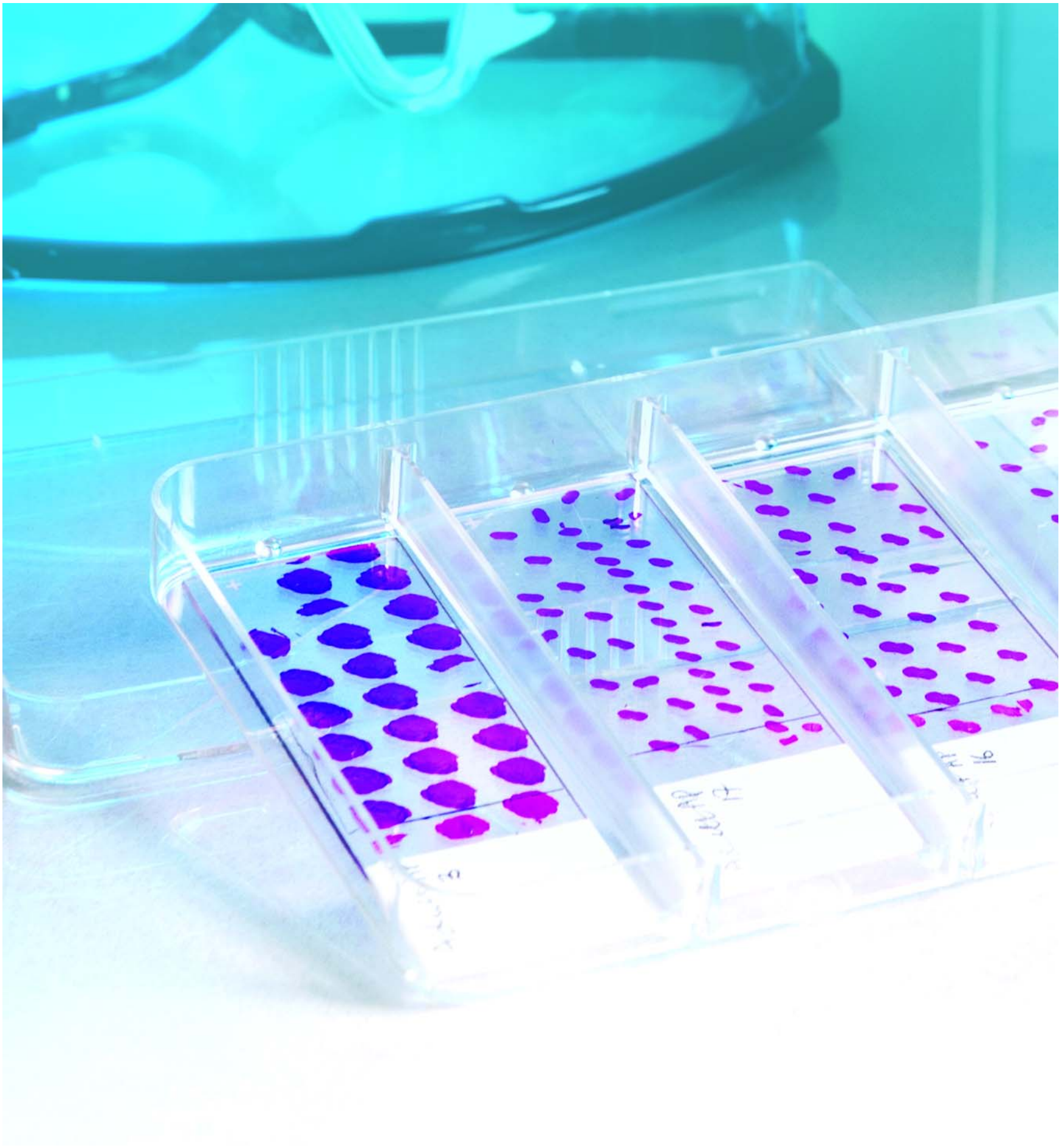
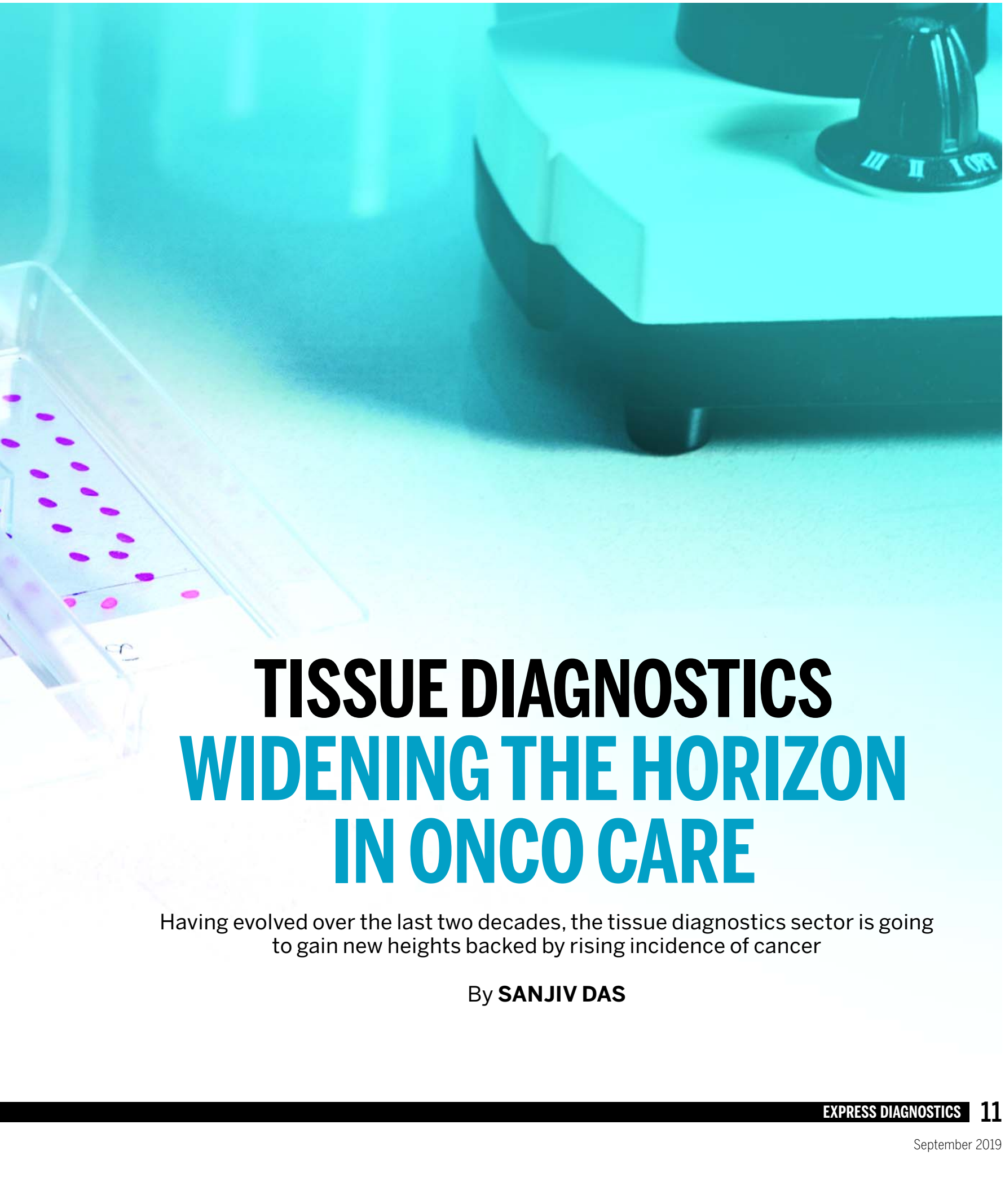
COVER STORY





TISSUE DIAGNOSTICS
WIDENING THE HORIZON IN ONCO CARE

Having evolved over the last two decades, the tissue diagnostics sector is going to gain new heights backed by rising incidence of cancer

By **SANJIV DAS**

Worldover, anatomic pathology has undergone a paradigm shift as cancer incidents are growing exponentially. This, in turn, is furthering the expansion of the field of clinical pathology. We are now witnessing a steady convergence of anatomic and molecular pathology, increased use of liquid biopsy for cancer detection, and digitisation of pathologies. With computational pathology already gaining momentum, there is a growing emphasis on integrated bioinformatics and analystics.

tissue diagnostics.

Let's understand the key drivers, opportunities and challenges that will determine the future of tissue diagnostics in India.

The evolution

Tissue diagnostics, as the name suggests, involves removal of tissue (at a micro level) from the patient's body, which is then processed, analysed and tested under the microscope to detect diseases such as cancer.

In medical parlance, tissue diagnostics refer to surgical pathological evaluation of tissues of the body. The concept started as a morphological assessment and evaluation of the surgically excised specimen using basic techniques of histopathology.

