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THE AWARE CONSUMER

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WORLD ACCREDITATION DAY

9 JUNE 2021

Accreditation: Supporting the implementation of the SDGs.

INTERVIEW
Mr. N Venkateswaran, CEO, NABL

Special Series on the role of NABL in India during COVID-19 pandemic

PLUS ROUND UP • MY MARKET • THE PRESCRIPTION

National Accreditation Board for Testing and Calibration Laboratories

NABL operates in accordance with ISO/IEC 17011: 2017

NABL is a full member signatory to Asia Pacific Accreditation cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRAs)

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VIEW POINT

MESSAGE FROM PUBLISHER & EDITOR

COVID-19
Role Of The Laboratory

JUNE 9TH 2021 marks World Accreditation Day (#WAD2021), a global initiative established by International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) to promote the value of accreditation.

This year's theme focuses on the use of accreditation in supporting the implementation of the United Nations Sustainable Development Goals (SDGs). It provides the opportunity for ILAC and IAF members to share examples with stakeholders, regulators and consumers of how accreditation may be applied to meet objectives such as increasing trade, addressing environment and health and safety concerns, and improving the general overall quality of output in an economy.

In 2015, 195 nations agreed with the United Nations that they can change the world for the better. This will be accomplished by bringing together their respective governments, businesses, media, institutions of higher education and local NGOs to improve the lives of the people in their country by the year 2030.

With primary health systems across the world groaning under the unprecedented burden of the pandemic, it is clinical testing that enables healthcare workers to quickly and accurately diagnose the SARS-CoV-2 infection and provide appropriate treatment and therapy. Rapid turnaround of reports is crucial for monitoring hospitalized patients with more severe complications. A positive test is also an indicator that the contacts of the infected person should be tested to control the spread of this deadly virus. A negative test report comes in handy to prove that the patient is safe and not liable to infect others.

Testing is not just limited to disease identification and patient monitoring. Serological testing of the antibody response helps in identifying whether a person was exposed in the past and got infected. It also enables epidemiologic surveillance of how many people have been infected, how the virus is spreading and determining the immunity level of the population. The results serve as a pivotal guide for policy decisions.

The clinical laboratories in India, on their part, have responded to the pandemic situation by developing, validating and implementing a variety of molecular and serologic assays to test for this new-found virus. The RT-PCR test is considered the gold standard for COVID-19 testing. This is a complex procedure that can only be conducted by experienced technicians, that too in sophisticated laboratories. On the other hand, the rapid antigen diagnostic test kits have been developed to give instant results and can be performed anywhere, at the bedside or in the field. The TrueNat and CBNAAT platforms have also been deployed for coronavirus testing – they have a quick turnaround time, but can test only limited samples per day.

Therefore, it is clear that medical laboratories and testing will continue to play a critical role till the end of this pandemic!

Prof. Bejon Kumar Misra
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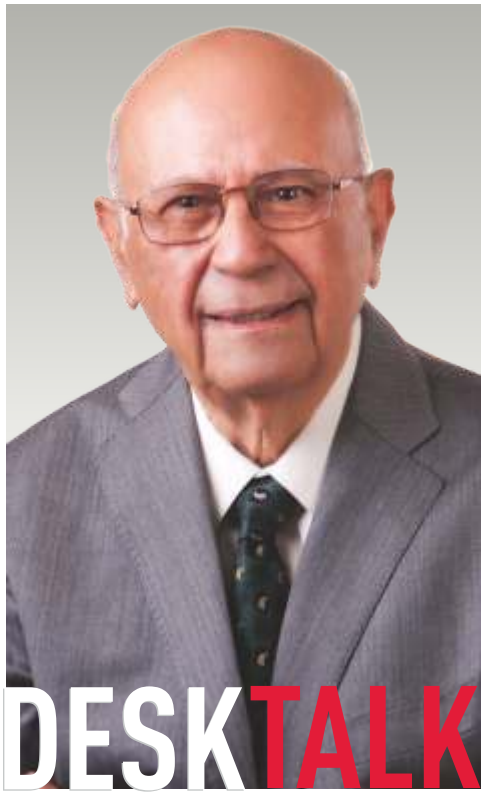

DESKTALK

HOW CREDIBLE ARE THE TESTING FACILITIES ?

ON THE OCCASION of WORLD ACCREDITATION DAY 2021: The theme this year is: Accreditation: Supporting the Implementation of the SDGs.

The pandemic has established the need for clinical testing, which has emerged as the first line of defence against the unexpected and lethal attack of the SARS-CoV-2 virus. The medical laboratories are crucial for identifying cases, informing isolation decisions and helping to curb the spread of the disease. They provide objective data to healthcare professionals that serves as a guide for appropriate clinical decision-making.

The importance of getting accurate results each and every time a test is conducted cannot be emphasized enough as incorrect results can lead to potentially fatal consequences. Safety in laboratories is another important issue; laboratory staff are at greater risk of exposure due to a higher concentration and invasiveness of the emerging pathogens.

It is commendable that laboratories from every part of the country are rising to the occasion and even readily ramping up their capacities to the parameters required for COVID-19 testing. But, given the level of reliance on test results, how can we trust that the labs are actually capable of delivering accurate, impartial and reliable test results?

Accreditation is globally acceptable as a public acknowledgment of an institution's standards of quality, illustrated by external independent peer review. In the COVID-19 context, this ensures both quality testing and correct interpretation of test results.

In India, the National Accreditation Board for Testing and Calibration Laboratories (NABL) is the chief accreditation body that provides conformity assessment accreditation through third-party validation of the technical testing capabilities of medical and calibration laboratories, proficiency testing providers and reference material producers.

Therefore, NABL recognition symbolizes the establishment's competence to carry out specific conformity assessment tasks. For clinical labs, it denotes accurate, reliable and efficient test results at par with international standards.

In fact, at the very beginning of the COVID-19 pandemic in March, 2020, the ICMR only identified NABL accredited medical testing laboratories that were capable of detecting the RNA viruses using the RT-PCR technique. Later on, it mandated NABL accreditation as the preliminary criteria for private medical laboratories to be listed for detecting the SARS-CoV-2 virus.

With the growing emphasis on accreditation and shift in priority from quantity to quality service in the diagnostic sector, we are poised to build a strong infrastructure of medical testing in the post-pandemic era!

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Serological testing - checking the presence of antibodies in the population is part of India's testing strategy in the fight against COVID-19.

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HORIZON

CAN WE STAND THE TEST OF THE PANDEMIC?

Accurate assessments of the extent of the virus are only possible with widespread testing. The WHO also stresses on extensive testing to overcome the pandemic. But can India enhance its testing capacity to the level of detecting all cases and breaking the chain of transmission?

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ROLE OF TESTING FOR COVID-19

While the world waits for substantial vaccinations across the globe and a potential cure, testing is the main weapon in our arsenal to get a grip over the relentless spread of the lethal COVID-19 disease.

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WILL THEY OR WON'T THEY – CAN TESTING DETECT NEW VARIANTS OF COVID-19?

Emerging variants of the SARS-CoV-2 virus present another cause for concern. Are the false negatives in RT-PCR tests on account of the new mutations?

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IN FOCUS

GLOBAL SPOTLIGHT ON COUNTRIES LEADING THE WAY IN COVID-19 TESTING

IAF and **ILAC** are pleased to announce the three winning designs in the **IAF/ILAC 2021** World Accreditation Day (#WAD2021) poster contest. This year's contest invited contestants to explore the WAD 2021 theme of **Accreditation: Supporting the Implementation of the Sustainable Development Goals (SDGs).**

Congratulations to Irene González, Soledad Pacheco, and Denise Díaz, who won the first-place prize of USD 1500. In their design, the accreditation infrastructure has been re-imagined as a colorful tree that supports each SDGs within its branches.

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CHAIRPERSON - FSSAI

FSSAI has recognized the role of credible, competent accreditation for inputs in decision making. This is because NABCB and NABL have worked closely to support Government and Regulators to ensure that the data provided by accredited conformity assessment bodies is robust, reliable, trustworthy in decision making, compliance testing and standards setting.

ROUNDUP

Multiple Measures Underway To Increase The Speed And Availability Of Testing

India's COVID-19 strategy is weighed down by an overload of testing and limited manpower.
The overburdened facilities have led to delays in results of suspected patients, sometimes by 72 hours or even longer. This causes delay in treatment of critically-ill patients as hospitalisation is based on the COVID-19 test report. It also increases the chances of spread of the infection.

DATA BRIEFING

SARS-CoV-2 (COVID-19) Testing Status

38,33,06,971

Cumulative total samples tested up to June 15, 2021

First Home-Based Rapid Antigen Testing (RAT) Kit For COVID-19

Quick detection is a powerful tool to break the chain of transmission of the SARS-CoV-2 virus. CoviSelf is the first home test that has got the regulatory nod in the country.

CoviSelf - India's first self-use rapid test for COVID19 – priced at Rs.250 per kit

ON MAY 19TH, 2021, ICMR gave a green signal to a home-based Rapid Antigen Testing (RAT) kit for COVID-19. The self-test kit, developed by Pune-based Mylab Discovery Solutions, allows people to test themselves within 20 minutes without the need for going to a lab or sample collection by a healthcare professional.

Right now, ICMR is advising CoviSelf home testing only in symptomatic individuals and immediate contacts of lab-confirmed positive cases to avoid overuse. Indiscriminate testing should be avoided as it will lead to shortage.

The apex health research body further reiterated that all individuals who test positive may be considered as true positives and no repeat testing is required. However, all symptomatic individuals who test negative should get themselves immediately tested by RT-PCR, because RAT testing can miss some positive cases that have a low viral load. These people should continue to be considered as suspect COVID-19 cases and follow the standard home isolation protocol measures while awaiting the RT-PCR test result.

Ease of Use

The self-kit requires only a nasal swab - it takes 2 minutes to conduct the test and 15 minutes to get a result. The testing procedure is described in the user manual. Both pictorial and video instructions are available on the mobile app and website. The ICMR has also issued detailed guidelines on how to use it.

The person undertaking the test has to download the Mylab CoviSelf app on the mobile phone from the Google Play store or Apple store, fill in the credentials and scan the QR code on the test card to link it with the credentials on the app.

Each kit has a pouch containing the testing materials like a sterile nasal swab, pre-filled extraction tube, one test card and a biohazard waste bag to safely dispose the items after testing.

Gently insert the swab inside both the nostrils (2 to 3cms) and roll it five times inside each nostril. Then dip the swab in the tube, pinch the tube at the bottom and

Testing on Wheels Increases the Outreach of COVID-19 Testing Manifold

First mobile lab for COVID-19 testing

Mobile testing labs present the best approach for addressing the severe shortage of critical testing facilities in the COVID-19 pandemic. This will not only increase the scope of testing, but also enable easy access to the facilities.

swirl the swab 10 times to ensure that it is properly immersed in the tube. After this, break the swab from the breakpoint. Press the tube to add two full drops into the sample well of the test device.

The test strip will have two sections - the control section and the test section. If the bar appears on both the control (C) section and test (T) section, the test is positive. But if a bar shows only at the C section, the result is negative.

All users are advised to click a picture of the test strip after completing the test procedure with the mobile phone on which the app has been downloaded. Data from the app will be centrally captured in a secure server which is connected with the ICMR COVID-19 testing portal for storing the data.

On 2nd June, ICMR approved the second home-based RAT kit developed by Chicago-based Abbott Rapid Diagnostics Division. The 'PanBio Covid19 Antigen Test Device' has been given provisional approval till 5th July after which the pricing will be declared by the company.

Manufacturer instructions must be strictly followed for disposal of the used test kit, swab and other materials.

Conclusion

Home-based RAT kits are the answer for making testing widely available and accessible, especially in the rural and remote areas. This will ease the burden on the already overstretched testing labs and reduce delays in results.

As the infected cases are quickly detected, people can get prompt treatment and recover much sooner. Another benefit is that as symptomatic patients will not have to step out for the testing, it will further lower the risk of transmission. Quick and early testing will also help control the spread of the disease.

Continuing its fight against COVID-19, Pune-based Mylabs is now mobile testing labs across the country to address the increasing demand for coronavirus testing.

INDIA HAD SET up its first mobile testing laboratory in June 2020 to meet the growing demand for COVID-19 testing and also extend testing facilities in remote and inaccessible areas of the country.

The I-Lab (Infectious Disease Diagnostic Laboratory) was developed within eight days by a team from Andhra Pradesh MedTech Zone Limited with support from the government department. This Biosafety level 2 (BSL-II) lab has the capacity to run 50 RT-PCR and 200 ELISA tests in a day.

Launched by Union Health Minister, Dr. Harsh Vardhan in New Delhi, the van is regularly deployed in the interior and inaccessible parts of the country.

Scaling up testing across the country with mobile testing labs

Many more mobile testing vans started following very soon and 16 ICMR-approved COVID-19 labs-on-wheels are operational now.

ShanMukha Innovations, a start-up incubated at Society of Innovation and Development (SID), Indian Institute of Science (IISc), announced the launch of its Mobile Infection Testing and Reporting (MITR) Labs in July 2020. It provides end-to-end RT-PCR-based testing with a processing time of just 4 to12 hours for confirmatory tests of COVID-19.

Spice Health launched its first mobile lab for COVID-19 testing at ICMR in November 2020 with a plan to provide 20 such facilities boasting of a capacity to conduct 3,000 tests per day with a turnaround time of 24 hours. They are NABL accredited and duly approved by ICMR. Three such laboratory vans were recently launched in Mumbai in February 2021.

By April 2021, Mylab Discovery Solutions had rolled out three mobile testing vans in Mumbai, one in Pune and one in Goa. It announced that it will deploy 50 more such high-volume mobile testing labs (ICMR-approved and NABL-certified) across the country to meet the huge backlog in RT-PCR testing amidst the second wave. Equipped with advanced machines that can handle parallel processing and automated handling, the vans can conduct testing three times faster than conventional labs and process 1,500 to 3,000 tests per day. These vans are automated and have very low need for human intervention which allows them to process samples continuously round the clock.

At the end of May 2021, the UP government also launched 11 COVID-19 testing vans in Lucknow. It further planned to add four government testing vans and seven private vans in collaboration with seven private labs to visit the homes of suspected COVID-19 patients and collect samples.

All the mobile labs are on par with conventional labs in terms of quality and reliability of testing – they use certified products and equipment, meet all testing parameters and have necessary safety protocols in place.

Conclusion

These mobile testing vans can be parked in a designated area or moved across localities, including slums and remote areas, thus providing easier and faster access to testing. They can also be quickly deployed to emerging hotspots and containment zones, thus controlling the spread of the infection.

Drive-Through Screening For COVID-19

The drive-in culture is being innovatively exploited for COVID-19 testing. Drive-through facilities are springing up in various cities to ensure testing with ease. They bring convenience right to the vehicle of suspected patients while increasing testing with safety protocols and contributing to mitigating the risk of the virus.

Swab collection for COVID-19 testing at a drive-through facility

The first drive-through COVID-19 testing centre in Delhi

ONE OF THE innovative modes of COVID-19 testing is a drive-through test. The first-of-its-kind drive-through COVID-19 testing centre was set up way back in April, 2020 by Dr Dang's Lab in Delhi. By the next month, SRL Diagnostics had also established similar centres in Mumbai, Gurugram and Chandigarh.

Similar drive-through testing kiosks have recently been set up in various towns and cities like Kolkata, Ahmedabad, Hyderabad, Pune and even Bhopal, Indore and Salem with many more in the pipeline. They now collect samples and deliver results even without a doctor's prescription.

All that a person has to do is pull up in a car (even bikes are allowed now) to a drive-through testing centre with a government identification like Aadhaar card, Pan card or passport. Some centres require scanning a QR code in the mobile provided by the lab and registering the information. Many of them even offer a completely digital and contactless process right from registration to payment.

A healthcare worker in protective gear will walk up to the car and take the nasal and/or throat swab of the driver and/or passengers through the window itself. You don't even have to leave the vehicle - just roll down the window, tilt our head and let the technician do his job!

The sample collection is done in a matter of minutes while remaining in the vehicle itself. Apart from being time-saving, it is also a safer option than home collection where the technician coming for the test itself poses a risk as he would have gone to several other houses to collect samples. Besides this, it ensures minimum exposure for the frontline workers even as it prevents asymptomatic patients from contaminating a public health facility.

These sample collection kiosks maintain quality and integrity in their operations. Quality processes, accuracy in testing and reliability of results is assured at all times.

Conclusion

Going for COVID-19 testing in a laboratory can take hours as there is scant manpower, limited resources and overcrowding. Rather than having to wait for so long, drive-through testing kiosks make testing quick, easy and safe while also reducing the risk of spreading the infection. And it goes without saying that the rate of testing will also ramp up manifold!

Source: Secondary research & media reports

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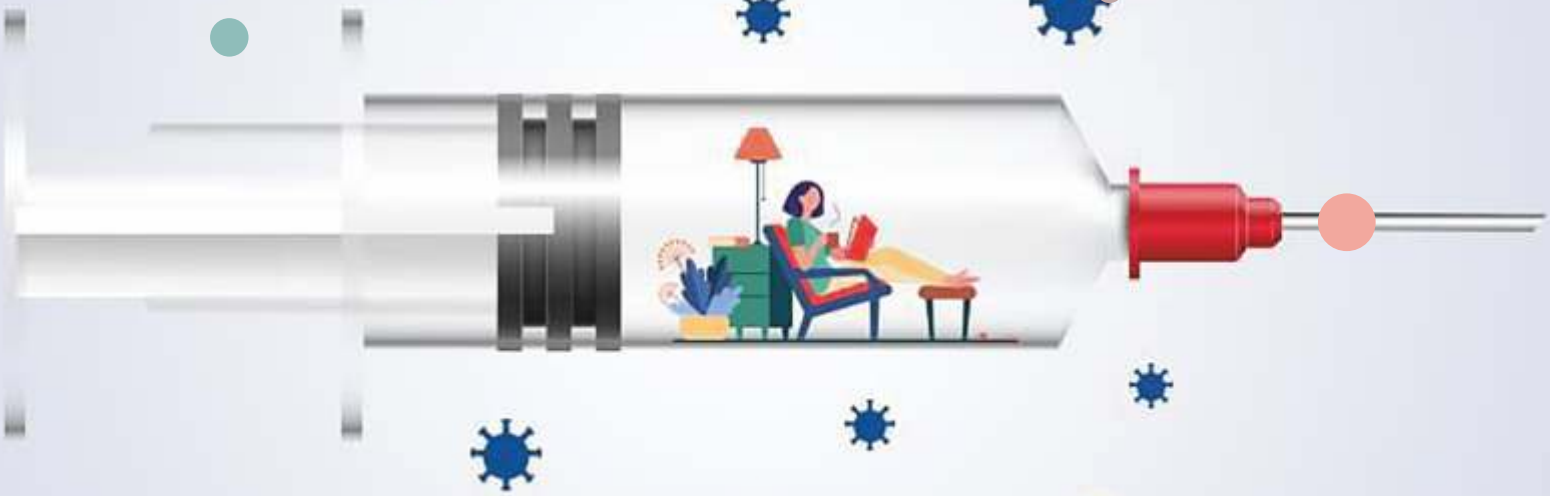

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Rajiv Nath

- Mg.Director@ HMD
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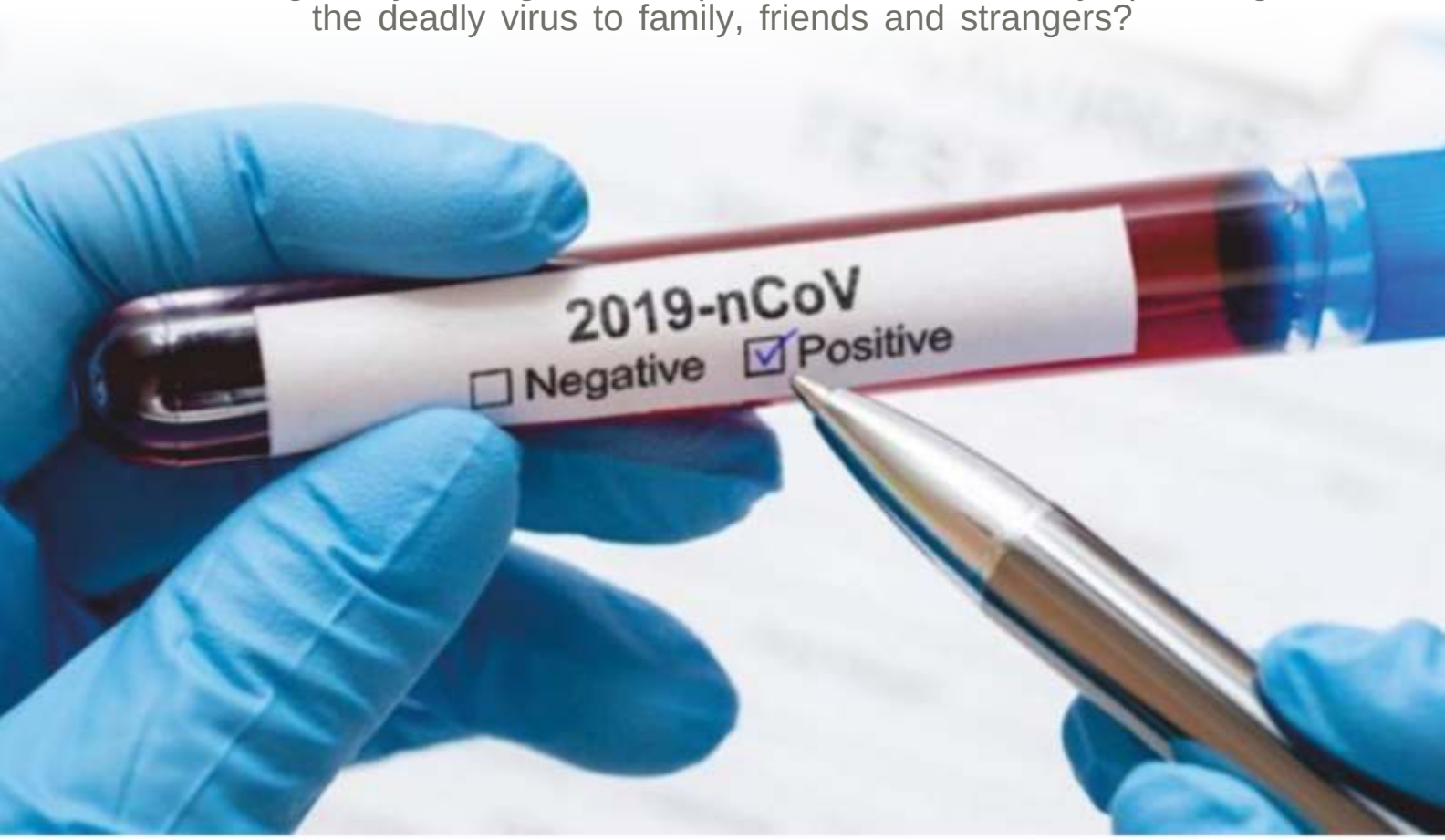
"Not every war is won on a battlefield. Some wars can also be won sitting at home."

