



# EXPRESS DIAGNOSTICS

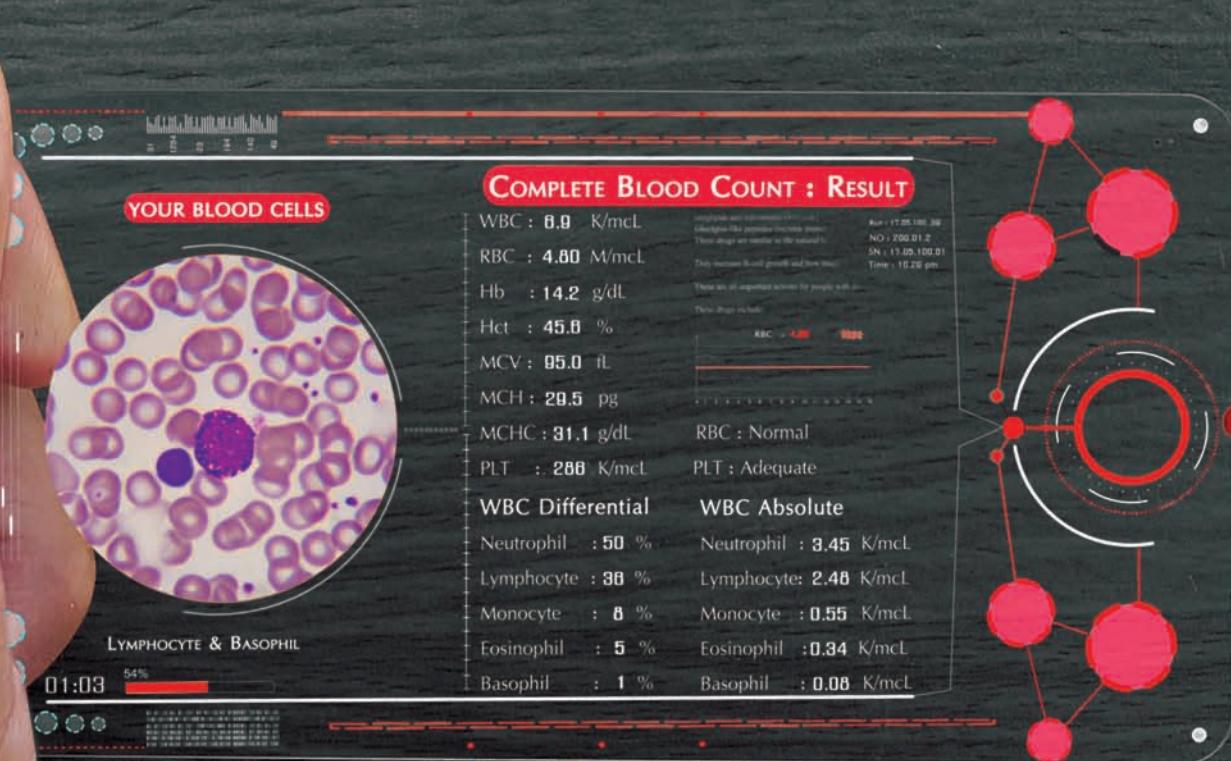
INDIA'S FOREMOST DIAGNOSTICS MAGAZINE



**On the  
Edge**

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AUGUST 2019, ₹50



## THE RISE OF DIGITAL PATHOLOGIES

As digital pathologies take centre stage, pathologists, clinical experts and technology providers look for untapped opportunities. But, this also calls for standardisation and accreditation of digital pathologies



Abbott

DIAGNOSTICS

## CARDIOVASCULAR DISEASE A SHIFT FROM DIAGNOSIS TO PREVENTION

Abbott has launched the first CE-marked claim for its cardiac specific blood test high sensitive Troponin I (hsTnI), that can now provide greater accuracy in identifying a person's risk of developing cardiac diseases in the future, compared to current prediction tools, even in people with no apparent signs or symptoms<sup>4</sup>.

Cardiovascular Diseases are the leading cause of death globally<sup>1</sup>. The number of prevalent cases of cardiovascular disease around the world in 2015 is reported ~422.7 million. The proportion of deaths projected to be caused by cardiovascular disease by 2030 is about 31.7%<sup>2</sup>.

Conventionally, Cardiac Troponin - I (cTnI) has been a preferred biomarker for the diagnosis of myocardial infarction (MI) because of high myocardial tissue specificity as well as high clinical sensitivity<sup>5</sup>.

### CURRENTLY, THE cTnI VALUES ARE USED:

- As an aid in the diagnosis of myocardial infarction (MI)
- As an aid in the assessment of 30-day and 90-day prognosis relative to all-cause mortality
- As an aid in the diagnosis of major adverse cardiac events (MACE) consisting of myocardial infarction
- To monitor the progression of the therapy in case of revascularization and cardiac death due to acute coronary syndrome (ACS)

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1. Cardiovascular Diseases Fact Sheet. World Health Organization, May 2017. [http://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](http://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)).

2. The Global Burden of Diseases (GBD), Injuries, and Risk Factors 2015; Journal of the American College of Cardiology.

3. Know the Facts about Heart Disease, Center for Disease Control. [https://www.cdc.gov/heartdisease/docs/ConsumerEd\\_HeartDisease.pdf](https://www.cdc.gov/heartdisease/docs/ConsumerEd_HeartDisease.pdf).

4. ARCHITECT STAT High Sensitive Troponin-I Package Insert G97079R01, June 2018

5. Thygesen, Kristian. Circulation. 2012;126:2020-2035. 2. Sigurdardottir, Fjola D. The American Journal of Cardiology. <https://doi.org/10.1016/j.amjcard.2018.01.004>. 3. ARCHITECT STAT High-Sensitive Troponin-I Package Insert



### IDENTIFY PATIENTS WHO ARE AT RISK WITH hsTnI

The apparently healthy population may not know they are at risk, but when identified early, heart disease can be prevented through lifestyle changes and medications<sup>3</sup>.

Risk Stratification is a tool to help identify and predict patients at high-risk or potentially at high-risk of heart attacks, heart failure or death, and prioritizing their care to help prevent unfavourable outcomes.

**With the ARCHITECT high sensitive Troponin-I assay, physicians now have a tool, wherein the cTnI values may now also be used, in conjunction with clinical and diagnostic findings, to aid in stratifying the risk of cardiovascular diseases, including cardiovascular death, myocardial infarction (MI), coronary revascularization, heart failure or ischemic stroke in asymptomatic individuals, now with a brand new proven indication.**

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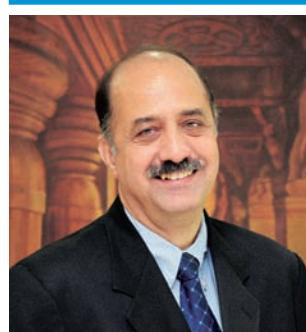
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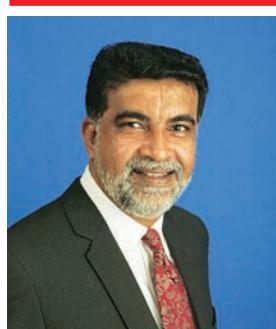
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# Essential diagnostics list set to disrupt sector

**I**t is ironical that though diagnostics influence about 70 per cent of healthcare decisions, WHO's first essential diagnostics list (EDL) was published in May last year, 40 years after its first essential medicines list (EML). A further irony is that only three to five per cent of healthcare spending goes into diagnostics tests, even though these tests dictate further treatment.

India was the first country to follow the WHO's lead on this front. The Indian Council of Medical Research drafted India's first National Essential Diagnostics List (NEDL) and released it last December for a month of feedback from the industry. Though modelled on the WHO's EDL released in May last year, India's list builds upon the Free Diagnostics Service Initiative which was launched by the Ministry of Health & Family Welfare (MoH&FW) in July 2015.

The NEDL could be both disrupt as well as destroy the diagnostics sector. While the ICMR has shown the way, will other stakeholders - from state health missions to diagnostic manufacturers and pathology chains - fall in line?

The NEDL is no magic bullet. Firstly, the ICMR cannot fix the prices of the tests as it is not the implementing body. As clearly stated in the NEDL document, the EDL will complement the national EML which has been successful in facilitating access to treatment and promoting affordable drug prices. The NEDL draft hopes that these measures will aid in the promotion of R&D for new appropriate and effective diagnostics which in turn will lead to reduction in costs.

The National List of Essential Medicines (NLEM) is implemented by the Central Drugs Standard Control Organisation (CDSCO), which sets the prices of medicines under the Drug Price Control Order, 2013. Hence unless the NEDL can fix the prices of these diagnostic tests, patients in India will still end up paying different prices for the same tests depending on the service provider. If implemented in the same spirit as NLEM, NEDL will disrupt the diagnostics sector. A rationalisation of prices of diagnostics will be good for the wallets of patients/caregivers. But on the flip-side, it will erode margins of pathology labs and diagnostic kit providers, etc.

Secondly, standardisation of technology/diagnostic services is as crucial, if not more than standardisation of prices. Thus the NEDL is not just about availability and accessibility, but also quality of diagnostic tests. Once we have all three aspects, healthcare outcomes will improve.

Once again drawing parallels with the pharma sector, the jury is still out on whether the NLEM has improved quality, accessibility and availability of medicines.

Thirdly, all the good intentions in the world are useless if the implementation is faulty. Since health is a state subject,



**While the ICMR has shown the way, will other stakeholders - from state health missions to diagnostic manufacturers and pathology chains - fall in line?**

it is up to the states to ensure that the NEDL is implemented in a way that it benefits the maximum number of patients, both in the public and private sector.

For instance, even though we had initiatives like the Free Diagnostics Service Initiative in place since July 2015, concerns were being raised on the availability of tests. A pilot study published in *The Lancet Infectious Diseases*, Volume 18, Issue 10, in October 2018, titled Availability of Essential Diagnostics in Primary Care in India, found major gaps in test availability, with large variations across the three districts chosen for this study. Between December 13, 2017 and March 22, 2018, the study authors assessed 21 primary health centres in Tumkur (Karnataka), 13 in Fatehpur (Uttar Pradesh), and six in Wardha (Maharashtra).

Though this was a dipstick survey and therefore not of much statistical value, there are some noteworthy pointers. For example, primary health centres in both Tumkur and Fatehpur had limited or no availability of blood counts and glycated haemoglobin A1c tests, whereas these tests were available in Wardha district. The difference between the three centres chosen was that Wardha district used a public-private partnership (PPP) model, in which diagnostic testing was outsourced to a private laboratory.

This observation is repeated for other tests as well. For infections, hepatitis (HbsAg) rapid test was available in 76 per cent of the facilities in Tumkur, 38 per cent of the facilities in Fatehpur, and 100 per cent of the facilities in Wardha. For HIV and syphilis, only 38 per cent of facilities in Fatehpur had these tests, whereas all facilities in Wardha provided the tests. Can we conclude that PPPs, when well run, can make a lot of difference to the availability of diagnostics, as with other healthcare interventions?

The study authors advise that a much larger nationally representative sample survey will be needed to confirm the findings of this study. The surveys should cover both public and private sectors and include all key dimensions of access—availability, use and quality—to generate a comprehensive diagnostics access scorecard.

The WHO has already released the second EDL on July 9 with the next update due in 2020. The second version includes more non-communicable and communicable diseases. It also focusses on certain cancers and blood donations. Whether ICMR/CDSCO will follow suit or not, there is no doubt that the NEDL is an idea whose time has long since come.

