

Deliberating the future of diagnostics in india



The onset of varied health challenges were magnified manifold with the global pandemic. The world is still reeling under the after effects of this deadly virus coupled by significant other daunting health challenges. Preparing for the future opportunities thrive for inventors, entrepreneurs, researchers and industry to come together to co-create an advanced diagnostic sector & new healthcare technologies. Embracing open innovation mindset can amplify the reach of healthcare professionals to benefit an extensive population.

Taking this mandate forward, over 43 speakers shared their outlook, thoughts and insights during 8 invigorating sessions and through industry & scientific presentations at the third edition of the Elets Diagnostics Leadership Summit.

The two-day summit saw discussions revolve around 'Need for Accreditation for ensuring quality testing and outcome'; 'CBC+ESR for chronic disease patient care - changing cost dynamic and Turn Around Time'; 'New Age Diagnostics for Infectious Diseases: Novel testing platforms, technologies and solutions'; 'Role, Scope and Opportunities in Lab Automation Market for enhancing diagnostics operations management'; 'Digitization and IoT for accelerating the pace of Innovation in Diagnostics'; 'Need for concrete framework in Co-creation of a Futuristic Diagnostic Sector'; 'Antimicrobial Resistance (AMR) - Use of novel technologies' and 'Focus on Accreditation and quality for Enhanced Diagnostics'.

The need for accreditation was synonymously echoed by panellists all across the two days

Embracing open innovation mindset can amplify the reach of healthcare professionals to benefit an extensive population.

of the discussions. Along with this, changing technological trends also garnered much attention. Dr Smita Hiras Sudke, Lab Director - Global Reference Lab & Zonal Technical Chief - Telangana, Apollo Diagnostics stated that everyone is seeking reports at a faster pace and automation is really helpful to enable that. Dr Sanjay Arora, MD and Founder, Suburban Diagnostics shared that CBC is the most common test and has now become all encompassing. He added that a lot more automation is being done in ESR testing.



The session on **'Role, Scope and Opportunities in Lab Automation Market for enhancing diagnostics operations management'** was moderated by **Indranil Roy Choudhury**, Chief Operating Officer, Apex Kidney Care Pvt Ltd. He shared that automation in the healthcare industry, especially in diagnosis, is reducing errors, enhancing efficiency and improving operations. He further added that as we move towards automation and a more technology-driven diagnostic industry, the government needs to look at reducing import duties on diagnostic equipment and technology.



Sukrut Jobanputra, CEO & Executive Director Labassure stated that without automation, we

Digitisation has enabled forming strategies and guidelines for integrating all the stakeholders in the diagnostic sector and its operations.

couldn't have survived the COVID scenario. He averred that at times it is felt that automation compromises your flexibility to handle variability & in terms of quality as well we need to balance the automation vs non-automated procedures. He added we need to realize that just with automation we're not assured to be more effective, efficient and better.



Dr Sarjana Dutt, Director- Molecular Biology and Cytogenetics, PathKind Diagnostics (P) Ltd said that Automation is not only at the instrument level but at the software level as well. She further averred that automation would certainly bring down the TAT, it will increase efficiency, reduce the error rate. However, only if we decide, automating which part of work planning would bring more benefit.

Dr Geeta Chopra, Chief of Labs & Technical Operations, North SBU,



Metropolis Healthcare Limited stated that there are three phases - pre-analytical, analytical and post-analytical and the pre-analytical phase takes up 60 per cent of the TAT. One can encourage use of online registrations, barcoding, etc. to reduce the time and logistics also need to be improved.



Dr Leena Appicatlaa, Head of Labs, HCG Hospitals (Pan India) shared that labs can opt for a cloud-based system/software which not only resolves problems of data storage but also helps reduce costs. On the question of whether automation take away jobs, she responded with a no but added that automation creates a new type of job and we need to be updated and upgraded for those opportunities.



Dr Shelly Mahajan, Lab Director & ClinicalLead - Genomics, CARINGdx Lab Director & Pathologist, Mahajan Diagnostics, Mahajan Imaging said that we are already advanced when it comes to automation in labs and I think there is a scope for more. She averred that we are practicing in a world with an ever-evolving need of delivering the best. I think we're moving in the right direction. And automation does not mean an alternative to the workforce but to make their jobs easy.

The session on '**Digitization and IoT for accelerating the pace of Innovation in Diagnostics**' had an all women empowered panel deliberating on how digitization is changing the diagnostic landscape.



Dr Jatinder Bhatia, Director, 360 Diagnostic & Health Services Pvt Ltd shared that in the past 2 years, digitisation has been adopted in the healthcare industry in a big way. It has also been instrumental in reducing the cost of tests and a test that was done at Rs 1000 earlier is possible at a cost of Rs 100 today.



Dr Barnali Das, Consultant Laboratory Medicine, Kokilaben Dhirubhai Ambani Hospital Executive Member, IFCC Scientific Division & Chair, AACC India Section, CAP Inspector & NABL Assessor stated that Digitisation has enabled forming strategies and guidelines for integrating all the stakeholders in the diagnostic sector and its operations. She added that digitisation has not only reduced human errors, streamlined lab processes and management, but has also helped in generating more revenues.

Dr (Prof) Group Captain Renu Madan (Retd), Head of the Department Pathology and Lab Medicine, Venkateshwar Hospital averred that We can bring our lab & testing at our fingertips with the help of technology. She also shared that when we have big data we also have a big responsibility to safeguard it and how IoT is going to



be the future of the world. Not just for the healthcare industry but for other industries as well.

Dr Sunita Kapoor, Director & Laboratory Head, City X Ray & Scan Clinic Pvt. Ltd. spoke on how inventory management and financial management have been optimized in a big way after the digitisation of processes and the adoption of lab information management systems.





Dr Anjali Bhutani, Director & Head - Department of Lab Medicine, Max Super Speciality Hospital - Mohali stated that digitisation and automation have increased the productivity and efficiency of the lab. It has also reduced the costs. We can handle each and every aspect of the lab operations effectively and in a hassle-free manner because of digitisation.



The session on '**Focus on Accreditation and quality for Enhanced Diagnostics**' was moderated by **Dr Ravi Gaur** Principal Advisor Spice Health (Spice Jet Promoters Venture) Founder Dr G Path Labs, Co Chair CII Delhi Chapter Health Committee who shared that Tech-driven concepts like QR code,

accreditation are an important part of the healthcare sector today.



Dr Simi Bhatia, Director Operations of SRL Reference Laboratory & Technical Director for Network and Fortis Labs averred that accreditation helps in building quality and safety, and it also helps in promoting staff skill development. It is meant for every process and holds criticality in terms of efficiency and quality.



Dr Neha Rathor, Consultant Microbiologist, Sr. Quality Manager, Chairman HICC, QRG Medicare stated that enhanced diagnostics has been there for 15 years now. But with the advent of BAR codes, enormous amount of efficiency is achieved.



Dr Puneet Nigam, Senior Vice President Medical Services & Quality and Chief of Laboratory Services, Metropolis Healthcare Limited, North India called for making accreditation user friendly. He commended the efforts of the country in delivering in adherence to accreditation, especially during Covid with a higher number of labs coming up and multiple numbers of diagnoses done.



Dr Sunita Deshmukh, HOD Lab Sciences & Blood Bank, Paras Hospitals stated that Accreditation involves a lot of documentation. So, unless you are in practice of keeping the records, you cannot clear the audit. ☺

“Collaborations between various stakeholders will form the backbone of a futuristic diagnostic sector”

(Honorary) Brig Dr Arvind Lal, Executive Chairman, Dr. Lal PathLabs Ltd in his keynote address at the third edition of **Elets Diagnostics Leadership Summit** shared how the pandemic has forced to envision and co-create more resilient Health Systems. Edited Excerpts:

The world has been battling against the COVID-19 pandemic for almost two years now. The impact of COVID-19 has been devastating for the world, pushing back our efforts in public health and economic growth by at least a decade. But at the same time, it has also forced us to envision and co-create more resilient Health Systems for the world's growing diverse health needs. For e.g. in India, while our agenda to control common infectious diseases is still unfinished, now the disease burden has actually shifted and 65% of all mortalities in India are accounted by Non-Communicable Diseases (NCDs), or what we popularly call- Lifestyle Diseases. These 65% deaths can be averted or significantly reduced with early diagnosis.

Diagnostics emerged as the backbone in our strategy to control and manage Covid-19, which relied on Testing, Tracking, Treatment or isolation, and Vaccination. The diagnostics sector has gained more prominence due to its crucial role in preparing for any new Covid-19 variants that as you all know are identified by genome sequencing which is also a sophisticated laboratory investigation. Diagnostics also play a key role in the identification of many other

infectious outbreaks that may include the newer influenza viruses, Japanese E encephalitis, dengue, malaria, chikungunya and many others.

COVID has taught us that in this complex and changing world, it is impossible to succeed alone. Finding better solutions and creating value requires collaboration between different stakeholders and organisations. This was further amply demonstrated by the ICMR asking the private diagnostic labs to start testing for COVID-19. Today, out of the total 3,000 odd labs carrying out RTPCR for COVID-19, more than 60% are private labs.