#Stay**Home**Stay**Safe**

Consumers, Beware

The Broad Canvas Of Illegal COVID-19 Testing

What if you test positive for COVID-19 and live through two weeks of quarantine in fear while taking all the necessary medications, checks and precautions only to find that you had not contracted the infection at all? Or, what if you get a negative COVID-19 report after having some flu-like symptoms or coming into contact with an infected person, but later come to know that the report was wrong/fake? Will you be able to forgive yourself for roaming freely among the unexposed and inadvertently spreading the deadly virus to family, friends and strangers?



Is the hand an authorized one or unauthorized?

LABORATORY TESTING FORMS the first and most important step for managing the COVID-19 disease. While the ongoing pandemic is straining our healthcare systems and devastating the economy, it is diagnostic testing that helps cap the spread of the virus in the community.

Given the dependence on test results, can we afford flawed or fake results? What if the person or agency collecting the samples turns out to be duplicitous?

Alas, illegal medical labs are a dirty secret of India's healthcare system. The technicians are not trained, the pathologists are not skilled, the services are not up to the standard and the reports are obviously not reliable. Even illicit technicians are cropping up to take advantage of the public's helplessness in the face of the pandemic.

It's Happening Everywhere All the Time

In July 2020, a lab technician in Hyderabad was running a scam by going to people's homes to collect their blood samples and charging Rs. 5500 for the COVID-19 testing, without any intention of conducting the tests. In April 2021, another instance of a lab technician's fraud came to light in Mumbai – he went to the COVID suspects' doorsteps to collect their samples but only sent the symptomatic cases to the lab for testing. For the asymptomatic ones, he issued forged results by modifying old COVID-19 negative test reports and pocketed the money.

In November, 2020, there was another health worker in Porbandar, Gujarat who collected samples from COVID-19 suspects without authority and sent them to a private lab in an unauthorized vehicle.

Similar news reports are surfacing on a frequent basis of innocent, unaware and scared consumers being easily conned by such scamsters.

In August, 2020 itself, the Delhi High Court had directed the state government to take action against illegal online health service aggregators that were misrepresenting themselves as medical diagnostic laboratories and collecting diagnostic samples for testing for COVID-19 infection. These aggregators are neither authorized nor approved/accredited and yet operate in an unconstrained manner, thus duping the gullible public.

However, even till March 2021, the state had not taken any action on the judicial order to regulate online health service aggregators and pathological labs and the court threatened to initiate contempt proceedings.

There are many more instances of illegal pathology labs and technicians openly advertising COVID-19 tests at attractive prices through pamphlets, SMS, emails and other online modes, thus playing with the lives of the common people.

Pandora's Box of Troubles

These kinds of illegal activities are risking lives in more ways than one. Giving a negative report to a COVID-19 positive person not only deprives him of appropriate treatment but also endangers many other people who may come into contact with the infected person.

Moreover, the swab collection without appropriate training can end up causing unnecessary harm to the patient. What's more, when the infection control protocols are not followed, the scamsters themselves can end up getting infected with the COVID-19 virus. After all, many of them only wear masks and may not even store the samples properly. Lack of due precautions in the disposal of the biomedical waste can also open up an explosion of impending dangers for the community.

Everyone is out to make a quick buck. Crooked folks and even labs are issuing fake negative RT-PCR test reports to help people travel abroad or even between states. Some travel agencies have also tied up with diagnostic labs to collect swabs and issue fake no-Covid reports.

Protecting Yourself from Frauds

The harsh fact is that the authorized testing labs are overrun in the wake of the furiously rampant second wave of the pandemic. Weighed down by massive backlogs, it can take as much as 3 days to book a slot for a test and as many to get the report. Meanwhile, many hospitals

Many laboratories have now started providing QR codes on RT-PCR test reports after cases of unscrupulous people editing the reports. The QR code connects to the lab portal where the test results and other details can be verified.

On 22nd May, 2021, the Union Ministry of Civil Aviation decreed that passengers travelling abroad should carry a negative RT-PCR report with a QR code. The rule is applicable to passengers who are required to carry a negative RT-PCR test report as per the guidelines issued by their destination countries. Some states are also mandating this rule for inter-state entry.

refuse to admit even critically-ill patients unless they have a positive report. People are also struggling to get the blood tests, X-rays or CT scans prescribed by doctors for managing the deadly infection.

In this scenario, it is easy to fall prey to the scamsters and illegal operations. Desperation and fear for the life of loved ones can drive people to trust just about anyone. Especially the offer of doorstep collection and online reports can seem irresistible.

Despite the emergency, it remains crucial that the consumers should take due precautions like:

- Book the test through the official website of the lab after affirming the legality and legitimacy of the testing authority on the government portal
- Check the identity card of the technician who comes to take the sample and take a photograph of the same
- Insist on a receipt for the payment
- Never book a test with someone who advertises their services or circulates their number on Facebook, WhatsApp or other social media platforms

Conclusion

The government should also come down hard on the illegal labs and fraudsters as they pose a serious threat to the life and safety of the citizens of the country.

Source: Secondary research & media reports

Comparing The SARS-Cov-2 Antibody Seroprevalence In India Across Three National Serosurveys

Serological testing - checking the presence of antibodies in the population - is part of India's testing strategy in the fight against COVID-19. Three consecutive national serosurveys have estimated the true prevalence of the disease (both symptomatic and asymptomatic) as against what is reported through regular tests.

EVER SINCE THE breakout of the respiratory tract infection, coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, terms like quarantine, pandemic, symptomatic, asymptomatic and lockdown have become local parlance. One more term that has become part of our coffee table or 'Zoom call' discussions is serosurveys.

As all of us are aware, the SARS-CoV-2 virus has infected millions of people across the globe. While many of the people with symptoms of the illness are identified with tests and treated accordingly, many of the asymptomatic folks escape the net of detection. So, how is a country or state to gauge the continued prevalence of the virus without clearly being able to identify how many people have actually been infected?

This is where serological studies enter the picture.

What happens is that the body naturally comes up with an immune response after exposure to the virus. These antibodies are made irrespective of whether the person had symptoms or was asymptomatic. While the infection dies down after a few weeks or so, the antibodies continue to linger in the blood for months.

A serosurvey uses serology tests to examine the serum (liquid part of blood) to check for antibodies. If the test detects sufficiently high quantities of the Immunoglobulin G (IgG) antibody, it shows that the person has been infected in the recent weeks/months and is considered sero-positive.

Dr. Jyotismita Pathak, Assistant Professor, Army College of Medical Sciences, Delhi explains the role of serosurvey, “An iceberg has a visible section which floats above the waterline, however, there is a larger, invisible section submerged in the water. Similarly, in the case of any infectious disease, we get to know about the cases that are reported; like, the COVID-19 numbers you see on state and national health portal. But there are cases that don't come to notice for various reasons – they are asymptomatic, or people didn't report. So, a serosurvey focuses on that submerged portion of the iceberg and tells us what the infection-to-case ratio is.”

Moreover, determining the proportion of population that has been exposed to the virus and has developed immunity against it gives an estimate of how far we are from achieving herd immunity. The sero-findings have served useful for planning both vaccine trials and deployments.

On a micro level, the results provide insight into which age groups/gender are at higher risk of getting the infection and which areas (urban/rural) are more exposed and containment efforts need to be strengthened. And the most crucial use of serosurveys is to monitor COVID trends and plan effective public health policies accordingly.

Blood sample collection for a serological survey drive

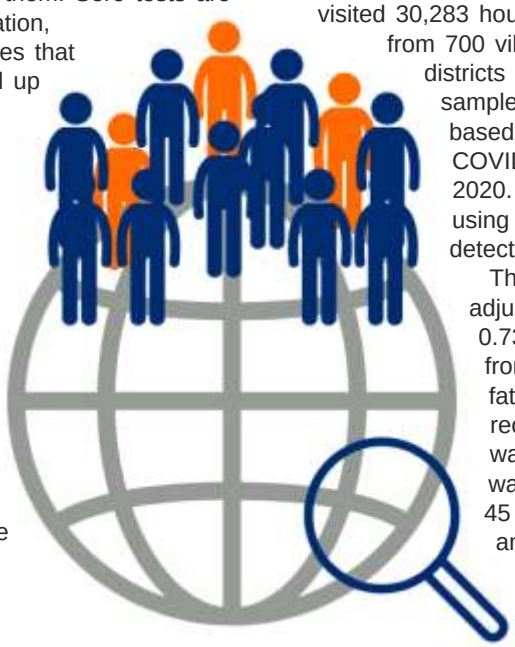
How Is Serological Testing Done?

Serological testing involves collecting blood samples of healthy people and testing them for IgG antibodies. As the sampling remains random, people cannot enrol for the testing.

However, it is not possible to test the entire 1.3 billion people in India or even a majority of them. Sero tests are conducted on a sample of the population, selected based on sampling techniques that ensure that the results can be scaled up to the entire population.

Sero-Surveys in India

SARS-CoV-2 sero-surveys are being conducted almost around the world and returning wide variations in the proportions of sero-positive individuals. In India, the Ministry of Health and Family Welfare (MoHFW) has also planned population based sero-surveys in representative samples to measure the spread of the infection. So far, three pan-India sero-surveys have been conducted by the ICMR and the National Centre for Disease Control in collaboration with key stakeholders and state health departments. Apart from this, many serological studies have been repeatedly conducted in different cities and states to measure the percentage of the population exposed to the disease.



- **First National Population-Based Serosurvey** - From 11th May to 4th June, 2020, a team of researchers visited 30,283 households and enrolled 28,000 adults from 700 villages and wards (urban) in 70 districts in 21 states of the country. The samples were categorised into four strata based on the number of confirmed COVID-19 cases there until 25th April, 2020. The serum samples were tested using the COVID-19 Kavach ELISA detection kit.

The national prevalence (after adjusting for test performance) was 0.73% - ranging across all four strata from 0.62% to 1.03%. The infection fatality rate (IFR) which is the ratio of recorded deaths to estimated cases was found to be 0.08%. Seropositivity was highest among adults aged 18 to 45 years with 43.3% having developed antibodies against SARS-CoV-2 virus

Wearing a face mask in public helps prevent the spread of COVID-19

making them the worst-affected age group followed by those aged 46 to 60 years with 39.5% testing positive. The least-affected were those older than 60 years with a seropositivity of 17.2%.

The seropositivity rate was highest in rural areas at 69.4%, while it was recorded at 15.9% in urban slums and 14.6% in urban non-slums. Moreover, males living in urban slums and occupations with a high risk of exposure to potentially infected persons were associated with seropositivity.

The prevalence percentage translates into a cumulative 6.4 million adults being exposed to the novel coronavirus by early May 2020 which is in stark contrast to India's reported case load of only 52,592 on 7th May. Going by this infection-to-case ratio, for every 1 person who tested positive on an RT-PCR test and entered India's official case tally, 82 to 130 more people were actually positive!

The overall seroprevalence was low with less than 1% of the adult population exposed to COVID-19 by mid-May 2020 and most of the population remained susceptible to infection.

■ **Second National Population-Based Serosurvey** – From 17th August to 22nd September, 2020, India went in for another round of serological testing, this time to estimate the prevalence of SARS-CoV-2 infection among individuals aged 10 years and above. It should be noted that by the end of September, India had reported the second highest number of COVID-19 cases in the world.

The survey was conducted in the same 700 villages/ wards from 70 districts from 21 states covered during the first survey. Blood samples were collected from 29,082 individuals from 15,613 households and tested using the Abbott SARS-CoV-2 IgG assay.

The weighted and adjusted national seroprevalence was 6.6% in people aged 10 and above, while 7.1% of adults aged 18 and above showed evidence of past exposure to COVID-19. The infection fatality rate (IFR) continued to be 0.08%. The seroprevalence was largely similar across age groups, sex and occupation. All 70 districts showed a rise in seropositivity between the two surveys, although the change was highly variable.

However, urban slum areas had higher COVID-19 infection prevalence at 15.6%, followed by urban non-slum (8.2%) and rural areas (4.4%). Therefore, the risk in urban slums was twice than that in non-slum areas and four times than the risk in villages. Yet, there was substantially more transmission among the rural population as compared to the previous survey largely due to large migration of people from urban to rural areas.

The prevalence percentage translated into a cumulative 74.3 million infections in the country with 1 in 15 individuals aged 10 years or older having been

infected by 18th August, 2020. However, India's reported case load totalled to only 6.3 million cases by the end of September. This means that for every confirmed COVID-19 case in August, the country had missed identifying 26 to 32 infections.

This significantly lower infection-to-case ratio (down from 81 to 130 in May) highlights the effect of the considerable scaling up in testing and detection as well as improved contract tracing across the country. Yet, it should be noted that the adult seroprevalence increased almost tenfold in the same period.

The overall seroprevalence of below 10% was actually worrying as a large proportion of the population had not yet been exposed to the virus and remained susceptible to COVID-19 infection.

■ **Third National Population-Based Serosurvey** – The third round of serological testing was conducted from 7th December, 2020 to 8th January, 2021, two weeks before the vaccination drive kicked off.

Blood samples were collected from 28,589 individuals aged 10 and above from the same 700 villages or wards in 70 districts in 21 states selected during the first and second rounds of the national serosurvey. For the first time, blood samples of 7171 healthcare workers were also collected.

Antibodies to SARS-CoV-2 virus were detected in 21.4% of adults. The seroprevalence was 25.3% in children aged 10 to 17 years while 23.4% of those aged 45 and above tested positive. Women showed slightly higher seropositivity at 22.7% while it was 20.3% in men. 25.7% of the health workers had also been exposed to the novel coronavirus. The infection fatality rate (IFR) dipped to 0.05%, or 1 in 2000.

Seropositivity was highest in urban slums at 31.7%, followed by urban non-slum areas at 26.2% and lowest in rural areas at 19.1%. However, between the second and third surveys, seroprevalence roughly doubled in urban slums, almost tripled in urban non-slum areas, and nearly quadrupled in rural areas.

Based on the overall prevalence percentage, around one in five Indians or approximately 28 crore of the population had been infected by SARS-CoV2 by mid-December 2020 while India's official reported case load stood at 1.07 crore.

The increase in seroprevalence was over three-fold compared to the second survey. But the most worrying fact was that more than a quarter of the children aged between 10 and 17 may have already contracted COVID-19, higher than the overall population found to have been infected.

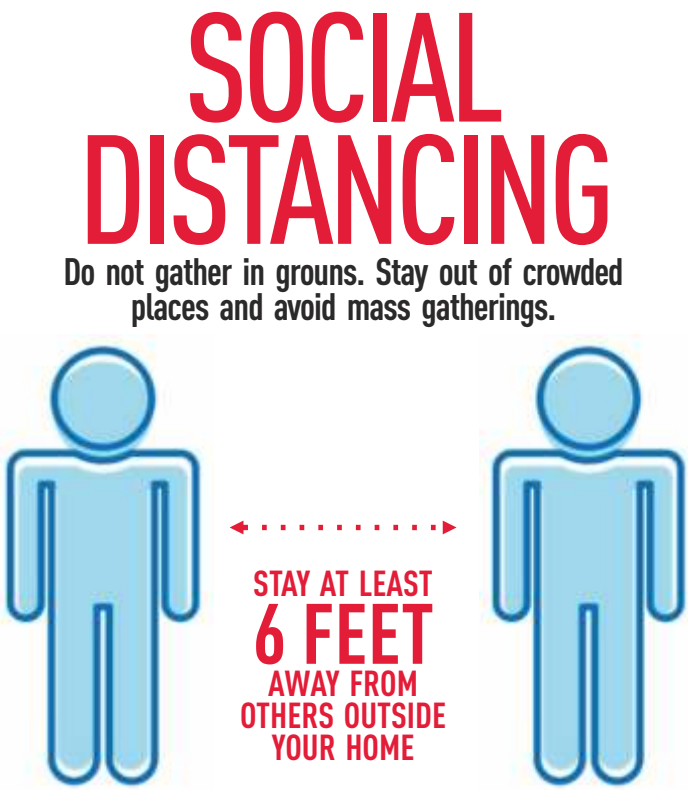
Experts voiced caution due to the large proportion of the population still remaining vulnerable to the infection coupled with the significantly underestimated prevalence of the third national serosurvey. Yet, they were drowned out as the country was rejoicing in both the hugely improved detections and the national wind-down evident from the decline in daily cases.

This turned out to be an early celebration as we were just on the brink of a massively devastating second wave of COVID-19 infections!

Conclusion

It is clear that the country needs regular serological testing to follow the footprints of the SARS-CoV-2 virus as it moves through the communities. The fourth serosurvey has been long-delayed and the ICMR planned to roll out the next one in June.

To extrapolate from the success of the serosurveys, all citizens (especially in villages and urban slums) must have mandatory health check-ups every two years in the primary health centres and other health and wellness centres in the country. The testing should be digitised and analysed by experts to predict prevalence of certain diseases and forecasting epidemics in the future.



In fact, the entire population should be required to undergo regular health checks and the results uploaded on a government portal so that it can be carefully scrutinised by the experts. Here, maintaining privacy and security of the personal data of the citizens is also crucial.

Such expansive exercises call for collaboration between the MoHFW, state governments and ICMR, along with other research bodies in the public and private sector.

Source: Secondary research & media reports

95% Of Indian RT-PCR Labs Tested By WHO Panels Pass Quality Test

Different methods are used around the world for COVID-19 testing. RT-PCR tests are generally more sensitive and reliable than antigen tests. However, the former also have to be regularly checked for accuracy.

THE FIRST COVID-19 test in India was conducted on 23rd January, 2020 at ICMR's apex virology laboratory, National Institute of Virology in Pune. We got our very first confirmed case on 30th January when a medical student came back to her native state of Kerala from the Wuhan University in China, the epicentre of the pandemic.

The world has not been the same again with positive cases spiralling by the day. The subsequent two waves brought the critical role of diagnostics into sharp focus. Indeed, accurate and quality testing is the first step for treatment, control and even prevention of the COVID-19 disease.

In the words of WHO Director-General, Dr Tedros Ghebreyesus, “Access to quality tests and laboratory services is like having a good radar system that gets you where you need to go. Without it, you're flying blind!”