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# Indian Diagnostic Services Market Outlook 2020

According to research diagnostic services market is expected to continue growing at 27.5 per cent for next five years

**D**iagnosis is the first step to disease management, as without accurate identification there is no possibility for accurate treatment. India is a land full of opportunities for players in the diagnostic service industry. The country has become one of the major destinations for various diagnostic services. Also, India's thriving economy is driving urbanisation and developing an expanding middle class, with rising disposable incomes to spend on healthcare. According to the new research report 'Indian Diagnostic Services Market Outlook 2020', the diagnostic services market is expected to continue growing at 27.5 per cent for the next five years. This growth is likely to be driven by improving healthcare facilities, medical diagnostic and pathological laboratories, private-public projects, and the health insurance sector. Moreover, with the rise in health consciousness in the society and the rising burden of chronic diseases, this market will swell to approximately Rs 860 billion in revenues market by 2020. Though a major portion of diagnostic business is being managed by the so called unorganised sector, the diagnostic service market is expected to become much more organised and consolidated with a lot of small and independent laboratory players becoming franchisees for the larger players. In order for clients and interested companies to



enter this industry, our report provides an in-depth analysis of the cost assessment comparison of most common pathological and radiological tests among Tier I and Tier II cities. This present report provides an overview of the Indian diagnostic lab services market delivering an effective overview of the market size and future forecast. In terms of services, the market is dominated by pathology services, which account for approximately 70 per cent of the

market. The report additionally investigates the current market trends and opportunities with their impact on the performance of the sector. Further, the report provides consumer behaviour patterns with respect to diagnostic services. Moreover, the report also provides insights regarding the prevalence and incidences of various diseases for which the diagnostic services are widely used. The report also covers various business models in the Indian diagnos-

tic services market, which generally scale up the level of diagnostic services and facilitate the entry of new market players. The report effectively assesses the implementation of commonly used models, such as PPP model, hub and spoke models, and even analyses their impact in generating revenue. Moreover, industry experts prudently analysed the regulatory and accreditation landscape with respect to setting up of diagnostic labs in Indian cities. The report, in

this context, investigates into the viability of accrediting such diagnostics labs. After an exhaustive study of the industry, the report presents a deep dive competitive landscape covering the top players along with business overview, strength-weakness analyses, recent developments, and growth strategies adopted by them to sustain their position in the Indian diagnostic services market.

EDx News Bureau

## Neuberg Diagnostics ties up with C-CAMP

Neuberg Anand Academy for Laboratory Medicine (NAALM) will partner with C-CAMP for technical training courses covering flow cytometry, genomics, mass spectrometry, other advanced technology platforms



**N**euberg Diagnostics announced a strategic alliance with the Centre for Cellular And Molecular Platforms (C-CAMP), an initiative of the Department of Biotechnology, Ministry of Science and Technology and Earth Sciences, Government of India.

The MoU was signed in the presence of Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Govern-

ment of India and Chairperson, Biotechnology Industry Research Assistance Council (BIRAC); Dr Taslimarif Saiyed, CEO & Director, C-CAMP; Dr GSK Velu, CMD, Neuberg Diagnostics; and Dr Sujay Ramaprasad, Medical Director, Neuberg Diagnostics.

As part of the arrangement, Neuberg Anand Academy for Laboratory Medicine (NAALM) will partner with C-CAMP for technical train-

ing courses covering flow cytometry, genomics, mass spectrometry and other advanced technology platforms. Also Neuberg Anand Reference Laboratory and Anand Diagnostic Laboratory - A Neuberg Associate will have access to high-end technology like electron microscopy at C-CAMP for analytical testing and for research into method development.

*EDx News Bureau*

**AS PART OF THE ARRANGEMENT, NEUBERG ANAND ACADEMY FOR LABORATORY MEDICINE WILL PARTNER WITH C-CAMP FOR TECHNICAL TRAINING COURSES**



# ICMR releases India's first National Essential Diagnostics List

NEDL has been developed for all levels of healthcare –village level, primary, secondary, tertiary care

Indian Council of Medical Research (ICMR) recently released India's first National Essential Diagnostics List (NEDL) which is a part of MoH&FW formulated guidelines for strengthening diagnostic services in the country. NEDL is an opportunity to build upon the existing initiatives of Free Diagnostics Service Initiative (FDI), Indian Public Health Standards (IPHS) and National Health Programmes.

NEDL provides an expanded range of tests and complements these guidelines. Existing tests (In Vitro Diagnostics(IVD), radiology and others) have been reviewed and available basket of tests expanded based on inputs from experts. NEDL has been developed for all levels of healthcare –village level, primary, secondary and tertiary care. Tests for each level of care have been proposed based on the utility and requirement of test at that level, infrastructure, training available or proposed to be made available through other initiatives.

The list also encompasses tests relevant for new programmes such as Health and Wellness Centres (HWCS) under Pradhan Mantri Jan Arogya Yojana. In addition to tests, corresponding IVD products have also been recommended.

The criteria for inclusion of tests in the NEDL: Following criteria have been used for including tests in the NEDL: Conditions with high disease burden/high public health relevance where diagnostics has a clear impact on the



diagnosis and management of a disease: -Diseases with existing national programmes for diagnosis and management -maternal health complications, HIV, tuberculosis, malaria etc. -For priority conditions with weaker support

programmes: NPCDCS (diabetes, hypertension, cancers, chronic kidney disease etc.). Tests that enable safe and rational use of EML medicines -For instance in case of HIV/AIDS-diagnosing the condition for which the

medicine is indicated (Rapid card, ELISA, etc.), monitoring for medication efficacy (CD4 count, HIV RNA load assays) and monitoring for medication toxicity (liver function tests). Conditions prone to outbreaks/epidemics (dengue).

Tests encompassing care pathways of diseases/conditions. Tests which are not mainstay of diagnosis but are critical supporting tests such as complete blood count (CBC) and C-reactive protein (CRP).

EDx News Bureau

# Strand Life Sciences joins the Global Diagnostics Network

The collaboration will help generate enhanced diagnostics insights to improve delivery of global healthcare



**S**tand Life Sciences, India, recently joined the Global Diagnostics Network (GDN), a strategic working group of major diagnostic laboratories collaborating to generate enhanced diagnostics insights to improve the delivery of global healthcare. The GDN, launched in October 2018 by US-based Quest Diagnostics, consists of the following companies: Al Borg Medical Laboratories, Dasa, GC Labs, Healius, KingMed Diag-

nostics, and SYNLAB. LSI Medience also joined GDN.

GDN initiatives will benefit patients, healthcare providers, pharmaceutical innovators, government agencies, non-governmental organisations (NGOs), and academic institutions. Starting priority areas of focus include the standardised delivery and development of high quality companion diagnostics for pharmaceutical companies, and the creation of an emerging pathogen pre-

paredness network to expedite infectious disease research and response. Additional initiatives will be rolled out based on regional and global priorities.

In India, Strand Life Sciences is focussed on oncology, mother and child and technology enabled wellness segments. "We are very pleased to join the GDN and learn from the rich experience of our fellow members as well as contribute through our special capabilities in genetics, bioin-

formatics and oncology" said Harish Natarajan, Chief Operating Officer and President, Clinical Diagnostics, Strand Life Sciences.

"We welcome Strand Life Sciences as a new GDN member, and are eager to continue acceleration of the network's programmes that will reach patients in every part of the world. The GDN continues to make great strides in increasing access to diagnostic technology and innovation, and in

building the largest global launch platform for rapid deployment of companion diagnostics," said Mark Machulez, General Manager, Global Markets, Quest Diagnostics.

Collectively, this worldwide community of nine leading healthcare companies has a presence in countries with two-thirds of the world's population, and over 90 per cent of the global pharmaceutical market.

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## INTERVIEW

# The GDN gives Strand a platform to showcase its strengths across the world

Strand Life Sciences, India, has recently joined the Global Diagnostics Network (GDN). **Harish Natarajan**, Chief Operating Officer and President, Clinical Diagnostics, Strand Life Sciences in an interaction with **Raelene Kamblu** talks about the opportunities that the company and the Indian diagnostics industry hold with this partnership. He also speaks about the future of genetics, bioinformatics and oncology in India

**What is the rationale behind joining the Global Diagnostics Network (GDN)?**

Global Diagnostics Network (GDN) is a strategic working group of major diagnostic laboratories collaborating to generate enhanced diagnostics insights to improve the delivery of global healthcare. Collectively, this worldwide community of 10 leading healthcare companies has a presence in countries with two-thirds of the world's population and over 90 per cent of the global pharmaceutical market. Strand Life Sciences is a leader in precision diagnostics in India and will represent the GDN in this country.

**What opportunities do you see for your company in the global diagnostics industry?**

Strand has recognised expertise in genetics, bioinformatics, molecular biology and oncology and is present across the country with 20 networked, high quality laboratories. Strand will continue to focus on oncology, mother and child,



**HARISH NATARAJAN**

Chief Operating Officer and President, Clinical Diagnostics, Strand Life Sciences

and technology enabled wellness segments - where its inherent strengths will help pave the way for the development of new diagnostic methods and better healthcare decision frameworks.

**How would joining the GDN add value to Strand Lifesciences' overall business?**

The GDN programme was launched in October 2018, with the intent of increasing access to diagnostic technology innovation and building the largest global launch platform for rapid deployment of companion diagnostics. The coming together of these two aspects will help Strand enhance its customer offerings in India and create market facing opportunities, specifically in Global Health and companion diagnostics.

The GDN gives Strand a platform to showcase its strengths across the world - and to learn from the other globally renowned members, thereby staying at the forefront of precision medicine science and diagnostics solutions. Through our participation in

**Through our participation in the GDN, we have the opportunity to collaborate to develop and bring new world solutions into India**

# STRATEGY

the GDN, we will have the opportunity to collaborate to develop and bring new to the world solutions into India at a much faster pace and a more affordable fashion.

## Any specific diagnostics areas that Strand will like to focus on and why?

In India, Strand Life Sciences will focus on oncology, mother and child, and technology enabled wellness segments. The number of people who would benefit from recent technological advances in these segments has sharply increased over the last decade - and we believe that our clinical strengths coupled with our genetics and bioinformatics expertise will help us address the needs of these segments best.

## What are the new innovations that Strand will now come up with in the genetics, bioinformatics and oncology space?

Strand Life Sciences through the HCG network has one of the most exhaustive repositories for oncology samples and is well poised to test and interpret complex clinical cases. As part of the precision pathology continuum of services,

## COMBINING TECHNOLOGICAL INNOVATION WITH EXPERTISE CAN HELP PATHOLOGISTS HAVE A POSITIVE IMPACT ON HEALTHCARE SYSTEMS AND PATIENT OUTCOMES

Strand offers the entire plethora of services from basic pathology, routine and the most sophisticated sequencing-based tests interpreted through cutting edge bioinformatics and artificial intelligence.

Strand Lab in Bangalore is the first one in the country to provide Breast panel - ER, PR, Her-2/neu and Ki-67 markers on a computational pathology-based software. This software is IVDCE approved and eliminates the subjectivity.

A key area of New Innovation for Strand in the next few years will be non-invasive detection of disease. Detecting disease deep inside the body is challenging, often needing invasive biopsies that are difficult. Non-invasive detection of DNA from body fluids is a powerful non-

invasive alternative. Our first publication last year showed that potentially >40 per cent of all early stage cancers are detectable from blood draws. Our ongoing projects have pushed that limit further to >70 per cent detection for early stage oral cancer from just a saliva draw. This technology will eventually be brought to the clinical use where it can hopefully help control morbidity and mortality due to cancer.

### While genetics and bioinformatics is still evolving in India, what prospects do you see in the future: both for your company as well as the industry?

Pathology is the keystone of cancer care. Today pathologists impact a huge range of clinical pathways and treatment decisions in cancer care. As treatments

continue to grow in complexity and volume, pathology and laboratory services must deliver timely diagnoses for effective, individualised cancer treatments. Increasingly detailed diagnoses will become more dependent on pathologist's skills and knowledge.

Combining technological innovation with expertise can help pathologists have a positive impact on healthcare systems and patient outcomes. More than ever, pathologists need a committed diagnostic technology collaborator who understands their needs, demonstrates know-how and offers a proven track record of implementing scaled digital workflows and innovative diagnostic technologies.

The Indian landscape is maturing and there has been

tremendous progress in the last few years. Adoption of genomics has grown several-fold in the last few years. As awareness levels increase, the adoption of genomics will rise dramatically, as it did in the US starting five years ago. For instance, Strand offers industry leading BRCA testing and has pioneering publications on Indian patients that show that 30 per cent of referrals to its centre carry mutations that confer risk, compared to the analogous figure of 10 per cent in the west. The volume of BRCA testing in the US has risen 100 per cent YoY in the US and similar phenomena are likely in India soon, given possibly even greater relevance in India.