It takes this opportunity to congratulate Elets on having selected the theme of the Summit as 'Co-creation of a Futuristic Diagnostic Sector' because collaborations between various stakeholders will form the backbone of a Futuristic Diagnostic Sector only.

I envision collaborations in the Diagnostics Sector that will be constituted by 3 As:

- The 1st A stands for Access to essential diagnostics for all
- The 2nd A stands for Accreditation to standardise



(Honorary) Brig Dr Arvind Lal
Executive Chairman
Dr. Lal PathLabs

quality of diagnostics services

- The 3rd A stands for Advancements in technology

First A stands for Access.

This is an area where we must focus on collaborations between the Government and the private stakeholders in Diagnostics sector. In modern evidence-based medicine, 70% of all clinical decisions are taken on the basis of lab reports. However, a vast majority of our population, living beyond tier

2 cities, lack access to essential diagnostic services. We need to invest in diagnostics capacities at the primary healthcare level.

The Government has a vast existing network of public primary health facilities in smaller towns and rural areas of the country. Strengthening diagnostics services at these primary health facilities can significantly improve utilisation of these facilities and patient outcomes. The required framework or roadmap for this has already been laid as:

- In 2019, India became the first country in the world to compile a National Essential Diagnostics List (NEDL), which was an adaptation of the WHO Essential Diagnostics List. The government is committed to provide Essential Diagnostics as per the NEDL at all levels of care.
- Under Ayushman Bharat-Health and Wellness Centres (HWCs) 1.5 lakh HWCs are to be created across the country by 2022. The Government has envisioned to provide Essential Diagnostics as one of the key components for

the success of these HWCs.

- Further, in the Union Budget 2021-22, the Government announced creation of public health labs with expanded range of diagnostic services in 3,382 Blocks across 11 High Focus States and Integrated Public Health Labs to enhance diagnostic capacities in all 730 districts

These announcements highlight that the government recognises that quality diagnostics will play a major role in the provision of Universal Healthcare. The government must continue to partner with the private diagnostics industry players to create and successfully run these diagnostic services, as was done for India's COVID response.

The second A stands for Accreditation

In India we have reportedly about 3 lakh diagnostics labs across the country, as proclaimed by Indian Express. However, the industry is highly fragmented with standalone labs accounting for 47% of the total labs. Less than 1% of these labs are accredited by NABL that is India's

largest lab Accreditation body. The quality of services and care is adversely impacted as half of these labs operate merely as 'Testing Shops', without any concern for quality and accuracy.

When we talk about a Futuristic Diagnostic Sector, we must address this. All medical labs, irrespective of whether they are Government or private labs, should be 100% accredited. But as all of you will agree that it is not possible for NABL to do this. Therefore, the first step towards provision of quality laboratory services has to be proper implementation of the Clinical Establishments Act across the country. This step alone, ladies and Gentlemen, will result in shutting down of more than half of these so called 'testing shops'. But, implementation of CEA requires maturity of political thought and has to be recognised by the lawmakers of all political parties, both at the Central and the State level.

The next step is to strengthen the capacity of NABL and leveraging NABL's leadership in creating possibly smaller accrediting bodies to supplement its efforts. One such effort is the accreditation of labs being undertaken by NABH. The time has come for NABL and NABH to work closely with Healthcare industry bodies, like FICCI, NATHEALTH and CII to further the cause of standardising quality of services provided by all medical labs.

The Government, on its part, should also provide financial and tax incentives to diagnostic labs for investing in accreditation and mandate accreditation for participation in various government programmes, as was done in case of COVID-19 testing. Empanelment



of only accredited healthcare providers for mega health schemes like Ayushman Bharat PMJAY, will promote quality healthcare in India in a big way.

A vast network of accredited diagnostic labs will also ensure collection of accurate and real-time data for disease surveillance, healthcare research and policy planning.

Last but not the least, the third A stands for collaboration for mainstreaming Advancements in technology.

Technology and its adoption are pivotal to providing quality healthcare in a cost-effective manner. Technology is the answer to, how we provide better disease surveillance, better patient engagement and better care delivery. I think technology, and our experiences during this public health crisis will lead our industry to progress more intelligently.

India has also been ushered into a digital revolution, especially in healthcare with the Prime Minister's vision of Ayushman Bharat Digital Health Mission or AB-DHM. The Govt. has formally given recognition to tele-medicine along with releasing detailed telemedicine guidelines, which was seen by everybody during COVID-19. If we had talked about a doctor prescribing 4th and 5th generation of drugs without physically examining the patient, what we call palpation and auscultation, 10 years ago, people would have laughed at us. But, ladies and gentlemen, 90% of COVID patients were managed by doctors by telemedicine.

A similar revolution is long due in the pathology or Tele-pathology-

Technology and its adoption are pivotal to providing quality healthcare in a cost-effective manner.

as the world calls it. Keeping in mind the fact that there are 3 lakh labs and only about 12,000 qualified laboratory specialists in India, we urge the Govt. to formulate and release guidelines for tele-pathology, so that satellite labs can be run remotely but by keeping a strong vigil on day to day quality parameters. Whether we like it or not, this is the writing on the wall and it is high time that tele-pathology was utilised for the benefit of people living in rural India. These remote labs will be operated by qualified DMLTs with the help of qualified phlebotomists. A person like Dr Avinash Phadke or Dr Ravi Gaur would be monitoring all quality parameters sitting 100s of kilometres away and will take the responsibility of giving quality services to such far flung remote areas.

Further, with the escalating demand for personalised care, innovations that target specific subgroups of patients are becoming increasingly relevant. Health systems will need to place a greater focus on shifting from reactive to proactive care and from sick-care to health-care.

The diagnostics sector has already witnessed acceleration in adoption of advanced technologies such Artificial Intelligence (AI), Machine Learning (ML) Analytics, and Robotics. The use of Artificial Intelligence driven clinical decision

support tools to analyze images, detect and grade cancer in biopsies and distinguish other clinically relevant factors, help pathologists reduce error rates and deliver more efficient, metric-driven, objective and accurate reports. Today, they are a complimentary tool for the oncopathologist and are expected to impact critical areas affecting both cost and efficiencies in healthcare diagnostics by reducing diagnostic errors, accelerating access to AI-based second opinions, improving patient care and increasing the body of knowledge in healthcare.

However, there is still immense scope to truly build a futuristic diagnostics sector, leveraging technology. Therefore, for mainstreaming advancements in technology, we need stronger collaborations between the Diagnostics labs, MedTech sector, Academia or research settings as well as innovators.

Collaborations and investments in R&D can help increase research capacity, bridge the gap in technology commercialisation and sustainable deployment of advanced technology in real life settings.

In our response to COVID-19 we have witnessed, the journey from R&D to commercialisation happened faster than ever seen before, whether it was for testing kits, tracking apps, ventilators or vaccine development.

From this important platform, I call upon policy makers, technology providers, academicians and researchers, diagnostics service providers and innovators, to join hands to build a conducive ecosystem for a Futuristic Diagnostics Sector in India. 🇮🇳

Co-creating a futuristic diagnostic sector

N Venkateswaran, CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL) during his address at the third **Elets Diagnostics Leadership Summit** talked of the various initiatives undertaken by NABL to ease the process of accreditation.

Edited excerpts:



N Venkateswaran
CEO, National Accreditation
Board for Testing and
Calibration Laboratories
(NABL)

Resonating with the collective thought, N Venkateswaran, CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL) elaborated on the role of accreditation in the futuristic diagnostic sector. He stated that big labs like Dr Lal Path Lab & SRL can be mentor labs for the small & upcoming labs for the diagnostic sector to evolve in a big way. He mentioned that for supporting industries & labs, NABL is trying to expedite the accreditation process. He talked about the portal where the process of application submission has been simplified, with all the information getting captured in its database and storing it for future reference.

Mr. Venkateswaran also spoke about the self-declaration model NABL is working on and the subsequent visits being carried out to ensure the quality standards of the infrastructure of the labs. "This is to ensure that the confidence in NABL's accreditation remains and also the entire process is expedited," he averred. Dousing concerns about the right quality of labs being established, Mr.

Venkateswaran talked about the unknown assessments being carried out to do a check on the infrastructure committed to NABL. He further mentioned that during the covid, NABL granted accreditation to over 1600 labs for RT PCR tests.

He stated that they get inputs from the market that the quality assessments done and it should give confidence to the customers and satisfaction that NABL has been serving up to the expectations. Another focus area for NABL is training programs because there are a lot of technical training programs needed into this sector by association with a skill development agency.

He further mentioned that the third sector NABL is looking at is point of care testing, medical imaging accreditation and bio banking. He mentioned that they are in touch with big labs for reference material as well and seeking support from all stakeholders to work for the betterment of the diagnostic sector. 🍷

“Digitalisation has been a keyword in the diagnostic industry”

Dr Ravi Gaur, Principal Advisor Spice Health (Spice Jet Promoters Venture) Founder Dr G Path Labs Co Chair CII Delhi Chapter Health Committee in his address at the third edition of Elets Diagnostics Leadership Summit spoke at length how the future belongs to integrated diagnostics. Edited excerpts:

Stating that diagnostics have to be in the centre of healthcare industry, Dr Ravi Gaur shared that post covid, diagnostics have transformed and today we are prepared to not only handle Covid, but also any future healthcare emergencies. “As we enter the era of mainstream medicine, the role of diagnostics will continue to grow. Digitalisation has been a keyword in the diagnostic industry. So technology is being adopted and diagnostics is digitally empowered... The future belongs to integrated diagnostics,” said Dr. Gaur.