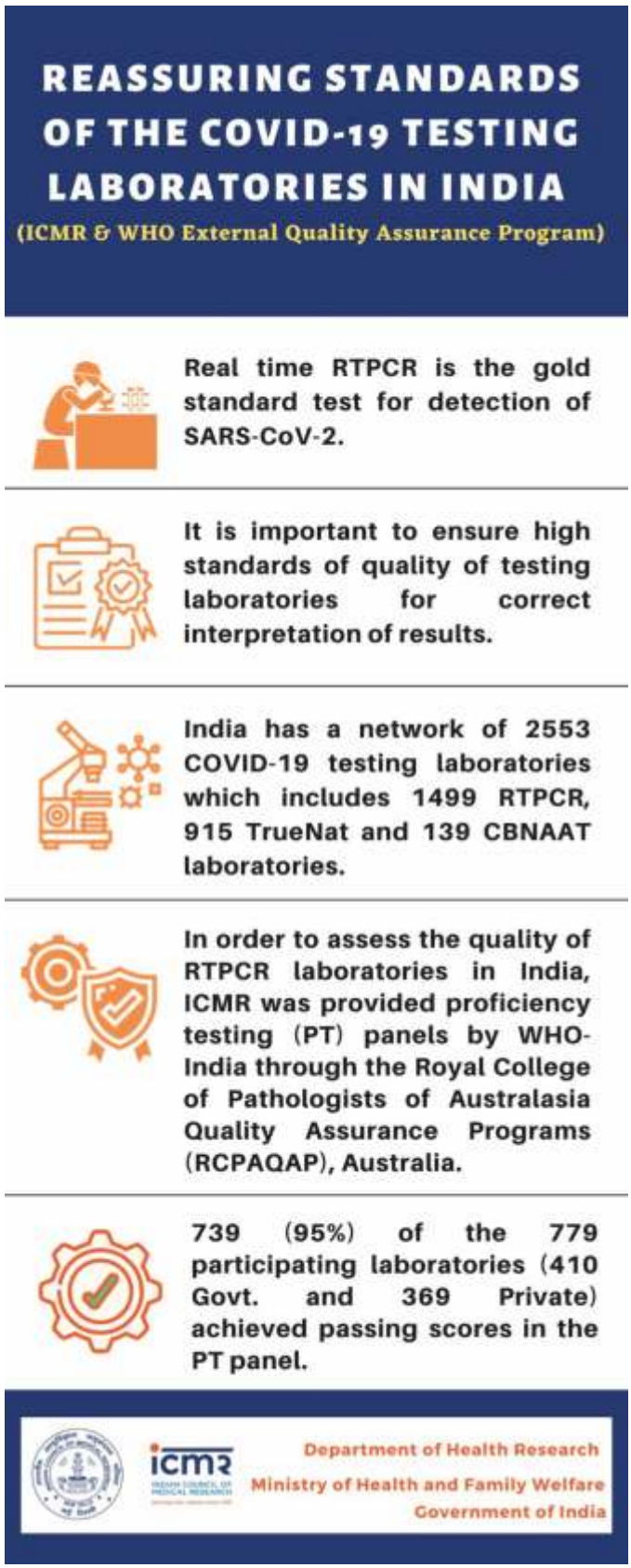
ICMR has been at the frontline in containing the contagion - in terms of testing, treatment, isolation, recovery and other guidelines. While targeting a focused increase in the country's arsenal of testing facilities, it mandated NABL accreditation as the criterion for recognition of private medical laboratories for testing the SARS-CoV-2 virus. The accredited labs have to abide by stringent quality control procedures before arriving at test results. Several other quality measures have also been implemented to ensure precise, reliable and efficient test results at par with international standards.

Adherence to the practicable aspects of quality is crucial in COVID-19 testing laboratories as it provides assurance of the reliability and standards of the laboratory functions. The RT-PCR tests being conducted in India have passed the proficiency tests conducted under ICMR and WHO's Quality Assurance Initiative.

Indian RT-PCR Tests Pass WHO Exam with Flying Colours

As part of the External Quality Assurance Program (EQAS) for substantiating COVID-19 testing standards and efficiency of Indian laboratories, 779 RT-PCR testing labs recently underwent quality assurance testing at specific Proficiency Testing Panels (PT) provided to ICMR by WHO India. Of these 779 labs, 410 were government and 369 were private.

The results were announced on 20th May, 2021 - 95% of the participating laboratories achieved passing scores in the proficiency testing panel. Indeed, 735 labs proved to have generated accurate reports of the samples tested and passed the quality test by the WHO panels.



The ICMR release on 20th May, 2021

Speaking on the occasion, ICMR Director General, Balram Bhargava decreed that there will be 45 lakh tests by the end of June, of which 18 lakhs will be RT-PCR tests and 27 lakhs will be RAT.

About EQAS

External Quality Assurance Scheme (EQAS) is a valuable tool for assessing the performance of a laboratory through periodic and retrospective checks by an independent external agency. Also known as proficiency testing, this will analyse the accuracy of the entire testing process from receipt of sample and testing to reporting of results. The results show the maintenance of quality services and reliability of results of the lab while revealing any shortcomings in the performance.

Apart from the WHO-prescribed panels, ICMR-NARI has also established a proficiency testing provider unit for providing external quality assurance (EQA) to the labs. The institute has been accredited by NABL as a proficiency testing provider.

Along with external assessments, NABL also prescribes Internal Quality Control (IQC) in the form of a set of procedures undertaken by the lab personnel for the continuous and immediate monitoring of lab work in order to ascertain whether the results are reliable enough to be released.

Role of NABL

NABL helps in sustaining and improving the conformity assessment infrastructure of the nation. The Board is an autonomous body providing third party attestation that works as a formal demonstration of a laboratory's competence to carry out specific conformity assessment tasks.

Consumers can easily search for NABL-accredited labs on the website www.nabl-india.org >> Laboratory search >> accredited labs >> Country: India >> field: Medical>> Group >> (please click on Molecular Testing) >> Search. The details of the labs will get displayed below the open menu. Click on 'Click here to view the scope of accreditation' of the laboratory. Another menu will open up. Click on MC-XXXX to view the certificate and accredited scope of the laboratory. Using this search mechanism, one can authenticate whether the laboratory claim of being accredited by NABL for particular tests are valid. The ICMR also lists the COVID-19-accredited labs along with their scope on its website www.icmr.gov.in/.

Conclusion

The excellent results of the WHO proficiency test reinforce the importance of NABL accreditation and the role of accredited laboratories in ensuring the safety of the citizens. NABL is spreading awareness about the benefits of accreditation of medical laboratories so that more laboratories come forward to obtain accreditation and devote their services to the service of the nation.

Indeed, India has more than 1 lakh organized and unorganized laboratories of which only 6000 odd facilities have been accredited. The sector still remains highly fragmented with unorganised standalone centres accounting for 50%, hospital diagnostic centres having 15% and the remaining 35% attributed to organised players.

Source: Secondary research & media reports

Can We Stand The Test Of The Pandemic?

Accurate assessments of the extent of the virus are only possible with widespread testing. The WHO also stresses on extensive testing to overcome the pandemic. But can India enhance its testing capacity to the level of detecting all cases and breaking the chain of transmission? What are the emerging scenarios for COVID-19 testing?

India's COVID-19 testing is falling short once again with the second wave overwhelming its testing infrastructure

RIGHT AT THE beginning of the pandemic, inadequate testing was red flagged as the biggest inadequacy of India's COVID-19 response. More than a year later, even after the waning of the colossal second wave of the fatal infection, lack of aggressive testing is still to blame for the rapid spread of this earlier-unknown virus.

Indeed, our testing infrastructure proved to be woefully insufficient and underprepared even during the second wave with testing abysmally failing to keep up with the soaring caseloads. The average daily new cases recorded during the second wave grew more than four-fold compared to the peak of the first wave, while the daily average testing grew only by 60% during the same time.

Fact of the matter is that even after the gargantuan scaling up of our testing capacity, we are still way below the testing levels of other countries - our testing ranks lower than that of 112 other countries. The average rate of testing is about 1.4 per 1,000 people as compared to 15 in the UK, 22 in UAE and 29 in Denmark (May 2021).

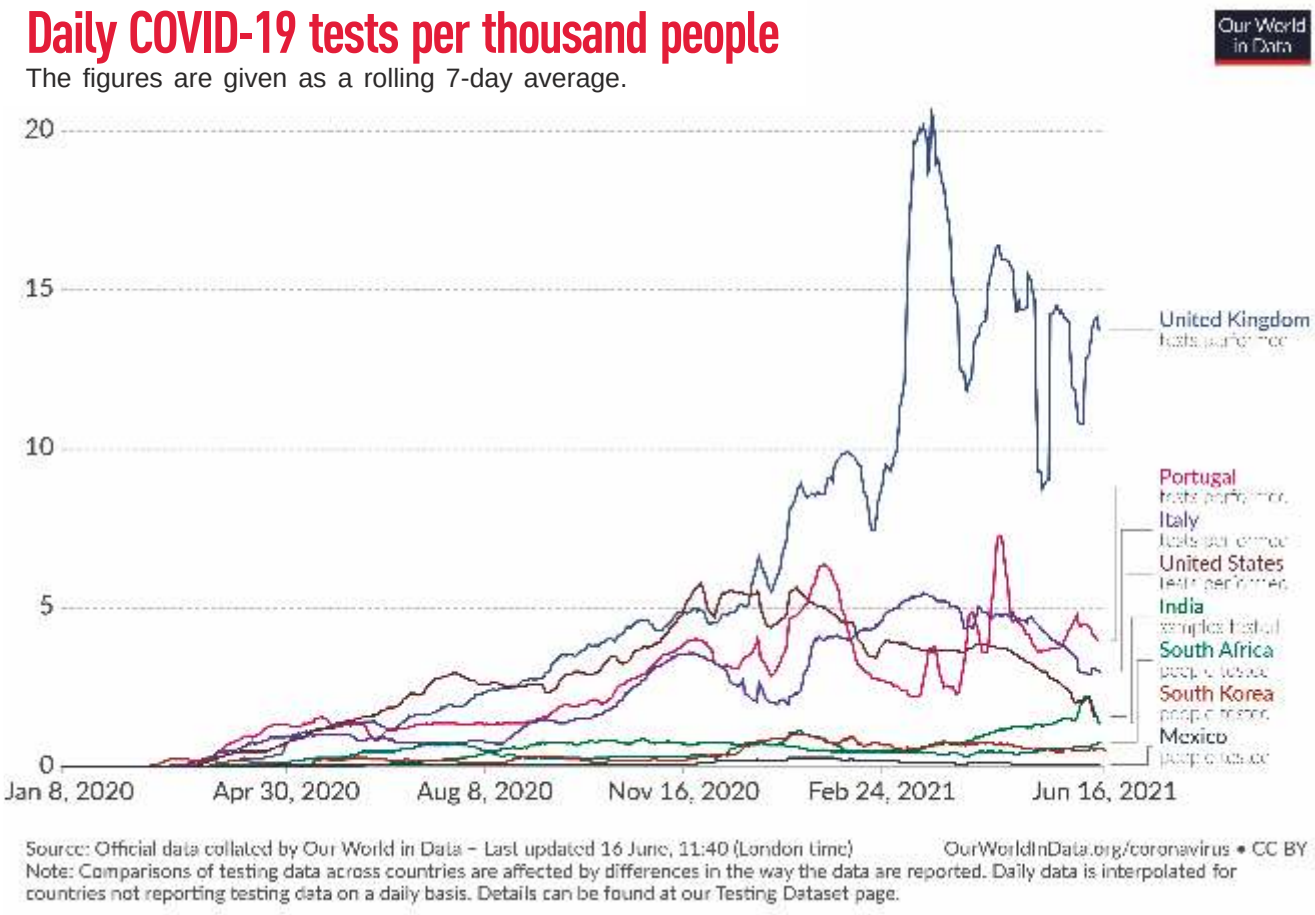
It's not just about the sub-par testing numbers; testing is also highly variable across the country as the different states are not conducting lab tests on a similar frequency. The tests range from a low of just about 76 tests per 1,000 people in Nagaland to 1,314 tests per 1,000 people in Lakshadweep. Among the larger states, Madhya Pradesh, West Bengal, Rajasthan and Uttar Pradesh are carrying out the lowest number of tests per 1,000 people while Delhi, Jammu & Kashmir, Kerala and Karnataka conduct the highest.

Charting the Future of Virus Testing

Alas, the country's testing growth has always been lagging behind that of the cases. But can India afford to have its testing chasing the pandemic curve? We need to get ahead of it to get a grip on the disease.

Rijo M John, a health economist at Indian Institute of Management, Kozhikode remarks, “Since contact tracing is almost impossible to do, you have to do mass testing to try and break the chain. According to me, we should do 3 to 4 million daily tests.”

The ICMR is stepping up its game for further strengthening of laboratory services riding on a more aggressive and widespread deployment of the simpler



Compared to other countries with high caseloads, India's testing levels continue to remain on the paltry side

'RAT Useful, Complements RT-PCR': Health Ministry On ICMR's COVID-19 Testing Guidelines

"RAT will be useful in surveillance and containment zone. This test complements RT-PCR testing, which is the gold standard. However, at times, RAT can take up the role of RT-PCR testing."

– Health ministry

and quicker Rapid Antigen Tests (RAT) that will exponentially expand testing rates in the coming months. The agency has validated more than 105 RAT companies and approved 41; 31 of these are indigenous. It started working to ramp up RAT testing to 27 lakh per day by the end of June.

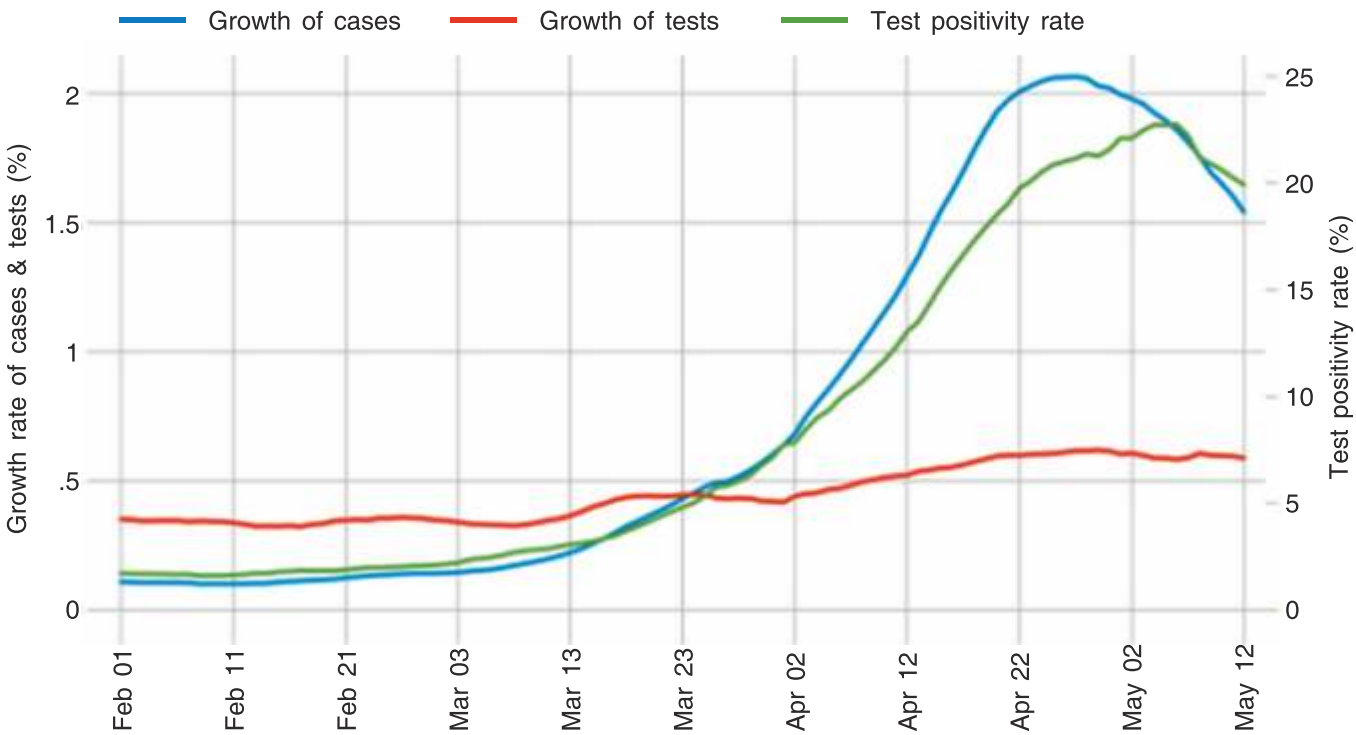
RAT testing has now been allowed at all government and private healthcare facilities - NABL accreditation is not mandatory anymore. This will allow more people - even those without symptoms – to be screened every few days.

Efforts are ongoing to increase the testing penetration in rural areas and extend it to the remotest parts of the country, thus facilitating faster isolation and treatment. Multiple 24*7 RAT booths will be set up in cities, towns and villages with focus on schools, colleges, community centres, RWA offices etc. ICMR mandates that the tests should be conducted in accordance with the algorithm defined by ICMR and results should be uploaded on the ICMR portal.

Two self-testing RAT kits have also got approval for home use.

Trends in daily test positivity rates & daily growth of COVID-19 cases & tests in India

The figures are given as a rolling 7-day average.



The second wave came a year later and still caught us with our pants down in terms of testing capabilities

A RAT testing booth

Role of NABL

NABL has eased the accreditation procedure for both new and existing labs that are scaling up their operations for COVID-19 testing. It is constantly creating awareness among labs to get accredited and encouraging the accredited ones to enhance their accreditation to cover critical sectors so as to ensure increased availability of accredited testing infrastructure.

The Board is coming up with a model scope in all fields (testing, calibration and medical testing) covering all disciplines (including all groups) to ensure uniformity in scope of accreditation.

Yet, the focus is not just on quantity but also quality of testing. Collection of samples being a critical aspect in providing correct results, NABL is planning to add a separate assessor for evaluating the sample collection facilities to the existing teams assigned for assessing a lab's scope of accreditation. More value addition in the assessments are in the offing. It also keeps reminding the already-accredited labs to ensure that the sample collection is being done as per the requirements.

Testing in the Face of Variants and Vaccines

Emerging SARS-CoV-2 variants and the COVID-19 vaccinations have augmented the challenge of testing.

Right from the start, scientists expected the virus to evolve and new variants to emerge. Now that we are seeing new mutations in different parts of the world, the question arises – how effective are the existing tests to detect these mutations? Will the tests return false negative, or even false positive, results when testing new variants?

Moreover, some of the variants can potentially produce different antibody responses in patients. Will the antibody tests be reliable when checking those who have already been infected with the virus?

Then again, can we assume that we will be done with testing in the post-vaccine world? It is being noted that some people who have been fully vaccinated against COVID-19 and are considered immune to the virus are still developing the disease. Though still a rare phenomenon, ongoing testing of immunized folks will become crucial for mitigating future outbreaks.

Conclusion

As we limp forward in the 'new normal', conducting extensive and varied tests will be the pivotal strategy for grappling further waves of the COVID-19 infection and ultimately, stopping the progression of the pandemic.

Inadequate testing is making it difficult for the health authorities to make reliable predictions of the future trajectory of the SARS-CoV-2 virus and its many mutations. Increased testing will deliver a better sense of the trajectories of transmission, thus enabling the government to make targeted decisions about where it needs to emphasize stronger responses.

Source: Secondary research & media reports

Scaling Up Testing Infrastructure On A War Footing

Early detection and treatment are the key interventions for getting a grip on the deadly COVID-19 pandemic. In view of this, the government has left no stone unturned to expand and diversify the national testing capacity for COVID-19 diagnosis.

India geared up to exponentially expand its capacity for COVID-19 testing

CLINICAL LABORATORY TESTING is front and centre in the global fight against the COVID-19 pandemic. Early testing is crucial for isolating the infected and controlling the transmission of the SARS-CoV-2 virus.

At the very beginning of the pandemic, India was bogged down by an infinitesimally low capacity and capability for conducting the sophisticated COVID-19 tests, marked by an acute shortage of both labs and kits.

Even after the first case was diagnosed at the end of January 2020, barely 14 labs were capable of testing for SARS-CoV-2 virus and by the end of March it was expanded to 106 ICMR-funded Virus Research and Diagnostic Laboratories (VRDLs) which had the capacity to test for similar viruses. The specialised RT-PCR test kits were also not easily available and the labs could hardly conduct some 2,000-odd tests per day.

It was obvious that India needed to speedily ramp up the national capacity for COVID-19 testing to handle the steady rise in cases as well as rein in the spread of the lethal virus. And the Government of India rose to the occasion by implementing a slew of measures to efficiently expand the scale of testing.