## While you enter a new business domain, what will be your focus and vision for the company?

Strand's vision is to be a leader in the precision medicine space - and to develop solutions that will improve the quality of healthcare decisions. We are committed to helping physicians make better clinical decisions - this theme will run through all our business explorations, product offerings and programmes in the future.  
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# Taking BLK Hospital to the next level

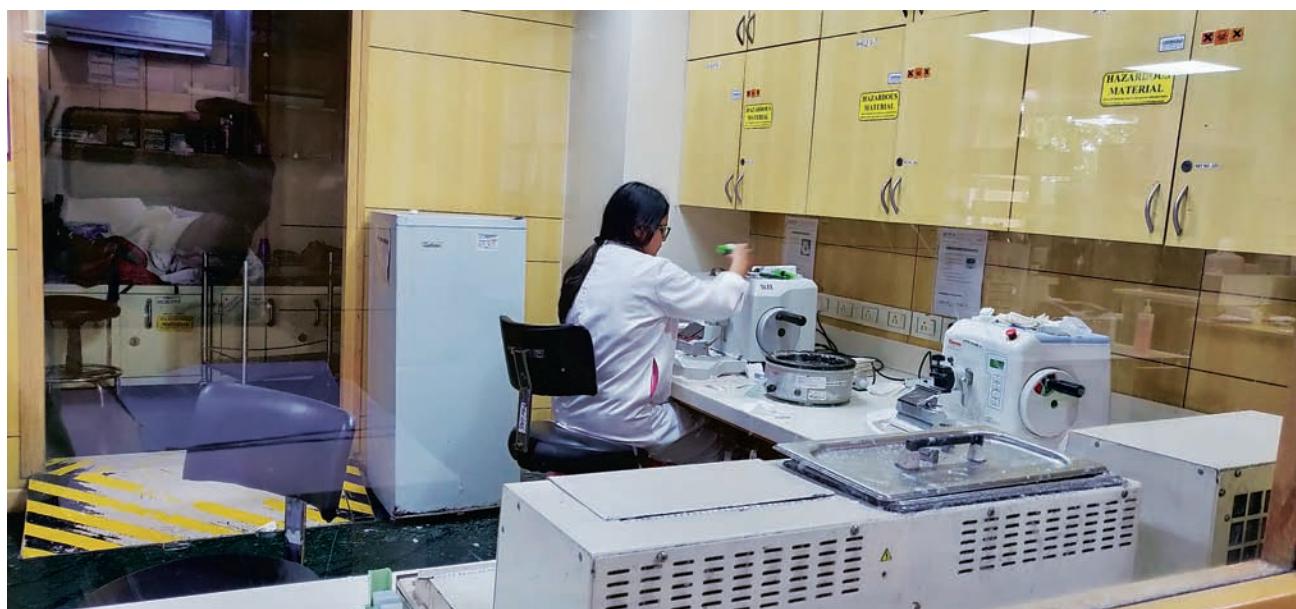
Hospital Based Labs (HBL) are evolving – of late, these are switching to automated open track systems. *Express Diagnostics* profiles the evolution of BLK Hospital's laboratory services

**N**estled in a busy locality of South Delhi, the 700-bedded BL Kapur Hospital deals with thousands of patients in a day. Out of the many specialities one of the busiest department is the department of lab medicine. With pneumatic tube sending blood samples every single minute and a multi-disciplinary team keenly attending to the blood samples to decipher the results, the amount of work done at this lab is truly enormous. The hospital's aim is to redesign its lab to automated open track system by the next financial year.

Giving details about the laboratory services of BLK, Dr Anil Handoo, Senior Consultant – Haematology and Director, Laboratory Service and AARCE, said, "The laboratory services in BLK started in 2008, lab operations were developed and designed to be futuristic. Most of the private hospitals are reluctant to invest and usually have a small room for a lab. However, they then try to evolve as the footfall of patients increase. BLK Hospital had a full-fledged lab as they considered laboratory services to be pivotal to patient care. From 2008 to 2009, the lab had seen an incremental growth and saw more growth from 2012 onwards. As of now, we get samples of about 1,500 patients in a day. One patient undergoes a minimum of three tests, so we have at least 4,500 to 6,000 tests done every day in the lab."

## HBL vs private labs

Speaking about the challenges of HBL compared to the private held labs, Dr Handoo informed that unlike private-run labs, HBL turn around time is



shorter and the laboratory services are quick and precise.

"In HBL, we are not given the leeway of getting the sample and releasing the results the next day. Majority turn around time is less than two hours. If we get the sample dur-

ing evening hours, then we get less time, even then the results are uploaded on the website. With a stringent time limit in one hand, we have a good number of samples to handle. Being a 700-bedded hospital, we do get samples for specialised in-

vestigation from the IPD. However, in HBL, the numbers for specialised investigations are less. This is not just in BLK but across the country tests are given to outside private labs -- for instance, sequencing, high-end mutation tests and molec-

ular tests. HBL doesn't carry out such tests because we don't have enough batches and it is also not commercially viable. In economic and financial terms, HBL will always be a bit more expensive, as the input costs are higher and the reagent



prices are always expensive than what the private labs get. They are able to give you a better rate in terms of pricing," he informed.

Dr Handoo also highlighted that HBL differs from the private-run labs. He informed that HBL scores out with the kind of expertise they bring in the investigations.

"When you go to a routine lab, you might get only values, but in HBL, you get more information which leads to a detailed diagnosis. Nearly 20 per cent of the cases coming to HBL are being misdiagnosed. For example, recently we had seen about six cases wherein the investigation had detected cancer but when we re-analysed them, they had no cancer. So, the tendency of HBL is that we review the case completely and provide holistic information which is not available in stand-alone labs. Each test takes place in silos and nobody collects all the information and evaluates it. In HBL, we correlate things which you don't get done in other labs. The other bigger advantage in HBL practice is access to clinical information."

#### Automation: New buzz word in HBL

When it comes to medical ad-

## CUTTING DOWN THE TURNAROUND TIME

Consistent advances in medical devices have helped the lab technology to diagnose precisely. As years pass by, these advanced medical equipment come handy to lab technicians. One such equipment is the New CAL 8000 Haematology Workstation installed by Mindray at Haematology BLK Hospital. The new workstation helps to report newer CBC parameters which are useful for clinicians in diagnosing diseases like dengue, malaria, etc., at an earlier stage and also remarkably supports in prognosis.

As mentioned above (in the article) by Dr Anil Handoo, Senior Consultant – Haematology and Director, Laboratory Service and AARCE, that one of the challenges faced by the Hospital Based Labs is less turn around time. Mindray's latest equipment helps BLK Hospital lab to efficiently manage its turn around time and ensures precise patient reporting as per lab technician.

Large laboratories like the one at BLK Hospital needs to have many instruments to complete daily workload. Complementing the same, Mindray - CAL 8000 helps the lab to test 400 samples in an hour. It is a highly automated workstation for smarter, faster and more accurate haematology analysis.

The usual way of running different tests for a patient is to collect multiple tubes of blood from the patient and have them distributed manually into separate instruments for analysis, which is both time- and labour- intensive. Making this simpler, Mindray's CAL 8000, the haematology analyser, slide maker and stainer, CRP analyser and HbA1c analyser are all integrated into one seamless production line through automated track modules and trolley. Simply by loading a single tube of blood sample onto the automation system, you can get all the test results you need. This innovative walk-away automation functionality has made possible the "CBC+CRP+HbA1c" testing all-in-one streamlined workstation for the first time in the industry.

Mindray CAL 8000; Haematology Workstation has helped BLK lab to streamline manual processes and integrating different analytical areas into a combined laboratory service. With less time needed to process manual differentials and slide reviews, technologists now have more time to do other things in the lab and contribute to a higher lab efficiency.



vances, laboratory technology is usually at the forefront. New advanced testing techniques to diagnose or screen have made testing more efficient and automated. The rapid advancement Lab Information System (LIS) has revolutionised the lab service and automation and open track system is the new buzz word in lab technology.

"Few years ago, majority of instruments used in laboratories were smaller and had less throughput. For example, in haematology, we had five-part instrument and three-part instrument and the workloads were less. Technology was relevant but not advanced. Over a period of time, we upgraded our requirement from smaller instruments to a modular system, right now redesigning the lab is our core concentration. By next financial year, we should put in place an automated open track system. There are various reasons why the lab needs transformation, viz lot of space gets occupied by

bench top instruments. Also, the instruments have become modular now – they are plug and play type. So, these have space redundancy. We are trying to remove these small cubicles and we will change it into an open track system where everything is automated and we don't want anyone to carry the samples. Anyway, the samples come in pneumatic shoot and from there, they are loaded into a loader to be sorted. Further, they get segregated to the respective labs and track takes it to the respective place. By the next financial year, the lab will be fully automated. We need this change primarily because of the increased volumes as BLK Hospital has taken over Max Hospital. Hence, an open track system will help and we will be creating hub labs – one in BLK Hospital and the other at Max Hospital in Saket. With automation in place, we will be able to provide high-quality results at shortest possible time," he informed.

Commenting about the cost of the transformation, he said, "Fortunately, the cost incurred for HBLs are lesser than the medium-sized labs. In HBL, the price of the instrument gets loaded on the reagents so you don't pay for the capex upfront based on the agent lease. Therefore, upgrading to a higher platform has become easier but you need to have a minimum volume to play around with. Any HBL will have 30 per cent high prices when compared to stand-alone prices from private labs."

Adding to it, Dr Handoo said that any HBL's aim will be imbibing latest technology and constant up-gradation. "BLK Hospital wants to increase the capabilities of the laboratory in terms of infrastructure, hardware and software requirements and make it user-friendly which is easily accessible and available," he added.

Touching upon the important aspect – the quality of HBL, Dr Handoo informed

that usually (National Accreditation Board for Testing and Calibration Laboratories) NABL-accreditation is taken by private hospitals, as they are able to get Central Government Health Scheme (CGHS) and government business. But he pointed out that BLK Hospital did not do it for business purpose, but they are keen on the quality offered by the lab.

"We got our first accreditation in 2010 and we get it every two years once. In the last cycle, NABL and APLAB had taken our labs as model lab. We run three-level quality controls thrice a day, it costs us and we pay the medical equipment company. Even then we do it as we do not compromise in the quality and it showcases in our lab results. For example, our expense on internal quality in haematology alone is Rs 1 lakh per month, which is a recurring cost. It doesn't happen in many of HBL practices, but we do it," he added.



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# THE RISE OF DIGITAL PATHOLOGIES

As digital pathologies take centre stage, pathologists, clinical experts and technology providers look for untapped opportunities. But, this also calls for standardisation and accreditation of digital pathologies

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Clinical pathology has played a significant role in maximising the effectiveness of healthcare delivery for several decades. While pathologies in the past have relied on the conventional microscopic methods, there is a sudden change in its methodology and processes. These changes are driven mainly by the emergence and advancements in digital technologies, pushing the field into becoming more efficient and scalable. The benefits of which can be mainly characterised by improvements in patient safety mechanisms, up-gradation of diagnostic workflow and enhancement in over-all service quality. It also makes the field more business-like, the specimen more reproducible and the work of pathologists less cumbersome. Experts call it the era of digital pathologies, wherein simple image acquisitions have now advanced to whole slide imaging (WSI) also referred to as virtual microscopy. The clinical usage of WSI ranges from telepathology for primary diagnosis to second opinions, remote interpretations of frozen sections and viewing immunostains for showing slides at tumour boards. Various publications have shown a good diagnostic concordance between WSI and glass slides. Moreover, these technologies have demonstrated an increase in productivity of pathologists by 10 to 15 per cent, thereby improving the overall efficiency of healthcare providers.

So let's understand the significance of digital pathologies in today's healthcare clinical environments.

## Digital pathologies changing the status quo

Interestingly, the momentum for the clinical deployment of digital pathology has reached a level where primary diagnostic use of whole slide imaging is no longer a distant future. The global digital pathology market size is expected to reach \$ 1.67 billion by 2026,



**DR JAYARAM IYENGAR**  
Head - Histopathology Services, Neuberg Diagnostics

“One needs to understand and take advantage of what these new tools can offer in adding objectivity to one's approach



**SATKAM DIVYA**  
CEO, Klinik App

“Consolidation of technology with diagnostic centres have resulted in online bookings being carried out by the customers to avail any type of blood test

according to a report by Grand View Research. It is anticipated to expand at a CAGR of 11.7 per cent during the forecast period. Therefore, driven by the need for more accurate testing and efficiencies in workflows, shortage of pathologists in the country and the demand for faster diagnostic tools for chronic diseases such as cancer, digital pathologies will soon become the new norm in India too.

In India, the pathologist-patient ratio is highly skewed, doctors face enormous time

pressure and have to examine a staggering amount of information to make treatment decisions, for every single cancer patient. Also, being a complex area, the skill and experience of the pathologists make a noticeable difference to the interpretation and patient results. The relevance of such pathologies is, hence, determined.

Speaking about the transition in India, Dr Ajay Phadke, Centre Head, Dr Avinash Phadke Pathology Labs, explains, “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. The most important side of technology adoption is to deliver a faster and advanced diagnosis. With around 70 per cent of medical treatment dependent on diagnostics, it becomes imperative for the industry players 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 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."