He further added that covid has highlighted the importance of diagnostics and it would be a right time now to constitute something like National Directorate for Diagnostics. He shared that digital and digitalization has become critical in the diagnostic sector and the future belongs to integrated diagnostics. He averred that labs have to gear up to deliver low cost preventive tests and genomics-driven or high-end technology-driven tests. “We are definitely in for a change. Many labs have adopted the technology path and the future of healthcare will be built around diagnostics,” stated



Dr. Gaur. He also mentioned how the molecular lab facility getting available in the country acted as an enabler in the detection of covid.

“Covid has accelerated the use of technology”

Dr Avinash Phadke, Founder, SRL Phadke Labs during his inaugural address at the third Elets Diagnostics Leadership Summit stressed on the need for more labs to get accredited. Edited excerpts:



Stressing on the fact that covid played a transformational role in upgrading the diagnostics industry, Dr Avinash

Phadke, Founder, SRL Phadke Labs added that the pandemic also accelerated the use of technology. He further mentioned that the different variants of covid are currently detected by gene sequencing. The government has not permitted private labs to do gene sequencing in the present scenario. He added that it is important to have S-gene incorporated in our system, if it's not incorporated yet to track variations in the covid virus.

Dr Phadke also called for urgent formulation of the booster dose policy, especially for healthcare

professionals who are at higher risk. He also mentioned that people are not coming forward for a second dose and that needs massive reinforcement. He also elaborated on how the lab-patient relation has changed and that labs are going to get hugely transformed in a couple of years. He also called for the need to have more and more labs accredited. He also averred that National Accreditation Board for Testing and Calibration Laboratories (NABL) has done a wonderful job in providing entry-level accreditation, especially during the COVID time.

“Pathologists are the soul of the diagnostic industry”

Dr Dinkar Desai, President, The Pathologist Association (TPA), President Association of Practicing Pathologist of India (APPI) during his address at the third **Elets Diagnostics Leadership Summit** called for collective efforts to tackle the growing menace of illegal labs. Edited excerpts:



Dr Dinkar Desai

President, The Pathologist Association (TPA)
President, Association of Practicing Pathologist of India (APPI)

Emphasising on the importance of the eyes behind a microscope and man behind a machine, Dr Dinkar Desai, President, The Pathologist Association (TPA), President, Association of Practicing Pathologist of India (APPI) shared that covid pandemic drew national attention to the diagnostic world. “Pathologist is said to be a doctor of doctors. But in reality the pathologist is struggling to survive,” stated Dr. Desai.

He mentioned about a 2018 judgment made by the Supreme Court stating that only qualified pathologists can authenticate a report. He stated that unfortunately

the SC judgment is not being followed with illegal labs and practices mushrooming. He called for strict adherence to this judgment. He shared that the vacant post graduate seats in pathology are a proof to this rise of illegal labs and called for collective efforts to address this issue as the basic soul of the diagnostic industry, the pathologist & the doctor behind the scene is getting forgotten.

He further added that the theme of the summit is very apt and timely and needs to be addressed with in-depth introspection as it will help to raise the bar of our standards. ☺



Discuss, Devise and Collaborate

Dr Atul Mohan Kochhar, Chief Executive Officer, National Accreditation Board for Hospitals & Healthcare Providers (NABH) in his address at the third **Elets Diagnostics Leadership Summit** stated that quality can only be ensured through co-sharing. Edited excerpts:



Dr Atul Mohan Kochhar

Chief Executive Officer,
National Accreditation Board
for Hospitals & Healthcare
Providers (NABH)

that everyone worked tirelessly without thinking of RoI and without compromising on quality, it was a true army operation which was carried out seamlessly towards the good of the nation.

While elaborating about the theme of the summit, 'Co-creation of a futuristic diagnostic sector', Dr Kochhar shared that NABH, a 15-year-old young organization, is running 21 programmes, has a presence in 13 countries and have 12000 partners. He added that NABH has 1500 fully accredited hospitals but we realized that one size doesn't fit all in vast country like ours. He averred that

Healthcare Organization Platform for Entry Level Certification (HOPE) was launched in 2019 for creating a stepping stone for creation of an ecosystem for quality.

He stated that if we are to make a tangible difference, if we are to brave future pandemics, if we are to really create an ecosystem of quality, we must take quality to the last man and we can only do that by co-sharing. He stressed on the need to discuss, devise and collaborate to reach out to small labs to eliminate quackery. He also called for taking up the mentorship initiatives to create a better system. ©

Complimenting and congratulating the resilience shown by all industry leaders, Dr Atul Mohan Kochhar, Chief Executive Officer, National Accreditation Board for Hospitals & Healthcare Providers (NABH) shared how the diagnostic sector and leaders scaled up & reinvented themselves to fight the pandemic. He mentioned





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Technology revolutionising customer experience

Abhimanyu Bhosale, Co-Founder & CEO, CrelioHealth shared his views on how technology is being used as a competitive advantage across multiple diagnostics labs to provide better value to their patients at the recently concluded Elets 3rd Diagnostics Leadership Summit. Edited Excerpts:

Technology has been transforming diagnostic sector and it is not only changing the conventional way in which diagnostics is actually managed, but also on the patient experience and furthermore on cost optimisation side to allow better access at the work costs across India", stated Abhimanyu Bhosale, Co-Founder & CEO, CrelioHealth.

He shared how multiple instances of tech-enabled transformations were witnessed across India, right from mobile testing centers to multiple labs switching to technology enabled access points as primary ways of capturing patient bookings, appointments or payment and reporting; a large scale shifted on digital means. He added that a number of health tech companies entered the market and contributed either by enabling better access or reducing costs or in some cases aggregating patient volumes.

He further added that technology is being used as a competitive advantage across multiple diagnostics labs and other tech enablers to show better value to their patients. He mentioned how Dr Phadke talked about patient experience being largely digital today and that shift will be very essential as it sets the tone for the next stage or the next phase of the diagnostics labs in the country.

He also cited Dr Gaur who talked about

cloud and mobile based lab solutions that are becoming the new norm and how technology is really crucial for this entire transformation. He further mentioned how technology has been used in addressing the issue of access and productivity in healthcare and across multiple industries, right from logistics, banking and finance. He cited how the diagnostic sector was able to scale up testing using technology during covid and still cater to the demand was unprecedented & unheard of in any other industry.

He also mentioned the importance of accreditation and how enabling labs to get accreditation is one of the important steps. He stated that multiple initiatives are being taken for getting better channels for accreditation. He averred that it is essential for having consistency in quality across labs and they don't remain as like testing units but they also are actually quality accredited and maintain a high standard of delivery, overall. He also mentioned how improving the quality and reliability of testing goes largely hand in hand with technology because it creates a vital role for tech to become that system of record and make it more auditable and reliable for things to scale.

He further talked about solutions that go far beyond that as a norm and actually help improve compliance as well as auditability of laboratories. He stated that compliance today by



Abhimanyu Bhosale
Co-Founder & CEO,
CrelioHealth

far is one of the largest challenges that are faced. He mentioned Mr Venkateswaran who had talked about training programs and they are actually much underappreciated. He called for having better training programmes for enhanced tech adoption which basically improves quality compliance and enables them to leverage better tools at scale.

He also mentioned how the industry has grown multifold in itself in the last 5 years & also witnessed changing technology needs. He shared that technology is crucial and becomes a key milestone for each lab to actually have and excel at. And not to mention how individual labs can actually improve productivity becomes a key challenge for everyone to reduce costs and improve access. ☺

Cloud-based systems driving diagnostics sector

In a panel discussion on **'Need for concrete framework in Co-creation of a Futuristic Diagnostic Sector'** at the virtual Elets 3rd Diagnostics Leadership Summit, industry thought leaders stressed on working together for the creation of a diagnostic sector, fulfilling future needs.

Edited excerpts:



Parag Khare, Head - Enterprise Solutions, Creliohealth stated that Covid was a great blessing in enabling the IT framework that has been built. He shared that Creliohealth is a cloud based platform that allows scaling the laboratories, in terms of getting them on-board rapidly. "During the course of the first wave, we were one of the companies to have a QR code on the report even before it became mandatory. So as a technology company, we have always taken a step forward

in terms of our customers who are spread across countries," shared Mr. Khare.

He further added that during covid times, they were able to create adapters and tools that can enable labs of all sizes to shorten the time of availability of reports, helping both the patients and the government. He also talked about the initial uncertainty that covid brought, affecting business. "But once the vaccination and the treatment protocols were stabilized over a period of time, we got the numbers back," stated Mr. Khare.