Says Dr BS Ajaikumar, Chairman and CEO, HealthCare Global Enterprises, "Tissue diagnosis is one of the gold standards for cancer diagnosis. The technique helps in determining the cause and effect of the disease in a patient. It is an essential part of decision making for proper care-giving. Without an accurate diagnosis, proper treatment cannot be given to the patient."

Speaking about the evolution of the field, Dr Harish Pillai, CEO, Aster Hospitals & Clinics (India) explains, "Over time, tissue diagnosis has gradually evolved and encompassed into higher and upgraded ancillary technologies like Immunohistochemistry (IHC), Immunofluorescence (IF), Fluorescence in situ hybridisation (FISH), Comparative genomic hybridisation (CGH/ Tissue Micro arrays) and finally, the much talked about next-generation sequencing (NGS). This evolution has been in accordance with the newer therapeutic and prognostic upgradations from the rapidly changing domain of clinical practice."

The sector has also witnessed phenomenal changes as evolution in cancer treatment procedures helped to drive the market to new heights.

Anu Acharya, CEO, Mapmygemone, believes, "Tissue diagnostics started out as generalised procedures, wherein biopsy samples would be sent to labs for further tests, usually post-surgery. Today, many physicians use this technology to decide on the care and treatment plan, to figure out if a surgery is required. With increasing demand and growing technology for 'personalised medicine,' we have seen great changes in this segment.

Similarly, Dr Ajaikumar adds, "The gradual increase in the awareness campaigns, technological research advancements and improving healthcare infrastructure is paving the way for a better market opportunity in tissue diagnostics. The market is also segmented into pre-analytical and advance stains on the bases of examination time."

Dr Kirti Chadha, Sr Vice President, Metropolis Healthcare, says, "The major factors that are driving the growth of tissue diagnostic market are growing incidents of cancer, organ donation and transplant movement, and rising awareness and acceptance of personalised medicine and companion diagnostics where every patient is being treated individually and advance diagnostics plays a huge role."

Dr Rajeev Vijayakumar, Consultant Medical Oncologist, Haemato-oncologist and BMT physician, BGS Gleneagles Global Hospital says, "Investigations have become more accessible - even in remote places - with improvement in logistics networks. The same phenomenon is seen worldwide, propelling the diagnostics market forward."

Leading markets

North America and Europe are leading in tissue diagnostics segment. Although the sector had been largely overlooked in the past, India is now quickly catching up.

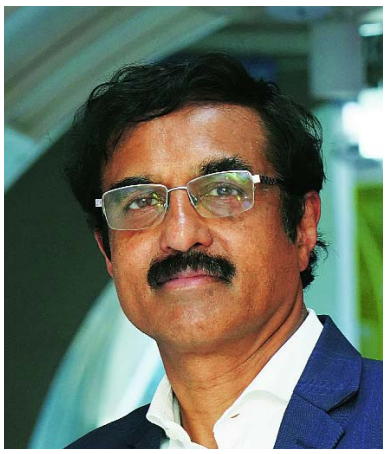
Dr Abha K Sabhikhi, Technical Director, SRL Diagnostics CoE & SRL Fortis Labs, believes, "Though dominated by North America and Europe, the tissue diagnostics market is shifting its focus to the Asian market and particularly India. Overall, the Indian diagnostic market has been growing at nearly 15-20 per cent and currently is estimated to be worth Rs 40,000 crore. In addition to Japan and China, we expect to see a growth spurt in India with expectations of the highest CAGR from this region. These expectations are leading to a rising focus of major players in emerging Asian countries."

Growth prospects in India

As stated earlier, higher incidence of cancer globally, growing awareness of genetics and heritability of cancers have been the key drivers fuelling the growth of the sector worldwide. Also, a rise in companion diagnostics for targeted therapies in areas such as transplant pathology, and increased organ

All these changes indicate an extremely bright future for the field of tissue diagnostics and its market. As per experts, the tissue diagnostics market has evolved over the last two decades with more sophisticated equipment entering into the market, eventually making life easier for pathologists and clinicians.

A report released by Markets and Markets mentions that the global tissue diagnostics market is expected to grow at a CAGR of 6.9 per cent from $3.6 billion in 2017 to reach $5.1 billion in 2022. The growth is likely to be driven by the rising incidence of cancer and technological innovations in



DR BS AJAIKUMAR
Chairman and CEO,
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DR HARISH PILLAI
CEO,
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ANU ACHARYA
CEO,
Mapmygemone

DR KIRTI CHADHA
Sr Vice President,
Metropolis Healthcare

transplantations and increased use of biomarkers for disease diagnosis are propelling growth. Tissue diagnostics represent overall 4-5 per cent of the total IVD market.

Dr Pillai says, "Not only the rising incidence of cancer, but non-neoplastic acquired conditions like thalassemia, inflammatory bowel disease, malabsorption syndromes, GLUT-4 deficiency associated with inherited lactose tolerance have led to the growth of the tissue diagnostic market."

According to Acharya, "There are several areas where tissue diagnostics has proven beneficial. One good example would be fertility treatments - genetic assessment for implantation failures in IVF cases through Endometrial Receptivity Analysis, and even diagnosis of female genital tuberculosis."

In India, hospital with increased focus on oncology, is likely to fuel the growth of tissue diagnostics segment. Elaborating further, Dr Sabhiki says, "Large network labs are also consolidating the segment with availability of quality test results and the early introduction of newer diagnostic tests that are made available across all geographies. Tissue diagnosis is critical for early diagnosis to ensure graft survival."

Dr Vijayakumar says, "Tissue diagnostics range from biopsy specimens, immunohistochemistry, molecular diagnostics and genetic studies. The purchase power of the average Indian has improved to a great extent in the last decade, running parallel to the advances in the laboratory."

In India, pricing is an issue in the tissue diagnostics sector. While talking about the cost-effectiveness the kind of RoI which the tissue diagnostic businesses can gain, Dr Chadha mentions, "Tissue diagnostics is largely a fragmented market for any hospital or individual players. The number of samples are not as huge as compared to the other segments in pathology, thus making it difficult for even large hospitals and large players to offer last mile services with best technologies and best set of histopathologist." Dr Sabhikhi also agrees, "In India cost would continue to be a challenge."

Digitisation of pathologies

As mentioned above, computerisation and digitisation of pathologies will play a crucial role in the advancement of this segment. For example, a digital pathology enables pathologists to view and diagnose digital images of surgical pathology slides prepared from biopsied and resectioned tissue. This improves clinical workflows, ensures accuracies in clinical outcomes and can help making critical health information available to patients and healthcare professionals faster and at lower cost. It will also resolve the problem of shortage of skilled surgical pathologists and sub speciality experts as well.

Says Dr Sabhikhi, "AI and machine-based learning would also play a role in the future. This cannot replace the surgical pathologist but would help the surgical pathologist make a more conclusive diagnosis. Largest growth share would be from the immunohistochemistry segment as reflex testing becomes more prevalent. Growth in personalised medicine with companion diagnostics is also foreseen."

Dr Ajaikumar reckons, "Through the mapping of genetic compositions in various cancers, prediction can be done through extrapolation of these onto imaging by AI-based platform, and non-invasively predict the tumor biology. This would be a significant benefit to the patients not only in terms of cost, but also being a non-invasive procedure."

According to Dr Vijayakumar, self learning AI-based software will play an important role in the tissue diagnostics segment. Besides, liquid biopsies and next generation sequencing will have the potential to bring in a revolution in the tissue diagnostics segment.

Dr Sudipta Roy, Director, Lab Services, Amri Group of Hospitals says, "Immunohistochemistry to molecular genomics, proteomics, image analyser and perhaps AI, cell free DNA, advances in next gen sequencing, are few of the technological advancements that seem promising."

Moreover, Acharya feels that the use of technology can enable the field to further resolve many complex medical ailments in future. "Where biochemical tests may yield false positive and false negative may result in extensive economic and social implications, tissue (molecular) diagnostics can help in accurate treatment as well as identification of novel variants to create datasets for screening, diagnostics and treatment."

Dr Chadha believes, "Technological advancements in the segment of tissue diagnostics is to support the complex workflow from specimen receipt to anatomic pathology report transmission, that is, to improve diagnosis both in terms of pathologists' efficiency and with new information. The future paradigm of pathology will be digital. Instead of conventional microscopy, a pathologist will perform a diagnosis through interacting with images on computer screens and performing quantitative analysis."

The future outlook

Though the tissue diagnostics market has seen an upsurge due to increasing opportunities in digital pathology, high demand for companion and molecular diagnostics, growth of personalised medicines challenges like limited customer base for tissue diagnostics, are hindering its growth prospects.

Challenges also include shortage of qualified pathologists, consolidation of laboratories leading to shrinkage of the customer base, reimbursement cuts and competition from novel technologies such as liquid biopsy and next generation sequencing.