Adding to this, Dr Rajesh Kewalramani, Consultant - Medical Microbiology and STIs/HIV, expresses, "One of the opportunities is to improve turnaround time to results—a challenging goal. Microbiology professionals often recount stories of distressed point-of-care providers urgently requesting STAT culture results. It is nearly impossible to grow bacteria faster, and with diminishing resources and increased volume, there may not be enough eyes to read plates when they are ready. However, a new technology may be able to help improve the turnaround time, and thus, patient outcomes, when used in conjunction with the highly specialised analytical skills in a clinical laboratory."

Likewise, Dr Shravan Subramanyam, Managing Director, Roche Diagnostics India, says, "With the majority of clinical decisions being dependent on pathology findings, digital pathology empowers the pathologists in such scenarios and many more. It helps them analyse a patient sample from a remote area without either of the patient travelling or the sample being transported. It opens door to telemedicine, which enables patients to get access to top clinicians without having to travel hundreds of kilometres. It enables pathologist and other specialists to collaborate and analyse complex patient cases. These solutions can bring consistency and accuracy to the pathologist by enabling them to analyse most complex cancers using approved artificial intelligence-based algorithms."

"Pathology laboratory has shifted in status from being an ancillary unit to its current role as an active partner in healthcare delivery. Digital pathology has added a new dimension to diagnostics with a paradigm shift from conventional to digital microscopy. It has opened new opportunities not only for day-to-day reporting of blood

**According to NHS England's National Pathology Programme and the Research Gate study, the benefits of digital pathologies are mentioned below:**

- With digitisation, pathology lab can increase organisation, streamline processes, increase caseloads, and reduce turnaround time, thus obviating many day-to-day logistic oriented delays in traditional lab.
- Pathology digitisation facilitates remote communication and collaboration across locations and specialities.
- Cross functional integration and aggregated views of a patient clinical data help better informed decision making.
- As larger sets of clinical data can be archived and tracked by digitisation, access to a larger volume of expert knowledge can lead to advancement in diagnostics and uncover of new insights.
- Digital pathology enables instant sharing of results with multiple departments and colleagues, inclusion of digital images with pathology report, computerised quantitative analysis for prognosis scores, eliminating risk of break of glass slides in transit and so on.
- Digital pathology enables performing automatic case reviews and tracking of slide assessment for completeness In addition to image analysis efficiency, precision and reproducibility, thus substantially improves quality assurance.
- As a teaching aid, digital slides with inherent robustness and longevity are a great advancement over glass slides which may fade, break or get misplaced. Digital scan of a single tissue specimen can provide slides for several teaching classes and enables students to experience a wider range of cases.
- Besides facilitating image sharing and collaboration for a variety of cases, enabling efficiencies in tumour boards, second opinions and access to sub-speciality expertise, automated digital imaging analysis in clinical setting such as diagnostic HER2 assay, enables reproducible and objective stratification of patients into cohorts of likely responses to drug therapies and eliminate inter-and intra-observer interpretation variability.
- With increased sub-specialisation of pathologists, the ability to engage with experts in a given field is greatly enhanced by digital pathology, which helps with difficult evaluations and streamlines access to the right experts, with ultimate improvement in turnaround time for decision support to the benefit of researcher, healthcare provider and patient.
- Digital pathology will enable pathologists and pathology departments to be more efficient. The ability to view images from any location in the world will allow them to be more flexible and to provide specialist or second opinion quickly, thus responding rapidly and accurately, especially with routine cases, which will give more time for dealing with difficult cases.
- As digital pathology enables collaboration between pathologists as well as within cross-disciplinary teams, pathology labs will be able to offer expertise to regions beyond their current scope where experienced or specialised pathologists are scarce.

and other smears and biopsies but also for an expert consultation, incorporation of artificial intelligence and teaching purposes. With digital pathology, it is easy for two pathologists, to view the same slide at the same time without sitting together in front of one microscope. They can do this from their own offices wherever they are. This reduces the time taken for the pathologist to provide a

diagnosis in a difficult case," opines, Dr Jayaram Iyengar, Head - Histopathology Services, Neuberg Diagnostics.

Talking about the current scenario in India, Satkam Divya, CEO, Klinik App informs, "Consolidation of technology with diagnostic centres have resulted in online bookings being carried out by the customers to avail any type of blood test. Now, well trained

phlebotomists reach their doorstep to collect the samples and transfer it to the labs. Followed by receiving of online reports as well through their email id's which they can directly be shared with doctors without visiting them at their clinic. This has reduced the waiting turn-around time of a patient to conduct a test and seamless collection of report. On a positive note it has

increased the potential of collecting more information to form a clinical database of any patient who came online to book an appointment. With this came the storage of large sets of digitised data that can be used for cross reference in the future. It has increased the chances of a more data-driven profession for the pathologists while allowing patients to receive faster diagnosis with more accuracy. Even the labs' workflow systems are now managed through software for better efficiency and error-free work. The blood test results have more chances of accuracy with less involvement of human interaction for most of the test. This automatically changes the status quo with wide acceptance by all type of customers from various cities across India."

#### **An array of new technologies ushering growth of digital pathlabs**

A digital pathology enables cellular, molecular, and genetic-imaging at high efficiency and accuracy to facilitate clinical screening and diagnosis. Dr Iyengar spells out, "Digital microscopy involves converting a glass slide that contains either a tissue section or a smear from blood or other body fluids, into a digital file that can be studied as a virtual file in a manner like what we do when we see the slide under a microscope. Various fields can be examined with zoom-in and zoom-out of areas of interest which can then be annotated and captured as still images if needed. The processes followed for preparing stained slides remains unchanged. The difference is that the stained slide is digitised and the digital file is viewed by the pathologist on their computer monitors instead of the microscope before making the final diagnosis and report."

Explaining further, Subramanyam adds, "They effectively replicate the way a pathologist would manually

# COVER STORY

score a slide. An objectively quantified analysis result of the entire slide is instantly available after a pathologist selects the entire tumour area they want to analyse. This allows the pathologist to more quickly and effectively diagnose marginal, difficult, or hard to read cases. WSA algorithms allow pathologists to work as they would under a glass microscope while providing fast and accurate results that are validated for clinical use. The new digital solutions are also supported with enterprise software's that enhance the efficiency of pathology laboratory workflow with connectivity and automation. They provide a universal platform that seamlessly enables communication between pathologists and technicians via usability, innovation, and digitisation."

Hence, the use of digital technologies could help make the field of in-vitro diagnostics more robust, producible, and it could push the field from a purely qualitative function to perform a multi-pronged role of focussing on improving quality and quantity as well as reducing cost facts. Additionally, technologies such as AI, machine learning and automation can support pathlabs in multiple ways.

"The latest technologies like web technology, Internet of Things (IoT), Artificial Intelligence, Machine Learning, predictive analysis have shown an exceptional impact on the way the labs and diagnostic centres are conducting their tests. Internet of Things (IoT) has introduced the temperature check on a blood test sample that is conducted through the software while earlier it was done manually. Web technology has proved beneficial for both the patients and the physicians to connect easily. Artificial Intelligence and machine learning have improved the accuracy rate of the reports, ease of navigation are helping the



**DR SHRAVAN SUBRAMANYAM**  
Managing Director, Roche Diagnostics India



**RAJEEV GAUTAM**  
President – HORIBA Medical

**“WSA algorithms allow pathologists to work under a glass microscope while providing fast and accurate results that are validated for clinical use”**

**“Using the latest automated digital pathology track systems can bring numerous additional benefits to the diagnostic laboratories”**

pathologists to work on imaging. In short, the array of vast technology has driven more centralised information stored in one set of database and image archives as well. This will automatically increase the patient's reliability more on those tech-enabled platforms to opt for their test centres", says Divya.

Dr Iyengar chips in, "Apart from automation of existing processes and testing platforms we have moved into the era of precision medicine. This is achieved with tech-

nologies like immunohistochemistry, cytogenetics, genomics, proteomics and metabolomics. Microarray and film array technology are being used to rapidly diagnose a wide range of life-threatening bacterial, viral and fungal infections giving the critical time advantage for effective treatment without complications. Mass spectrometry is being used for accurate quantification of medications, hormones, vitamins and steroids. These are only a few examples."

## **Digitised workflow – from electronic microscopes to cloud to big data analytics**

Turning microscopic slides into digital files has enabled labs to generate big data analytics and more. It opens several avenues for unlocking medical breakthroughs, solving complex healthcare problems, enhance medical education, and foster clinical research.

Speaking about how the digital workflow connects labs with patients, "The digitised

workflow has now simplified the accessibility for both the diagnostic centres and at the patients' end. With the usage of AI and machine learning, a value-chain is created right from the web portal of online booking to collection of the sample, to transferring of the blood sample to sharing of e-reports. It has given a better scope of recording patient data which can further be utilised for future reference. While accepting the booking online for an appointment, clinical/health information is



**DR RAJESH KEWALRAMANI**

Consultant - Medical Microbiology and STIs/HIV, expresses



**DR AJAY PHADKE**

Centre Head, Dr Avinash Phadke Pathology Labs

“One of the opportunities is to improve turnaround time to results—a challenging goal

“Consolidation of healthcare will be fuelled by more automation, point of care devices and higher accessibility

retrieved from the customers. Besides, it has given liberty to the customers to conduct their blood test and also collect it at their preferred location and time. The medium of sample collection and report generation has also been changed with the coming in of the technology. The reports are being shared on the respective email id of the patients provided at the time of booking”, informs Divya.

Moreover, this also allows having opportunity to have digital archives of patients'

samples rather than having to rely on preserving a slide or frozen section that requires physical space for storage, makes immediate peer consults challenging, and may be subject to degradation, informs experts.

Dr Iyengar shares his experience of utilising the digital pathology. “Our initial experience with use of digital microscopy using WSI began seven years ago, when we applied this technology in a limited manner to share virtual slides to over 50 laboratories

across India as part of a quality assessment programme. The full-fledged utilisation of digital pathology to study and report on biopsies received every day began in November 2014, which was preceded by a series of validation studies. At that time, there were very few pathology centres across the world and none in India to have achieved this. Our pathologists have adapted to the transition from microscope to monitor quite comfortably. Digital technology has also been applied in our lab for routine reporting of

blood smears and urine samples by use of dedicated slide scanners that not only digitise the image but also categorise the subtypes of cells, casts and crystals into different classes based on analytical algorithms. Video image analysis is also employed for the study of semen samples in individuals with infertility. In addition to the above, we utilise digital technology for consultation of difficult cases with experts across the globe, for teaching purposes and to conduct quality control programmes in

histopathology. Our quality assessment programme (Neu-QAP) conducted by Neuberg Anand Academy of Laboratory Medicine has 138 laboratories that are enrolled for the digital histopathology QA programme. Majority of these are accredited labs. Lastly, digital technology is used to archive the whole-slide scanned files for defined period of time. Storage on the digital platform has inherent advantages of ease of retrieval and preservation of the integrity of staining characters.”

To suit the requirements of the pathology sector, some technology companies are developing solutions that span the entire digital pathology IT environment from high-performance compute and high-resolution displays to servers, networking, storage, and software to multi-cloud and big data analytics platforms. “As an e-diagnostic company, we are serving our customers end-to-end, right from online bookings to sample collection to reports through our phlebotomists. One can easily book a test or package by either going to our website or by downloading the app or they can also directly call us at our toll-free helpline number. The customer gets to choose where and when they would like to avail the service. One can also pay online as well while booking or pay at the time of the sample collection either through cash or online. Our trained phlebotomists visit at the preferred time of the customer to collect the sample. The sample is then sent to one of our certified partner labs and later on gets delivered at the preferred location mentioned at the time of booking. For most of the tests the reports are usually available in 12-24 hours depending upon the kind of tests which are also available online”, shares Divya.

#### **AI, deep learning and automation: Making a difference**

Many technology companies

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believe that the true value of digital pathologies is in leveraging the data that is collected from digital images to create actionable insights. In a brief interview with *Express Healthcare*, one of the major diagnostics company had informed about the significance of the big data generated through digital archives. Using AI and deep learning, this data can be thereby converted into valuable insights for drug discoveries and developing therapeutic solutions, the company's spoke's person informed. Besides, AI, deep learning and more bring immense business value to the overall functioning of labs as well. "A combination of expertise in the lab can take this field to the next level. AI brings consistency and reliability to the lab. It ensures that the pathologist can spend quality time on diagnosis", reckons Subramanyam.