He also detailed his thoughts on why digitisation is important, especially in the covid times. "The mode of payment has changed to digital mode of payment. So the number of UPI payments and number of online payments have gone up," he added. He also stated that in the present healthcare ecosystem, the expectation is there to become more patient centric and Creliohealth has been able to be an early adopter of this. "Even before covid, we have had digital payment options and logistics tracking for home visits were already part of our

platform offering," shared Mr. Khare. He averred that Creliohealth caters to all lab sizes in India and across the globe.

He also stressed on the need and adoption of automation for quicker results and how it is also a requirement of the clinicians. He also mentioned that due to covid, the cloud based system has become more relevant and allowed all the stakeholders, especially the patient, clinician, pathologist, labs & others in this entire health ecosystem to be able to witness what's happening and deliver according to the expectations. Cloud-based systems have also enabled us to get results faster and meet the requirement of quality as well.

Cloud-based systems have also enabled to get results faster and meet the requirement of quality as well.



Dr Abhik Banerjee, Zonal Technical Chief, East Zone, Apollo Diagnostics stated that the Indian diagnostics industry has a huge potential and we can do much better, but stressed on the need for extensive quality assurance. He added that the introduction of digitisation in the form of QR code on reports began with lab reports or LIMS. Now the data gets directly into the lab information management system. "There should be an access control device in every small lab to ensure safety and privacy and prevent unauthorized access," added Dr. Banerjee.



Dr Dinkar Desai, President TPA, President APPI averred that the diagnostic industry is divided into India and Bharat. "It is so because at one end we are finding new labs with quality assurance and audit, digitalization and latest technology. But at the same time there is equally good presence of individual labs, stand alone labs and also illegal labs," said Dr. Desai. He called for a necessity of law to eradicate the illegal centers. He averred that we are talking about digitization and automation but the basic infrastructure is lacking. "We need to rebuild the diagnostic sector. One also needs to look at post graduate infrastructure. There is a strong need to work on that to improve," stated Dr. Desai.



Dr Varsha Vadara, Consultant & Head Laboratory Medicine & Advanced Diagnostics, Kokilaben Dhirubhai Ambani Hospital stated that there is an increase in the number of tests for various reasons. She added that automation is very important for the growth of the industry and added that Indian companies need to look at using these facilities to ensure quality control in a more stringent way. She shared that while automation has entered across fields, there data management, Cyber security and many other factors where automation may fail. "There should be a manual method also," said Dr. Vadara. She also shared how healthcare has become a fancy word that has gained a lot of significance post covid.



Dr Asha Sudha, Lab HOD/ Pathologist, Fernandez Foundation spoke about how many labs are not going for accreditation because of the costs involved. "If this can be done at an affordable cost then it would be easier for all," said Dr. Sudha. She stressed on the need for internal audits and averred that NABL should give the option to upload and update internal audit findings every sixth month to ensure quality assurance. She further elaborated on how public and private partnership is very important for the growth of the diagnostic sector. "Ayushman Bharat should also be combined with the diagnostic sector to ensure it reaches to more people. Even diagnosis should be combined with medical insurance to ensure even weaker sections can take the benefits," stated Dr. Sudha.

Need for Accreditation for Ensuring Quality Testing and Outcome

In a panel discussion on **'Need for Accreditation for ensuring quality testing and outcome'** at the virtual **Elets 3rd Diagnostics Leadership Summit**, industry thought leaders stressed on accreditation for an enhanced patient experience. Edited excerpts:



Dr Ravi Gaur Principal Advisor Spice Health (Spice Jet Promoters Venture) Founder Dr G Path Labs,

Co Chair CII Delhi Chapter Health Committee while moderating the session stated that providing healthcare, especially of an adequate standard, is complex and a challenging process. He shared that healthcare is a vital and emotive issue, its importance pervades all aspects of society and it has got medical, social, political, ethical business and financial ramifications. He averred that in any part of the world healthcare services can be provided either by public sector or private sector or by combination of both and the site of delivery health can be located in the hospitals or can be accessed through practitioner working community or through home care

in the present times. Dr. Gaur stated that it's important to have some kind of a quality benchmark or yardstick. A truly affordable and high-quality healthcare services and tools are the only means by which quality healthcare can be provided to all. He shared that accreditation recognizes the labs commitment to excellence and high professional standards of operations and providing affordable healthcare for the last man in the line is the main aim. He further added that in the last two years, SEO of healthcare has seen Covid, Pandemic, RTPCR and NABL accreditations topping the common man's minds when it comes to healthcare in the present times.



N Venkateswaran, CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL) stated that when accreditation is talked about, in simple terms it means competency of the entire

set of the laboratory. "Accreditation is a kind of recognition where the competency of the laboratory for a particular scope or a task is being looked into," shared Mr. Venkateswaran. He averred that NABL is a voluntary accreditation body that has been set up to ensure the quality of the lab. He added that accreditation and competency is important because the patient needs to know whether the results are accurate and reliable. He also shared how automation is playing a major role now in accreditation unlike before. Post the pandemic, NABL has started doing online visits through video calling and geo tagging. "We ensure that lab presence is there, all equipment they are having they are geo tagged

so that the infrastructure is in place and then

the demonstration takes place through video conferencing," shared Mr. Venkateswaran who foresees hybrid assessments in the future. He also informed about the NABL initiative of medical entry-level testing labs. "NABL Medical Entry Level Testing (MELT) Labs Program" for sensitizing the medical testing laboratories performing basic testing to quality practices and access to quality health care for the majority of citizens especially those residing in villages, small towns. The program is based on satisfactory proficiency testing (PT) performance.

"Accreditation and competency is important because the patient needs to know whether the results are accurate and reliable"



Dr Seema Kochhar, Principal Director - Quality Management & Excellence, Dr Lal PathLabs Ltd stated that 70% of all the medical decisions which are taken by the physicians are based on the laboratory investigations. She

added that the accredited labs follow a structured process; they have a procedure framework for operations which is based on the guidelines set by standards which in the case of medical testing laboratories is ISO 15189 and also NABL 112 standard which is guiding them on various department level requirements to maintain the quality.

"So it's ensured that the patient's results have passed through the various steps, various checks which are required throughout the total testing process, thereby assisting in making the correct diagnostic and better patient outcomes. It also enables trust in the customers on the services which are provided

by the laboratories because the accrediting bodies recognise formally the competence of the said laboratory which is a very important aspect now," said Dr Kochhar.

She also elaborated on the growing public awareness about the whole process of lab tests, especially during the covid pandemic times. She stated that along with this, the awareness around medical errors as well as the adverse patient outcomes has so significantly gone up during this time and it continues to increase among the patients. She averred that patients today are well read and well prepared and how accreditation keeps patients' safety supreme & helps in enhanced patient experience.



Anand K, CEO, SRL Diagnostics stated that in India there has been a trust deficit not only for the clinicians but also for patients in terms of how much of reliability on

the quality of the reports they can place. He added that accreditation is going to play a very important role with a low number of accurate laboratories present. He further shared how the Covid scenario has created awareness amongst the general public and they know the value of accreditation. He stated that in the present times, accreditation is voluntary and still not mandatory & it is critical to look at different aspects of quality. He added that lab investigations are important for patients and doctors and "diagnostics and clinical patient management they are in an interdependent relationship". He further stated that it's important to look at accreditation and its impact

on the performance of laboratories.

He averred that when a lab enrolls into a professional testing program over a period of time, over two or three cycles, the quality and the reliability of the reports improve. Further, with the presence of standalone labs, government sector labs, private labs and more, the expectations of clinicians also seem to vary in terms of what they want to see in the reports. "Accreditation will play a very important role and accreditation bodies also need to evolve and be able to handle these requirements which are coming up for the future," added Mr. Anand.

"Accurate and reliable reports are an extremely important aspect of quality"



Dr Ravi Gupta, Founder & CEO, Saral Diagnostics shared that accreditation is directly linked to the word quality and unfortunately

either at a graduate level, undergraduate level, post-graduate level, people are never told about quality in healthcare. "So quality in healthcare should begin as a small tiny little chapter at the graduate level. Also, quality is not just giving a correct report but quality is a total experience that a patient takes home. Therefore, a reliable report is an extremely important aspect of the quality, right from the entry point to the exit point," shared Dr. Gupta.

He stated that most of the people have been talking about lab sciences, but quality in radiology is very different. "We start from justification of referral. Many-a-times even we as a radiologist are unaware whether a CT is required, an ultrasound is required or MRI

could do a better job or molecular imaging would do a better job. So justification of referral, shifting the patient from radiation modality to non-radiation modality has become part of the quality," averred Dr. Gupta.

He added that in radiology, technologists play an extremely important role. He also elaborated on the use of artificial intelligence (AI) in interpreting images whether in radiology, cytopathology or histopathology. He shared that there are a large number of companies that are working really hard and have seen 95% accuracy outcomes in their lab. He averred that accurate and reliable reports are an extremely important aspect of quality.



Dr Vipul Bhargu, Marketing Manager, Clinical Diagnostics Group, Bio-Rad Laboratories (India) Pvt. Ltd highlighted that with automation and availability of more quality control material and detailed reports, there has been a significant decrease in errors. "At the end of the day, labs are responsible for driving the clinical decisions and they are striving to reach that zero per cent error rate, which is most important, & towards

this end it is of paramount importance that labs keep on participating in the global Proficiency Testings (EQAS) with advanced statistical analysis as well as in global interlaboratory peer programs."