But at the same time, technology providers have been engaged in the development of new innovative technologies backed by automation, AI and more. To tap business prospects in this segment, techology providers are also looking for partnerships with pharmaceutical companies to build information management systems in order to deepen solution expertise for success in the long run.

In future, experts should implement new technological innovations which will help the tissue diagnostics sector bring in a revolution in solving complex medical conditions. There is a clear need for more research initiatives in this space to further propel growth in this sector.

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DR ABHA K SABHIKHI
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Consultant Medical Oncologist,
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INTERVIEW

Cobots the new lab assistants

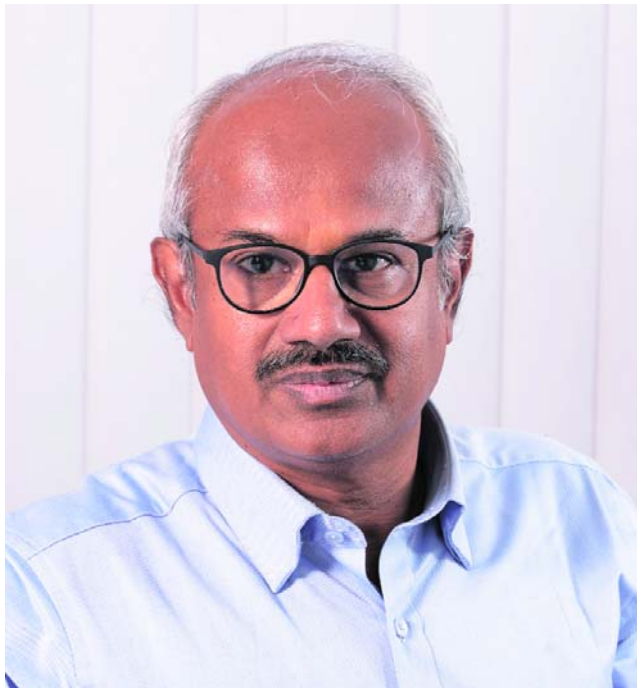
Sriram RD, Managing Director, AuroLab and **Pradeep David**, General Manager, South Asia, Universal Robots in conversation with **Prathiba Raju** elucidate on how automation via cobots is reshaping the medical devices and diagnostic industry

Why is it necessary for the Indian medical devices and diagnostics industry to be automated?
Sriram RD: There is a lot of work in the medical industry that needs to be automated like packaging and other activities of the same kind. Pharma industry is considered as the sector which is established in a better way and several machines remain fully automated. There is a lot of scope in the medical devices and diagnostic industry for automation via cobots as well. All the repetitive tasks can be handled by cobots in a highly safe ambience, while humans coordinate with them.

Labour-intensive jobs in our medical industry which include less logical or mindful applications, are automated in better ways.

How did you come up with this idea?
SRD: We were looking for a solution which will help in the process of pick and place, as our lenses need to be handled delicately. We thought of putting up a robot but that didn't seem to be a safe option and it has to be caged. Eventually, we came across the concept of Collaborative Robots by Universal Robots safe for our staff to work with and this needs not be caged. Each lens is held accurately by a cobot, preventing any damage to the lenses.

Tell us about the potential for cobots in the healthcare domain?
Pradeep David: Collaborative



SRIRAM RD
Managing Director, AuroLab

PRADEEP DAVID
General Manager, South Asia, Universal Robots

> There is a lot of scope in medical devices and diagnostic industry for automation via cobots. All repetitive tasks done are handled by cobots in a highly safe ambience, while humans coordinate with them

> The cobot is not designed to replace human workforce, but to take over strenuous or even dangerous tasks. As a result, human employees can use their creativity to turn to more complex projects

robots, the fastest growing robotic technology is increasingly becoming the go-to automation tool in all sectors from manufacturing, auto, textile and now medical industry as well. Unlike traditional robots, cobots can be redeployed time and again for different applications and in different locations through its easy programming that takes only a few hours. All enterprises, big or small, that have deployed cobots, are seeing their businesses grow significantly. Cobots are one of the most affordable technologies, giving an ROI within the first few years of work.

Which is more in use – robots or cobots? What is the difference between the two? Which is more useful when it comes to diagnostics industry?
PD: Cobots are a much newer concept and in fact, they are a niche type of robots – 'cobot' is a portmanteau for 'collaborative robot'. When we say collaborative, it means that it is safe to work with humans without the need for any caging, safety scanners, etc. (subject to risk assessment), unlike traditional robots. Due to this, they can work in close quarters with humans, sharing the same physical space as them. They are portable, easy to install, and easy to programme, unlike their bulky predecessors (industrial robots) that required much more space, time for deployment, and specialised programming knowledge. This makes them more than ideal for a multitude of applications. For example, Copenhagen University Hospital in Gentofte, Denmark uses cobots to ensure blood sample results are delivered as quickly as possible. Matternet in Switzerland has also implemented UR cobots in drone deliveries, to shuttle blood and other medical samples between hospitals and testing facilities.

How do robots help in precision of clinical decision?
PD: They are ideal for working as assistants of medical practitioners. There are a lot of examples of the same, for instance, one would be -- a robot dentist in China which recently performed an hour-long surgery based on 3D printing of the structure. Some other examples include robots which are manufactured to remodel the operating rooms. The precision of the clinical decision is reflected in various such functions and applications of robots. The Broca project in Spain stands to justify how robots could be utilised in the best way possible. The Broca project is based in Spain, which has prepared a surgical robot to support medical practitioners. It allows surgeons to work with a secure and precise device that enables them to carry out operations that usually require laparoscopy surgery.

THE BROCA PROJECT IS BASED IN SPAIN, WHICH HAS PREPARED A SURGICAL ROBOT TO SUPPORT MEDICAL PRACTITIONERS. IT ALLOWS SURGEONS TO WORK WITH A SECURE AND PRECISE DEVICE THAT ENABLES THEM TO CARRY OUT OPERATIONS THAT USUALLY REQUIRE LAPAROSCOPY SURGERY

How receptive is the Indian diagnostics industry in being machine dependent, what does the future look like?
PD: We are definitely seeing a lot of traction here as more and more people are seeing the value propositions of collaborative robots. We have even made sales to various Indian medical universities and doctors who are doing R&D on how cobots can be used for various applications in healthcare, including neurosurgery and endoscopy.

With increasing automation and robots in labs, what will happen to skilled and unskilled workforce in medical diagnostic centres? How have you dealt with this?
SRD: There are many jobs which are performed by unskilled labour and they can't be automated because of the complexities of the job profile; and we cannot completely eliminate low-end jobs for obvious reasons.

Although there is still a shortage of labour as many workers fly abroad for work or education. However, automation solutions like cobots are proven to be beneficial in the long term.

Talking of Aurolabs, workforce constitutes of 90 per cent of the women in our centre. We have been deploying cobots since 2012 to solve the issues of running late-night shifts, product variability, worker transition and the ergonomic challenges that the staff faced.
PD: The cobot is not designed to replace the human workforce, but to take over strenuous or even dangerous tasks. As a result, human employees can use their creativity to turn to more complex projects. For instance, when robots take over minor assembly tasks, employees can move on to more nuanced assignments that require human ingenuity. The fact that the cobot can be used as an extension of the human arm, cobots can be used for dangerous applications, where the human workforce might be at risk.

While low-end jobs are being eliminated, increasing automation does not have to negatively impact employment. Instead, the introduction of cobots almost always results in net job creation; human employees are being unburdened from performing repetitive tasks that may hurt them or present some ergonomic risk which cobots can perform with optimal speed, accuracy, cost and with no safety hazards.

How cost effective is automation? Give example
SRD: Deploying cobots at our centre is economically viable as it has helped us in increasing the productivity and work-quality. Cobots is slightly cheaper as compared to hiring labour due to long term benefits of cobots. We have CNC lathe to grind the lenses. Each lathe cost us $160,000. We can't risk the labour handling all of this on their own, hence, with cobots being programmed as per precision and speed, it becomes easier to work on it and also the best part remains that the inaccuracies with the manual method are eliminated smoothly.

The cobot loads the collection of CNC lathe with 0.1mm repeatedly precision. Besides fitting in seamlessly with the workforce, the cobots from Universal Robots were picked for their affordability, reduced power consumption and safety, which ensured that the protective stop measure turns the power off when a load is applied to it.

With the help of cobots we have increased productivity by 10-12 per cent. Along with the productivity increase, the quality of production has also increased. All of this has made our investment in cobot work well, certainly the best ROI in the field of technology.
PD: Collaborative robots are now the fastest growing segment of industrial automation and are designed to work in collaboration with humans to amplify their professional potential. Cobots have been tested by DARPA to explore new levels of automation across various industries.

The small footprint, low energy consumption, easy programming, allows companies to have the flexibility of automating different production lines at different times for customised batch productions. With none of the traditional costs associated with expert robotic programming, set-up and fenced off work areas, the average payback of cobots have, in some cases, been less than six months, but on an average about two years.