From a practitioner's point of view, Dr Iyengar believes that deep learning in histopathology digital platforms enable accurate and consistent quantification of positive signals required for interpretation of immunohistochemistry. They also help in grading tumours such as prostate cancer. "Deep learning is increasingly being used in precision and predictive medicine, based on volumes of data that are used to build such algorithms. Using this technology, one will be able not only to diagnose cancer but also forecast the probable behaviour and even suggest appropriate treatment modalities" he says.

"Laboratories are evolving rapidly with the introduction of AI, as it helped in managing big sets of clinical data. It has enabled the medical practitioners to gather information on individual patients, right from their daily habits to complex, microscopic information such as their genetic code. The AI system is proving to be the most useful tool for pathologists, as they can now use machine learning for incorporating clinical, genomic and



radiologic data of a patient to predict the accuracy in diagnosing a disease. The real value derived by the laboratories through AI and machine learning has yielded the cross-functional integration of patient information in their decision making process in prediction and prognosis with more accurate results than earlier. The pathologist can now invest less amount of time in most of the technology oriented results. It can also be applied to analyse the information collected and predict outcomes with potential remedies" adds Divya.

Speaking about how digital technologies can enhance the functioning of automated labs, Dr Rajeev Gautam President - HORIBA Medical notifies, "A simple procedure of slide review is a time consuming and an error-prone activity in any diagnostic laboratory. When

automated systematically using the latest automated digital pathology track systems, can bring numerous additional benefits to the diagnostic laboratories. These benefits may range from saving the time of the pathologist, enhancing the accuracy of results, making progress in their research projects and training future pathologists on unique and rare findings that laboratory experts find during their routine practice."

While experts examine the future of in-vitro diagnostics backed by digital images and more, they say that if digital imaging methods are powerful enough to analyse individual cells, pathology could become an entirely different branch of medical sciences. There seems to be an immense opportunity for the field to expand further and unlock complex medical puzzles. But some pathologists

continue to worry about their future. Answering to some concerns raised by pathologists on whether digital pathologies could make them redundant, Dr Iyengar replies, "The fear of redundancy that haunts some pathologists is unfound. Most pathologists rely rather heavily on their gut feel while studying a slide and with experience they get good at this. One needs to understand and take advantage of what these new tools can offer in adding objectivity to one's approach. In my view, these tools will serve to reinforce and not to replace the gut feel". As Dr Iyengar pointed out, digital technologies could transform the job of pathologists into a more creative and data-driven profession.

## Need for standardisation in future

Well, the adoption of digital pathology is still at its nascentcy

and the implementation it will indeed come with some challenges. One of the most important concerns expressed by pathologists and clinical experts is standardisation. Processes such acquisition of images, storage and management, image manipulation and editing, image viewing, transmission and sharing will certainly need standardisation. Lack of standardisation can jeopardise the very purpose of building such advanced technologies. Therefore, experts suggest that in future to integrate digital pathology into a clinical setting, rapid and stable scanning must be achieved. An international standard for digital archiving is also required. This includes re-working laboratory protocols and developing new scanning rules to attempt standardisation of digital imaging procedures.

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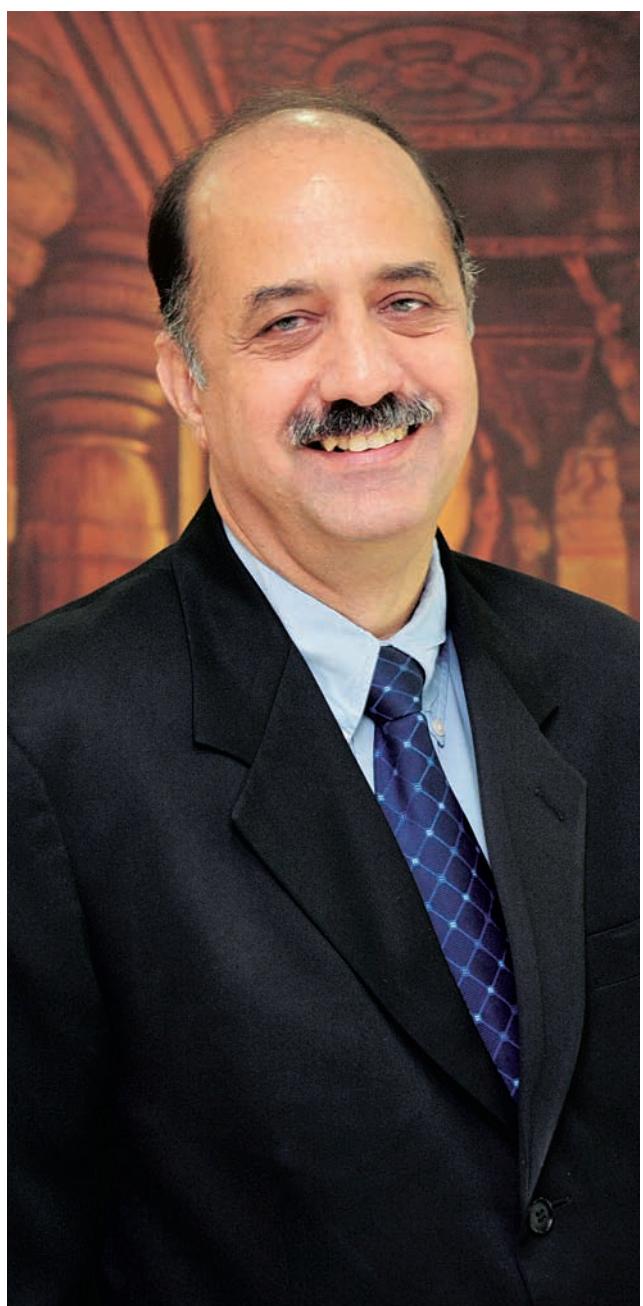


## LEADER'S CORNER

### INTERVIEW

# Transparency with strict enforcement of regulations is a definite need

**Dr Ravi Gaur**, COO, Oncquest Laboratories, talks to **Prathiba Raju** about how the lack of strict regulations has led to many illegal path labs cropping up all over the country and how these labs pose a major challenge to the organised pathology sector



**How is the increasing illegal pathlabs and widening shortage of pathologists in the country a major pain point for diagnostics industry? What steps should be taken to mitigate it?**

Pathology diagnostics plays a major role in health management. There are more of medical laboratories in India than there are certified pathologists to supervise and direct them. This is becoming a source of conflict. On one side are patients who want quality-driven laboratory testing services which they can trust and government regulators who want to enforce the law. On the other side are tens of thousands of illegal pathlabs that continue to operate without certified pathologists and other

trained lab scientists who lack knowledge, skill and adequate qualifications. Such illegal pathlabs are a threat for the diagnostic ecosystem in our country and pose a major challenge to the organised pathology sector. However, these labs, despite being run by under-qualified people, contribute significantly to the growing healthcare sector in India.

The lack of strict regulations has led to many illegal pathlabs cropping up all over the country. The government should work more aggressively to enforce regulations/court orders that dictate who may or may not operate medical laboratories, diagnose test results or issue reports. The lack of enforcement puts patients at increased morbidity and mortality, misdiagnosis,

malpractice and casts suspicion on the entire field of clinical pathology.

**How such labs are being a constraint to major diagnostic centres/chains? Are there any statistics on this?**

These illegal pathlabs run by under-qualified technical staff are prepared to go to any lengths to secure their 'business'. It is degrading for qualified pathologists to compete with technicians, but many consultants accept these reports from these labs. However, when it comes to the consultants' own relatives or friends, they always go to a qualified pathologist even for the simplest of tests. What's good enough for other patients is not so for the doctors' kith and kin. There

**"The lack of strict regulations has led to many illegal path labs cropping up all over the country. The government should work more aggressively to enforce regulations/court orders that dictate who may or may not operate medical laboratories, diagnose test results or issue reports"**

are no such official numbers but a mere fact that there are about 3,000 pathologists registered in Maharashtra, but the state has over 12,000 pathology labs. The numbers speak of the problems itself. There are nearly 1.4 lakh pathlabs, of which 60 per cent are run by under-qualified technicians.

**What are the immediate measures that should be taken to curb this practice? As an industry player, what measures have you taken or would you like to take in this regard?**

New stricter laws, strong enforcement of current regulations, penalties, mandatory registration, accreditation, quality compliance, etc. is the need of the hour. Nearly 70 per cent of clinical decisions are based on pathological findings. It is highly unfortunate that this section of the healthcare

## THE GOVERNMENT SHOULD MAKE IT A POINT TO HAVE DIFFERENTIAL PRICING FOR REGISTERED PATHOLOGY LABS

industry is so undermined, simply due to lack of awareness of the role of pathology. It is necessary for the government to intervene and take immediate measures to ensure patient safety and quality-driven pathology lab reports.

At Oncquest, we ensure that almost all clinically relevant reports are explained by qualified pathologist to patients and if need be, to our

clinicians too. This creates awareness among consumers about the importance of having qualified technical force behind your report, which is essential for one's good health. We do conduct drives and public awareness campaigns besides explaining importance of accreditation and quality control programmes to our consumers and public at large. **What kind of regulatory**

mechanisms need to be in place before and after opening of a pathological or diagnostic lab in Delhi? Registration of pathology labs, along with qualified signatory, should be made mandatory. All labs should participate in external quality assurance scheme which should be available online and displayed prominently. I am sure the establishment of the Clinical Establishments (Registration and Regulation) Act of 2010, though it needs to be revisited on many clauses, will definitely help in cracking down such illegal pathlabs.

**Do you think capping of prices on the essential diagnostic tests will have any impact on the unorganised path labs?** I don't think it would be much of a deterrent to such

illegal labs. Quality-driven reports cost a bit more. The government should make it a point to have differential pricing for registered pathology labs. This would not only help the already strained organised sector, but also create awareness in public about such illegal labs.

**Can digitisation or technology help to curb these unorganised labs?** Definitely! It would be of big help. Digitalisation should occur across all aspects of sample processing. This should include pre-analytical, analytical and post-analytical processes. Not only the sample-related information, but also the lab registration details should be available online. Transparency with strict enforcement of the regulations is a definite need.

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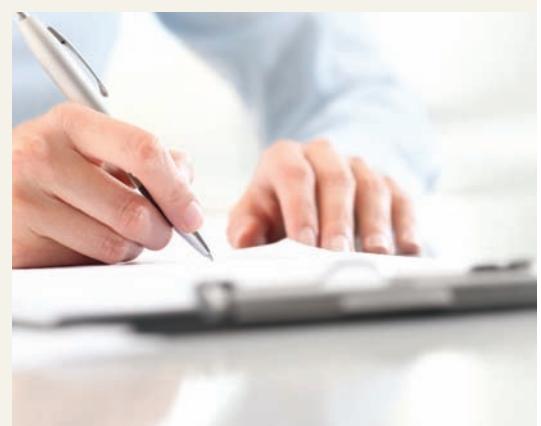
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# ON THE EDGE

## INTERVIEW

# Oesophageal cancer is 7<sup>th</sup> most occurring cancer in men, 13<sup>th</sup> in women

**Dr Richard Turkington**, Senior Clinical Lecturer, Queen's University Belfast in conversation with **Tarannum Rana** discusses the research that the university is conducting on personalised medicine approach, tailoring treatment for cancer and the new oesophageal cancer-detecting test that his team has developed in collaboration with Almac Diagnostic Services

**Worldwide, what is the rate of oesophageal cancer and how is it being managed? Why is it so widespread in the UK?**

Oesophageal cancer is the seventh most commonly occurring cancer in men and the 13<sup>th</sup> most commonly occurring cancer in women. There were over 500,000 new cases in 2018. Oesophageal cancer is classified into two main types: squamous cell carcinoma, which occurs in the upper part of the oesophagus, and adenocarcinoma, which develops at the junction of the oesophagus and stomach. Globally, squamous cell carcinoma is the most common type and accounts for the vast majority of cases; however, the proportion of adenocarcinomas is increasing dramatically in affluent nations. The UK has the highest incidence worldwide of oesophageal adenocarcinoma with 9000 cases per year but the causes of this are unknown.

Increased rates of obesity causing persistent acid reflux are a factor but does not account for all of the increased incidences.

**What is the significance of personalised medicine in oesophageal cancer care and why is there a need for such**



**DR RICHARD TURKINGTON**  
Senior Clinical Lecturer, Queen's University

**a device?**

Tumours which are localised are treated with chemotherapy prior to being removed by an operation. However, at the time of surgical resection, only around 15 per cent of cases demonstrate a profound response to chemotherapy. A

test to predict which tumours would respond to which type of chemotherapy would enable the most effective therapy to be selected for each patient.