Comparison with global labs will have labs in India strive for excellence & have better scores than them, averred Dr. Bhargu. He also elaborated on the entire diagnostic testing process and averred that the clinical labs have responsibilities for the whole testing process, whether the test requested is appropriate or not and how quickly the clinician can interpret it. He suggested that the maximum scope of improvement lies in the pre-pre-analytical steps, where proper patient identification, specimen identification, whether the staff is well-trained to collect the sample and further where sample transportation is required.

"The challenge is that there is a shortage of real skilled staff and the phlebotomy facilities are overloaded," stated Dr. Bhargu.

He further stated that clinicians may sometimes either ignore or overlook the results and this has also been found by multiple peer reviewed studies & journals. He shared how in many instances in ICUs and emergency departments, the tests which are asked and are released, never get accessed. "If we look at it holistically, this comes to the point that if an MRI or a radiology test has been ordered, is it really needed and what is really needed," said Dr. Bhargu. He called for more standardization of processes that needs to be done in the analytical and post analytical steps. He also stressed on the need for training of staff, need for more set protocols and for the accreditation agencies to have detailed SOPs.

"It is a misconception that accreditation increases cost. Accreditation needs to be considered as a cost of prevention"



"Accreditation helps the organization to transfer the quality intent to all levels. It helps not only manufacturers but pathological laboratories as well, to understand what national or international standards to follow. It is difficult to maintain quality only by means of controls; developing systems and processes helps to maintain quality in the long run. It is a misconception that accreditation increases cost. Accreditation needs to be considered as a cost of prevention. The overall benefits in

terms of cost of poor quality, cost of lost opportunities and benefits of gained opportunities should be considered while calculating the overall impact of accreditation costs", said **Mr. Manish Airan**, Vice President, Quality Assurance, Regulatory Affairs, Business Excellence & Digitalization, Transasia Bio-Medicals Ltd during the panel discussion on 'Need for accreditation for ensuring quality testing and outcome' at the 3rd Diagnostic Leadership Summit.



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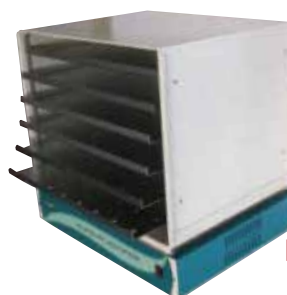
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Effective solutions for tackling antimicrobial resistance

Antimicrobial Resistance (AMR) is a growing concern across the globe with the World Health Organization (WHO) also working with countries to tackle it effectively. 148 countries have action plans on AMR in place. To deliberate on this growing concern, a panel discussion on **'Antimicrobial Resistance (AMR) - Use of novel technologies'** was organised during the recent **3rd Elets Diagnostics Leadership Summit**. Edited excerpts from the discussion:

Expressing deep concerns over the global rise of AMR, especially in light of the global pandemic, a slew of thought leaders shared their insights in a discussion on 'Antimicrobial Resistance (AMR) - Use of novel technologies'. Present during the deliberations were Dr Yatin Mehta, Chairman Institute of Critical Care and Anesthesiology, Medanta -The Medicity Hospital; Dr Sonal Saxena, Director Professor & Head, Microbiology Department, Maulana Azad Medical College; Dr Manisha Khandait, Professor and head Department of Microbiology, Shree Guru Govind Singh Tricentary Medical College, Hospital and Research Institute (SGT University); Prof (Dr) Chand Wattal, Chairman Institute of Clinical Microbiology & Immunology, Sir Ganga Ram Hospital and Dr Shahzad Mirza, Associate Professor, Microbiology, Hospital Infection Control Officer, DYPMCH. The session was jointly moderated by Dr Debkishore Gupta, Director, Medical Affairs, Cepheid and Garima Pant, Assistant Editor, Elets Technomedia.



Prof (Dr) Chand Wattal, Chairman, Institute of Clinical Microbiology & Immunology, Sir Ganga Ram Hospital, stated that Antimicrobial Resistance (AMR) is akin to global warming, which is why it is a global problem. It's a huge problem with nothing in the pipeline. He called for evolving the concept of one health. Increasing awareness and understanding of the aspects of antimicrobial use in the agriculture sector and their impact on the environment are necessary in order to address AMR from a One Health perspective. He called for following Infection control prevention practices in letter and spirit.



Dr Sonal Saxena, Director, Professor & Head, Microbiology Department, Maulana Azad Medical College averred that steps need to be taken to ensure quality in results and also the rapidity in results. She stated that Microbiologists have to step up and take up the role of epidemiologists in the current scenario. She also stressed on the improved & enhanced coordination between various agencies to prevent infections in the animal, environment & agriculture sector.



Dr Yatin Mehta, Chairman, Institute of critical care and Anesthesiology, Medanta - The Medicity Hospital shared that one of the pertinent gaps today is the delay in diagnosis. He stated that we waste time, money & face increasing morbidity because of inappropriate antibiotic therapy as the diagnosis takes time. He added that if inappropriate antibiotics are used, the burden will increase. He advised that all microbiologists should be clinicians first and should come out of their laboratories and interact with clinicians.



Dr Manisha Khandait, Professor and Head, Department of Microbiology, Shree Guru Govind Singh Tricentary Medical College, Hospital and Research Institute (SGT University) shared that we are lacking at the diagnostic level and at the antimicrobial susceptibility testing. She called for wide availability of technology to further address the issue of AMR.



Dr Shahzad Mirza, Associate Professor, Microbiology, Hospital Infection Control Officer, DYPMCH stated that while the lab has to be equipped with hi-tech things for rapid results, the process starts with a basic thing like sample collection that has to be accurate. Further, correct diagnosis has to be made for the clinician to treat it correctly. He averred that being a microbiologist it's important to understand that while we can follow guidelines but we need to understand our own flora to ensure that treatment is done in time. He shared that if for a report even a minute can be saved, it can bring in a huge change for the hospital and the patient.

Sequencing the spread of omicron for prevention

In the light of the mutating Covid variants, a panel discussion on **'New Age Diagnostics for Infectious Diseases: Novel testing platforms, technologies and solutions'** was organized as part of the **3rd Elets Diagnostics Leadership Summit** recently. A number of industry experts shared their collective views on the present variants of concern and the way ahead to detect them. Edited Excerpts:

Highlighting the novel testing platforms, technologies and solutions, experts shared their insightful views during the 3rd Elets Diagnostics Leadership Summit. Present in the discussion were Dr Varsha Potdar, Scientist D, NIV, ICMR; Dr (Col) Jyoti Kotwal Senior Consultant & Head Dept of Hematology Sir Ganga Ram Hospital; Dr. Tanu Singhal, Consultant, Paediatrics and Infectious Disease, Kokilaben Dhirubhai Ambani Hospital; Dr Rohit Chawla Professor Maulana Azad College; Dr Suryasnata Das, Associate Director- Microbiology Department of Laboratory Medicine, Jaypee Healthcare Limited and Dr Disha Bhatia National Head, Microbiology and Serology, CORE Diagnostics. Dr Debkishore Gupta, Director, Medical Affairs, Cepheid co-moderated the session along with Garima Pant, Assistant Editor, Elets Technomedia.



Dr Varsha Potdar, Scientist D, NIV, ICMR shared that the testing protocols being followed by our testing labs are equipped to find the virus variant. She further added that in a good number of cases in our country, S-gene target failure was not observed for Omicron

cases. She stated that the kits being used are not missing any variant. She further added that during the pandemic, ICMR took up a lot of labs and ensured that all labs have NABL accreditation in place. She added that ICMR has also made a centralized portal for the IQC program. She averred that people should not forget that influenza viruses have the potential to stimulate a pandemic and stressed on the need to have the surveillance active, as also suggested by the WHO. She also called out to people to get them vaccinated. "Only reporting H1N1 is not the key. Other strains of influenza viruses should also be kept in consideration," said Dr Poddar who reiterated that vaccines and preventive measures like masks are the two primary weapons to fight the pandemic.



Dr Rohit Chawla, Professor, Maulana Azad College averred that sequencing of the virus is the best way to identify it and also the best way to track the Omicron variant. He called for a multi-target approach towards identifying the new variant of concern and might be cost-intensive. He stated that people should be prepared as the new variants are bound to come and it's the preparation that matters. "We should be prepared for the worst and hope for the best," stated Dr Chawla.



Dr Disha Bhatia National Head, Microbiology and Serology, CORE Diagnostics shared that there are no commercial kits available for sequencing for Omicron and stressed on the need to ramp up sequencing. She added that while the number of influenza cases has been low globally this year, the awareness around the flu vaccines has also increased and people are considering taking annual booster shots for the flu as well.



Dr Suryasnata Das, Associate Director- Microbiology, Department of Laboratory Medicine, Jaypee Healthcare Limited stated that sequencing is not easily available and there are issues & challenges for ramping it up. She added that if a rapid antigen test is taken in the beginning, it can help with easy identification. She further averred that in the country, at times the cost of anti-viral medicines is lower than that of the test. "Our main challenge is to bring down the cost of tests for better diagnosis," shared Dr Das.