From the scientific and research industry, Aurolab is an integral part of Aravind Eye Care Systems; provides high quality eye care products like products used in cataract surgery, as well as intraocular lenses that assist people in regaining vision after the operation.

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INTERVIEW

Skilled manpower will be required in order to validate automated process

Dr Ajay Phadke, Centre Head, Dr Avinash Phadke Pathology Labs, shares with **Prathiba Raju** on how automation in diagnostics sector is becoming an essential factor as it brings in efficiency, speed, precision and cost efficiency

DR AJAY PHADKE
Centre Head, Dr Avinash Phadke Pathology Labs

> Automation reduces efforts invested into inventory management and consolidation of equipment, and also expedites diagnostic processes such as sample barcoding, separation, processing and archival. In contexts where manpower is expensive, or where trained manpower is hard to find, automation works well in terms of economic sustainability

Why is it necessary for the Indian medical diagnostics industry to be automated?
Adding technology to pathology testing to automate processes can be precise, accurate and a quicker option. It not only allows a larger throughput, but also reduces the chances for errors.

In addition to this, there are many changes that constantly occur in testing methodologies, which automation can easily adapt to.

Automation reduces efforts invested into inventory management and consolidation of equipment, and also expedites diagnostic processes such as sample barcoding, separation, processing and archival. In contexts where manpower is expensive, or where trained manpower is hard to find, automation works well in terms of economic sustainability. Artificial Intelligence (AI) has proven to be helpful in analysing slides and to understand complex specimens in segments like molecular diagnostics and histopathology. When we look at the speed and efficiency of technology, one must also think about access. Functional medical practice is something that must have wide geographical accessibility for it to be most effective. Technology, verticals such as molecular diagnostics have become more accessible to rural areas with the use of portable products and point of care devices.

How and why robots and AI are considered to be smart and a better option than qualified pathologists? Aren't there any possibilities of malfunctioning? If yes, how do you resolve it? Any instances?
AI is a technology that can imitate human thoughts to perform certain actions. AI can perform simple as well as

complex tasks, depending on the level of programming used to create it. In medical lab testing, robots can find effective application to analyse slides and produce organised results for certain simple tests. One concern that is often raised pertains to whether these robots will replace pathologists in the near future. Well, the answer is no. While, technology is accurate, it does require human interpretation. The results produced by AI need to be analysed by a pathologist with hands-on experience in order to be sure. Of course any robot can malfunction and that is why quality control in this field is absolutely essential. When it comes to errors, technology always needs to be calibrated to keep it up to mark. This helps to reduce the incidence of malfunctions and can also alert professionals to stop processing samples in case of such issues. Moreover, healthcare is not limited to addressing the functional needs of patients; it also needs to provide psychological assurance to them. A robot can't serve this function, and hence, will never be able to fully replace a pathologist.

Which is more in use — robots or cobots?
Currently, the diagnostics segment has a mix of both. What sets a robot and a cobot apart is the level of autonomy that they have in the tasks they perform. A robot is something that has the ability to completely replace a person. In simple manual tasks like barcoding of samples, this is definitely possible. For such tasks, the programming of the robot can help it reach higher accuracy and efficiency than a human. However, with more complex tasks, a cobot would be a better option. A cobot is a collaborative robot that assists humans in their activities. In histopathology report, for example, a cobot would look at the regions of a slide that seem important for the pathologist to examine. This makes it easier for experts to focus on potential areas of concern with greater efficiency. Such processes can aid quicker diagnosis. Similar collaboration can be applied for c tests and Pap smears. In future, cobots seem to be the technology of choice, as they allow a balance between automation and the human intervention rather than completely replacing human professionals.

TOTAL AUTOMATION IS SOMETHING THAT IS HARD TO DO, AS PATHOLOGISTS, WHO SOMETIMES FOCUS ON NICHE PROBLEM AREAS, NEED TO BE PRESENT IN ORDER TO UTILISE THEIR SKILLSETS AND ADD QUALITY AND SURETY TO THE AUTOMATED DIAGNOSTIC PROCESS

With increasing automation and robots in labs, what will happen to the skilled and unskilled workforce in medical diagnostics centre?
The possibility for complete automation of laboratory testing depends on context, as well as the number of samples being dealt with. Let's take a simple example. In countries such as New Zealand and Sweden some labs run up to 10,000 samples daily, with only 7-30 human staff. But in India, the same volume, if not more, are handled by around 50-100 individuals. Total lab automation means that barcoding, aliquoting, processing, reporting of data, filtering abnormal data and archiving data are carried out by automations. However, the need for qualified and experienced professionals, who can provide their expertise at important junctions involving deeper investigations, is undeniable. Skilled manpower will always be required in order to validate automated process. Moreover, increasing use of automation in the West is also associated with higher cost of manpower. In many cases, automated equipment is sourced by laboratories from a host of different vendors. However, the functionality and cost is improves immensely when one vendor provides uniform, seamless automation. This potential is hard to achieve. Total automation is something that is hard to do, as pathologists, who sometimes focus on niche problem areas, need to be present in order to utilise their skillsets and add quality and surety to the automated diagnostic process.

How do robots help in the precision of clinical decision?
When we look at the precision that robots bring to diagnostic processes, the advantages are considerable. In the context of pathology, diagnoses and barcoding are based on fixed processes that are performed with greater accuracy by automated technology. Thus, the variability introduced by human action can be reduced. Higher accuracy and precision in diagnosis can be achieved, when clinicians and robots are able to collaborate effectively.

How does the Indian diagnostics industry respond to the utilisation of automation?
With both sustainability and technology at the forefront of Indian society, the changes are more than welcome. India's deep affinity for technology reflects in the rampant use of screens and mobile devices across the country. It is no wonder that there is a positive connotation associated with technology in medicine as well.

Moreover, as the years pass, the cost of manpower will increase, leading to higher company expenditure to attract and retain employees. With time, there will be more pressure on smaller laboratory ventures to increase productivity by acquiring technology to stay competitive. That is one side of automation. The other and probably the most important side of technology adoption is to deliver faster and advanced diagnosis. With around 70 per cent of medical treatment being dependent on diagnostics, it becomes imperative for the industry to consistently provide accuracy in a timely manner. And technology will serve as a critical enabler to deliver quality healthcare support to patients as well as clinicians.

Consolidation of healthcare in larger metro cities and tier 1 cities is inevitable. This will be fuelled by more automation, point of care devices and higher accessibility by providing services in the patient's home environment.

How cost effective is automation?
The crux behind using technology in medical laboratory testing lies in efficiency and cost-effectiveness. As mentioned before, a high load of sample on a daily basis is made easier to handle by technology. However, if a laboratory receives five samples daily, and the machine requires a 100 minimum, it does not make sense to automate the process, as the revenue being made by such a small turnover will take a long time to meet the down payments for such equipment. Another case is moving from ELISA to CLIA, which provides better signal detection, but requires more expenditure. In case where manpower is expensive, as in most western countries, automation can be effective towards reducing expense of larger workloads. The cost savings in terms of reagent pricing as well as manpower hour reduction only works when the workload is substantial.

Earlier, smaller labs would outsource a lot of tests such as vitamin D, thyroid etc. to central chains since they didn't have a cost-effective option to start these parameters in-house. Now the advent of smaller, fully automated systems with a wide test menu, it is possible for them to process a lot of these samples in-house at a very cost-effective rate.

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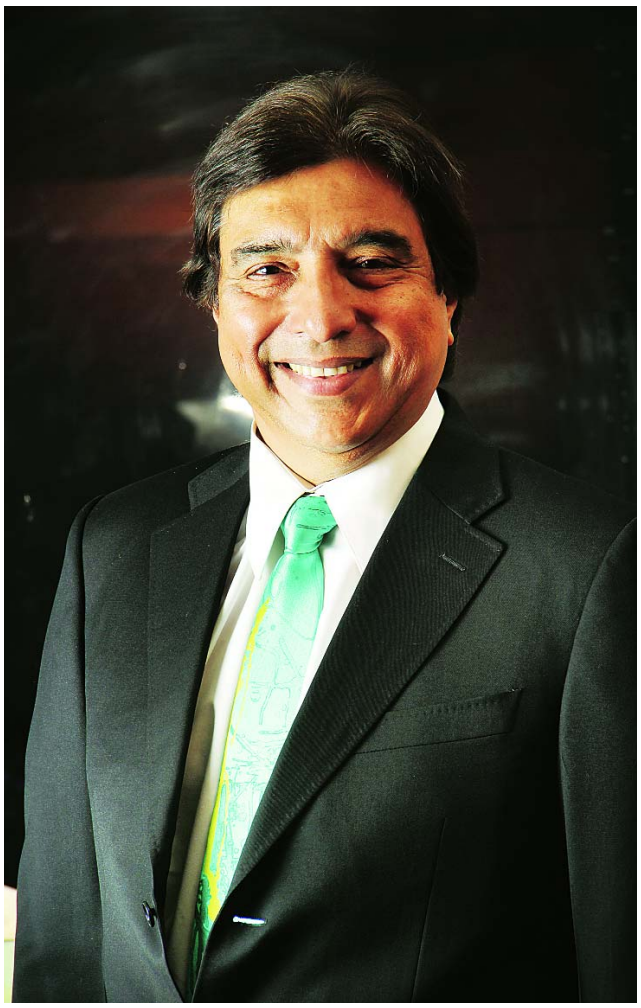
INTERVIEW

Pathology has the power to be able to strengthen the core elements of global health

As the field of pathology in India continues to evolve and bring answers to some complex medical conditions, there are certain issues that need to be resolved in order to propel growth. **Dr Sushil Shah**, Founder and Chairman of Metropolis Healthcare shares insights on the same in an interaction with **Raelene Kambli**



DR SUSHIL SHAH
Founder and Chairman, Metropolis Healthcare

What according to you are the most fascinating aspects of pathology that you see today? And how would you describe its relevance in the coming years?
Pathology has greatly evolved over the past few decades. What has remained unchanged though is the dependence on pathology reports to make an accurate medical decision. This means greater accountability on pathology labs to deliver the utmost quality and care in performing a test as well as a report that practitioners can rely on.