**How does this device function?**

The DNA Damage Immune Response (DDIR) assay is a 44

gene expression signature which utilises routine clinical oesophageal cancer biopsies to generate an assay score.

**What are the key indicators/markers of this device that will determine that a specific amount of chemo is to be delivered to a patient?**  
Rather than determining the amount of chemotherapy to be delivered, the assay identifies those tumours with a higher likelihood of responding to DNA damaging chemotherapy. We hope that this will allow these patients to receive this treatment and those patients with a low likelihood of response could be offered alternative chemotherapy.

**What is its accuracy rate?**  
At present, the DDIR assay has trialled on a retrospective cohort of 273 clinical samples and is able to be evaluated on 98 per cent of biopsies.

Further testing is required in other retrospective and clinical trial datasets to assess the sensitivity and specificity of the assay.

**Are there any clinical trials done on this? Can you elaborate on it?**

This research used archival samples but, after further validation, we hope to move forward with prospective

clinical trials.

**Can this technology be utilised in other types of cancer treatments as well?**

Yes, this assay was originally developed in breast cancer and can predict sensitivity to both neo-adjuvant and adjuvant chemotherapy in this cancer type. The presence of a sub-group of patients with a high likelihood of response to DNA-damaging chemotherapy is a common theme across a number of cancer types and this assay has the potential to be applied to a number of cancers.

**Will the test be cost-effective? What will be its cost?**

The test is available commercially for research use from Almac Diagnostics as part of their ClaraT platform and costs are available from the company.

**Are there any other cancer study areas that the institution is currently working on?**

The Centre for Cancer Research and Cell Biology at Queens University Belfast has a broad range of research programmes covering gastrointestinal, prostate, breast, ovarian and blood cancers.

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## INTERVIEW

# SPIT SEQ has recorded with 100 per cent sensitivity and 98.04 per cent specificity

Drug resistant TB is a major cause of concern in India. Many diagnostics companies are researching on the ways and means to identify mycobacterium tuberculosis at an early stage. MedGenome is one such company, investing immensely in this area. They have recently come up with a novel culture-free WGS test.

**Dr VL Ramprasad**, Chief Operating Officer, MedGenome Labs gives more details on the same in an interview with **Raelene Kambli**

### Tell us about the growing drug resistance mutations in tuberculosis bacteria in India?

According to a WHO report, India saw 2.7 million TB cases (incidence + relapse) in 2017. India accounted for 27 per cent of global TB deaths. Globally, 3.5 per cent of new TB cases and 18 per cent of previously treated cases had multi-drug resistant/rifampicin resistant TB (MDR/RR-TB). India is one of the top three countries with the largest number of MDR/RR-TB cases that constitute 47 per cent of global MDR/RR-TB cases.

### What is Direct Whole Genome Sequencing and how does it help in early diagnosis of drug resistant TB?

Direct Whole Genome Sequencing is getting the sequencing of the whole mycobacterial genome from the DNA extracted from clinical samples (sputum).

Typically, the process of analysing the drug resistance is very long which delays treatment for a TB patient. The current expertise allows testing resistance only on four drugs hence the patient had to wait until testing on all



**DR VL RAMPRASAD**  
Chief Operating Officer, MedGenome Labs

possible drug concluded. In such a situation, where long turn-around diagnosis time, repeated testing led to multiple changes in the course of treatment along the way. Direct Whole Genome Sequencing reveals information on drug resistance mutations for all anti TB drugs in a matter of 10 days. Soon, this technology will help in optimising the precise management of a TB patient.

Hence, SPIT SEQ not only brings accurate results but also saves a lot of time where TB treatment is concerned.

### What is the significance of your breakthrough DNA test?

The conventional tests available in the country equip us to identify resistance in a limited fashion. *Mtb* (*Mycobacterium tuberculosis*) is slow-growing, taking 6-8 weeks for

culture growth, thereby delaying not only TB diagnosis but also the drug resistance testing. SPIT SEQ is a culture-free WGS (whole genome sequencing) method for identification of *Mtb* and prediction of drug resistance with a turnaround time of 10 working days. WGS helps to resolve the so called non-interpretable (NI) results that occur when a locus of interest has neither the wild type nor the specific mutation of interest present the currently available LPA test. In addition to these loci that are covered in the LPA test, Information regarding the other first line drugs like Pyrazinamide and Ethambutol can also be extracted from the WGS data.

### How does this test function?

Whole genome sequencing of *Mycobacterium Tuberculosis* (*Mtb*) directly reveals mutations in the bacterial genome that provides crucial information on drug resistance mechanisms. The test is performed directly on sputum sample which eliminates a time-consuming step of growing culture. The bacterial DNA is isolated from sputum sample and

sequenced with tiling probes (specific for *Mtb*) detecting mutations in the whole genome of *mycobacterium tuberculosis*.

### What kind of impact would this test have in controlling TB?

SPIT SEQ not only brings accurate results but also saves a lot of time where TB treatment is concerned. In lines with India's objective to counter TB effectively and quickly, this test aims to benefit the last person living with TB today. Over and above the advantages at individual level, SPIT SEQ can also be used for strain typing, epidemiology studies and disease surveillance due to its voluminous data availability.

### Has this test been validated?

SPIT SEQ has been validated with over 100 samples where it recorded with 100 per cent sensitivity and 98.04 per cent specificity when compared with Line Probe Assay (LPA). 50 out of those samples were in association with P D Hinduja Hospital and Medical Research Centre, Mumbai. A manuscript is under review for publication.

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# The prudent entrepreneur

Leading two genomics companies one after the other, **Anu Acharya**, CEO, Mapmygenome, has been able to become a successful women entrepreneur. She opens up on her life, entrepreneurial journey and the learning experiences. By **Sanjiv Das**

**B**eing an entrepreneur, Anu Acharya has always had it her way. She is revered for not one but building two companies over the years, the first being the co-founder of Ocum Biosolution, where she led as the CEO from 2000-2013 and later becoming the CEO of Mapmygenome, a molecular diagnostics company. Alumni of IIT Kharagpur, Acharya completed her two post-graduate degrees in Physics and Management Information Systems (MIS) from and University of Illinois. Several accolades during her robust career motivated her to rise to newer heights.

Despite travelling extensively, learning the importance of work-life balance helped her to reach newer heights, thus helping her to prioritise the goals, scope for improvement and even schedule.

## Care-giving

There are different layers and perspectives to care-giving. While many people associate it with caring for an invalid family member, Acharya believes it is so much more.

Says Acharya, "Let us start with self, the most neglected entity in many people's lives. It is about knowing ourselves better, for me it starts at the molecular level, what does my DNA say about me, my quirks that make me what I am, my habits, and my health. With this knowledge, I can define what I want from life, my goals, the scope for improvement, even my schedule. The last step is applying mindfulness and productivity principles to achieve day-to-day and



long-term goals."

Family is a key part of care-giving and is not limited to the old and the invalid. According to her, caregiving is compassion and empathy we share for our family. Sometimes it may involve just listening.

She believes, "As an entrepreneur, I believe that the term extends to my team. It means policies and practices to build a strong and productive team and strong communication channels. For a preventive healthcare expert, it means finding answers that will help save lives. From a rapidly ageing population to newborns, we are building solutions that would work for the people of India."

## Work-life balance

Family and friends are important for Acharya and so is fitness. Experimenting with food is fun for her and reading is essential for the mind. As an entrepreneur and heading not one but two companies, she has learned the importance of work-life balance. She believes, that there are some tasks that one can do and some that may be delegated. Though travelling for work is a key part of her schedule, she ensures that there are precious moments spent with family.

A fitness enthusiast, she believes fitness is all about the journey and it certainly adds life. While keeping in mind about the fitness quotient, Acharya ensures that there is time for fitness activities. She says, "Oh! And I sleep very little."

Elaborating more on fitness, Acharya says, "Fitness is a key part of our healthcare portfolio. The genetics of nutrition and fitness are of special interest to me and my entire team."

## Learning other forms of art

Acharya stresses on today's mindfulness-based activities which encourage art forms like collage and art journaling. Tea ceremonies are one interesting art form, according to her. Passionate about teas, her journey has helped to build a huge collection of age-old and exotic blends of spices and infusions.

Says Acharya, "Learning in children happens through music, theatre and dance. These art forms can help adults too. A new sport can be an excellent way to challenge yourself while learning something new."

She is fond of writing poems. My book of poems, *Atomic Pohe*, was published a few years ago.

Acharya opines, "There is nothing like a good cup of tea to clear the mind and to enthuse us with agility and zeal. Many a problem can be solved over a cuppa. Poetry, on the other hand, is about creativity, empathy, and all the positive feelings that we need."



**DESPITE TRAVELLING EXTENSIVELY, LEARNING THE IMPORTANCE OF WORK-LIFE BALANCE HELPED HER TO REACH NEWER HEIGHTS**

## Favourite book and the learnings

An avid reader, Acharya's favourite book is *Against The Gods* by Peter Bernstein, which she says appeals to the scientist, innovator, and entrepreneur in me. Says Acharya, "My father taught me to appreciate books and reading at an early age. I love books and read as many as possible — a love that I have passed on to my daughters. When it comes to books, variety is the spice of life; I

don't confine my reading to a particular category."

## Travel memoirs

Being the CEO of Mapmygenome, the job profile makes her travel extensively all around the world. Travelling is part of an entrepreneur's job description. Acharya travels to participate in events and conferences. However, the best travelling according to her is with family. Visiting a new place, soaking up the culture, treading the paths where so many great people walked, sampling the local cuisines, and of course, the mandatory pictures with the family are all part of the experience. Japan and Goa are the best destinations according to her.

## Gadgets and gizmos

Acharya believes that gadgets and apps are an essential part of lives today. From productivity to music, everything happens through gadgets. Wearable tech is one favourite, especially for fitness.

"When it comes to new wearable tech, I'm an early innovator. I have been using fitness and health trackers for several years. Often, I recommend them to friends and team members. They are a great way to promote fitness and health awareness. I have initiated many fitness challenges within my team and friend's circle, most of them involving step count," admits Acharya. "As important as gadgets are, one should also learn the art of switching off," she says

## Going ahead

Giving top priority to ones health despite hectic schedules is something which Acharya would like to recommend to professionals. "Work and success are important, but so are fitness and family. Your health is your priority – take care of that first," she says.

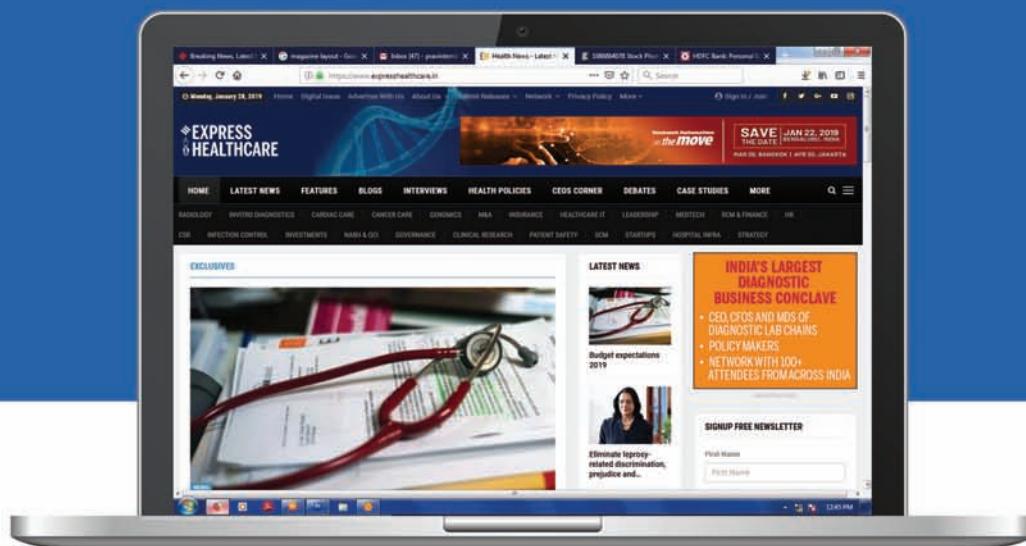
Acharya signs off and says that there are days when 24 hours are not enough, but it is important to pace yourself and to organise things for optimum productivity.