Dr (Col) Jyoti Kotwal, Senior Consultant & Head, Department of Hematology, Sir Ganga Ram Hospital mentioned that till now we've had 8 confirmed cases of Thrombosis with Thrombocytopenia Syndrome (TTS) in India and detailed the gold standard confirmatory test for TTS in India. She also shared how new age diagnostics help in diagnosis of HITT and HITT mimickers. She further mentioned that social distancing and masks have helped in prevention against the virus and also reduced the number of patients with other respiratory infections. "I don't know about the new variant, how bad or ugly it's going to be. But we are hoping it's going to be good and maybe it's acting as the vaccine against the other variants," added Dr Kotwal.

In a good number of cases in our country, S-gene target failure was not observed for Omicron cases



Dr Tanu Singhal, Consultant, Paediatrics and Infectious Disease, Kokilaben Dhirubhai Ambani Hospital called for a need to understand that Covid is endemic in our country. She added that focus should be on not missing people with severe disease. She stated that in the pandemic induced times and as per their clinical procedure, patients are first tested for COVID and then for other diseases or other strains of influenza virus. She also mentioned that in an ideal scenario, it would be good if the real causative pathogen causing the respiratory illness could be found. But in reality, it does not always happen. She wished that from the clinicians end, if they could get real-time data without any lag for effective treatments and for finding the accurate cause behind infections.

Quality control enabling better patient outcome

In an industry presentation, **Dr Anjali Singh**, Medical Advisor Bio-Rad Laboratories India (Pvt) Ltd shared her views about 'Role of Quality Control in Improvement of Laboratory Testing & Patient Outcomes'.

Edited Excerpts:



Dr Anjali Singh

Medical Advisor Bio-Rad
Laboratories India (Pvt) Ltd

Quality Control (QC) has been talked about for quite some time now and Bio-Rad has been associated with this product education, hand holding as well as association with major institutes for over two decades now. Dr Anjali Singh, Medical Advisor Bio-Rad Laboratories India (Pvt) Ltd shared the basics of QC.

She talked about how the entire patient impact comes from a number that labs give out in their report and how that number is dependent on multiple factors, for which they work day in and day out.

She also gave an example of an instance when a report has poor quality and how it can lead to inappropriate action for the patient, one can over investigate

the patient when they don't require so many investigations; high costs, harassment involved for a sick patient or the patient can also be over treated or even given a wrong treatment. She also shared how there can be delay in action if the report is to be repeated or done in another lab for confirmation, which can lead to loss of credibility of the laboratory. She added that legal actions can also be taken against the laboratory.

She shared her views on how does a lab ensure good quality results and how can a lab ensure or demonstrate to their patients that their reports are correct? She stated that there are certain materials that help like mimicking the patient's sample.

We run it before running any patient's sample, if the results are okay we assume that most likely the patient report is going to be okay. If the results are not okay, patients' results may be compromised," said Dr Singh. She further elaborated that by the term mimic, it is meant that it should have a similar matrix to patient samples, should be independent of any one instrument, different from calibrator, cover the clinical decision values, should be

Even after using QC there is a possibility that lab reports do not match with other lab reports.



easy to use, stable for long periods and have at least 2 levels.

She elaborated that once all these materials are available and they run this QC material. And if the value of this material is as expected the value to be, then it is believed that their instrument is fine and their patient report is correct. If the QC value is not as expected, then patient testing is stopped. "We first investigate the problem, QC is rerun and if the QC is okay then only we run the patients sample.

There are various causes that can lead to wrong reports, such as instrument maintenance; change of instrument part; major repair of instrument; change of reagent lot; recalibration; calibration failure; change of light source; change in incubation temperature (for enzymes only); failure of reagent dispensing system; failure of

Both internal and external QC are equally important/ one cannot substitute another.

sampling system and change in environment (temperature/ humidity).

Sometimes, we see the values are close together but they are not the real values, true values and it is impossible to find the true value from IQC because IQC is repeatable," said Dr Singh.

She also averred that even after using QC there is a possibility that lab reports do not match with other lab reports. "And the question

arises that why our lab are reports not matching? There comes the concept of EQAS (External Quality Assurance Scheme), so believe that our report has to be accurate, that is near the value that is expected and it has to be precise that is if we repeat it ten times, it still gives the same outcome," said Dr Singh.

She shared that if a lab is accredited, the accrediting agencies come and perform regular audits, check if QC was run at required frequency, was corrective action taken in case of QC failure and if any patient tests were done if QC was not ok.

She added that QC is an important step in maintaining quality of patient testing. Both internal and external QC are equally important/ one cannot substitute another. As a clinician, an accredited lab can be believed to be running QC at required frequency. ©

“Digital and digitization has become a key word in the diagnosis and healthcare recently”

Dr Ravi Gaur, MD Pathology, Principal Advisor Spice health & Founder DRG Path Labs shares his views on the creation of a futuristic diagnostic sector. Edited excerpts:

What is the framework required for the creation of a futuristic Diagnostic Sector?

The COVID-19 pandemic has highlighted the integral value of diagnostics in managing the healthcare system. Diagnostic testing provides critical information at every step of the patient pathway, from prognosis, screening, and diagnosis to monitoring the progression of disease, predicting treatment responses and preventing diseases.

There has been significant under investment in diagnostics (technology, infrastructure, and skill and delivery models) over many years. There is a strong need for a strategy which can deliver a resilient, scalable and holistic diagnostics and augment capability and capacity for testing.

For diagnostics to play its true role in health care, it should be placed at the centre of disease and health management and increase investment in the sector. We must retain the infrastructure built to support COVID-19 testing and continue to accelerate adoption of new diagnostic delivery models for accessible & affordable and innovative diagnostics.

Point-of care approaches can provide results at the point of use and in resource-limited settings. By empowering clinicians and even patients to make decisions at the “point-of-care”, we can make a significant impact on healthcare delivery and address challenges. The Indian healthcare system urgently needs disruptive affordable, accessible, and efficient solutions to address the current challenges. As digitally connected point-of-care diagnostics become more data-centric, they can benefit the primary healthcare system and help India achieve universal health coverage. Government must now continue the strong partnership models with the researchers, policy makers, diagnostic providers and manufacturers to build a diagnostics industry of the future.

How has Digitization and IoT accelerated the pace of Innovation in Diagnostics?

Digital and Digitization has become a key word in the diagnosis and healthcare recently. The need of the hour is to digitally empower the lab with state-of-the-art technologies and integrate them with the entire health pathway of an individual for best clinical outcome. Lab information management software is now in essential list



Dr Ravi Gaur

MD Pathology, Principal Advisor Spice health & Founder DRG Path Labs

of all diagnostic centres and is providing end to end solutions .It covers all steps of sample testing – pre-analytical, analytical and post analytical .Smart reports with better analytical interpretations, advice on reflux tests and tracking are fast becoming a norm.

What is the Scope and Opportunities in Lab Automation Market for enhancing diagnostics Lab Management?

Laboratory automation is no longer optional. From growing demand for faster turnaround time, increasing

patient expectations, shortage of skilled staff and safety as a big concern, labs are facing several challenges to deliver quality results. The input cost, which includes – reagents & instruments, manpower, infrastructure, accreditation, IT, logistics, administrative expense, etc – has gone up substantially. There is a strong pressure on the labs to maintain control over the influx of samples, to improve workflow, and deliver for better clinical performance to improve upon profit margins to sustain their operations. As the automation is going to cost substantially, there is some reluctance in Indian Diagnostic labs to adopt these measures. But with increasing fixed costs, labs need to scale up the testing to sustain their operations. With time automation will help not only scaling up the capacity but also in improving margins for sure. Thus labs are left with no option but to adopt automation for survival.

What are your views on the need for Accreditation for ensuring quality testing and outcome?

With time automation will help not only scaling up the capacity but also in improving margins for sure

There are approximately close to 150,000 pathology labs in India. But only about 3000 are accredited by the National Accreditation Board for Testing and Calibration laboratories (NABL). This puts a question mark on diagnosis, quality of reports and clinical outcomes. Some will raise concerns of growing cost of tests and higher investments in infrastructure but as we understand, "Every sample is a life", and thus balance should be struck between cost, quality of reports and clinical outcome. Accreditation drive to create more awareness and get

more labs to get accredited, is vital to make accurate, more accessible and affordable diagnosis for all Indians.

What are the factors that will drive the change in the Diagnostics sector in the coming times?

Diagnostic testing provides critical information at every step of the patient pathway, from prognosis, screening, and diagnosis to monitoring the progression of disease, predicting treatment responses and preventing diseases. It has now become an indispensable tool in clinical practice. Today it is playing an increasingly important role in driving personalised and cost-efficient healthcare delivery. Growing life span & awareness towards better health, point of care testing, wearable devices, AI driven analytics, biomarkers of early prediction of diseases and precision medicine will drive the change.

What are your business expansion plans to align yourself to the changing sectoral requirements?