A report recently by a journal suggested that medical information is set to boom in the coming years; at the current rate medical information is expected to double every two months. Newer and sophisticated diagnostic tools, molecular and genetic tests are leading to newer discoveries on diseases, more than ever before. It is therefore important that pathologists remain updated on newer evidence-based knowledge that they will have to process and apply while making diagnosis each day. In coming years, all this knowledge will have to be put together with the help of technology which will save time, costs and get even complex diagnoses right at a singular attempt.

There will be a greater deal of communication between pathologists/labs and the patient care teams in the future. Artificial Intelligence is something that everyone is talking about in healthcare, but it will always play an assistive role and help companies perform better and faster.

What is the biggest issue about pathology in India that you think needs to be addressed?
Pathology in India as all of us know is fragmented. Today, not everyone has access to accurate pathology services as public at large are not aware of good laboratory practices. There is no regulation that is governing this industry. Accreditations are voluntary. It is therefore important to enforce good laboratory practices so that

> It is important for us to realise that the developments in the field of research and technology is huge and without proper investment, our country might remain way behind developed nations

medical decisions are accurate and treatment outcomes are better for patients .

Setting up a diagnostic centre in India is as simple as investing capital and obtaining a 'Shops and Establishments' license. No relevant qualification or certification required. There is no official checklist of basic requisites to set up a laboratory and standardisation to be followed. A change in the regulatory scenario can transform the landscape of the pathology industry. These improvements ought to begin with the emergence of a set of practice standards along with making accreditations by NABL (National Accreditation Board for Laboratory) mandatory for any operator in the industry. This will ensure labs maintain basic protocol, at the very least.

With the EDL coming into play what kind of changes do you foresee?

India has become the first country in the world to compile an Essential Diagnostic List that will help the government to facilitate diagnostic needs in the remotest part of the country. A lot of inputs has come from the first edition of essential diagnostics list released by WHO last year. However the list released by ICMR is customised to the needs of the country and its population. With Essential Diagnostics List coming into play, it is set to be beneficial to large established players like Metropolis as we have the strength to deliver in any corner of the country. With effective public private partnerships and with government taking the role of a facilitator, it is possible for the highest healthcare quality services to be delivered to every single citizen of this country.

What is the best model for the provision of molecular pathology in the future in India?

Modern medicine is dictated by developments in molecular medicine and technical advances. Molecular pathology aims to achieve the integration of a research and diagnostic activities. Academic molecular pathology, at the interface between diagnostics and research, drives such integration. The future of molecular pathology in India is already here. Add digital pathology into the mix and we are not only personalising medicine but also taking everything global. Tissue diagnostics, sub-speciality onco-pathology and digital pathology has already been adopted at Metropolis; all three are the central areas of molecular pathology and is driving the transformative phase. We are proud to have been the first movers in this phase; adopting to change and bringing about the best that technology has to offer. In my view, molecular tissue pathology will be the future and a lot of academics and training will go behind before this becomes the norm like how molecular haematology is a norm today.

INDIA HAS BECOME THE FIRST COUNTRY IN THE WORLD TO COMPILE AN ESSENTIAL DIAGNOSTIC LIST THAT WILL HELP THE GOVERNMENT TO FACILITATE DIAGNOSTIC NEEDS IN THE REMOTEST PART OF THE COUNTRY

Do you think 'global health' is something that pathology as a field needs to prioritise? And how does this help to unlock diagnosis for complex medical conditions?

Pathology has the power to be able to strengthen the core elements of global health and hence efforts on a global level should be made to ensure sustainability. Every country has their own set of unique health issues, requirements and access to healthcare. At present, the technologies and solutions we utilise are adopted. But in order to be able to secure the lives of people in developing countries, we need to be able to create technology at our end for which pathology has a critical role to play.

What changes would you like to see in funding for diagnostics and life science research in India?

In India, medical research receives proportionately much less funding compared to other fields of science. What we need to understand is that medical research leads to much advanced solutions to healthcare issues and no nation can advance without sufficient investment in science and technology. If we want to retain truly outstanding talent in India, we need to be able to provide them the environment where there is enough value for scientific talent. In medical research, our academic structures are set up almost to dis-incentivise research, with much stronger focus on clinical service and teaching than on research, even in our premier institutes. It is important for us to realise that the developments in the field of research and technology is huge and without proper investment, our country might remain way behind developed nations. We should realise that research is not solitarily for academic promotion but also for a wholesome development. A good quality research will always make way to ideas, innovations and progress.

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HCG's hospital lab: A good example of an outsourced model

HCG's partnership with Strand Life Sciences has allowed the hospital to look meticulously at building efficient processes for operations and maintain highest quality standards

Dr BS Ajaikumar, Chairman and CEO, HealthCare Global Enterprises

Raelene Kambli

Outsourcing of laboratory services within hospitals is a growing trend. This facilitates hospitals to save operating and labour costs and bring in more efficiencies to operations. However, the drawback of this model is that hospitals lose control on certain functions within the lab which can be critical and may spend more time in internal evaluations. Having said that, the trend has still accelerated in recent times, thanks to the aggressive moves taken by major lab companies seeking hospital customers looking to outsource lab services. One such hospital which has opted for outsourcing their lab services is HCG Oncology Speciality Hospital, Bangalore. The hospital informs that this model has been a win-win situation for them as well as their partner. *Express Healthcare* spoke to Dr BS Ajaikumar, Chairman and CEO, HealthCare Global Enterprise, to find out how this strategic move benefits his business.

The collaboration and service offering

As per Dr Ajaikumar, the agreement between HCG and Strand Life Sciences is on revenue sharing basis. Strand Life Sciences provides laboratory services to hospital including phlebotomy for outpatients. As a part of MoU, HCG management provides/shares services including facility management (including biomedical waste), registration and billing, customer care including customer feedback. The laboratory provides, OPD phlebotomy services, clinical biochemistry, clinical pathology, haematology / flow cytometry, microbiology and serology, anatomic pathology and cytopathology, molecular pathology, cytogenetics and phlebotomy.

Apart from laboratory services, the lab team contributes to the hospital functioning by being a part of various committees including infection control and ethics. Laboratory doctors participate actively in weekly tumour board meetings, cyber knife OPD meetings, MDT and other clinical meetings. The laboratory actively supports HCG Academics programme in conducting DNB course in oncopathology, resident course in oncopathology and B. Sc in Medical Laboratory Technology. The laboratory also supports quality activities in the hospital including NABH accreditation and related programmes.

APART FROM LABORATORY SERVICES, THE LAB TEAM CONTRIBUTES TO THE HOSPITAL FUNCTIONING BY BEING PART OF VARIOUS COMMITTEES INCLUDING INFECTION CONTROL AND ETHICS

When asked on how does outsourcing work for HCG, especially because the lab offers a large menu of oncology-related tests including tests like BCR ABL (Quant), IRMA, ALK Mutation, Minimal Residual Disease (MRD), EGFR Mutation etc., Dr Ajaikumar replied, "Strand Life Sciences is equipped in handling oncology-related services in respective departments unlike other labs. The laboratory provides wide range of testing from routine to next generation sequence testing as one-stop shop solution."

He further mentions the varied services offered by the lab:

a) Immunohistochemistry: The laboratory offers a very comprehensive range and disease-specific IHC markers. 118 markers are available on completely automated platform within premises.

b) Expertise: Pathologists and other consultants in laboratory are specialised in oncopathology.

c) Molecular pathology: Offers all the molecular markers like BCR ABL, PML Ra Ra and MGMT methylation studies within the premises.

d) Cytogenetics: Karyotyping and FISH techniques for ALK, ROS-1, BCR-ABL are

HCG Lab members

standardised and are available.