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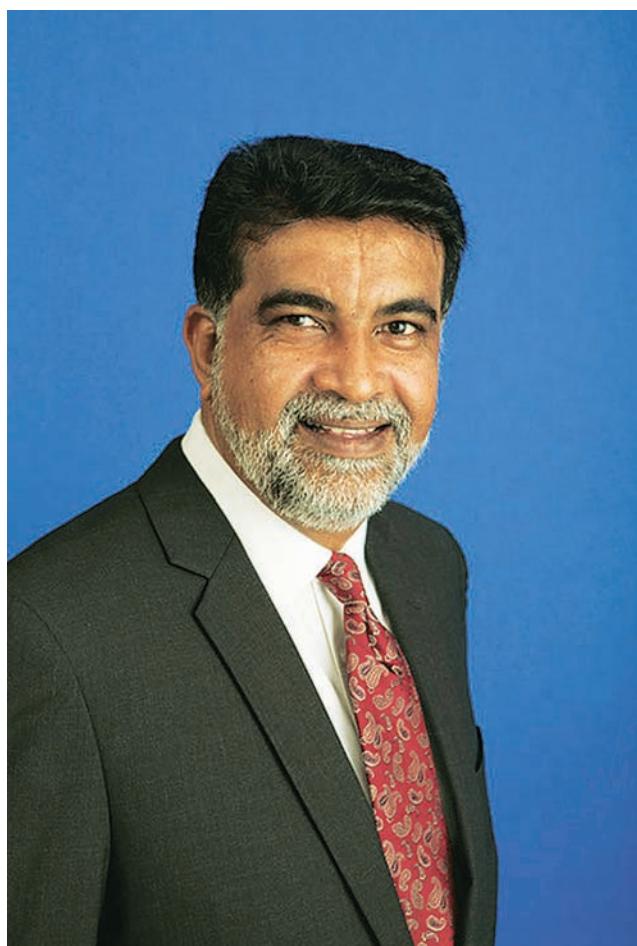


# ARCHITECT hsTnI assay: Enhancing risk stratification for CVDs

The company's CMEs cover every vital technical aspect for haematology range of products used by Indian diagnostic medical laboratories

**C**ardiovascular disease has been projected as the leading cause of death globally and it would account for more than 23 million deaths per year by 2030 (WHO atlas, 2017). In India, mortality due to cardiovascular diseases showed to have a 13 per cent increase from 1990 until 2016 (Prabhakaran et al., 2018). It is important that we should be considering reducing this incidence by primary prevention.

The recently CE approved claim of ARCHITECT hsTnI assay for risk stratification in apparently healthy adults for developing future cardiovascular diseases would be paramount. Several risk assessment tools are available for cardiovascular risk assessment. Tools like Framingham risk score (Wilson et al., 1998), American College of Cardiology/American Heart Association (ACC/AHA) risk calculator (Goff et al., 2013), SCORE (Systematic Coronary Risk Evaluation) risk charts (Conroy et al., 2003), QRISK2 (Hippisley-cox et al. 2011), the Joint British Societies' (JBS3), (JBS3 Board 2014) have been currently used. These tools calculate risk based on risk factors for CVD such as age, blood pressure, smoking status, lipid profile to estimate the 10-year risk of a CVD event. These tools present many limitations as these depend on factors that are not cardiac specific and give us a general correlation about CVD risk. These tools are heavily dependent on age as a determinant of CV risk



**DR JAGANATHAN SICKAN**

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thereby underestimating CV risk in young individuals, despite the presence of multiple other risk factors. This is particularly relevant for Indians due to the higher risk of CAD in the younger population as compared to other populations (Dalal et al., 2016).

In addition, there is no sin-

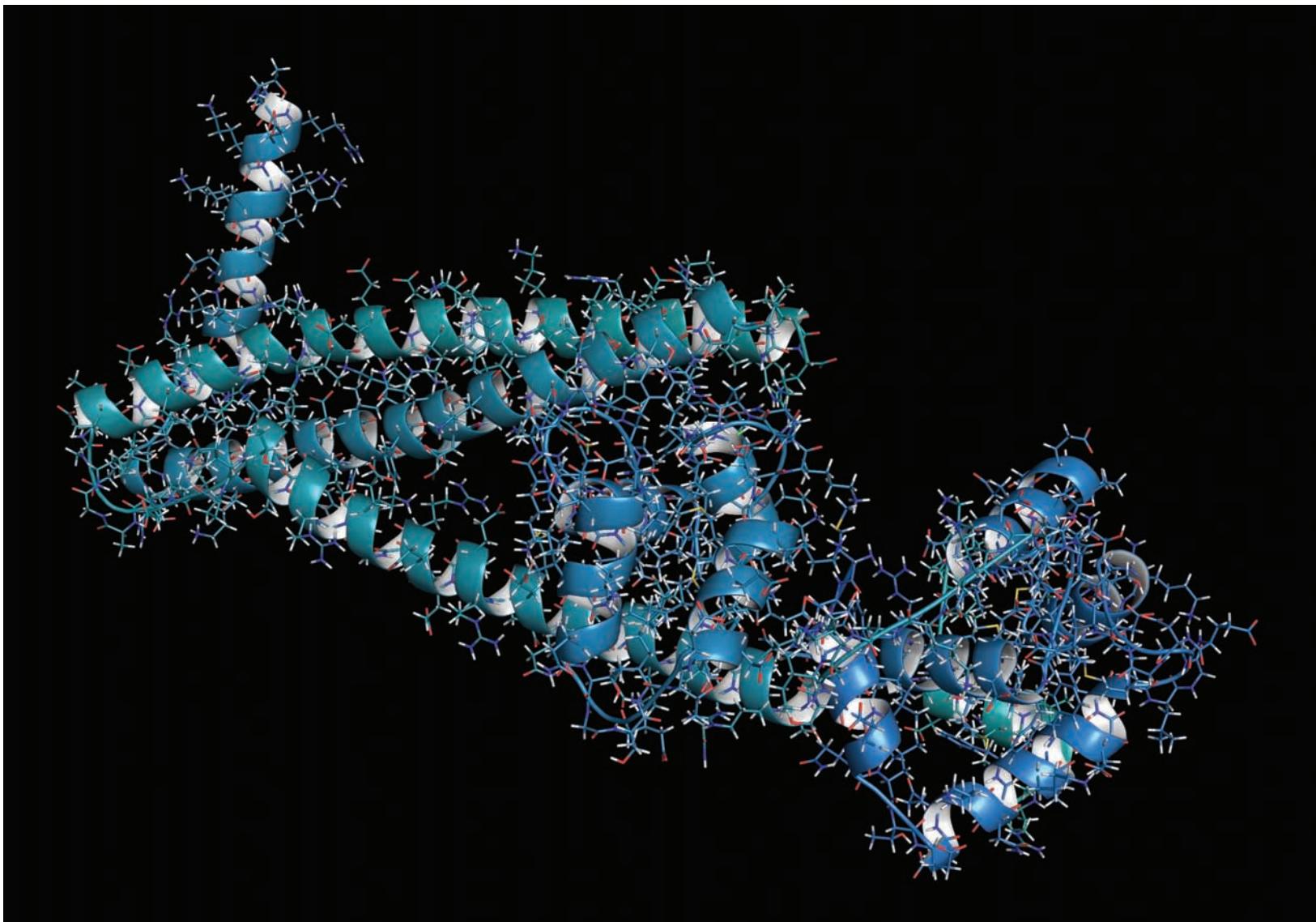
gle tool that works for all populations, as they are derived from epidemiological data that are applicable for a population. The Framingham score has been reported to overestimate the risk in some low-risk populations [D Agostino et al., 2003] with an overestimation of the mortal-

ity in CHD in European populations [Brindle et al., 2003]. An Indian study demonstrated that in comparison with the Framingham score and ACC/AHA risk calculator, the JBS3 risk calculator detected the largest proportion of the Indian patients at 'high-risk' [ Bansal et al., 2014] while QRISK2 was demonstrated to perform better with the UK population (Hippisley-cox et al. 2011). Also, an overall improvement in the traditional risk factors did not lead to improvement CV outcomes at the population level (Jorgensen et al., 2014). Thus, there is scope for improvement in the current methods of risk stratification for cardiovascular diseases.

The high analytical sensitivity and cardiac specificity offered by ARCHITECT hsTnI assay makes it an ideal candidate marker for use in risk stratification of healthy individuals. In a population-based cohort study named the Nord-Trøndelag Health (HUNT) Study, hsTnI was strongly associated with increased risk of cardiovascular death [adjusted hazard ratio (HR) 1.23 (95 percent CI 1.15–1.31)]. The strong association of elevated ARCHITECT hsTnI levels to increased global CVD incidence in the general population independent of traditional risk factors wherein hsTnI provided complementary information thus allowing improved risk prediction. In a community-based cohort evaluation of risk factors-BNP, CRP and hsTnI, only hsTnI were associated with incident AF (Reinstra et al., 2015). hsTnI is also reported to be better suited for cardiovascular risk assessment for general population as compared to hsCRP (Sigurdardottir et al., 2018). Moreover, the addition of hsTnI to the pooled cohort equation model improved risk assessment for heart failure, atherosclerotic

enberg et al., 2016). In line with these reports, the JUPITER trial reinstates that incidence of cardiovascular mortality and non-fatal MI was elevated for the individuals in the high-risk category of hsTnI as compared to the low risk category (HR 2.61 (95 percent CI, 1.81–3.78) (Everett et al., 2015). In fact, elevated hsTnI were associated with increased incidence of obstructive coronary disease as per the PROMISE trial (Januzzi et al., 2018). The hsTnI cut off which showed a strong association in cardiovascular risk assessment and better outcomes in various studies.

The evaluation of hsTnI in comparison to existing risk stratification algorithms and biomarkers also show promising results wherein there is improvement in the prognostic accuracy. Elevated hsTnI is strongly associated with increased global CVD incidence in the general population independent of traditional risk factors wherein hsTnI provided complementary information thus allowing improved risk prediction. In a community-based cohort evaluation of risk factors-BNP, CRP and hsTnI, only hsTnI were associated with incident AF (Reinstra et al., 2015). hsTnI is also reported to be better suited for cardiovascular risk assessment for general population as compared to hsCRP (Sigurdardottir et al., 2018). Moreover, the addition of hsTnI to the pooled cohort equation model improved risk assessment for heart failure, atherosclerotic



CVD, and global CVD (Jia et al., 2019). hsTnI assay has been reported to detect more at-risk patients and improve current risk-stratification algorithms (Velez Martinez et al., 2013). hsTnI has also been shown to be a robust predictor in diabetic patients without CAD wherein increased levels of hsTnI was strongly associated with increased risk of MACE, heart failure and cardiovascular mortality in diabetic patients (Yiu et al., 2014). hsTnI is also reported to differentiate between no plaques, non-calcified and calcified coronary plaques (Rusnak et al., 2017) and it is also holds potential in being able to discriminate between different Agatston

## IN INDIA, MORTALITY DUE TO CARDIOVASCULAR DISEASES SHOWED TO HAVE A 13 PER CENT INCREASE FROM 1990 UNTIL 2016

scores (Rusnak et al., 2017).

The circulating levels of troponin I, measured with high-sensitivity immunoassays, in healthy individuals may be considered as a reli-

able estimate of the physiological turnover of human myocardial tissue (Giannoni et al., 2009). Additionally, hs-TnI may identify at-risk individual candidates who require more

intensive primary prevention and it could allow early disease-modifying treatment (Ford et al., 2016). Also, hsTnI assay being a simple blood test would be cost-effective on a hospital level compared to other cardiac evaluations like echocardiography, CT angiography etc. thereby providing benefits of lower exposure to radiations and overall reduced cost to patient.