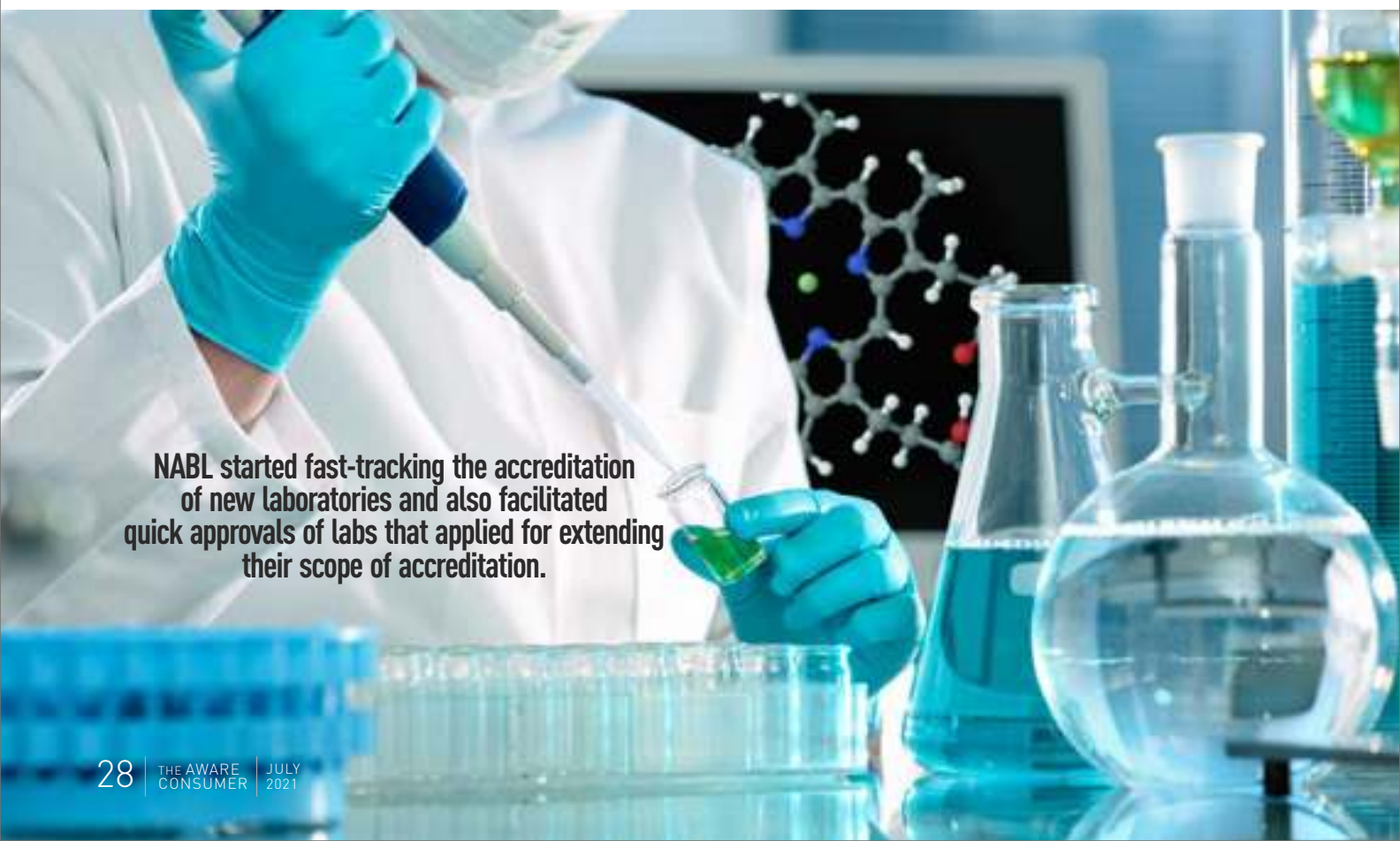
Augmenting COVID-19 Testing Laboratories

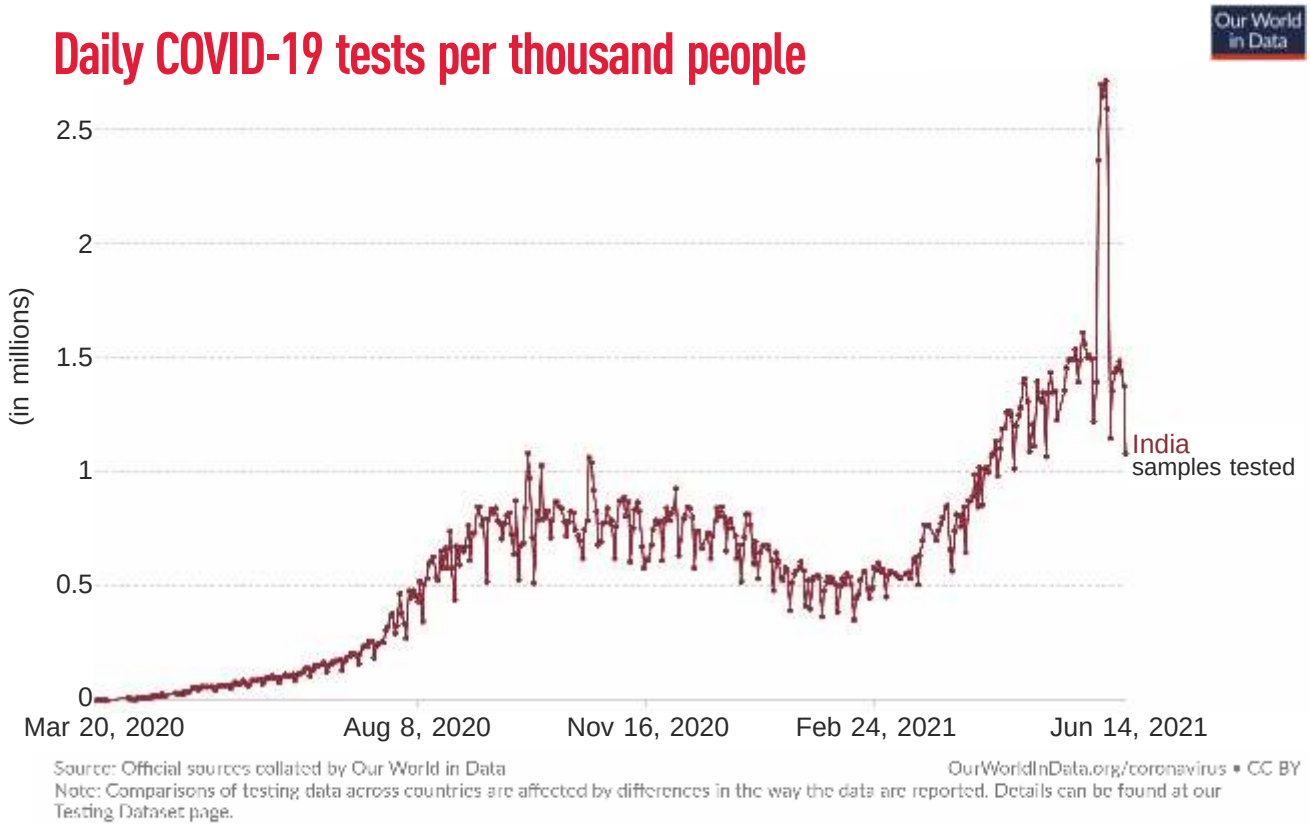
Scores of medical testing laboratories were the need of the hour for making testing widely accessible across the country. ICMR was focused on creating a broad molecular virology laboratory network. It adopted a two-pronged approach –

- establishing new labs with the VRDLs provided the platform for launching the new facilities.
- upscaling testing capacity in government and private medical colleges. Centres of Excellence were set up in different medical institutes for mentoring the capacity building in medical colleges. Both public and private medical colleges were upgraded by establishing Biosafety Level-2 (BSL-2) COVID-19 testing facilities.

It was critical for the government to bring the private testing infrastructure to the required level. Therefore, ICMR subsequently moved to onboarding certified private labs that had accreditation from NABL. In April itself, around 100 NABL accredited medical testing laboratories with scope of molecular virology were listed by ICMR for testing of SARS-CoV-2 virus. NABL worked rapidly and granted accreditation to more than 300 private medical testing laboratories for RT-PCR RNA virus testing in June.

NABL started fast-tracking the accreditation of new laboratories and also facilitated quick approvals of labs that applied for extending their scope of accreditation. It moved to remote assessments as the ongoing pandemic was limiting the ability to conduct on-site assessments. Digitization and technology have been incorporated into every aspect of the accreditation process to ensure that all the requirements are met properly. Changes in the accreditation policies, simplifications in the process for changes in activities and removal of the mandatory 4-day internal auditor training requirements have drastically eased the process of accreditation.





India has ramped up testing capacity exponentially since the beginning of the pandemic

Armed with quick response to the applications, the agency accredited more than 950 private medical testing laboratories in record time by November, 2020.

New schemes – like NABL Medical (Entry Level) Testing Labs Program - were launched so that new labs can get accredited easily. It was envisioned as a stepping stone for labs outside the network to understand the benefits of accreditation. It also introduced two new categories of Micro and Mini laboratories (in addition to the existing categories of Basic Composite, Medium and Advance) to encourage the scores of small non accredited labs to come forward and prove their competence to gain accreditation.

To enable ongoing sustainability of the laboratory community, NABL is extending its support in various ways. It has extended the validity of accreditation for all labs for a year. They are allowed to use their existing reference materials and/or reference standards for an additional period of 6 months. A one-time revocation from the adverse decisions (suspension, withdrawal or debarment) is also being allowed.

With an exponential increase in the number of labs for testing the SARS-CoV-2 infection, we can now boast of more than 2620 government and private molecular testing labs offering COVID-19 tests across the length and breadth of the nation. It is especially commendable that low-income states like Jharkhand, Bihar and Madhya Pradesh have managed to ramp up their testing infrastructure and have set up COVID-19 labs in almost all their districts.

Augmenting COVID-19 Testing Resources

RT-PCR testing being the mainstay for diagnosing COVID-19, ICMR established and trained validation centres for evaluation of RT-PCR kits, RNA extraction kits and VTM kits following standardized scientific protocol. An online portal for kit validation was rolled out and more than 700 diagnostic kits had been validated by August 2020 itself.

As RT-PCR testing calls for skilled manpower, advanced testing facilities and also takes time, ICMR started deploying indigenously-developed point-of-care tests like TrueNat that require minimal training, skills, infrastructure and biosafety measures and can deliver results within 30 to 60 minutes. In June 2020, it approved the Rapid Antigen Test (RAT) as another quick diagnostic test with a turnaround time of just 15 to 30 minutes including sample preparation.

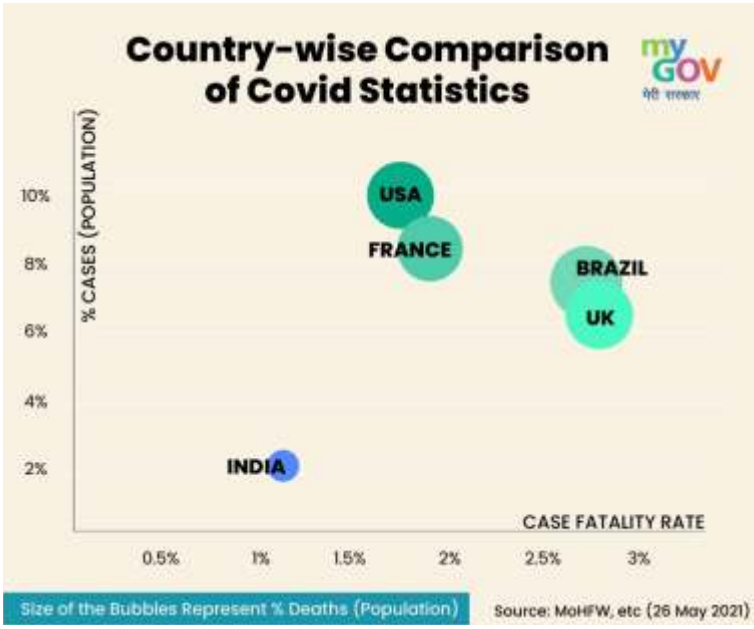
In May 2021, the labs were using over 7,000 RT-PCR machines and over 3,800 TrueNat and CBNAAT machines to conduct COVID-19 tests.

It follows that India's testing rates have seen a significant uptick. From testing around 3 lakh samples per day in June 2020, the medical labs were testing more than 10 lakh samples in March 2021. The numbers doubled in less than 2 months and we are now conducting more than 20 lakh tests per day. In a landmark achievement, India managed to conduct a whopping 19,45,299 tests on 30th April, 2021 for the first

time - the highest number of tests by any country ever, surpassing even the USA.

This was followed by another record on 22nd May of conducting more than 21.23 lakh fresh tests on a single day! At the end of May, our RT-PCR testing capacity ranged around 16 lakh per day and RAT capacity was around 17 lakh per day.

Apart from this, ample support was extended to indigenous manufacturers to produce swabs and other diagnostic materials. NABL started identifying various laboratories capable of testing PPE kits, sanitizers, gloves, masks and medical devices along with calibration laboratories for medical equipment. In August, 2020, more than 130 accredited testing laboratories enhanced their facility to assess whether the various COVID-19-related products meet the specifications or not. By April 2021, there were 2999 accredited labs for testing materials and 896 for calibration in the country.



Around 2% of India's population has been infected with COVID-19 as compared to 6% in the UK, 8% in France and 10% in the USA.

NABL further updates the accredited laboratories to avail the emerging business opportunities by enhancing their scope of testing accordingly and also contribute their bit in the nation's fight against the pandemic. For instance, it is currently requesting the labs to come forward and obtain accreditation for testing of medical oxygen under chemical discipline.

Augmenting COVID-19 Testing Quality Control Processes

The focus is not just on expanding the diagnostic capabilities, but also ensuring high-quality services on an ongoing basis. To ensure that there is no lax in the quality of testing and maintain continued compliance by the labs, NABL officers conduct surprise audits to check for malpractices and improper reports. Strict action follows, as per procedure, for any fraudulent activities or other violations of the requirements.

For quality assurance purposes, ICMR has identified 30 quality control (QC) laboratories to verify results of other labs. The medical testing labs are required to send randomly selected positive and negative samples to the nearest designated QC labs where they are carefully checked to ascertain the quality of diagnosis.

Other measures are also in place to make sure that the labs follow due diligence to safeguard quality testing and reporting of samples. The government releases advisories related to expanding the testing platforms and strategies as per the changing epidemiology of the COVID-19 infection, standard laboratory protocols, reporting guidelines and other quality control measures on a periodic basis. ICMR issues standards for sample collection, storage of specimens and even revised guidelines for testing. This ensures that the labs stay on the same page and practice uniform testing protocols.

Maintaining COVID-19 Testing Prices

Given the crucial role that testing plays in identifying COVID-19 cases, it is very likely that private diagnostic laboratories will start exploiting the situation. This is why the government-imposed price caps on testing rates right from the start of the pandemic to ensure affordable access to quality healthcare services at large.

While testing was free in government hospitals in the beginning, with the entry of private labs, RT-PCR tests were capped at Rs. 4500. This was followed by rate revisions over the months given the decrease in testing-related costs due to increased market competition and availability of indigenous testing materials and kits.

Current prices for testing have been capped at Rs 500 in the labs and Rs. 750 for home collection of samples.

Conclusion

Given the humongous population challenge and speedy rise in cases, it is truly remarkable that the authorities have risen to the challenge and successfully managed to ramp up the testing infrastructure across the country in a relatively short span of time, literally overnight. As India moves through different stages of the pandemic, the number of diagnostic labs equipped to run COVID-19 tests has seen a consistent and robust growth. These labs are working 24*7 to meet the rising demands for testing despite the manpower limitations as more and more lab staff are hit by the infection.

In sum, the government is effectively implementing its test, track and treat policy. It is noteworthy that at the peak of the second wave, our numbers were rising, but our testing capacity has been immensely upgraded and the recoveries were steadily improving as well.

Source: Secondary research & media reports

"Lab Accreditation Gains Importance During Pandemic"

Mr. N. Venkateswaran

CEO of NABL is armed with a Master of Science (M.S.) in Quality Managementf rom BITS Pilani and Bachelor's in Mechanical Engineering from Madurai Kamaraj University and has an extensive knowledge in quality management standards. He has around 26 years of working experience, out of which 15 years are at NABL itself, heading all verticals with first-hand knowledge in accreditation, PTP, RMP, complaints and appeals, etc.

He elaborates on the role of NABL accreditation and how it has evolved into a valuable tool during the pandemic.

Q Why do you feel we need NABL accreditation in our country? With the onset of the COVID-19 pandemic, it was for the first time the nation woke up to the functioning of laboratories and standards.Can you elaborate what are the benefits for a common citizen?

NABL accreditation is required because it gives confidence to any user that a third-party has assessed the competence, impartiality and consistent operation of a specific activity carried out by the laboratory.

Our country is always cautious about quality, and regulations are enforced from time to time wherein use of accredited laboratories is mandated, thereby ensuring trust in end users. Hence, it is not the first time that use of NABL accredited laboratories and standards are being insisted upon.

With the onset of the COVID-19 pandemic, everyone has understood and acknowledged the importance of reliable and accurate test results from NABL accredited laboratories.

An independent and impartial assessment of the laboratory for ensuring the competence is conducted by NABL and is the basis for trust in consumers who are utilizing laboratory services.

Some of the benefits of accreditation for the common citizen are assurance of accurate and reliable results (time and money efficient), enhanced customer confidence and satisfaction (robust quality management system).

The results from other NABL accredited laboratories are also used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services. Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL website (www.nabl-india.org) or Directory of Accredited Laboratories. Users of accredited laboratories enjoy greater access for their products, in both domestic and international markets.

Q How does NABL accreditation ensure compliance to international standards of quality and best practices to assure quality to the Indian Consumer?

NABL, as an accreditation body, has implemented the requirements mentioned in the International Standard ISO/IEC 17011: 2017 and thus NABL operations conform to ISO/ IEC 17011: 2017.

NABL is a full member and a signatory to International Laboratory Accreditation Cooperation (ILAC) as well as Asia Pacific Accreditation Cooperation (APAC) Mutual Recognition Arrangements (MRA) since the year 2000. NABL implements the requirements of ILAC and APAC and is peer evaluated every four years.
Such international arrangements facilitate acceptance/equivalence of test/calibration results between countries which MRA partners represent.

Accreditation uses criteria and procedures specifically developed to determine technical competence. The criteria

"NABL regularly assesses the laboratories (within 2 years) through on-site assessment and also conducts a yearly surveillance to ensure that the system in the laboratory is complying to the international standard requirements, thereby ensuring quality and competence of the laboratory."

are based on various international standards which are used for evaluating laboratories throughout the world.

NABL provides accreditation based on the following International Standards:

- Testing laboratories as per ISO/IEC 17025
- Calibration laboratories as per ISO/IEC 17025
- Medical testing laboratories as per ISO 15189
- Proficiency Testing Providers (PTP) as per ISO/IEC 17043
- Reference Material Producers (RMP) as per ISO 17034

Compliance to the above international standards ensures that best practices are being implemented and continuously complied with by accredited labs in India at par with any other accredited laboratories globally. NABL accredited laboratories use various international test methods (like ISO, IEC, ASTM, AOAC, etc.) for conducting testing. For instance, the IT equipment safety testing laboratories test the products in accordance with IEC 60950-1.

Adherence to these international standards brings about uniformity in the conformity assessment thereby assuring quality and safety to Indian consumers.

Q How is NABL encouraging laboratories to get accredited during the pandemic and lockdowns and what kind of digital innovations have you adopted to grant accreditation for laboratories?

NABL encourages laboratories to obtain accreditation (both during normal and pandemic times) by regularly conducting awareness and outreach programs for laboratories, consumer forums, government/Ministries, regulators and industry associations to sensitize them about the benefits of NABL accreditation.

NABL has digitized the entire process of accreditation, right from filling of application till the issue of Certificate of Accreditation.

The NABL accreditation process involves various steps:

- Online submission of application for accreditation (NABL Web portal)
- Online document review for sufficiency (NABL web portal)
- Pre-check for readiness to undergo assessment (Remotely)
- Conducting assessment to adjudge the technical competence of laboratory (Web Portal, Assessment App).
- Review of assessment report by independent committee (accreditation committee through video conferencing) and
- Issue of accreditation certificate (through Web portal)

Q Have you made any changes in the existing standards owing to the pandemic? Will the simplifications affect the quality of testing?

No changes have been made in the existing standards during the pandemic. No compromise is made while

assessing the laboratory at any time. The compliance to the International Standard and NABL requirements are ensured in all the assessments.

However, to benefit small diagnostic laboratories in small towns and villages. NABL has launched NABL Medical (Entry Level) Testing labs {NABL M(EL)T Labs} testing program aimed at small diagnostic laboratories to overcome their apprehension of the enormous preparation required for NABL accreditation and try to bring in basic quality in all the laboratories operation at grassroot level.