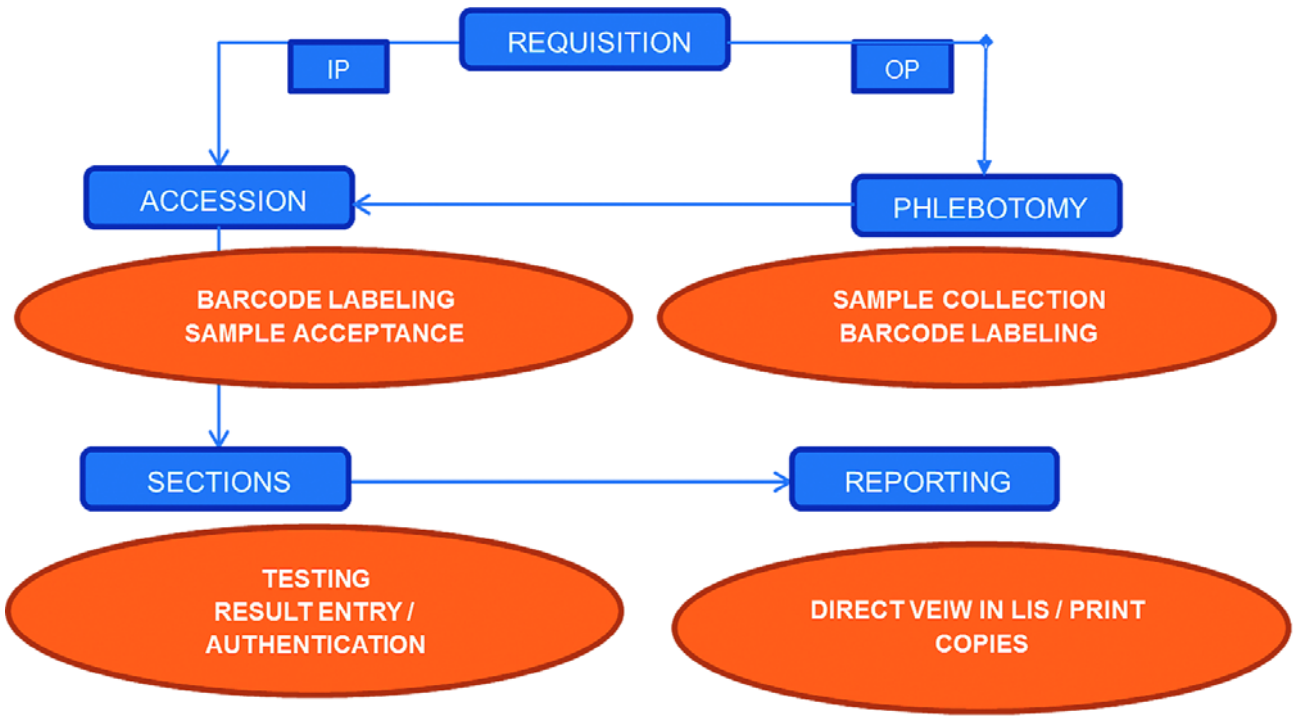
e) Tumour markers: Range of tumour markers including CA 125, CA 19.9, CA 15.3, PSA, AFP, Beta hCG, Free PSA are available as in-house tests

f)Bio repository services: Strand Life Sciences has established a division of Bio repository in the premises which acts as a huge database for oncology cases for prospective studies

g) Clinical research: Strand Life Sciences has a division for clinical research as well which collaborates with HCG clinicians to conduct research activities for advanced cancer diagnostics.

The daily activity using automation and digital technologies

As told by Dr Ajaikumar, on a daily basis, the lab receives around 500 samples. He informs that the lab handles over



HCG Lab Process Flow

KEY PROCESSES AND GUIDANCE FOLLOWED

◗ **Quality control (Internal / External): Quality control practices followed in the laboratory is again as per guidelines of ISO 15189:2012 and College of American Pathologists and include the following:**
1. Two levels of controls every day for quantitative analytes;
2. In built or process control for qualitative analytes;
3. Participation in proficiency testing / external quality programmes for peer review of results;
4. Retained sample testing;
5. Calibration of methods and equipment as per defined intervals;
6. Validation / verification of equipment / methods on installation and at periodic intervals;
7. Processes documented are defined for all the activities from pre-analytical, analytical and post analytical procedures.

◗ **Operating parameters**
Seek inputs from referring clinicians and improve upon the tests to be introduced

a. Saving turnaround time
1. Consultant availability during operating hours so that reports can be released;
2. Hospital staff at different units are given access to LIMS to access the results as soon as available;
3. Walk away analysers for most of routine investigations;
4. Most of the auto analysers are interfaced to reduce manual intervention in result entry.

◗ **Accuracy of results**
1. Internal quality control as per defined protocol;
2. Results reviewed and authorised by qualified and competent consultants;
3. Participation in external quality control programmes;
4. Equipment maintained and calibrated at defined intervals.

◗ **Robustness of system**
1. Use of validated / verified equipment and methods;
2. Use of walk away analysers;

◗ **Maintenance of equipment**
1. Major analytical equipments are under comprehensive / annual maintenance contract to ensure faster response;
2. Equipments and analysers are calibrated as per manufacturer guidelines and / or NABL 112;
3. Operator maintenance (daily / weekly / monthly) are performed at defined intervals and guided by SOPs.

◗ **Team empowerment**
1. The laboratory functions under the leadership of laboratory director;
2. Critical and day-to-day functions are delegated to the respective section heads and lab manager for effective implementation;
3. Sections in turn have section supervisor or senior technicians for assistance to section heads;
4. Operators are given exposure to the systems / equipment through regular trainings;
5. Consultants / staff are encouraged to participate and conduct continuing educational programmes;

◗ **Waste management**
Waste management is done as per the guidelines of HCG and applicable regulatory requirement.

The logistics operations are handled by the supply chain department of Strand Life Sciences as under:
a) Shipping of specimens / samples from other Strand Laboratories;
b) Transport of samples from local laboratories and hospitals;
c) The transport is done in UN3373 certified material and cold chain is monitored as required;
d. IATA guidelines are followed for all specimens being bio-hazardous in nature

100 histopathology samples and immunohistochemistry markers each day. This is best supported by the technical staff and the equipment that the lab has. Moreover, the lab has two state-of-the-art automated tissue processors from Leica – ASP 6275 and rotary microtome that are capable of handling about 700 tissue cassettes a day. The grossing room is equipped with a cryostat from Leica, that is placed in a separate enclosed area to avoid aerosol exposure during frozen section diagnosis. The lab is also equipped with an embedding station from Leica — it is provided with a hot plate and cold plate. The laboratory has three rotary microtomes from Leica and Thermo scientific to handle the sample load. The lab is provided with an automated stainer from Leica for automated staining of H&E stain, papanicolaou stain and other special stains. This instrument can process about 100 slides in one go. This ensure accuracy, quality norms and decreases any human error.

Further, the lab is provided with a cytospin machine from Thermofischer for handling CSF and urine samples. The lab is also provided with an LBC machine – Eziprep for liquid based cytology. Apart form this, HCG's lab has an immunohistochemistry laboratory with two automated IHC machines — VENTANA from ROCHE and Intellipath from BIOCARE. These systems are in place for effective antigen retrieval techniques. The laboratory also has a camera attached to the consultant's microscope so that microscopic images are captured and incorporated in the reports. All these daily activities are conducted with the highest level of efficiency and Dr Ajaikumar attributes this success to his extremely competent staff. "The main strength of the department lies in the highly competent pathology staff that has a team of skilled technical staff and expert pathologists who strive hard to uphold the vision of HCG Hospitals. The pathologists are experts in the field, well trained to provide accurate and timely report even on scanty tissue samples. They are highly competent not only in handling oncology cases, but even non-oncologic cases including brain biopsies and lymphomas. The pathologists are competent in handling guided FNACs / biopsies. The pathologists are approachable for case discussion which makes us unique among other diagnostic centres. The reports at Strand Life Sciences are based on AJCC / CAP guidelines so that all relevant information for patient management are effectively communicated to the clinicians."

The overall performance analysis

HCG invests around Rs 3 crore in their regular maintenance of this lab. When asked about its true success measure Dr Ajaikumar with a lot of conviction replied that successful patient outcomes is the true measure of success and for that reason they have system in place that on a regular basis measures this success. They conduct the following process for the same:

◗ Conduct internal audits and periodic intervals to assess the compliance of systems to QMS;

◗ Collect feedback from patients and clinicians on lab operations;

◗ Implement and monitor quality indicators including reports turnaround times, rate of rejections, sample labelling accuracy, reporting errors and communication of critical values;

◗ Observations from external assessments from CAP and NABL.