As we move forward, adoption of new automated technologies, digital pathology, genomics, rapid molecular diagnosis, investments in bioinformatics for better data analysis & interpretation and offering customised solutions for an individual for better understanding of disease & clinical outcomes are part of my expansion plan. There is a need to augment the central lab with more advanced technologies, while offering more tests at satellite and primary or remote labs. Also, we will be working on faster accreditation of all labs and integrating them using the IT for rapid clinical decisions and better patient experience. 🌐



Need to THINK about Genetics

In a scientific presentation titled 'It is not Rare, till you're aware', **Dr Neha Rai**, Chief Strategy Officer, Sandor Specialty Diagnostics gave detailed insights about genetics and the need to broaden the horizon while dealing with genetic issues. Edited Excerpts:

Sharing an anecdote from her childhood, Dr Neha Rai, Chief Strategy Officer, Sandor Specialty Diagnostics shared how people often simply fail to think of genetics when a diagnosis is made, which is often just the tip of the iceberg. The topic is considered like the poster child of future diagnostics but in reality it is not that common.

"What we see today in form of genetics is we only diagnose severe genetic and chromosomal abnormalities, but we don't really look at hidden signs and symptoms which are on Intellectual disability, Dysmorphology, Delayed development milestones, Primary Infertility and Refractory Seizures. The reason that this is an iceberg of an issue is because the healthcare professionals really need to think about genetics as a cause. We simply fail to think of Genetics," shared Dr. Rai. She added that whenever genetics is thought about by the diagnostics players, they think about buying Next Generation Sequencing Instruments and other such high CAPEX investments.

She stated that the most important thing in genetics is thinking smaller and simpler. More machines are not needed but what is needed is to equip our doctors and patients to think about genetics. She elaborated further on a typical pedigree map that is made by

genetic counselors, just by talking to their families and understanding whether a particular trait or symptom is running in the family. "It is an extremely inexpensive method and all laboratories can equip themselves to be able to do genetics just by having a genetic counselor. It's an extremely simple and much needed thing that we need to do in our healthcare industry. Not all hospitals, not all maternity centers have genetic counselors. So as laboratories, we could help these doctors and patients in identifying genetic disorders," shared Dr. Rai.

She added that the diagnosis and the arrival at a result is a very tailor made approach. "Being able to correlate the clinical symptoms along with the genotype of the patient is the need of the hour, until we have a database robust enough where we could do this more in an automated fashion. The business model of Genetic diagnosis is of 'Care continuum' vs 'Volume and Automation'. One thing that hallmarks our speciality segment is that the information asymmetry that exists between the doctors who are prescribers & the labs that are equipped to do these tests. Genetics is not part of the regular medical curriculum," stated Dr. Rai.

"Whenever we talk about genetics we only think about next generation sequencing (NGS). But there are a



Dr Neha Rai
Chief Strategy Officer
Sandor Specialty Diagnostics

lot of genetic disorder that either can be diagnosed without an NGS or an NGS has to be coupled with these technologies to be able to give more confirmative diagnosis, prognosis and enable better treatment choices. As a company we have focused on inborn error of metabolism as a specialized segment in genetic disorders because a lot of these disorders are treatable, are manageable and there are children who can have a healthy or a near healthy life, even if they suffer from this disorder," said Dr Rai.

She averred that simple steps towards closing the information gap and collaborating together to make these tests available and affordable is the way forward for growth. ☺

“COVID 19 pandemic has increased awareness towards the need of preventive healthcare”

Dr Abhik Banerjee, Zonal Technical Chief, East Zone, Apollo Diagnostic, Regional Reference Laboratory, Kolkata shares his insights on what lies ahead for the diagnostic sector in the country.

What is the framework required for the creation of a futuristic diagnostic sector?

The advantages of the Indian diagnostic sector are its highly competent manpower along with its service which is quite affordable in comparison to European or American markets. However the disadvantage lies in the unorganized, unregulated, fragmented players which largely dominate the Indian market.

Reaching the masses is a challenge for the Indian health sector due to the country's huge population. If we consider rural areas and remote places which are relatively far from metro cities or towns, there are lots of scopes for improvement. Practically, it is not possible for the government alone to have infrastructure everywhere. On the other hand, the organized private players are concentrated mostly in urban areas. Hence to ensure availability of adequate and timely health care service, PPP model has a great role to play in India. PPP in appropriately selected segments may actually be the role model in India to materialize the dream for "Health for all".

Setting up more laboratories and hospitals in rural and remote areas,

digital pathology, telemedicine, point of care devices (bedside testing), mobile health care applications, better availability of government authorized healthcare training and lab technician training courses, promoting basic quality norms and importance of accreditation. Moreover, the Government should invest more in healthcare product manufacturing units so that the country can be self-sufficient especially in life saving medical devices and equipment.

How has digitization and IoT accelerated the pace of innovation in diagnostics?

Innovation in diagnostic processes and digital technology will definitely improve diagnostic accuracy, precision and will thereby promote better diagnostic facilities for patients. Use of point of care and home monitoring devices, bar codes, robots, artificial intelligence, machine learning in diagnostics will ensure faster operation, workflow efficiency and better safety by minimizing human interface in laboratories. Moreover technologies enabling remote diagnosis through digital pathology will reduce cost burden and help easier access to the latest diagnostic facility for patients residing in remote areas.



Dr Abhik Banerjee
Zonal Technical Chief, East Zone, Apollo Diagnostic, Regional Reference Laboratory, Kolkata

Though we have seen a lot of development and enhancement in connectivity, communication, and digitalization and automation, there is a long way to go to achieve the best benefits of these technologies as the laboratories are still skeptical and cautious about their implementation beyond a certain point. Everyone is expecting someone else to make the first move and see the result. Significantly, the Union Health & Family Welfare Ministry of India has recently approved the Health Data Management Policy of the National

Digital Health Mission (NDHM). This is going to be a major step forward for gradual implementation of "Security and Privacy by Design" for the protection of patients' data privacy during healthcare delivery.

What are the scope and opportunities in the Lab Automation Market for enhancing diagnostics operations management?

Today the expectation from a modern medical laboratory is not only limited to accuracy and reliability of test results but a faster turnaround time (TAT), "state of the art" technology with global quality standard, affordable cost and reports carrying simple and useful information preferably with a direction to therapy. To meet such ever increasing demands, modern medical laboratories in India have adopted several ways and no doubt automation, robotics and use of artificial intelligence (AI) are cornerstones of this attempt. We have already seen commissioning of automated extractors by many laboratories in their Molecular Pathology departments to minimize

PPP in appropriately selected segments may actually be the role model in India to materialize the dream for "Health for all"

manual handling of COVID 19 specimens.

Whereas automation has helped medical laboratories streamline their day to day operation and more rational utilization of the workforce, too much dependence on automation may have its own drawbacks. Inertia of staff to go back to manual operation especially during automation downtimes, lack of accountability, engagement, deterioration of manual skills are some of the major challenges which the clinical laboratories might face due to over dependence on automation. Moreover "Man behind the machine" will always remain important. Even with the highest

degree of automation in a clinical laboratory, the need for continuous supervision of equipment function and requirement for daily, weekly or monthly maintenance by laboratory staff cannot be overlooked.

If we aspire for better quality laboratories and a good standard in laboratory medicine in India, at least a basic level of automation is mandatory for all laboratories. Hence it is high time that we think about customized and commercially viable automation for these small but important players also. The "Made in India" initiative has led to the launch of smaller but fully automated compact and robust bench top systems with wider test menus. Such automation has made it possible to reduce outsourcing of important test parameters (e.g. hormones, tumour markers etc.) by these small labs and rather process them in-house with better confidence and lesser cost. This has also made such tests easily available and affordable even in remote areas which were beyond imagination even a few years back. With such an encouraging picture, it is expected that, Government would consider investing more in all types of laboratory equipment and reagent kit manufacturing units so that the cost of automation in a laboratory can be drastically reduced. Automation under supervision of a trained laboratory medicine practitioner has already proved to be a game changer and can significantly reduce errors in a laboratory.

With every passing day, the cost of manpower is increasing in India. The laboratories will have to spend more to attract and retain





efficient manpower. With a slow but steady increase in the number of diagnostic chains in India, even smaller laboratories need to spend more on automation and cutting edge technology to stay competitive. Peer pressure on laboratories to consistently deliver accurate and timely reports will go on increasing and judicious use of automation, robotics and AI under supervision of trained, competent manpower can be laboratory's response to all these challenges. However, we need to remember that automation comes with a price. The balance between revenue generated from the workload of a laboratory and cost of automation must be carefully balanced.

What are your views on the need for Accreditation for ensuring quality testing and outcome?

Raising awareness of quality, sensitizing the unorganized, fragmented healthcare facilities (HCF) to follow basic quality norms, regulation and standardization should be the foremost agenda of the Government and health department. Accreditation can play a major role here. Accreditation bodies and Government authorized agencies should come forward

to arrange for regular CMEs, symposiums so that the owners of private healthcare facilities understand the competitive advantage that accreditation confers and also the potential cost savings that HCFs can achieve through continuous quality improvement. Once the basic quality practices are ensured, organizations should be encouraged to achieve the next level of quality standards for further improvement.

What are the factors that will drive the change in the diagnostics sector in the coming times?