Q Normally accreditation takes months, but NABL is shrinking the time to a few weeks in the face of the pandemic. What challenges do you face in maintaining the quality of accreditation while fast-tracking the process?

The accreditation process at NABL had always been a time-bound activity. There is no change in the process. On receipt of application, it is scrutinized and the management system document is reviewed for sufficiency. Deficiencies, if any, are informed to the lab to address in a time period. Thereafter, a pre-check for readiness of the laboratory to undergo assessment is carried out. In case of non-conformances, the lab is informed to take necessary corrective actions. Final assessment is scheduled based on a mutually acceptable date and assessment team.

A lead assessor and technical assessor(s) are deputed to conduct the assessment of the laboratory. The assessment team carries out test witness, interview, record review, proficiency testing performance, document review, etc. The findings are shared with the laboratory.

The laboratory has to take corrective actions on the non-conformances raised within a stipulated time period. The assessment report along with corrective actions is reviewed in the accreditation committee and decision on grant (or otherwise) of accreditation is communicated to the laboratory. A certificate bearing a unique number is issued to the laboratory.

The misconception of taking months for accreditation can be attributed to a number of reasons:

1. Readiness of lab for the scope applied (previously without being ready, in case any lab submitted application, it was allowed to take corrective measures after identifying deficiencies. But now if lab is not ready, then the accreditation is denied)
2. Time required for taking corrective measures (quick actions are taken by lab unlike in previous time of 60 to 90 days, etc.)
3. Number of assessors (one or two) based on scope of accreditation. Increased availability of assessors for conducting assessment remotely.
   Thus, saving the time required for booking tickets (cost of travel) and accommodation for the assessment team (almost nil, as the activity is done remotely).
4. Timelines defined for the lab to address deficiencies are reduced at present. The labs are acting fast now, and if not, it is made clear that accreditation will be denied.
5. Currently, NABL has adopted a web portal wherein a laboratory can apply for NABL accreditation and submit their application instantly online.

NABL Awareness Program for Government Water Testing Laboratories on 22nd Jan 2021

We have observed many cases of laboratories obtaining NABL accreditation within 30 days due to their readiness and making the best use of the NABL web portal. This has further helped us during the pandemic wherein we could optimize our system for medical laboratories which were applying for a particular fixed scope of RNA viruses using RT-PCR technique. The existing web portal could make use of templates which greatly reduced the time for application and further processing.

The accreditation committee meeting is done every day (unlike weekly meetings earlier). The accreditation certificate preparation time is almost nil as the scope is explicit and fixed. So, we could manage granting or denying accreditation to the labs within a week's time. Wherever deficiencies were there, we have conducted assessment again to verify the correctness and then granted accreditation. Thus, we are happy to share that NABL had accredited more than 1300 private medical testing laboratories for RT-PCR technique RNA viruses in a year time

Q What quality requirements have been instituted to allow only competent and capable laboratories to be recognized for their quality and competency?

There are many quality requirements, like use of Certified Reference Materials (CRM) regularly, retesting of retained items, replicate testing, participating in PT/ILC with another laboratory, use of control charts, calibration of equipment with traceability to SI units, intermediate checks of equipment, qualified and educated personnel

NABL – Supporting Partner in Diagnostic Leadership Summit 19-20 Feb., 2021

Mr. N Venkateswaran, CEO, NABL spoke about NABL Accreditation and the importance of Quality in diagnostic sector and how NABL has come forward in support of all laboratories throughout the pandemic.

conducting tests and/or calibration, etc. which are being checked to ensure only competent and capable labs are recognized.

The individual standards list out the various requirements that the laboratories are required to comply with at all times. These requirements, if followed in the lab such that a system exists in the laboratory which is geared towards regular monitoring of laboratory activity, ensure that the test results obtained from the lab are reliable and trustworthy. Further, if the lab complies with the requirements of metrological traceability and participation in proficiency testing activities, then it can clearly provide an indication about the competence of the laboratory.

NABL regularly assesses the laboratories (within 2 years) through on-site assessment and also conducts a yearly surveillance to ensure that the system in the laboratory is complying to the international standard requirements, thereby ensuring quality and competence of the laboratory.

Q How do you ensure that the citizens can make an informed choice based on your accreditation so that they are not victims of misrepresentation and/or deceptive communication made by laboratories who falsely claim to be NABL accredited? Please share the key indicators for the readers to differentiate between the genuine and illegitimate laboratories?

NABL has taken utmost care to ensure that the NABL symbol is a symbol of trust. We have brought changes in our requirements to ensure that test reports which contain only the parameters accredited by NABL bear the NABL symbol. This eliminates the need for multiple checks. Further, we have brought uniformity in usage of the NABL symbol which mentions the certificate number of the laboratory. This ensures that the end user can verify the authenticity of the laboratory accreditation by simply entering the certificate number of the laboratory on NABL website and verify the authenticity of accreditation.

NABL has instructed all laboratories to ensure an authentication mechanism (QR code) on all test reports/certificates which are issued by laboratories such that any person who needs to check the authenticity of the report can simply scan the QR code on the test report and check its authenticity as issued by the laboratory. This would eliminate the fraudulent/illegitimate test reports being issued in the market and provide a mechanism to boost the trust.

Q How do you maintain collaboration with the regulators and the government?

NABL participates in the meetings called by government authorities and regulators. NABL is also one of the members in their various committees and participates actively. Regulators publish and inform their requirements from time to time and we at NABL ensure accredited laboratory infrastructure availability in those areas. There is an interaction with the regulators and government authorities and we update them about the accreditation facilities available in our database which are also publicly available on NABL website.

In few cases, the NABL assessment process includes requirements of the regulators also. NABL-127 document contains the requirements of regulators like FSSAI, EIC, APEDA, etc. NABL even invites experts from government and regulators to take their inputs and guidance in various technical and accreditation committees and also as an assessor for conducting assessments.

NABL accreditation is increasingly being used by regulators and government to ascertain the quality of

NABL, in collaboration with Healthy You Foundation

organized A webinar on 30th July 2020

Mr. N Venkateswaran, CEO, NABL urged all the participants to share the awareness obtained on NABL accreditation and activities of NABL through the program, for the benefit of the end consumers in different fields.

Prof. Bejon Kumar Misra, Founder Trustee, Healthy You Foundation explained about the importance of NABL Accreditation and the usefulness of bringing about awareness of accreditation to ensure the quality to the consumer.

NABL, in association with Institute of Quality, CII conducted the National Laboratory Conclave: Focused on Molecular Testing Laboratories

Mr. Venkateswaran, CEO NABL, reiterated that all the requirements in accordance with ISO 15189 are thoroughly checked which includes calibration with metrological traceability, competence of laboratory personnel etc. NABL has also denied accreditation to laboratories which could not ensure the required competence.

products. Accredited Conformity Assessment Bodies (CABs) can objectively state conformance of products to specified requirements.

Q The concept of laboratory conclave was your brainchild for bringing together the various laboratories in the nation with NABL for the first time. Please elaborate further on the benefits of the conclave.

Thank you.

The concept of laboratory conclave was started in the year 2012 jointly by CII Institute of Quality and NABL in order to bring out a mechanism where laboratories can come together and discuss their issues on a common platform. Many issues of the laboratory and their views on how to move forward could be discussed and improvement took place. This type of conclaves would boost the morale of laboratories and help in taking steps towards betterment of laboratory services thereby benefiting the common man.

The following are the benefits of the conclave -

- Policy developments at the international level in laboratory practices and metrology are exchanged
- New emerging business areas for laboratories are shared
- Importance of laboratory results in trade gets explained
- How to engage and derive benefits from the National Accreditation programme (for non-accredited laboratories)
- Cross learning through experience sharing and success stories
- Knowledge sharing on new technologies and scope/capacity expansion
- Knowledge sharing on meeting regulatory requirements
- Bridging the gap between accreditation requirements and practices

Q Despite the increased accreditation, many unauthorized labs are still offering COVID-19 testing on the sly. What steps have you taken to control them?

NABL updates accredited labs list on the website regularly. The NABL accredited medical labs register with ICMR and after due authorization, start testing COVID samples.

NABL being a voluntary accreditation body, cannot step beyond the mandate and start exercising control on any laboratories. Whenever we come across such incidents of unauthorized labs doing unethical work, we inform the regulators and respective state government authorities for appropriate action.

NABL has ensured that all tools are being made available for the common man to reconfirm/authenticate and ask for the best of quality.

Q How do you expect the diagnostics space to change after the end of the pandemic?

I believe there is going to be a change in the way services are being provided and the new focus will be on quality of services in the diagnostic sector. Also, expect to see medical testing laboratories voluntarily coming forward to demonstrate their quality through accreditation and thus increase their business and brand value.

The nation, in the struggle to overcome the pandemic, has gained the understanding that they can demand quality and they can get it through NABL accreditation. I feel happy to see many requests being received for authentication and information being shared with NABL on various aspects related to all types of laboratories.

AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Fighting The Unknown With The Weapon Of Credible Testing

The SARS-CoV-2 virus causes the highly-infectious COVID-19 respiratory illness and calls for sophisticated lab testing for diagnosis

IN DECEMBER 2019, a novel coronavirus emerged in Wuhan, China and was initially deemed as an outbreak of severe pneumonia. The virus spread extremely rapidly across the globe with cases reported from as many as 25 countries within a month itself.

In the beginning, it was very difficult to diagnose the COVID-19 disease as it shares many symptoms with other respiratory pathogens, including influenza and parainfluenza viruses.

In India, the ICMR's National Institute of Virology (NIV), Pune quickly jumped into action to establish screening as well as confirmatory assays for what has now been named as the SARS-CoV-2 virus. Within a week, the test was standardized and 13 Virus Research and Diagnostic Laboratories (VRDLs) were provided with the e-gene screening real-time reverse transcription-polymerase chain reaction (RT-PCR) assay. The VRDLs were based close to international airports/seaports and started testing all individuals with travel history to Wuhan and symptomatic individuals with travel history to other parts of China.

And we got our first confirmed case on 27th January, 2020.

With the rapidly rising cases and reported high morbidity, the WHO declared a pandemic on 11th March, 2020. Strict restrictions were rapidly imposed by various countries and India also went into a complete lockdown from 25th March.

Laboratory Testing and Diagnosis

Testing is the cornerstone of an effective public health response and has proved crucial for the clinical management of this unforeseen disease. Test results are essential both for treating the patients as well as implementing disease control strategies. However, it is not just about increasing the test capacity to handle the rising volume of cases. High-quality laboratory operations have to be maintained to ensure accuracy of results.

And such reliability can come only from certified accreditation after conducting proficiency testing of the labs.

Indeed, the importance of accredited laboratories and accurate test results has been emphasized all over the world. This will bring parity among all the laboratories based on standards of robust quality management systems and documented quality procedures.

The need for reliability is not limited to just the diagnostic tests in medical testing laboratories that determine the presence of SARS-CoV-2 virus. Other critical products like masks, gloves, sanitizers, personal protective equipment (PPE) kits and a range of medical devices have to be properly tested to check whether they fulfil the specific requirements or not. The ventilators, oxygen concentrators and other medical equipment have to be calibrated as well to ensure accurate results.

After all, with more and more manufacturers jumping onto the bandwagon to meet the increasing demand for the above products, testing whether they meet the specifications is what will ensure quality, reliability and safety in use.

Even ICMR went ahead and mandated NABL accreditation as the criteria for recognition of laboratories for testing the SARS-CoV-2 virus. Additional Director General of ICMR, Dr. G.S. Toteja said, 'Many of the labs are doing this test for the first time and in view of this, it is prudent to comply with NABL norms and obtain accreditation of private labs'.

Role of NABL

NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India, has authorized NABL to enhance the capacity of testing RNA Viruses to deal with the Covid-19 Pandemic situation in the country.

NABL has been accepting the requests of labs that are capable of testing RNA viruses using the RT-PCR technique and conducting assessments to enhance their scope of accreditation.

Using its newsletter, NABL is also informing all labs with the required competence or that are conducting similar testing to come forward and get themselves accredited to serve the nation. Testing laboratories are encouraged to extend their accreditation to cover critical products like PPE kits and medical devices and support the healthcare sector at this critical juncture.

NABL assessors, accreditation committee members and other officers are working hard to ensure that there are adequate numbers of laboratories to cater to the ongoing necessity for testing.

The list of accredited laboratories is regularly updated on the website www.nabl-india.org. Consumers can easily check whether a particular diagnostic centre is accredited and follows the specified norms or not.

Considering the urgency of testing, NABL has expedited the process of accreditation. NABL has launched It is launching new schemes and categories to enable the scores of laboratories existing in the country to get themselves accredited.

During pandemic, NABL has taken proactive steps and adopted alternative ways to conduct assessment remotely in place of onsite assessments. All types of meetings were being conducted through videoconferencing mode to arrive at a quick decision.

NABL has played a vital role for enhancing the capacity of testing of RNA viruses by which the country has grown from just a single laboratory testing centre at NIV, Pune for testing the SARS-CoV-2 virus in January, 2020 to around 100 NABL accredited medical testing laboratories by April, 2020 itself.

By the end of May, 2021, independent testing was ongoing in more than 2600 laboratories reporting to ICMR and more than 35 crore cumulative samples had been tested for COVID-19. Of these, 1345 are private labs with NABL accreditation for molecular COVID-19 testing itself.

However, this does not mean that there is any compromise in the quality of assessment. In every instance, all the requirements are checked thoroughly, including calibration with metrological traceability, competence of laboratory personnel, etc. NABL has, on occasion, denied accreditation to laboratories when they failed to confirm the required competence.

These kinds of concerted efforts have resulted in a well-coordinated action at each level. In sum, there is value in getting tested, but the testing should be credible to be reliable and effective!

Source: Secondary research & media reports

Role Of Testing For COVID-19

While the world waits for substantial vaccinations across the globe and a potential cure, testing is the main weapon in our arsenal to get a grip over the relentless spread of the lethal COVID-19 disease. Clinical testing plays a multi-faceted role – identifying, isolating and treating people who are infected, understanding the virus better and deciphering the spread of the disease in the community. Other forms of testing also come into play here.

A combination of different technology platforms has boosted the country's capacity to expand COVID-19 testing capabilities

SEVERE ACUTE RESPIRATORY syndrome coronavirus 2 (SARS-CoV-2) is the pathogen that causes coronavirus disease 2019 (COVID-19). The virus is spherical in shape and has proteins called spikes protruding from the surface resembling a crown (earning it the name Corona). These spikes get attached to human cells and undergo a structural change that allows the viral membrane to fuse with the cell membrane. The viral genes can then enter the host cell where it multiplies, producing more viruses.

Managing the unprecedented outbreak of the COVID-19 pandemic calls for different kinds of testing. Laboratory services can be used in various manners:

Medical Diagnostics

Clinical labs play a key role in etiological diagnosis, patient monitoring and epidemiologic surveillance. SARS-CoV-2 being an RNA virus, all available RNA detection formats and newly-developed tests - can be applied to detect the virus.

Different forms of technology platforms are currently in use, like:

- **Molecular-based Test -** Nucleic Acid Amplification Test (NAAT) - testing the nucleic acid of the virus itself - is the primary technique for tracking the viral agent responsible for the COVID-19 disease. While there are different types of NAAT tests, the reverse transcription polymerase chain reaction (RT-PCR) test is considered the gold standard for COVID-19 and is also the most commonly used method till now because of its high specificity to the virus.

A swab sample is collected from a location that is likely to have high virus concentration – like the back of the nose or mouth or deep inside the lungs (using a bronchoalveolar lavage). The test uses multiple cycles of cooling and heating – a chain reaction – to check for the presence of SARS-CoV-2 genetic material in the sample. A fluorescent signal is created when amplification occurs. Once the signal reaches a threshold, it is considered positive.

SARS-CoV-2 molecular detection tests depend on nucleic acid amplification from the virus which is usually extracted from the nose or throat through a swab

India's first coronavirus testing kit was developed by Pune-based Mylab Discovery Solutions – team headed by Research and Development Chief, Minal Dakhave Bhosale - in just six weeks.

The homegrown kit called Patho Detect was launched on 28th March, 2020 with a capacity to test 100 samples and costing Rs 1,200, about a quarter of the Rs 4,500 that India was paying to import testing kits from abroad.

The PCR assay is a sensitive testing involving a complex procedure that is conducted by experienced technicians in a sophisticated laboratory setting. Of the four biosafety levels for medical labs testing for lethal pathogens, BSL-2 labs are authorized to handle the SARS-CoV-2 virus. The testing requires an RNA extraction kit and PCR machine for mounting the kit. The time duration for the testing process is around four to eight hours.

Till date, 346 RT-PCR kits have been evaluated by ICMR validation centres, of which more than 180 were found to be satisfactory.

CBNAAT and TrueNat tests involving cartridge-based assays - originally designed to detect tuberculosis - have been indigenously repurposed for detecting the SARS-CoV-2 virus. CBNAAT still calls for a BSL-2 facility; TrueNat does not need an elaborate set-up or even

Testing in a trice

TrueNat, a Cartridge Based Nucleic Acid Amplification Tests (CBNAAT) platform

- Meant to test TB but has been repurposed to detect SARS-CoV-2
- Truelabs workstations are portable, battery operated and fully automated chip-based PCR systems weighing just 3 kg
- No format training required for people handling the systems

- **Ideal for remote locations and has network data transfer ability and automated reporting system**
- **Highly accurate results within an Hour or 45 minutes**

trained microbiologists to handle swab samples from patients, making it a point-of-care option at district facilities and primary health centres. In fact, the Truelab platform for TrueNat consists of a small machine that can be fitted in a suitcase, earning it the moniker, laboratory-in-a-suitcase!

While the customized cartridges for these tests are widely available and they have a quick turnaround time (30 to 60 minutes), only 1 to 4 samples can be tested per run, thus limiting the maximum testing to 24 to 48 samples per day.

■ **Antigen Detection -** Molecular tests remain the mainstay of diagnosis, however the time lapses involved in testing the vast number of samples calls for faster modes of testing. A new type of diagnostic test designed for quickly detecting SARS-CoV-2 operates on the premise of identifying the antigens (or proteins) on the outer shell of the virus.

The test involves immersing the nasal swab in a solution that deactivates the virus. Then a few drops of the solution are put on a test strip that contains artificial antibodies designed to bind to the coronavirus proteins. If a person is infected with COVID-19, the test lines will appear on the strip within 15 minutes. This has to be done within an hour of the immersion of the swab in the solution.

A RAT test kit

This Rapid Antigen Test (RAT) can deliver results in minutes and can be done at the bedside or in the field without the need for elaborate equipment. In June 2020, ICMR permitted the use of the quicker and cheaper RAT testing which gave a big boost for early detection and isolation of COVID-19 cases.

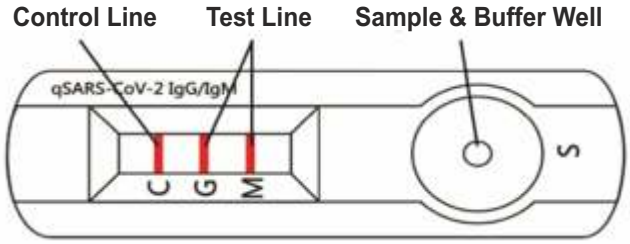
However, fact is that antigen tests are less sensitive and not as precise as the PCR testing; they often fail to detect all active infections. While positive RAT results are highly accurate, they are known to miss almost half of the positive cases by returning false negatives. This happens primarily because the swab samples may lack enough antigen material to be detectable.

Therefore, negative RAT results do not rule out infection and symptomatic patients should follow up with a PCR test to ascertain the validity of the testing.

However, RAT is being deployed on a large scale to ease the burden on RT-PCR testing and enable quicker isolation of positive patients. Till date, 112 antigen-based RAT kits have been validated by ICMR validation centres, of which almost 50 are found to be satisfactory.

■ **Serological Testing -** Testing for the COVID-19 pandemic is not limited just to detecting the presence of the virus. The immune system produces antibodies against the specific antigens of SARS-CoV-2 to fight off future infections. These can usually be detected two to three weeks after the onset of symptoms.

An antibody test is a blood test where a few drops are placed on a cassette or cartridge that contains the SARS-CoV-2 proteins. If the blood samples contain antibodies, they will immediately bind to the viral proteins and will be indicated in the form of lines.