At this point of time, the partnership with Strand Life Sciences has allowed HCG to look meticulously at building efficient processes for operations and maintain highest quality standards. But, with outsourcing there are some challenges associated with coordination and integration of organisational culture. As per HCG, outsourcing of their lab services has been beneficial to the organisation and they believe that in future too this will be a sustainable model to provide highest quality cancer diagnostic services in India.

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Empathy empowers care giving

Dr Jyoti Kotwal, Chairperson & Prof, Dept of Haematology, Sir Ganga Ram Hospital & GRIPMER, Rajinder Nagar, New Delhi and President, Delhi Society of Haematology, opens up about being a professional and how her empathetic attitude towards her patients has made her successful both professionally and personally

By **Prabhat Prakash**

Dr Jyoti Kotwal, a vivacious lady with a wealth of knowledge at first sight would appear to be very strict, disciplined and meticulous in whatever she does. But there is also a very soft side to her once one gets to know her better.

While being an clinical expert, a teacher, an administrator, and more, Dr Kotwal believes, that working in healthcare means care giving at all times and successful human beings are those that find the right balance in life — be it work, family, social and self.

Well, in a brief interaction with this dynamic person, I truly understood that the sense of patient care should be a primary principle for every healthcare provider, no matter how much more or less the interaction with the patient may be. Dr Kotwal is currently the Chairperson and Prof at Dept of Haematology in Sir Ganga Ram Hospital & GRIPMER. She is also the President of Delhi Society of Haematology. She is an Ex-Professor & Sr Advisor Path & Haemat Army Hospital (Research & Referral), Delhi Cantt and also Ex-Professor, Dept of Path & Haemat, Armed Forces Medical College, Pune. She has years of experience both as a haematologist and as an academician. Her work and experiences add a better perspective to her professional as well as personal life.

Care giving

As Dr Kotwal lays immense emphasis on care giving, I asked her how she would define the concept of care delivery. "There are different aspects to care giving varying from individual to individual, which can be largely categorised into paid or unpaid. Care giving is largely used to address impairments due to old age, disability, disease or a mental disorder," she accentuated

For Kotwal, empathy is paramount in care-giving. At work, Dr Kotwal puts in her best to deliver care with her empathetic attitude and vast knowledge and skills in pathology that she has amassed over the years. "Important aspects which I always keep in mind are: promptness in investigations to enable a speedy diagnosis and management; empowerment of the patients and their care-givers so that they take an informed decision regarding the treatment modalities and appropriate soft skills always," states Dr Kotwal.

While knowledge on the latest development in the field of pathology is important, she works towards updating her knowledge and skills on a regular basis which helps her to get better at care giving. "Healthcare is such a domain which is evolving all the time and it really helps to stay updated with advancements," she says.

Work life balance

To be successful, one has to have a balance in life, she believes. “One just shouldn’t be pre-occupied with work all the time. It starts to deplete other aspects of one’s life. Work is important but so is time spent with family and friends,” she strongly advocates.

Dr Kotwal maintains her work life balance by managing time efficiently, prioritising, scheduling and rarely multitasking.

Taking out time for oneself is also very important to maintain work life balance which Dr Kotwal achieves by exercising and yoga during her leisure time. She is a firm believer of living in the moment and spends time with family as and when time permits.

She likes to travel and is very fond of beaches where she enjoys swimming. She just likes the ambience of beaches along with sea food. Other hobbies that she indulges in to unwind are reading, travelling, cooking and charity. She states, “I am also lucky to have full support of my spouse and family members in whatever I do.”

Learning other art forms

Times have changed and life has become challenging with every passing day. To cope with the challenges and to perform at the optimum level, one has to be alert and attentive at all times.

Yoga, transcendental meditation and theatre helps Dr Kotwal professionally as well as when she interacts with her patients. She wakes up at 5 am everyday and dedicates 1.5 hours to yoga diligently. She has a keen interest in debates and also was a radio artist in her school days. She emphasises that teaching and research help her in her capabilities as a doctor.

She stresses, “The involvement in other activities helps in recharging and also improves concentration and uptake, improved interactions with the patients and their care-givers, and also better research.

DR KOTWAL ALWAYS SAYS THAT ONE NEEDS TO STRIKE A BALANCE WITH THEIR PROFESSIONAL AND PERSONAL LIFE TO LEAD A HEALTHY AND HAPPY LIFE

Passion for books

Being an avid reader, Dr Kotwal reads all kinds of books and articles including books on medicine and leadership. She does enjoy enjoy fiction and literature as well.

Dr Kotwal usually reads on her travels. The last book that she read was *Code Name God* by Mani Bhaumik. She has a long list of books that she calls her favourites but the books that outranks the other are *Atlas Shrugged* by Ayn Rand. A few other books that she can recall at the moment are *Animal Farm* by George Orwell and Catch 22 by Joseph Heller and she also mentions that the teachings from these books are applicable in all situations, which helps to develop a better perspective as well.

Gadgets and gizmos

Technology has been a boon to mankind ,especially when used for the betterment of oneself and others. Dr Kotwal’s latest gadget being an Apple watch has made her life easier with all that functionalities that the watch has to offer. She doesn't have to carry her phone at all times.

Stay healthy and stay happy

Life comes with its own challenges. Dr Kotwal always says that one needs to strike a balance with their professional and personal life to lead a healthy and happy life.

“Everyone must try to take out time for themselves be it for exercise, leisure activity, music or any activity which gives a person happiness. Complete involvement with family members whenever we are with them makes our life enriching and also helps to strike the right balance,” states Dr Kotwal.

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INTERVIEW

Autolabs: a new beginning

Thomas John, MD, Agappe in a conversation with Express Diagnostics talks about how automation can help reduce human errors and overall improve the business of diagnostics

Why is it necessary for the Indian medical diagnostics industry to be automated?
The number of laboratory estimations in India is increasing annually. From common tests which can be performed by manual methods, now the doctors are looking for specific diagnostic tests to have better diagnosis. Accuracy of the results is of prime importance. Even though manual methods can give accurate results, when it comes to mass testing there is always a chance for human error. Fast and accurate result is now becoming the need for the day and the doctors are looking for a fast report to start the treatment. The IVD segment in India is not well organised even though India has the second largest population. Majority of the testing happens in rural India where manual methods are still at large and quality manpower is always an issue. Because of these limitations only routine tests are performed in independent laboratories and any specific tests like protein testing or immunology testing is required, are sent to reference centres in bigger cities. The best way to elude diagnostic errors is using automated systems. The IVD laboratories should have automated systems based on the workload. Further to the above, the medical regulations is also strengthening in India and this will boost the growth of automated solutions in the IVD sector. Fortunately, there are affordable systems available in the market and we believe that by the year 2025 majority of the IVD centres in India will have automation.

With increasing automation and robots in labs, what will happen to the skilled and unskilled workforce in medical diagnostics centre?
Even though automations are there in the pre analytic, analytic and post analytic phase of the laboratory, there is not much threat to skilled or unskilled workforce of the diagnostic centre. Still there are many areas in diagnostics where the human intervention is required like sample collection, phlebotomy or like validating the tests with clinical condition etc. In today's scenario, automation with robots are not matured enough to become independent of human intervention.

How cost effective is automation? Give example.
The new generation automated systems require very low reagent volume and sample volume which means that the laboratories can have a greater number of tests with same volume of the reagent. This will make the monthly consumption of reagent to reduce (one - third). Also, the automation will help to improve the efficiency in terms of accurate results and better turnaround time which in turn increase the laboratory credibility and business.

What are the challenges faced in clinical laboratory?
Studies show that 70 per cent of the diagnostic error happens in the pre-analytical stage. One of the reasons behind this higher share is the fact that each laboratory is having a unique way of collecting, transporting and testing the samples which is based on the working style of individual laboratories. The major errors happening in the pre-analytical phase are illegible patient name, sample collected in the wrong container, sample not collected etc. There are efforts made to minimise the pre-analytical error with the help of barcoded labels and still there persists another issues like consistency of the label quality and the consistency in pasting the label on the sample container which leads to relabelling the sample container and increases the turnaround time.

Proper specimen labelling practices are critical components of effective and accurate patient identification. Accurate and timely labelling of specimens is an integral part of patient identification. It is critical because errors resulting from a failure in this step can, at best, provide results of no clinical value and, at worst, lead to the most adverse of patient outcomes. When things go wrong in the pre-analytical phase, more expenses do occur, like the cost of redrawing the specimen where the phlebotomy labour and supplies are involved. Further, the cost of reanalysing the sample comes into picture. Moreover, there would be additional costs in the non-phlebotomy labour also, considering the additional nursing and physician time. When limited resources become an issue, even the best-trained, experienced staff member may deviate from proper and generally accepted practices. The best way to minimise pre-analytical errors are with the help of automated labelling platforms called as tube labelling systems, automated sample transport systems and automated sample sorting systems.