COVID 19 pandemic has increased awareness towards the need of preventive healthcare. Predictive testing is rapidly gaining momentum. Hence laboratories which will invest time and money in molecular testing will be benefitted the most as such tests are integral parts of personalized, predictive, preventive medicine.

With the rapid growth in the online healthcare space, laboratories should implement online test booking platforms and related digital services to reach the mass population. Digital pathology, point

of care testing, molecular pathology, integration of morphology and molecular pathology and automation are going to be the game changers in the future in vitro diagnostic industry.

What are your business expansion plans to align yourself to the changing requirements of the sector?

Apollo Diagnostics has already spent crores to achieve a high level of automation in the form of fully automated, high throughput Haematology and Biochemistry analyzers since the last few years. Further expansion by opening new centres are also on cards. The company has very recently set up its Diagnostics Global Reference Lab (GRL) in Hyderabad with a menu of over 3,000 tests to cater to its clients from across India and South East Asia. The infrastructure available here can support processing of over 1.5 lakh samples per day. It has the most modern molecular biology lab with RT PCRs, CB NAAT and GenXpert testing. The end-to-end biochemistry, immunology, and hematology services with flow Cytometry for routine testing on the same floor with immunofluorescence, are on par with the international standards. This Reference Lab is one of the few labs performing maternal and newborn screening tests in the country. We are also going to launch the latest Genetic laboratory very soon at this facility. Like all our laboratories, GRL will be frequently enrolled in stringent clinical laboratory proficiency testing (PT) programs that are used to validate our testing protocols. Periodic review of QC results is a frequent tool for maintaining quality control of patient samples. @

“Diagnostics is the foundation for good clinical care”

Dr Leena Appicatlaa, Head-Lab Services Pan India, HCG Enterprises Ltd shares her insights on the roadmap ahead for the diagnostic sector that evolving with the ongoing pandemic. Edited Excerpts:

What is the framework required for the creation of a futuristic Diagnostic Sector?

Diagnostics is the foundation for good clinical care. 30 years back, Clinical Lab diagnosis was still in an early stage, with, manual methods of estimation, no readymade kits and maybe a colorimeter to read the test results. Within 30 years, there have been rapid strides in this field, and we have reached the era of modern diagnostics and evidence-based medicine. Clinical diagnosis needs an appropriate and accurate lab report, for optimal patient care. Future of diagnostics should also look at the future of healthcare and modern medicine. The basic objective of a diagnostic test is to prevent, diagnose and/or monitor disease. Hence Lab diagnostics should be structured around a clinical framework. This would make the diagnostics approach more disease specific and add value to the patient care.

Further, we need to be clear as to what information we are providing to the user. And here comes the issue of the relevance of a test. If we are flooding the user with too much information, then the whole purpose of the test would be lost.

Looking into the legal and ethical aspects of healthcare is extremely

important. As diagnostics advances in the field of genomics, AI, precision and personalized medicine, vast amounts of human data are generated. The diagnostics industry needs to look into measures for ensuring data integrity and patient confidentiality.

Futuristic diagnostics must always keep the patient at the center of all developments.

How has Digitization and IoT accelerated the pace of Innovation in Diagnostics?

Sensors transmit patient information to healthcare professionals and researchers and the data is analyzed using AI, to make a timely diagnosis. Cloud computing has enabled a lot of these technologies. The IoT network enables quick communication between hospitals and labs. Thus, AI and IoT converge to design a smart healthcare system. For the Diagnostic sector, this means remote monitoring, real time data availability and better disease management. Several companies focus on designing biosensors for clinical purposes and there are interesting papers published in this area. In healthcare, we have several examples like Glucose monitoring devices, Monitoring of Parkinson's disease, connected inhalers etc.

The scope of innovation is huge and



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all of us need to be prepared for the advent of technological revolution in diagnostics.

What is the Scope and Opportunities in Lab Automation Market for enhancing diagnostics operations management?

There is a tremendous scope in the lab automation market. The beauty of Laboratory medicine is the immense propensity of automation at every step of the workflow. The first Autoanalyzer was invented in 1957 by Leonard Skeggs and commercialized by Technicon corporation. The Robot chemist was invented by Hans Baruch and commercialized in 1959. Since then,

the possibilities in automation in labs are endless.

Automation can be done at the all the phases of analysis and reduces errors, reduces reagent use, ensures accuracy of reports, and aids efficiency of lab operations. Nowadays we have robotics, AI, machine learning, deep learning, and computer vision which are all used for automating the Laboratory processes, for a seamless report delivery.

I was recently reading about solutions provided by Intel Technologies for Lab automation. Researchers at TGen sequence patient genomes, perform genomics analytics on a High performing computing infrastructure powered by Intel processors. This HPC hardware helps genetics counsellors and physicians to identify timely treatment options. It can also apply machine learning to massive data for precision medicine and opens immense possibility. In India, especially, healthcare is coming into the forefront with increasing public awareness and more investments in this sector, thus increasing the opportunities in Lab automation.

What are your views on the need for Accreditation for ensuring quality testing and outcome?

Accreditation should be made mandatory for all clinical laboratories. There are tangible and intangible benefits of accreditation. For instance, the level of staff training, staff awareness of processes, Lab doctors' involvement, error detecting mechanisms, in the Laboratory operations is deeply engrained in accredited labs. All this translates into reliable results and robust processes. Accreditation must be taken in the right spirit. It is often perceived as costly and labor intensive with lot of documentation. Healthcare organizations feel that they are anyway doing a good job, so why do they need an accreditation. However, an accreditation is like a Road traffic signal or an Air traffic Controller! It is no longer a good to have, it is right on the top of the priority list as a must have. Labs which focus on incorporating quality into their daily workflow, must go in for accreditation, as a commitment to their customers.

What are the factors that will drive the change in the Diagnostics

sector in the coming times?

The Covid 19 pandemic has thrown up several learnings and challenges for this sector and a lot of variability in the key focus areas is to be expected. I would say that the growth drivers for this sector would be preventive healthcare, home healthcare services, cancer genomics, molecular biology, and a rise of evidence-based medicine. Insurance penetration, rising income groups and a health-conscious population are going to be catalysts for this growth.

Technology is going to be a game changer and labs which deploy cutting edge technology, like digital pathology, with customer centricity, will be at the fore front. Labs must focus on in- depth clinical interactions, case discussions and accreditations, to benchmark their services. Indian diagnostics market is very diverse, and each geographical region or zone has its own drivers. Ultimately, labs must choose the focus regions and plan the services accordingly.

What is your business expansion plans to align yourself to the changing sectoral requirements?

I am privileged to work with HCG, the country's leading cancer care network with hospitals in India and abroad. The objective of HCG is to improve patient outcomes and Harvard Business School has studied the HCG model which delivers outcomes comparable to the best in the world. The future of Oncology would be molecular diagnostics, genomics, AI, digital pathology and precision diagnostics and HCG would be focusing on these areas, along with technological advancements in diagnostics, in the coming years. ☺



“AI has an important role to play in the healthcare offerings of the future”

Dr Shahzad Mirza, Associate Professor, Microbiology, Hospital Infection Control Officer, DYPMCH, Pimpri, Pune shares his views on the various facets required for the creation of a futuristic diagnostic sector.

What is the framework required for the creation of a futuristic diagnostic sector?

The need is to have amalgamation of the clinical data and expertise with IT and AI to ensure easy, speedy and correct information to aid the clinicians for better patient outcome.

Most important of these is Artificial Intelligence. AI has an important role to play in the healthcare offerings of the future. Machine learning is primary capability behind the development of precision medicine. Although current efforts are at providing diagnosis and treatment recommendations in future it might be a multifaceted affair. Already rapid advances of AI in imaging analysis have been made and also, speech and text recognition are already employed for patient communication and their usage will increase further.

How has Digitization and IoT accelerated the pace of innovation in diagnostics?

Digitalization and IoT is sort of a Nitro boost to a car which is not limited to the technology only but also the workflow of transforming that information. It is needed even by any high end machine or equipment to have a desired or better outcome. Recently, we have



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started to understand this during the pandemic that changes in the digitalization in workflow apart from the technology itself, like automated processes, has increased precision. When applied at a facility, this has made practices more consistent over time.

What are the scope and opportunities in lab automation market for enhancing diagnostics operations management?

Scope should be continual improvement at every opportunity. Automation makes the process

easy, decreases the turnaround time and chances of error is also minimised. It also ensures consistent and reproducible results and in turn improves the patients' and doctors' confidence

What are your views on the need for accreditation for ensuring quality testing and outcome?

Accreditation pushes institutions to meet and maintain their high standards. It not only benefits patients, but facilitates organisation with better clinical outcomes, better community coverage and also the healthcare workers.

What are the factors that will drive the change in the diagnostics sector in the coming times?

The emerging and re-emerging diseases, new infections requiring platforms for rapid diagnosis and a inclusion of a predictiveness with AI for the existing diseases is going to play a major role.

What are your business expansions plans to align yourself to the changing sectoral requirements?

We look forward to being associated with many organisations, institutions and groups that provide in depth perspective of these dynamic changes in diagnostics. ☺