A typical serology test

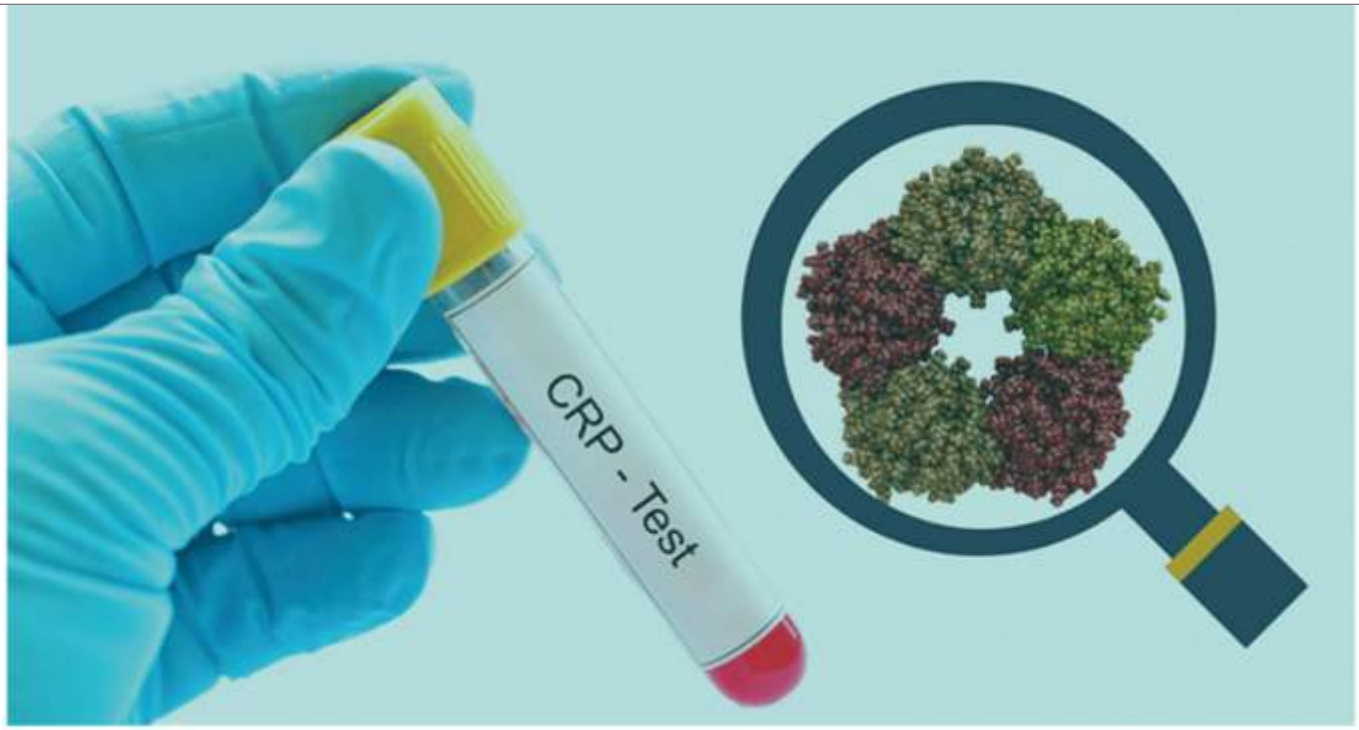
ELISA and CLIA antibody tests are being used to check whether people have mounted an immune response to COVID-19. A positive result shows that infection has greatly decreased and the body has developed some immunity from future infection.

This kind of serological testing has dual functionality – it detects people who have been infected or exposed to the virus in the past and also provides a measure of the evolution of the pandemic across the population. This will help in policy decisions, like when people can safely return to work, restarting of economic activity and most importantly, when a threshold for herd immunity has been reached.

Till date, 196 antibody-based rapid tests have been validated by ICMR validation centres, of which 30 have been found to be satisfactory.

Apart from the above tests, regular imaging modalities like chest CT scans and x-rays also play a limited role – they are used in conjunction with lab tests, medical history and a physical exam, for diagnosing COVID-19 strictly on a case-by-case basis, especially when there is high clinical suspicion of infection. More than diagnosis, they prove useful for determining the severity and progression of the disease and determining a plan of care accordingly.

Various blood tests are prescribed for COVID-positive patients – like ferritin, D-Dimer, CRP and LDH – to check the inflammation, blood clots and level of proteins. The reports will influence the treatment and aid in proper recovery of the infected patients.



Testing and Calibration Laboratories

The fight against COVID-19 is not limited to clinical testing alone. Healthcare relies on a range of products like masks, gloves, sanitizers and PPE kits along with medical equipment like swabs, ventilators, oxygen concentrators and other devices to ensure proper treatment to the infected as well as safety of the population at large.

But how do we know if these products and machines are working properly and up to the required standards? Testing labs check that the products meet the laid down requirements while the calibration labs ascertain the metrological traceability of measuring equipment to ensure that they deliver accurate results.

Proficiency Testing

How do we know that the labs actually operate as they are supposed to? How can we be sure that the SOPs are actually followed in letter and spirit and do not remain mere words on paper?

Proficiency testing (or interlaboratory comparison or round robin test) evaluates the performance of the labs against pre-established criteria by means of inter-laboratory comparisons. Blind samples of known properties are sent to different proficiency centres and the results are compared to determine the validity of a test method and assess the accuracy of the test results. It also indicates whether proper protocols are followed in the lab and the competency of the testing personnel. This works as an external quality assurance method with Z scores assigned based on the cumulative average of the results of the different proficiency testing centres.

What is C-reactive protein (CRP) Test?

- It is a blood test mainly conducted for patients who are hospitalised for Covid virus treatment.
- It is not a diagnostic test but it has prognostic value.
- It tells about inflammation level in the body during any ailment and indicates about the infection level.
- The higher value of CRP level than the normal level indicates that the infection is increasing.
- It is a marker which shows the level of C-reactive protein, which is made by the liver, in the blood.

Quality Control Crucial to Ensure Reliability

NABL is driving a revolution of quality in the testing arena for COVID-19 with almost 3300 testing labs, 900 calibration labs, 1915 medical labs and 50 proficiency testing labs as of May 2021.

With all the accredited laboratories working double time, people don't have to think twice whether their test results are reliable, whether the products are up to the mark and whether the medical equipment or treatment is endangering their lives.

Conclusion

Riding on a strong ecosystem of quality testing infrastructure, we will be better prepared for a possible new wave of COVID-19 infections!

Source: Secondary research & media reports

The SARS-CoV-2 virus is constantly changing

Will They or Won't They – Can Testing Detect New Variants of COVID-19?

Emerging variants of the SARS-CoV-2 virus present another cause for concern. Are the false negatives in RT-PCR tests on account of the new mutations? Labs and healthcare centres are now using a combination of methods to detect infected patients. NABL accreditation still symbolises reliability of the results.

"COVID-19 IS MORE than just the common cold. It represents a perpetual challenge for which we have to be perpetually prepared. Of all the viruses I have dealt with, I am impressed by the extraordinarily wide spectrum of disease ranging from asymptomatic to mild (in bed for a few days), more severe (in bed for a few weeks with post-viral syndromes), to hospitalization and intensive care, need for ventilation, and death," stated Anthony S. Fauci, MD, Director of the National Institute of Allergy and Infectious Diseases (NIAD), USA.

And with new mutations of SARS-CoV-2 now cropping up in different parts of the world, it is no longer just about the range of the disease alone. The variants originating in the United Kingdom, South Africa, Brazil and now in India are the most common, even though other variants are also circulating. These mutations present a new challenge for both the COVID-19 testing platforms and the efficacy of the vaccines.

A Moving Target

It is normal for all viruses to evolve over time; there will be minor changes as the virus keeps replicating or making copies of itself. These changes are called 'mutations' and when a virus has one or more new mutations, it is called a 'variant' of the original virus.

Alarm Bells Are Ringing

Now the focus is shifting from availability of tests and getting the results as soon as possible, to the concern whether the new variants of concern are evading detection by tests. Indeed, questions are being raised about the efficacy and reliability of testing once again. The fear has intensified with the recent spate of RT-PCR test reports returning false negatives for people who are actually infected.

Is Testing Still Accurate?

Till now, the SARS-CoV-2 variants have affected the spike protein of the virus. However, the RT-PCR test looks for genetic material of the virus and detects the most conserved part

of the genome of the virus. Therefore, the tests are continuing to efficiently identify the variants of concern and no variant can escape the double gene test.

The Indian government has emphatically corroborated that, "The RT-PCR tests being used in India do not miss these mutations as these tests target more than two genes. Sensitivity and specificity of the RT-PCR tests remain same as earlier."

While there is no clear correlation linking false negatives to infection by variants, test developers and health officials must remain vigilant. Further research is especially needed to decipher whether the variants display varied detectability by the tests. Continued surveillance of emerging variants is essential for maintaining diagnostic test accuracy in the future.

Why the Discrepancies in Test Results?

A private lab in Uttar Pradesh's Bahraich district was banned from conducting COVID-19 tests in May 2021 after it gave a positive report to a person who then tested negative (within 24 hours itself) at a government hospital in Lucknow!

Given how 70% of the final outcome is dependent on the initial diagnosis, such wrong test results increase the risks of incorrect treatment, patient care costs and even potential death.

However, the discrepancy in test results is attributed to other factors and not the mutations of the virus. Scientists uphold that even RT-PCR tests can miss 30-40% of cases due to:

- The swap sample was collected too early in the infection when the virus replication is not prolific
- The swap sample was collected too late in the infection when the viral counts are dwindling
- Improper collection of the sample or defective techniques, like the swab not being pushed far enough into the nose or mouth
- Environmental contamination of the sample
- Technical errors in testing processes

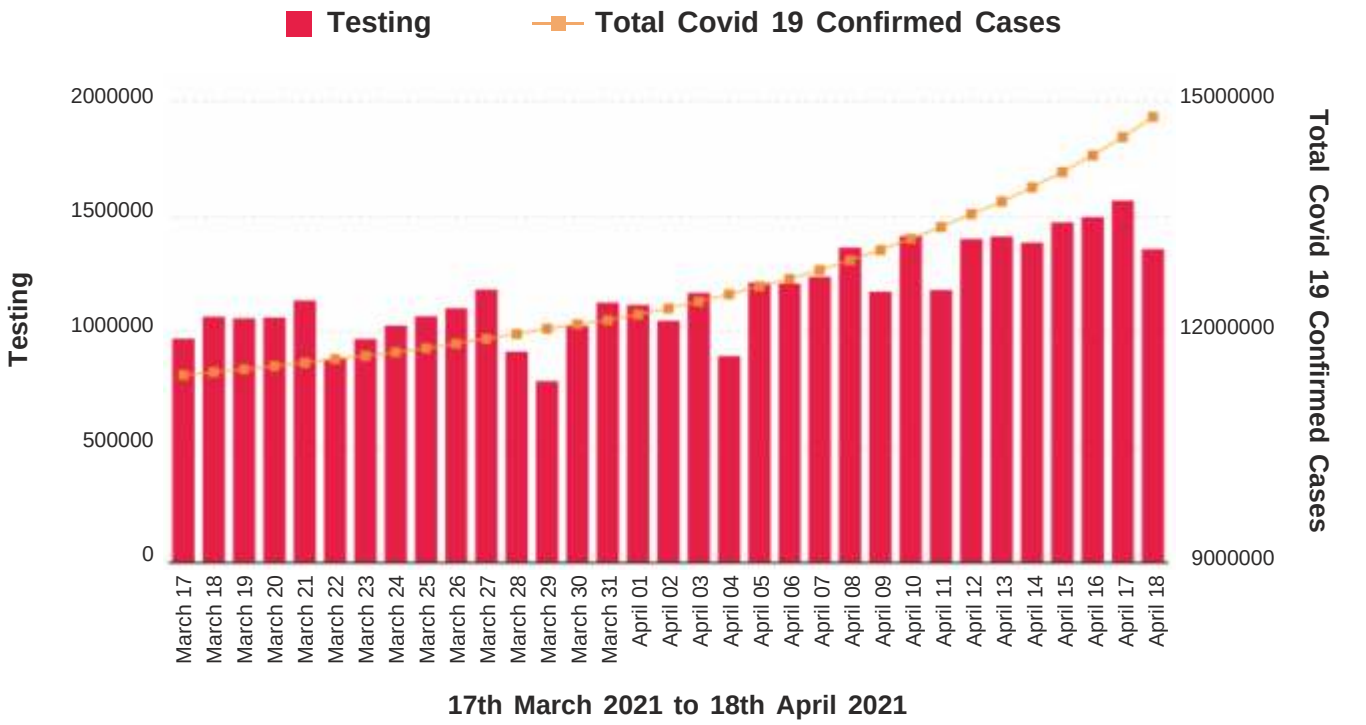
The NABL Advantage

Building an efficient laboratory system is crucial for staying on top of the testing game in the face of health shocks like the COVID-19 pandemic, emerging variants of the virus and so on.

Accreditation is the key to ascertaining the technical competence of laboratories and NABL is our sole accreditation body providing accreditation to Conformity Assessment Bodies (laboratories), with its accreditation system established in accordance with ISO/IEC 17011. It is a constituent board of Quality Council of India which is an autonomous body setup under the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India.

NABL provides the government, industry associations and industry in general with a system for third party assessment of all kinds of laboratories in the country. It also

Let's Take A Look At The Stats: Testing And Rising Covid 19 Cases



holds the right to withdraw, suspend or reduce the scope of accreditation for these labs.

International Alliances

NABL has adopted the international criteria for laboratory accreditation set by the International Organization of Standardization (ISO) so as to maintain quality standards that are on par with globally accepted norms. It further ensures global acceptance of the test/calibration results issued by the accredited conformity accreditation bodies (CABs) by maintaining linkages with international bodies like the Asia Pacific Accreditation Cooperation (APAC) and the International Laboratory Accreditation Cooperation (ILAC).

The Board entered into Mutual Recognition Arrangements (MRA) with ILAC and APAC for the accreditation of testing and calibration laboratories (ISO/IEC 17025) in the year 2000. This was extended to medical testing laboratories (ISO 15189) in 2008. Proficiency testing providers (ISO/IEC 17043) and reference materials producers (ISO 17034) were covered by MRAs in 2016. This is based on peer evaluation and acceptance of other MRA partner accreditation systems.

These arrangements provide visibility and credibility to Indian laboratory test results, promote international acceptance in other MRA partner countries and also reduce technical barriers to export trade.

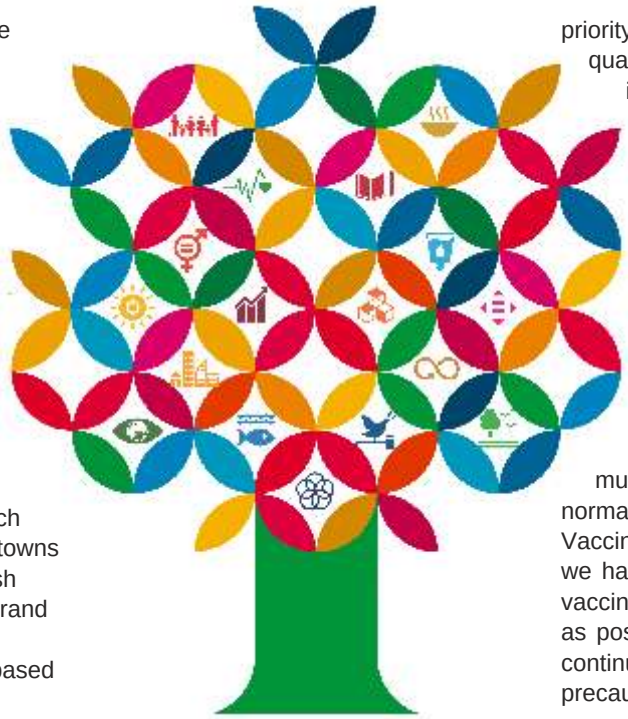
NABL being a full member of ILAC and APAC and regularly taking part in their meetings, conformity assessment results produced by accredited labs enjoy assurance of accurate and genuine reports, confidence in personnel, elimination of the need for re-testing and satisfaction from the services.

Increasing the Testing Capacity of the Nation

The ongoing COVID-19 pandemic has underpinned the central position of accurate and reliable diagnostic testing in outbreak control. NABL is making proactive efforts to exponentially increase the number of samples which are being tested and thereby supporting the diagnosis of COVID-19 patients. Foremost among this is a deliberate easing of the accreditation process to benefit labs that are eager to prove their competence and contribute their efforts to supporting the country in these dire times.

The recent amendment of the Clinical Establishment Act (CEA), 2010 classified the labs into Basic Composite, Medium and Advance based on the scope of their services. In addition to this, NABL has introduced two additional categories of Micro and Mini laboratories so as to encourage small laboratories to come forward for accreditation.

NABL Medical (Entry Level) Testing Laboratories {NABL M(EL)T Labs} program aims to provide the recognition to such laboratories which are in small towns and tier three cities to distinguish themselves and promote their brand by adhering to the basic quality requirements. This program is based on the laboratory's successful participation in a Proficiency Testing Program and other NABL requirements. The process is optimized and made simple that in a couple of days' time, the laboratory can apply and receive the accreditation by the end of the week.



This program was designed keeping in mind the aspirations and acknowledgement which people understood during the pandemic that quality alone ensures accurate testing and value for the service.

To familiarize and encourage more and more labs to get accredited, NABL regularly conducts awareness programs in different cities on topics like benefits of accreditation, requirements for accreditation, information/process to obtain accreditation (documents, web portal), about NABL etc. In association with the Institute of Quality, NABL recently conducted the National Laboratory Conclave on molecular testing laboratories in Oct 2020.

Therefore, NABL is constantly endeavouring to deliver the benefits of accreditation to all the citizens and achieve the goals of universal access to equitable, affordable and quality healthcare services. And the number of accredited labs has been dramatically spiralling – doubling from 2154 in 2014 to 4500 by 2018 and scaling to the level of 6175 accredited laboratories by April 2021.

Indeed, one good thing about the pandemic is that it has changed the priority of the diagnostic sector from quantity to quality service. With the increasing awareness of quality and accreditation, the diagnostic sector is poised to create greener pastures benefitting the nation as a whole.

Conclusion

While clinical testing (backed by accreditation by NABL) is helping us surf the COVID-19 disease along with its various mutations, the potential answer to normalcy rests in immunization. Vaccines are the only solution and we have to move forward with vaccination programs as expeditiously as possible. Meanwhile, we have to continue observing the same precautions of washing hands, wearing masks and observing social distancing.

However, testing will continue to play an imperative role in the scheme of things. “The idea that we could be entirely done with testing in the post-vaccine world is probably not a good one right now; for example, even fully vaccinated people who develop respiratory symptoms should consider getting tested for COVID-19. Conversely, exposure to individuals with known infection, even if fully vaccinated, should be taken seriously and again individuals should consider getting tested” - Robert B. Darnell, Robert and Harriet Heilbrunn Professor, Rockefeller University.

Source: Secondary research & media reports

World Accreditation Day is a global initiative jointly celebrated on 9th June every year by the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) to raise the awareness on the importance of accreditation related activities and to promote it amongst all relevant stakeholders.

This year, NABL organized World Accreditation Day 2021 with the theme, 'Supporting the Implementation of Sustainable Development Goals (SDGs)'.

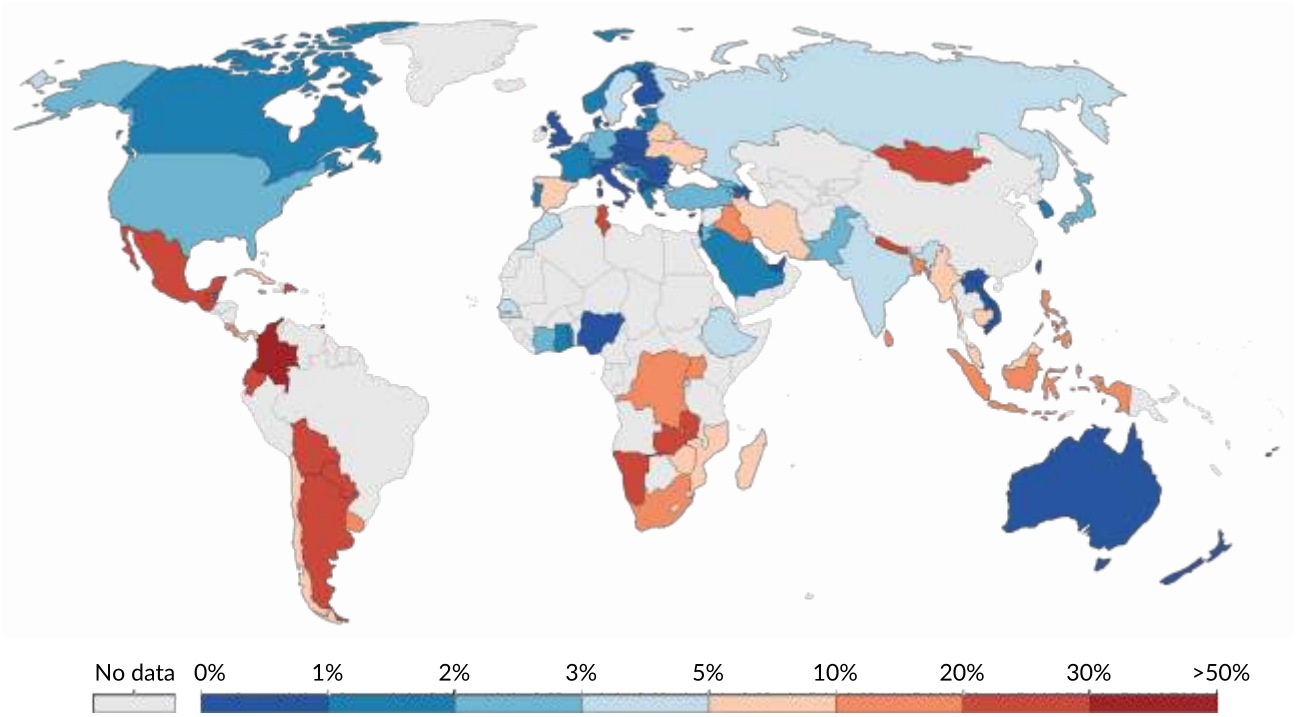
Global Spotlight On Countries Leading The Way In COVID-19 Testing

With COVID-19 severely testing the competency of healthcare systems around the globe, let us take a look at the testing strategies that have managed to turn the tide, even if for a temporary period. While the world aches to return to life as it once was, other countries can take a leaf from their book to get a better grip on the rampaging virus.