THOMAS JOHN
MD, Agappe

What does the future of pre-analytical automation in India look like?
In India the pre-analytical automation is in a nascent stage. Only few systems are available in the market in pre-analytical segment and majority of these platforms are designed based on requirements in developed countries and having huge investment and recurring cost. When we look at countries like India, majority of the testing is performed in the tier -II cities where space requirement for automation also plays a role. A highly compact affordable system with ease of use and better interconnectivity is the need of the day. Indigenisation is going to change the market dynamics and there is a huge untapped market. Agappe is known for quality-innovation and affordability. We have entered the pre-analytical segment by introducing MISPA LABEL, the compact automated tube labelling platform. The system is designed considering the scenarios in countries like India and nearby nations. The hardware is designed based on minimal robotic architecture for low maintenance and with a highly flexible software to suit the industry demands. The compact design is made keeping in mind the space constrains in the medium segment laboratories and the tube loading mechanism design is so simple to allow the user to load the tubes while running the system without interrupting the process. Our plan is to bring pre-analytical automation to all segments of laboratories ranging from rural areas to metro cities.

HELO Solution: Revolutionising an era of automation in Haematology

HELO is modern mélange of innovative design, robust manufacturing standards, undisputed efficiency, unflinching accuracy, standardisation and bullet-proof patient data safety

HORIBA Medical is a world leader in the Haematology market present in over 110 countries on all five continents, with internationally recognised instruments. Annually HORIBA is producing more than 7500 haematology instruments across the world. In addition, to 6000 tons of corresponding reagents annually. We are not just producing instruments but are well established and globally accepted for our unique automation solutions for high-end laboratories across the globe.

HELO (HORIBA Evolutive Laboratory Organisation) is a modern mélange of innovative design, robust manufacturing standards, undisputed efficiency, unflinching accuracy, standardisation and bullet-proof patient data safety. Embedded with advanced technologies of Yumizen H2500/H1500 which are well-established with over three decades of unbeatable experience in Haematology diagnosis with highest analytical performances.

Customers across the world are moving towards HELO automation workflows. Experiencing difference in capacity, efficiency and reliability on results. HELO is a promising answer to the constant evolution and changing work-flow of medical laboratories with increasing pressure from regulatory bodies and accreditation agencies to maintain quality and accuracy without any compromise.

High-end laboratories have each step in the sample lifecycle from collection to dispatch of reports is automated, thus assuring testing of the highest quality. Automated checks and balances are introduced by our globally diverse team of engineers and clinical subject experts, that ensures utmost diagnostic accuracy and reliability of services desired. The solution not just addresses customers routine needs but also assists them in optimisation of TAT, reconfiguration of floor space, and ease of reagent storage and minimised reagent wastage.

P8000, a specially designed middleware platform acts as a brain of HELO that performs automatic validation based on bespoke configurable rules like sample re-run, reflux to confirm results of critical samples, smear preparation or performing Reticulocyte count. This also helps to save time and least human intervention leading to improved TAT. QC rules are also configurable and error free MIS reports.

HELO comes along with HORIBA's accreditation assistance programme which has been developed in accordance with ISO:15189 certification. Unique automated slide preparation system (SPS) can easily smear and stain your sample with high throughput of at 120 slides per hour. SPS has a specially engineered flexibility to regulate staining protocols i.e. MCG, Wright or Wright Giemsa.

T6000 is an automated in-built conveyor with multi-configuration options having special monitoring system of rack transfers to provide optimised flow and accurate results.

Digitalisation of slides with RBC and WBC sub-classification and an optional remote review software application and a body fluid additional application is an added functionality of choice available to its users.

Considering environmental sustainability and economic viability our team has developed special waste treatment solution for HELO i.e. EFFLUNET which is of European standards that can neutralize biological and chemical fluid waste from up to three connected analysers in this automated solution. Single reagent with bacterial, virucidal and fungicidal properties can neutralise 40 litres per hour and allows the discharge treated waste directly into the drain without any manual contact. This additional feature is used internationally, in India, this may be available in future based on the demand of medical laboratories.

To sum up, HELO is a uniquely optimised amalgamation of artificial intelligence and digital technological advancement that has been predicted to play a major role in medical laboratories of the future where healthcare is going to be integrated providing maximum convenience to both diagnosed patients, as well as to those opting to get preventive check-ups. HELO is an unbeatable promising solution of future laboratories which needs to be backed up strongly without exception on automation and digital technologies that will enable clinicians and pathologists to spare more time with patients, allowing technology to do the routine operations.

Transasia, PATUT unveil vision for ‘Thalassaemia-free India’

Organise an awareness and blood screening camp for over 500 students of HR College

Pankaj Udhas, President, PATUT, Jackie Shroff, Brand Ambassador, Thalassaemia India and Suresh Vazirani, CMD, Transasia Bio-Medicals shared their vision of a ‘Thalassaemia-free India’ at HR College of Commerce & Economics in Mumbai in the presence of Dr Suhas Mohnalkar, Head, Sickle Cell Disease programme, Maharashtra, Kishu Mansukhani, President, Hyderabad (Sind) National Collegiate Board and Parag Thakkar, Principal, HR College & Economics and Mala Vazirani, Executive Director, Transasia Bio-Medicals.

As a part of this project, over 500 students from HR College and other nearby colleges participated in the thalassaemia awareness and blood screening camp where they were briefed about thalassaemia and their blood samples tested for the disease. An informative documentary was also shown to the students during the camp.

On this occasion, Transasia donated a sophisticated ERBA fully automated haematology analyser to PATUT and sponsored the blood tests of all students. Developed at Transasia’s European subsidiary, ERBA H360 is customised to meet India’s need for quality and affordable diagnosis.

The students underwent a Complete Blood Count (CBC) test on H 360, Transasia’s recently introduced fully automated ERBA haematology analyser. As the instrument analyses the sample in one minute, the students were given the reports immediately. Those suspected of any abnormalities were given proper counselling. The whole event was organised by the NSS volunteers of HR College.

On this occasion, SAVIOUR, a first-of-its-kind blood donation app which connects patients and donors while maintaining complete anonymity, developed by Vazirani Foundation, the CSR arm of Transasia, was also unveiled.

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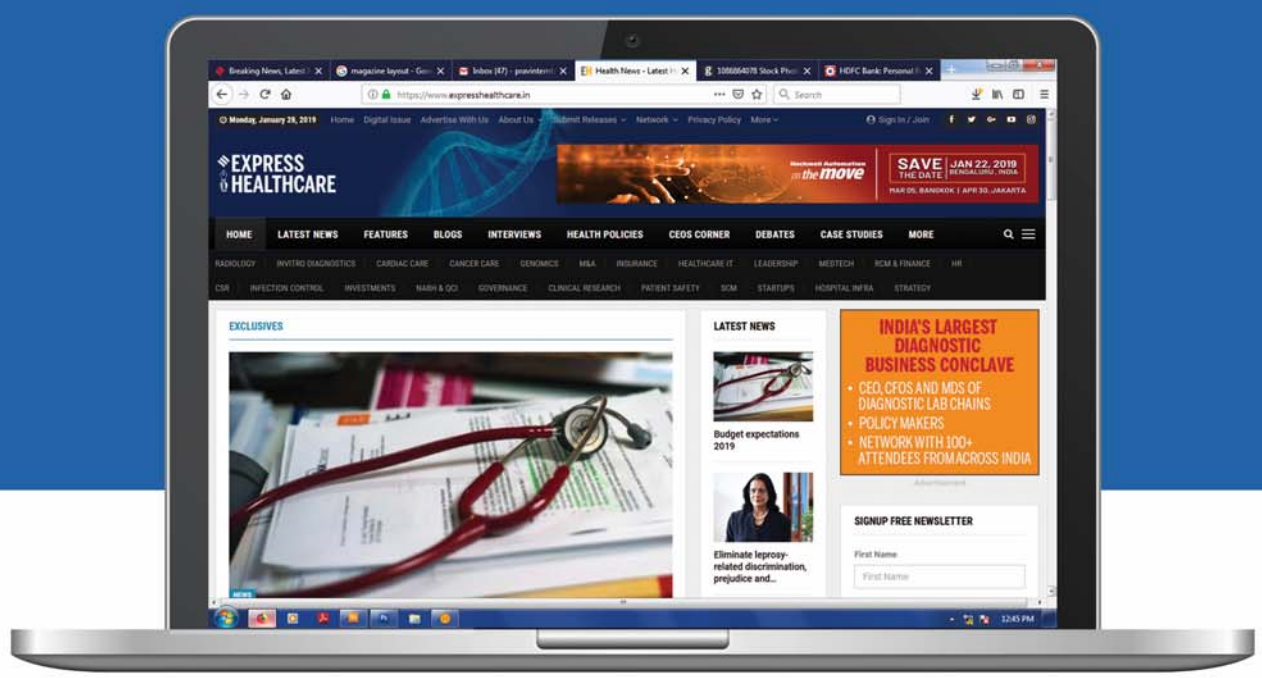

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