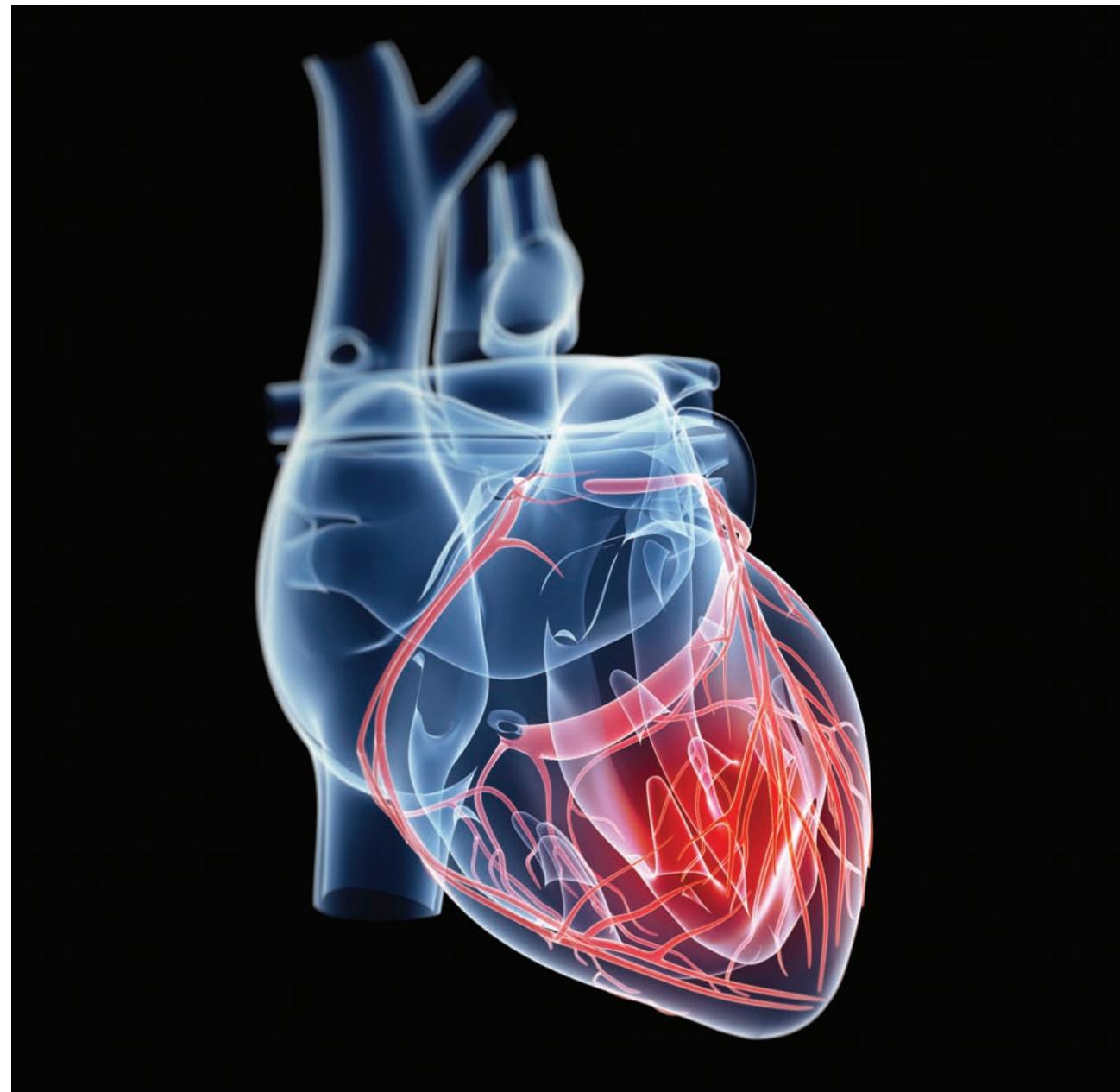
Several studies suggest hsTnI to aid in better selection of patients for further evaluations as compared to current risk stratification practices. The HUNT study showed 34 per cent improvement in net reclassification index over Framingham and re-

ported hsTnI to have better prognostic accuracy in risk stratification as compared to hsCRP (Sigurdardottir et al., 2018). The COMPASS trial demonstrates hsTnI improves the selection of patients for further investigation and treatment (Adamson et al., 2018). This may thus reduce the need for more unwanted costly imaging investigations in low risk individuals. The addition of coronary artery calcium score to hsTnI also improves the identification of low-risk subjects in whom CT-angiography might be avoided (Korley et al., 2015).

Serial troponin measurements have potential to assess cardiovascular risk and

monitor the impact of therapeutic interventions. The WOSCOPS study puts forth the utility of hsTnI in guiding therapy and monitoring disease too (Ford et al 2016). Regular and timely evaluation of hsTnI may have a role in prevention strategies either by intensifying therapy in patients at high risk of CV events or by developing novel therapeutic strategies. It may identify patients who need more evaluation to prevent worse outcomes and also reduce unwanted evaluation in low risk individuals (Adamson et al., 2018). Recently, it was shown that the relative and absolute increases in hsTnI are independent predictors of cardiovascular risk and the most recent hsTnI values should be used in clinical practice (Lyngbakken et al., 2019). Additionally, hsTnI may identify at-risk individual candidates for more intensive primary prevention long before the development of overt events (Ford et al., 2016). The addition of hsTnI to the traditional risk factor may aid in developing personalised therapeutic strategies. For instance, a diabetic individual with low hsTnI and one with elevated levels of hsTnI would be managed differently depending on the level of myocardial injury due to metabolic derangement.

Serial measurement of cardiac troponins using high sensitivity assays for monitoring the effect of life-style intervention appears promising. Presence of elevated troponin along with co-morbidities requires intervention and follow-up after six months and then once in a year. Medication and lifestyle modification should be encouraged. However, based on hsTnI and other clinical and diagnostic findings, moderate and high risk may be directed for further cardiac evaluation like CT coronary calcium or CT angiography as required. Furthermore, statin therapy has been found to be effective in reducing troponin concentration, which was associated



with reduced risk for CHD (Ford et al 2016). These group of individuals may undergo hsTnI assessment every six months. In addition, the serial hsTnI evaluation would provide hsTnI baseline value which could be monitored to identify the cardiac status. Another study showed that a significant and prolonged (>24 hours) troponin elevation after endurance exercise is associated with obstructive CAD (Skadberg et al., 2013). This rise and fall pattern of hsTnI could be harnessed by

evaluating the decline in hsTnI post 72h of exercise induced stress test. This may add to the prognostic utility of stress testing in high risk individuals.

In conclusion, the cardiac specificity, cost effectiveness of this non-invasive blood-based biomarker makes it suitable candidate for screening in apparently healthy individuals as compared to existing tests like CT coronary calcium, CT angiography. hsTnI sampling at multiple time points may have the po-

tential to refine biomarker-based risk estimation (Hughes et al., 2017; Lyngbakken et al., 2019). Mortality due to CV diseases is continuing to rise. The contribution of CVDs to mortality and disease burden in India has almost doubled since 1990.

The leading individual cause of disease burden in India was ischaemic heart disease in 2016. Measures are to be thus taken to prevent and control disease burden through early screening. Current tools e.g. SCORE, Fram-

ingham have limitations to their use: inaccurate categorisation, not cardiac-specific. Abbott ARCHITECT high sensitive troponin-I more accurately predicts the risk for a future cardiac event which would thereby help in reduction of the cardiovascular disease burden. It is now time to translate these observations into practice and to demonstrate whether the use of cardiac troponin to guide non-invasive testing can improve care in patients without myocardial infarction.

## Erba Group introduces NEXUS

The NEXUS range employs advanced technology including AI-based blood cell image analysis, advanced CLIA magnetic beads, thick film ISE analysis, an intuitive sample transport system to deliver affordable modular automation

**E**rba Mannheim, an In-vitro Diagnostic Company and a part of the global Transasia-Erba group, recently participated in the 71st Annual Scientific Meeting of AACC (American Association of Clinical Chemistry). In addition to showcasing their latest, high quality, affordable IVD solutions in haematology, clinical chemistry, urinalysis and immunoassay, the Erba Group also introduced NEXUS, its advanced automation range.

Aimed at delivering mid-scale, advanced automation across immunology, clinical chemistry and haematology, the Erba NEXUS range employs advanced technology including AI-based blood cell image analysis, advanced CLIA magnetic beads, thick film ISE analysis and an intuitive sample transport system to deliver affordable modular automation.

"Mid-sized labs need to streamline workflow, optimise space usage and accelerate turn-around time (TAT) with high result quality to keep their operations viable. But the challenge that they face, is that they are either too small for big automated systems, or too big to keep adding stand-alone auto-samplers. We developed the NEXUS range to fill this gap, giving mid-scale labs access to advanced modular automation. It offers technology specifically designed to improve workflow with high analytical test quality at an affordable price," said Alastair McLeod, Vice President Global Marketing, Erba Group.

Nikhil Vazirani, Managing Director, Erba Group further added, "NEXUS is an exciting development based on years of close customer feedback. Our vision is to make total lab au-



tomation more common in emerging markets and allow the average mid-sized lab to offer higher quality diagnostics to

millions of underserved patients."

Besides unveiling NEXUS, the Erba Group showcased

new Erba LIMS software with mobile app providing high function device interfacing and remote online approval of patient reports, eliminating need for expensive LIS systems.

Along with new products, the existing suite of Erba solutions was also featured, including the LAURA XL, fully automatic urine analyser and the H560 and ELITE 580, fully automatic haematology analysers.

The product display was supported by four on-booth insightful sessions by Erba's team of product experts. Varied topics on AI enabling urine analysers to achieve efficiency of sample processing, choosing the appropriate lab method for ovarian reserve test, assessing the performance of biomarkers for clinical chemistry analysers and affordability of LIMS software apps to add flexibility,

**ERBA ALSO INTRODUCED  
NEW ERBA LIMS SOFTWARE  
WITH MOBILE APP  
PROVIDING HIGH FUNCTION  
DEVICE INTERFACE**

some other products such as, XL 200 and XL 640, clinical chemistry analysers now upgraded to include a touch screen with improved software for easier operation, longer walk-away time and faster TAT. Elan 30s, a fully automated compact benchtop ELISA microstrip processor was also showcased. Elan 30s can perform six different tests simultaneously.

Not just the analysers, the Erba Group also introduced the

quality and speed to data management were covered.

AACC welcomed more than 20,000 medical professionals and healthcare leaders to the 71st Annual Conference held between August 4-8, 2019 at California. The meeting featured pioneering advances in medical testing to help patients get the right diagnoses. The clinical lab expo also featured 835 exhibitors, the highest in the history of AACC!



# HORIBA Medical gets award for conducting best CMEs

The company's CMEs cover every vital technical aspect for haematology range of products used by Indian diagnostic medical laboratories



HORIBA Medical has been recognised as the only brand that systematically organises excellent CMEs. The company recently received the award from Union Minister of Health and Family Welfare Ashwini Kumar Choubey. The company's CMEs cover every vital technical aspect for haematology range of products used by Indian diagnostic medical laboratories.

The selection was made on the basis of HORIBA's uniquely designed initiatives in conduct-

**THE SELECTION WAS MADE ON THE BASIS OF HORIBA'S UNIQUELY DESIGNED INITIATIVES IN CONDUCTING CMES, WORKSHOPS AND TECHNICAL TRAINING PROGRAMMES**

ing CMEs, workshops and technical training programmes, which are well recognised throughout country among pathologists and laboratory experts. Some of the flagship initiatives include Hematology Analyzer Based Xchanges (HABX), HORIBA interpretation Training (HIT), Horiba Operational Training (HOT) and various workshops, which the company organises in collaboration with government institutes, medical colleges and reputed hospitals and

laboratory chains across the country.

In addition to this, HORIBA Medical has its International Technical Training Centre, located at New Delhi, where they have state-of-the-art simulated laboratory set-up. Along with the help of internationally certified trainers from France, the US and Japan, their centre trains hematologists, pathologists and technical experts of hematology range of instruments from across the globe throughout the year.

# HORIBA launches HELO

Say 'HELLO' to 'HELO': HELO is flagship high-end automation technology, complete project that can handle entire haematology work-flow for almost any size of laboratory

Following the phenomenal success of haematology and biochemistry for last 30+ years in global IVD Industry, the next generation haematology automated track system was launched by HORIBA Medical India in Hyderabad and got an overwhelming response as the event was value added with invaluable scientific content, presentations, case studies, discussions and a much grander pomp and show.

Aimed at revisiting the fascinating world of virtual microscopy and looking beyond just numbers in the CBC, HELO System is a flagship high-end automation technology that treats haematology not just as a small section of laboratory but a complete project that can be handled entire haematology work-flow for almost any size of laboratory existing in India.

Over 250 delegates across India participated in this launch event. Delegates from the UK and the US also participated along with renowned pathologist Dr Sanjay Arora, Director, Suburban Laboratories, who shared his technical insights and sessions on haematology analysers and appreciated HORIBA Technology at the event. HELO solution is a globally well-established laboratory solution that has been installed at 150 prime locations across eight countries.

HORIBA Medical is actively looking for partnerships with big hospitals and laboratory chains to support them through this renowned HELO solution.





HORIBA Evolutive Laboratory Organisation



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