The share of COVID-19 tests that are positive (June 2021)

Our World in Data

The daily positive rate, given as a rolling 7-day average.



Source: Official data collated by Our World in Data – Last updated 18 June, 11:30 (London time) OurWorldInData.org/coronavirus • CC BY
Note: Comparisons of testing data across countries are affected by differences in the way the data are reported. Daily data is interpolated for countries not reporting testing data on a daily basis. Details can be found at our Testing Dataset page

CORONAVIRUSIS A LARGE family of virus that cause illnesses ranging from the common cold to fatal diseases. A new strain of novel coronavirus SARS-CoV-2 - not previously identified in humans – manifested as the COVID-19 disease and has snowballed into the current global pandemic.

Right from the start, the WHO has been calling for increased testing response across the world as it would help identify both symptomatic and asymptomatic cases, assist clinical management and support contact tracing. Tedros Ghebreyesus, Director-General of WHO exhorted the nations with, “Testing is part of a comprehensive strategy to suppress SARS-CoV-2 transmission and save lives. Testing should be strategic, make the best use of available resources and link to clear public health goals.”

WHO also published laboratory testing guidance for COVID-19 cases. It reiterated that sound laboratory practices will produce accurate results and ensure that the lab results translate into the right public health response.

Different countries have taken very different approaches for testing during the pandemic with varying impact. However, it is clear that the high rate of testing is what has enabled some countries to effectively control transmission and get a grip on the infection.

The German Game Changer

Even though the infection curve was pretty steep in the initial days of the pandemic, Germany is one country that actually emerged as one of the top performers in managing the SARS-CoV-2 virus.

“It is much more expensive to test too little than to test too much!” Riding on this mantra echoed again and again by the health minister, the country mobilized a vast network of private and public laboratories to quadruple its early COVID-19 testing capacity to almost 1.6 million tests a week by October 2020.

Indeed, Germany's early success is backed by powerful weapons – it has a strong public health care system, expert scientific institutions and a robust national network of private labs that are well-connected and work together in cooperation. This is further complemented by a pre-existing 'epidemic strategy' outlining costs and funding, robust health insurance system, extensive medical infrastructure and advanced laboratory equipment.

Germany has led the way in Europe with large-scale testing of its population

The government's strategy of intense testing and early development of testing capacity paid off with prompt identification and treatment of COVID-19 patients, thus keeping the death rate comparatively low. Yet, the country claims that its widespread testing is not as comprehensive as it would like it to be!

Moreover, one of the first COVID-19 diagnostic tests was proactively developed in Berlin in January 2020 itself and later adopted by the WHO for widespread deployment. It was a boon for the country that the labs already possessed the expertise, accreditation, and equipment to conduct PCR assays and could deliver accurate diagnoses with quick turnaround times.

This kind of rapid scaling up of testing capacity combined with an aggressive track-and-trace strategy enabled it to stall the outbreak and keep it from overwhelming the health

1ml saliva of Covid 19 infected patient contains approx. $1.2 * 10^8$ copies of the virus

system. And the European Union's most populous state can boast of bringing its positivity rate below 3% just about 50 days after the daily cases surpassed 30.

However, there was again a massive rise of cases in October and this second surge refused to subside for months. Buoyed by the onslaught, Germany did not hesitate to tweak its testing strategy and shifted to increasing rapid antigen tests from February, 2021. It even announced free RAT tests for everyone. The country is poised to soon restore a sense of normalcy in the pandemic once again.

South Korea's MERS Legacy Kicks into Gear

Given South Korea's proximity to China, it was expected to become the next hub for COVID-19 cases very soon. In contrast, the island nation's impressive response at stabilising the rate of infections and flattening the curve, that too without closing businesses, issuing stay-at-home orders and other drastic measures has taken the world by surprise.

The country relied on aggressive testing measures along with contact tracing and clear guidelines for the public. The focus was on preparing for large-scale testing right after the first case was reported. The government built innovative, high-capacity screening facilities which led to ramping up of testing capacity by 600% by November 2020. It was also working closely with the private sector to maintain an adequate supply of tests at all times.

Fact of the matter is that, in the aftermath of the flawed response to the 2015 MERS outbreak, the authorities instituted a spate of reforms to boost public health emergency preparedness and response. This strong enabling environment in the form of a well-functioning national health insurance system, efficient testing network, ample human resources and other infrastructure positioned the country to act quickly and effectively.

Drive-through clinics have helped South Korea implement rapid and widespread testing to successfully blunt the spread of the COVID-19 disease

Inspired by the drive-through counters at McDonalds and Starbucks, South Korea set up drive-through test stations in February 2020, much before the novel coronavirus outbreak was declared as a pandemic. Medical workers in PPE kits go to the patients' cars to collect the samples and can test up to 10 people within an hour itself.

By March, 2020, there were almost 50 drive-through centres, screening more than 100,000 people and delivering results within 3 days via SMS. It takes just about 10 minutes to register the person, check the symptoms, collect the swab samples and also disinfect the car. Moreover, this mitigated the need to disinfect waiting rooms that takes quite a long time.

Following South Korea, such centres have been established in the USA, UK, France, Spain, Ireland, Israel, South Africa and India.

91.7%
of Covid Patients are found with Covid virus in their saliva samples.

It is particularly noteworthy that the testing setup stays uniform across the country - the labs use the same testing equipment, do the same training and make decisions based on the same information.

By March 2020 itself, nearly 20,000 people were being tested every day in South Korea, more people per capita than anywhere else in the world. It was also amply praised by the WHO for developing innovative testing strategies.

This way South Korea has repeatedly managed to check the virus's spread and bring down the infection rate, curing outbreaks in March, August and a massive one in December 2020. That too, without overwhelming the hospitals or disrupting the health system.

Israel – A Role Model for the World

At the outbreak of the COVID-19 pandemic, Israel was battling the world's third-worst infection rate. Even though the country had hundreds of medical labs, only about 40 of them were capable of conducting COVID-19 tests. These were soon stretched to breaking point under the mounting burden and it would take one to even five days to get results of an RT-PCR test. The extended wait time was in part due to the high demand and partly because the samples were manually processed in the labs.

The Middle East nation quickly realized the shortage of facilities and staff and turned to additional bodies to conduct the testing, thus ramping up its ability to test the population. The testing infrastructure was rapidly strengthened with investments and long-term thinking.

The authorities also zeroed in on the fact that faster and more accurate testing is essential for identifying carriers and sending them into isolation before they can infect others. They started using innovative technologies to develop quick and reliable testing methods like mass sampling, point-of-care kits and even a pathbreaking breath analyser.

For instance, while other countries have also opted for the attractive pooling strategy to test samples from many people at once, Israel's P-Best testing is based on an algorithm that is used to easily detect rare genetic mutations. This accelerated the testing manifold and attracted world attention.

Along with this, the country uses artificial intelligence to analyse the RT-PCR tests, thus eliminating human error, achieving standardization and doubling the number of samples tested per day without additional staff.

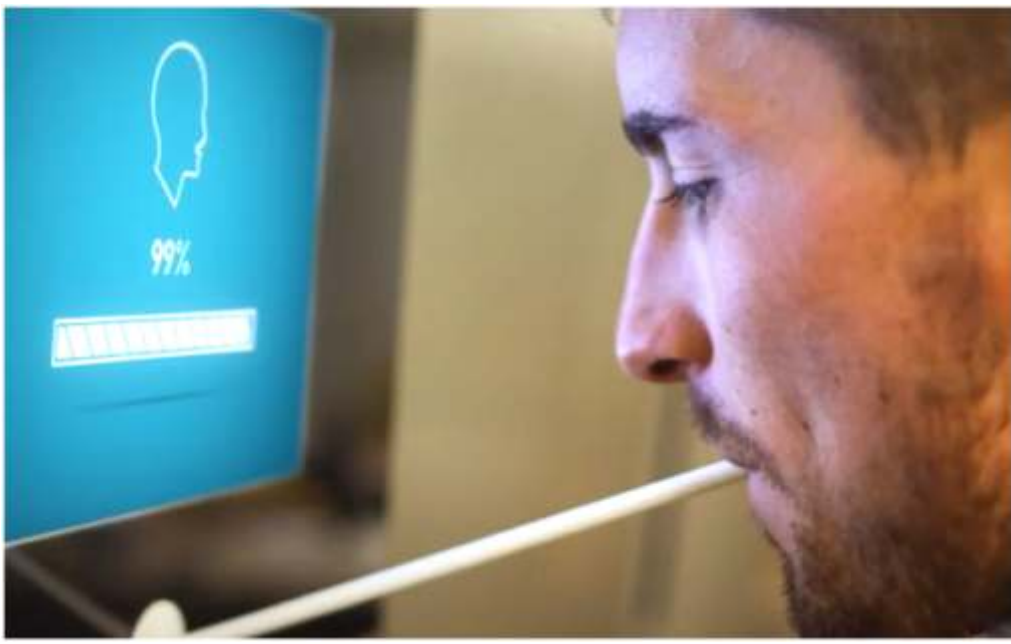
The Reliance Group has entered into a purchase agreement for installing this breath testing system in India

What stands in Israel's favour is the vast public health infrastructure crafted through heavy public investment since its creation about 70 years ago that could deliver value when push came to shove. Combined with the strictest and longest national lockdowns and a well-planned immunization program, the country moved from successfully lowering the caseload to attaining herd immunity and finally going mask-free from April 2021!

Prime Minister Benjamin Netanyahu proudly observed, “We are leading the world right now when it

The COVID-19 pandemic has shown the importance of data and science to build back more resilient health systems and equitably accelerate towards our shared global goals.

- Dr Tedros Adhanom Ghebreyesus



Israel's breath test can sniff out the SARS-CoV-2 virus

Covid-19 in Singapore: Nearly 50% residents vaccinated, says health ministry

comes to emerging from the coronavirus".

Singapore Leading by Example

Singapore is a country defined by a steady strengthening of its ability to manage emerging infectious disease outbreaks. It has been quietly, efficiently and effectively fighting the pandemic with large-scale testing underway for all suspected cases. The city-state pivoted quickly to combat COVID-19 with a testing strategy that included people with pneumonia and also people that died of a possible infectious cause/ influenza-like illness being tested in sentinel clinics in the first stage itself.

It is hailed for the prompt response of the government which kicked in as early as just 21 days since the news of the virus emerged! Very soon, it scaled 2,200 RT-PCR tests a day for a population of 5.7 million.

Testing has been deployed in primary care centres, hospitals and drive-through testing stations. It's not just about managing to contain the spread of the virus and having lower infection rates; Singapore is also enjoying the lowest COVID fatality rate in the world. By December 2020, it had reported only 29 deaths while more than 58,000 people were infected by the SARS-CoV-2 virus.

The pandemic strategy is defined by relentless efforts to find and isolate every case of COVID-19. The government has been systematically building up the national capacity to conduct tests for COVID-19. The laboratory infrastructure has been scaled up from around 2,900 PCR tests at the onset of the pandemic to a capacity of 60,000 to 70,000 tests per day from January 2021 onwards.

In May 2021, there were 27 laboratories capable of conducting 70,000 tests daily, with all testing operations mounted for active case finding and screening purposes. Even the utilisation of total lab capacity has significantly increased from 30-40% to over 80% in early May 2021. Moreover, the government insists on isolation for patients awaiting the results of their COVID-19 test and maintains swab isolation facilities for this purpose.

A case in point - once the authorities realized that the infection was spreading rapidly among migrant workers living in dormitories, the East Asian nation quickly ramped up its diagnostic capacity to test all 323,000 workers.

Given the recent resurgence in infections, the country quickly moved back into lockdown-like conditions to check the transmission and combat the disease.

Conclusion

While the health systems have been badly rattled by COVID-19 in both rich and poor countries, some countries stand out for their extraordinary health outcomes on the pandemic prevention and control frontier. Even though the highly-infectious virus continues its rampage, these countries are marked by massive testing and tracking programs early in the outbreak.

While they are still not spared the ups and downs with repeated waves, these countries still appear to be better prepared to handle the onslaught of the virus. Based on the evidence-based narratives of these countries, the rest of the world should endeavour to adapt the successful models to their own circumstances!

Source: Secondary research & media reports

Adv. Srishty Jaura
Editor –
"SPEAK UP!"

Time To Haul Up The Accreditation Scenario In The Country

Diagnostic testing is an intricate and sensitive process that calls for the right expertise and experience

PROFESSOR BEJON KUMAR Misra, Founder-Director, Patient Safety and Access Initiative of India Foundation had moved a Public Interest Litigation (PIL) in the Delhi High Court in September 2018 stating that unauthorized laboratories and diagnostic centres, managed by unqualified technicians, were conducting tests and providing unqualified inferences in the test reports which unnecessarily endanger the lives and safety of the common people and should be closed down. The plea also sought the formulation of a policy to regulate setting up and running of such entities and as an alternative, guidelines be framed for implementation of the Clinical Establishment Act (CEA), 2010 to deal with the entire issue.

The court had directed the Delhi government to take appropriate steps in accordance with the Supreme Court guidelines to contain illegal and unauthorised labs, but no concrete steps were taken by the authorities.

Therefore, in November 2020, in the wake of the COVID-19 pandemic, the leading consumer activist filed another application seeking urgent and strict implementation of the Delhi government's Health Bill, 2019 or the CEA, 2010, alleging that illegal and unauthorised pathological laboratories and diagnostic centres continue to operate without any checks and balances. Some are run illicitly, some do not have qualified pathologists and some do not even meet the other norms, leading to serious health repercussions, including death.

It also sought issuing of directions to the government to formulate a 'robust policy' in the interest of patients for regulating the opening and functioning of pathological laboratories in the National Capital Territory (NCT) of Delhi and to constitute an appropriate authority for regular checking of such laboratories. It contended that the efforts by the government continue to be an eyewash as only 10% of the 1,000 odd diagnostic labs in Delhi are actually accredited by the NABL.

In May 2021, he filed another petition seeking to ensure that all COVID-19 tests are conducted by NABL-accredited, ICMR-approved and registered pathological labs as the labs of NCT of Delhi are not conforming to the directions or orders of the Supreme Court. It also sought to direct the respondents to ensure the collection of COVID-19 samples is done by qualified lab technicians only along with the appointment of a Nodal Officer where consumers can report any illegality or foul practices detected in COVID-19 reports.

The Backstory

With the rapid unfolding of the pandemic, the importance of diagnostic testing cannot be overemphasised. Despite the urgency of scaling up testing, ICMR has thoughtfully tailored an effective testing strategy limited around NABL-accredited laboratories. However, as per clinical reports, many pathological labs are still conducting COVID-19 tests without any registration/accreditation and generating false/inaccurate reports.

The consumers obviously cannot judge the quality and efficacy of lab results on their own. It is the accreditation symbol on the reports or a NABL certificate hanging on a wall of the diagnostics lab which assures them that they can trust the facility and its results. Indeed, the certification is a confirmation of the efficient standards maintained by the labs in terms of testing, personnel and quality management systems. It denotes both technical competence and quality.

Present Scenario of Laboratories

Accreditation of medical labs is still a purely voluntary process in India. The entry barrier is low and almost anyone can open a lab today without any questions asked about the quality of services. There is no legal framework to validate their existence and most of them are simply registered under the Shops and Establishments Act.

This has led to the mushrooming of numerous small and unorganized clinical labs that are run by under-qualified technicians and rely mostly on automated testing to deliver substandard results at steeply discounted package deals.

Then there is the nexus between such labs and doctors with the latter prescribing tests in the former. The labs get steady business and pass on substantial incentives to the doctors. This poses a huge risk to delivery of quality healthcare as wrong reports can lead to mistreatment.

The Other Side of The Coin

The labs are faced with their own challenges. They already bear huge economic costs for purchasing the

NABL accreditation is the only way that consumers can ensure they are choosing a quality medical laboratory. Yet illegal labs are thriving in the absence of strict regulations. Can we afford to continue to consider accreditation as a proxy for quality of the institution? Shouldn't laboratory accreditation be made a regulatory mandate? There are voices repeatedly calling for tougher government regulation of diagnostic service providers.

supplies and equipment, deploying trained manpower and carrying out the testing.

A classic conundrum comes into play - Accreditation involves heavy expenses for fulfilling the diligent processes of test runs, record maintenance, infrastructure and trained human resources. This will force the labs to increase their prices which will only end up in loss of existing clients as well. Moreover, there is no empirical evidence correlating accreditation with increased revenue generation.

Many of the small and medium labs run by pathologists and microbiologists choose to avoid the NABL accreditation because it does not abide by the modifications in the CEA regulations which allows lab reports to be signed by medical practitioners qualified in pathology instead of a doctor.

While many of the clinical labs want to come forward and help in fighting the pandemic, they are limited not just by the regulatory obstacles but also the substantial capital investment involved in procuring specialized and expensive equipment and trained manpower for initiating COVID-19 testing.

Why Are the Rules Not Being Followed?

The Clinical Establishment (Central Government) Amendment Rules 2018: Rule 8A states that 'Every clinical establishment relating to diagnosis or treatment of diseases…... shall comply with the minimum standards of facilities and services as specified in the Schedule'.

However, most of the states and union territories have still not implemented the CEA and some operate their own clinical laws. There is strong opposition from the private sector healthcare providers, medical practitioners and even the Indian Medical Association.

Time for Change

NABL accreditation should be made compulsory for all pathological laboratories and diagnostic centres

NABL accredited testing laboratories in India have to go through an assessment, re-assessment, and surveillance from time to time. This is to ensure that these laboratories commit to quality in a continuous manner.

and they should start on the accreditation journey as soon as possible. Along with this, there is a pressing need to revisit the NABL guidelines to incorporate provisions that are resilient during public health emergencies.

The NABL on its part, expedited the approval mechanism with fast-track approval being granted to proficient labs within seven days. There are easy entry level schemes for labs which are not confident of full accreditation.

However, further measures are essential to make it feasible for small and medium labs to adhere to the current NABL standards of minimum equipment and human resources. There should also be incentives for getting accredited and focusing on providing the right quality.

The authority should devise a one-stop platform for the accredited labs with ratings, costs and reviews while ensuring standardised pricing or price ranges for the diagnostic tests.

These measures will make accurate diagnosis more accessible, available and affordable for all consumers.

Conclusion

In the words of Prof. Misra, “Encouraging the existence of only accredited path labs in the country is important - irrespective of whether it is commercially viable or not. We cannot and should not allow mushrooming of path labs managed by unqualified professionals and non-calibrated testing equipment. The state governments need to engage them professionally and encourage them with business in the interest of the poor. It has to be part of the Public Health Delivery System supported by the government and managed by qualified pathologists. Citizens' health is paramount and we can never compromise on patient safety and quality!” ◗

Source: Secondary research & media reports

The COVID Effect: A Look Into The Future Of Diagnostics

The COVID-19 pandemic has turned the world on its head. Even as we adjust to the 'new normal' in our work, our behaviour, our communication and our lifestyle, diagnostic testing is also primed to undergo a sea change in the post-pandemic world.

CEO and Founder of Healthians – a health test at home service provider - has 14 years of experience in IT and healthcare marketing. He shares his views about how the diagnostic industry has adapted, evolved and survived this global health crisis and is headed for a brighter future.

THERE IS A reason why adages on adaptability are in abundance. Adapting is the only way to survive, and survive the diagnostic industry definitely did. At the start, the industry was ill-prepared for a pandemic of this scale, but now it has learned plenty of valuable lessons from this global healthcare crisis. As the industry continues to plough through the current disruption, it is imperative that we prepare for another such possibility and build on the following lessons:

Lesson 1: Home Diagnostics Is the Future of the Industry

COVID-19 has already made a massive dent on the diagnostics sector with a steep fall in patient volumes since the beginning of this year. Before COVID struck, it was easy to manage and take care of your health, but post-COVID, people have been consumed by an eerie sense of fear that has impacted the visits to hospitals/clinics or labs. Regular check-ups have either been put on hold or become a cumbersome, stressful and time-consuming ordeal. But while the overall diagnostics sector seems to have suffered a decline, the area of home diagnostics has emerged as a silver lining in the new scheme of things.

Home diagnostics has risen as a saviour for people confined at home, and positive experiences have triggered a mindset shift amongst masses from lab-visits to at-home check-ups. Just like Telemedicine, Home Diagnostics is still at a nascent stage and lacks penetration at the moment, but this is bound to change as people have understood the convenience of at-home tests. Soon, home diagnostics will define how we view medical tests and health check-ups. Whether it's the chronic conditions like diabetes or thyroid that require constant and frequent monitoring or preventive health check-ups, the diagnostics category's inflection point has arrived this year with home diagnostics set for unprecedented growth.

Healthians is India's largest test@home service that guarantees highest quality results at honest prices.

Lesson 2: Digital Health Ecosystem Is Incomplete Without Diagnostics

As a whole, the healthcare industry has realised that healthcare has moved beyond the four walls of a hospital and has become agile.

The proliferation of health tests at home also helps patients complete the entire health management sequence from home - from blood tests to tele-consultation with doctors and finally, medicine delivery. A complete ecosystem by itself. People would probably visit a lab in the future only for complicated and specialist tests. The treatment of chronic conditions through home health check-ups is gradually becoming a habit, as people are realising the value and convenience they offer. Many players who were into home delivery of medicines earlier have realized the importance of diagnostics and therefore, now have included diagnostics as an offering through partnerships and affiliations.

Lesson 3: Technology-Led Diagnostics to Improve Customer Experiences

COVID-19 has demonstrated how important it is to have access to fast, reliable tests. Getting swift results not just for COVID-19 but for various other medical conditions is a primary need. There is also a requirement to adopt a more analytical approach towards gathering health data to monitor public health and establish trends. All this is possible only through digital means and advanced technologies like machine learning, AI, IoT, etc. With a more aware and knowledgeable generation, we know there will be a demand for greater access to such data-driven approach even in the healthcare industry.

Using technology, the diagnostic sector can better communicate, analyse and use information to overcome disruption and meet cost and quality objectives. Health diagnostics is on the verge of transformation and will need to shift towards more forward-thinking, long-term solutions.

Lesson 4: Being Self-Reliant and Streamlining Logistics Need to Be Given Primacy

The COVID-19 pandemic exposed the cracks in the Indian healthcare system. It highlighted the lack of preparedness on the part of manufacturers, and with global supply chain disruptions, the situation was dire. With too much dependency on imports for diagnostic kits and supplies, the Indian healthcare sector was not quite ready for an unexpected health crisis like COVID-19. In case a similar pandemic strikes again in the future, in that case, the diagnostic industry needs to be prepared for testing in a manner that will allow the sourcing of

critical raw material at a moment's notice. Manufacturers of diagnostic kits and material need to strengthen, expand their facilities and even enhance the supply chain and make it agile enough to cope with sudden demands and speed up the mitigating response to a crisis. Efficient logistics is an important aspect that defines success in the diagnostic industry and a dependable, well-connected logistics and supply chain will be the most significant difference between this pandemic and the next.

Lesson 5: Continuous Upgradation of Lab Infrastructure and Accreditations Need to Be Taken Seriously

One major observation we had last year, is when the pandemic hit us, testing as many people as possible became the need of the hour. However, not many labs had the necessary infrastructure or the accreditations required to be able to offer COVID testing facilities.

Hence, it's a big learning for the category, that to be prepared for any such sudden unprecedented crisis, labs need to be ready with all necessary approvals and accreditations instead of applying for them when the need arises. This will avoid unnecessary delays and chaos.

Lesson 6: We Are All in This Together

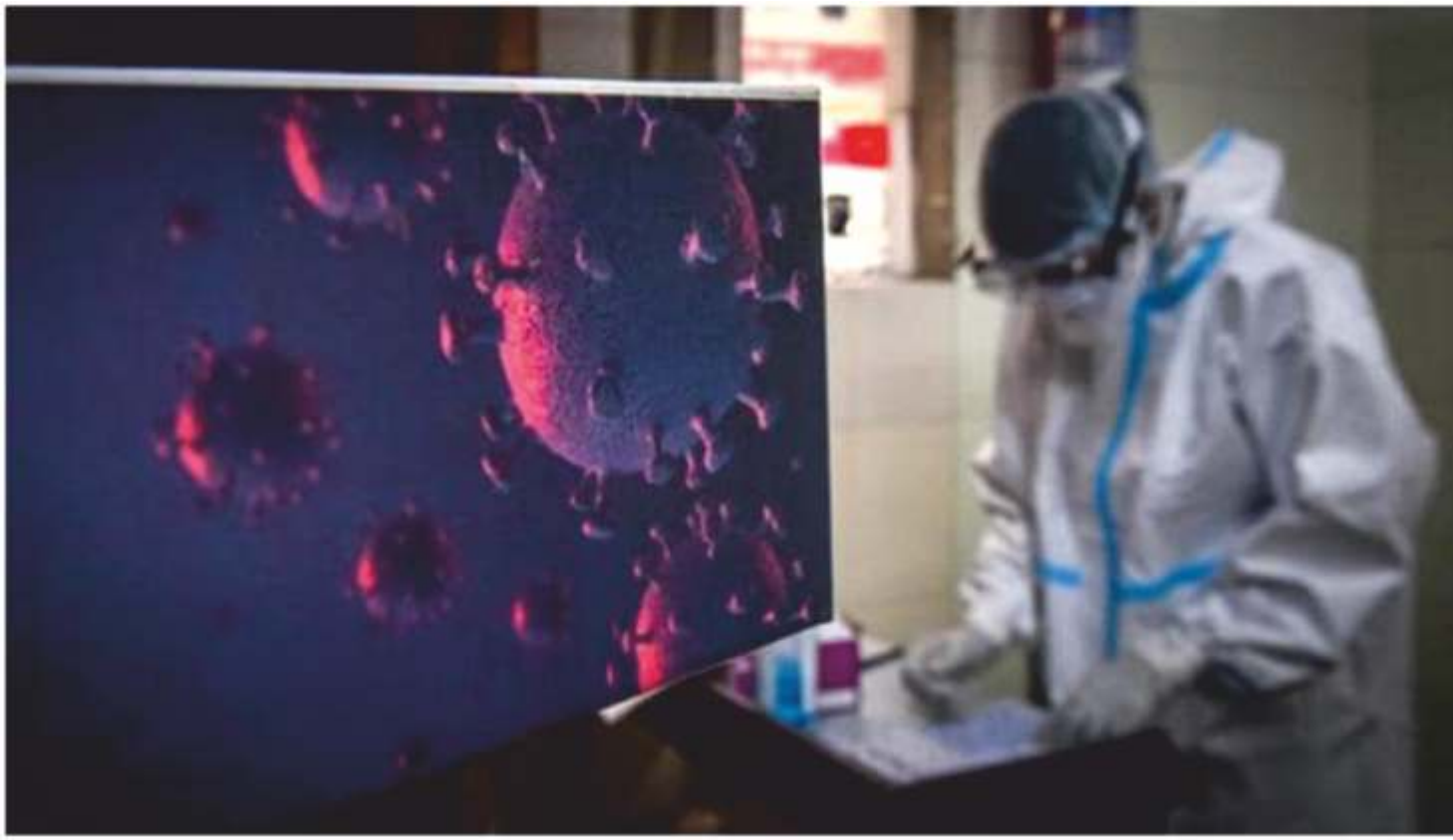
Faced with an unprecedented crisis like COVID-19, many diagnostic players were exposed to the risk of extinction since there was a considerable decline in patient footfalls. This inconsistency in diagnostic performance highlighted the need for close partnership between large and small players to play on each other's strengths and deliver better service experience to their customer base, thus reducing the risk of suboptimal performance at an individual level.

The healthcare industry was pushed to the edge by this pandemic, and adapting to the new normal was the only way to survive the onslaught and serve the masses. The rapid adoption of technology and digital means in the healthcare industry to find solutions to the various hurdles created by COVID-19 is a harbinger of times where healthcare services, mainly diagnostic services, can fulfil the needs of many without putting any extra strain on the existing system. The pandemic, with all its challenges, has taught some valuable lessons to the diagnostics industry. These lessons will help build a solid and dependable foundation for a connected and united industry that is driven to innovate and serve.

The article was originally published on ETHealthworld.com - https://health.economictimes.indiatimes.com/news/diagnostics/6-lessons-learned-how-the-diagnostic-industry-is-headed-towards-a-brighter-future-/80144661

Does Unaccredited Testing Jeopardize Quality Of COVID-19 Healthcare?

The importance of accreditation and the contribution from accredited laboratories cannot be denied during today's tough times. But should we continue to maintain accreditation as a mandatory requirement for the COVID-19 testing laboratories? The question calls for careful deliberation after taking both sides of the coin into account.



The raging debate of accreditation versus non-accreditation

MORE THAN A year ago, in the initial days of the pandemic, it was only specific ICMR agencies that were allowed to conduct COVID-19 tests. The testing strategy was steadily evolved and specific government labs and hospitals were empowered to conduct the sophisticated RT-PCR testing. Then, private medical laboratories were brought into the net so as to expand the testing facilities manifold and cater to the rising number of cases in the country.

However, the testing authorization has been kept limited to NABL-accredited labs and other agencies approved by the ICMR or WHO only. The names and locations of the authorized labs along with the approved test categories and other details are regularly updated on the website www.icmr.gov.in.

In July, 2020 the ICMR did make a concession by allowing non-accredited private labs - who are seeking NABL accreditation - to carry out the diagnostic tests for the viral disease. Dr. Nivedita Gupta, a senior ICMR scientist reiterated that, “Private labs that can complete accreditation in one month can, in parallel, submit their application to the council to carry out COVID-19 tests”.

The Ground Reality

It follows that no private lab is allowed to conduct any of the COVID-19 tests without due permission. However, many unaccredited and unrecognized labs are still sneakily going ahead with the SARS-CoV-2 virus testing.

In May 2020, the first instance of a private lab in Kolkata illegally testing swab samples without any authorisation from the ICMR came to light. The lab was sealed, slapped with a hefty fine and operations closed down very soon.

20 residents of Noida got positive COVID-19 reports from unaccredited private labs in June 2020 and were quarantined at a government isolation centre only to later find that they had not been infected at all when their samples were declared negative by the National Institute of Virology.

At the end of April 2021, the Jharkhand police cracked down on a private diagnostic lab in Jamshedpur for illegally conducting the Rapid Antigen Test (RAT). It was revealed that the lab had been doing the tests right since September 2020 without any kind of approval from the health department of the district administration, let alone the ICMR.

The Pressure is Mounting

Right since the beginning, various pathologists and their associations have been urging ICMR to permit non-accredited but registered medical laboratories – that are operated by certified pathologists and microbiologists and abide by ICMR guidelines and respective state governments - to conduct the RAT test to check for COVID-19 infection.

The non-accredited labs uphold that this will bring them in line with laboratories in government hospitals as

COVID-19 antigen tests provide fast results and don't require extensive laboratories to process

they are not subject to the stringent rules of getting accredited by NABL. As of May, there were 1266 ICMR-approved COVID-19 testing labs in the public sector that return standard and quality reports.

It follows that NABL accreditation cannot be considered the only criterion for quality and accuracy of medical test reports. The argument is that RAT testing is quick, simple and safe and is already being done by many labs for other viral diseases like dengue, HIV etc. These non-accredited labs have the capability to deliver quality and accurate laboratory reports as long as they fulfil other perquisites laid down by the respective state governments. Many of them are actually already providing other lab services as required for treatment of COVID-19 patients.

To tackle the deadlier second wave of the pandemic, many state governments are also pushing for permission to non-accredited laboratories for ramping up the testing facilities. The pathologists' associations are vociferously echoing the demand to allow non-accredited laboratories to carry out testing as they are capable of escalating the operations and will help increase testing while easing the pressure on the already-overwhelmed accredited labs.

The Health Ministry finally relented in the middle of May 2021 and permitted all government and private health facilities to conduct RATs by doing away with the necessity for accreditation. However, ICMR should also take into account that many of the established labs are equipped with the machines and know-how to efficiently conduct RT-PCR testing as well.

NABL accreditation is being viewed as an unnecessary regulatory obstacle that is actually depriving the common man of timely medical treatment and violating the basic human right of health. It is also contradicting the country's efforts to augment testing for SARS-CoV-2 and contain the wildly rampant COVID-19 pandemic. For instance, there are only about 140 NABL accredited private labs in Maharashtra as against the more than 5000 labs run by pathologists and microbiologists.

NABL has established its management system in accordance with ISO/IEC 17011: 2017 and is signatory to International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Accreditation Co-operation (APAC).

In fact, the prerequisite of NABL accreditation being mandatory itself is becoming a major hurdle for ramping up testing.

The Risks Are Real

Accreditation is a footprint of the quality and accuracy of a laboratory. It further signifies that the entity complies with international standards.

The process for NABL accreditation is clearly defined and easy to implement for the laboratories. Considering the urgent requirement for scaling up testing, NABL is further easing and expediting the procedures for labs which desire to enhance their capabilities to test all the parameters of the SARS-CoV-2 virus. It is also constantly encouraging and assisting small labs to ramp up testing and get accredited in order to ensure that the nation gets increased availability of accredited testing infrastructure to fight the pandemic.

This accreditation checks all the functional aspects of the laboratory – from a well-defined organizational chart, standard operating procedures, good laboratory practices and human resources to equipment management, reagents, inventory of records and proper communication. They have a well-established and functional quality management system in place and follow stringent quality control procedures before arriving at test results which ensures trust and reliability.

The accredited labs also have enhanced biosafety parameters in place in accordance with the guidelines laid out by the WHO and the Indian government for carrying out diagnostic work in the laboratory. These prevention and control measures are especially essential for staff safety given the high biosafety hazards of the SARS-CoV-2 virus.

Moreover, the accredited labs are mandated to adjudicate strict measures to prevent fraudulent activities and always stay vigilant for any such underhand activities.

On the other hand, the unaccredited labs may lack trained professionals to conduct tests or have inadequate lab facilities to analyse the samples. Many of the smaller labs are at best capable of testing and not diagnosing. A false report or analysis can be the precursor of grave consequences.

A Harvard study by Professor Ashish Jha reveals that over 5.2 million medical error cases are registered in India on an annual basis. A major chunk of misdiagnosis occurs in the smaller labs which are run by technicians rather than qualified medical professionals.

Can we afford a wrong diagnosis at this stage of the pandemic? Not to mention that the lack of proper biosafety precautions while conducting the tests can lead to leakage, resulting in further spread of the disease.

Conclusion

On its part, ICMR is continuously augmenting the country's testing facilities for COVID-19 by giving approval to both government and private laboratories. But it grants the coveted testing permissions to labs if and only if they have the proper infrastructure, personnel and capability to handle such samples. The requirements range from proper infrastructure (including a BSL-2 cabinet), uploading lab reports online and verification of equipment to imparting basic training to the staff.

Many medical labs across the country are pooling their resources and improving their capabilities to provide medical testing services during this crisis. However, the fact remains that just about 6200 of the more than 1,00,000 labs in India have been accredited by NABL in different genres.

Changes are underway and government labs in medical colleges and hospitals will also be required to obtain NABL accreditation in the near future.

Source: Secondary research & media reports

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Level Of Laboratory Preparedness For SARS-CoV-2 Testing In India

All of us have realized the value of getting tested. It is the only way to identify whether someone has been infected with COVID-19. All treatments, therapy and recovery will be based on the test results. Accordingly, all people who recently came in contact will be informed and tested if needed. Antibody testing is also important as it will show whether someone has been infected in the past.

COMMON FOLKS SHARE their experiences with COVID-19 testing and bring forth their views on the testing infrastructure in the country.

Getting tested for COVID-19 was a fairly easy process for us. We called a diagnostic centre for home sample collection. The technician was wearing a kind of semi-PPE kit only. I understand that it is practically impossible for a field technician to wear the kit many times over as he is zipping through the city, collecting anywhere between 40-50 samples per day. I am glad that he was masked properly and sanitised his hands before and after collecting the swabs. The most difficult part was giving a sample for the nasal swab - it felt terrible to have the bud pierced into the nostrils! For me, giving blood samples is much easier!

The only drawback is that the reports came in after more than a day. We know that labs are fully booked and many of the lab staff are getting infected which is causing significant delays in the test reports. But if we have to break the chain, we must get results in a few hours. People with symptoms are unable to get themselves tested or have to wait for days to know if they are infected or not. In many places, the lack of a COVID-positive report means seriously ill patients are unable to access hospital admission and oxygen cylinders.

While the scale at which testing has ramped up is remarkable and labs are working round the clock to meet the increased testing demand, there is still a pressing need to further increase the testing facilities during the times of surge so that people can isolate themselves quickly and inform their primary contacts too. Also, the Arogya Setu app must be updated automatically by the testing centre. I feel the app has now become redundant!

Sidharth Shah, Hyderabad

I visited the lab for my COVID test and the person in charge took the sample immediately. It went off smoothly and even the report came on time. I am glad that both the Indian government and the healthcare professionals have come together in a timely fashion and are able to protect the citizens and avoid preventable deaths.

Ajay Kedia, Kakinada

The COVID-19 pandemic posed an unsurmountable challenge to the public health system of India. The country was caught in its own web of ill-equipped medical facilities and diagnostic testing parameters. We went into a complete lockdown last year to buy time and mount an effective response. We expected the government to come up well now, but the second wave has exposed the frailty of our healthcare system for all the world to see. There are so many wrong test reports that we are afraid to rely on the results – if the report comes positive, we wonder whether we really have COVID or are being forced to quarantine and take medicines for no reason? And if it comes negative, there is a lingering fear that we could still be infected and playing with our health or infecting others around us.

Sumeet Vohra, Siliguri

Diagnostics are a key element of the health infrastructure – it plays a key link in the context of disease identification and surveillance. However, India's daily testing rate of 1276 samples per million population is significantly less than most western countries. We still need to deploy tests more broadly, especially in the rural areas. Someone I know in Kalpi, Ambala was running from pillar to post to find a good COVID-19 lab to test his father. Finally, he travelled miles by rickshaw to the town to get the testing done. Given the high infectivity of the virus, he was afraid that he would also contract the disease. Alas, his father died while undergoing treatment in an Ambala hospital. Do we also have to resign ourselves to becoming a statistic in the lakhs of deaths across the world?

Soham Rasoiwala, Sikkim

It is disgusting to see private labs looting the helpless public with their arbitrary charges for COVID testing. We were charged Rs. 1500 by an accredited lab for the RT-PCR test when the government had clearly fixed it at Rs. 500. The labs know that consumers are at their mercy and continue playing such capricious games with us. They are taking advantage of the fact that our desperation will make us shell out whatever they demand. Is it justified? Are there no ethics or morality left in the world to fleece the vulnerable at such a tragic phase of time?

Yograj Kutty, Wayanad

Every day we are reading about people selling fake COVID-19 RT-PCR reports. When I insisted on getting quick test results from the home sample collection person, he told me he can immediately give a positive report or a negative one – as I wish – for a small amount of money.

I know it is quite easy to use computer software to edit original reports and give bogus ones. Also, there are reports of fake coronavirus testing kits being sold in the market.

We are in the midst of a public health emergency of an unprecedented scale. Why are people out to make money even during such grave times? Don't they realize their selfishness is playing with people's lives and can become the cause of their deaths? Has humanity died completely in this hour of need?

Sunita Singh, Chandigarh

Source: Secondary research & media reports

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National Accreditation Board
for Hospitals and Healthcare Providers

QUALITY COUNCIL OF INDIA
Creating an Ecosystem for Quality

NABH AYUSH ENTRY LEVEL CERTIFICATION PROGRAM

TAKING QUALITY TO OUR ROOTS

NABH
is a constituent board of Quality Council of India (QCI).
It is playing a pivotal role at the National level in propagation, adoption and adherence to healthcare quality standards in AYUSH healthcare delivery systems.

With an objective to bring more light to AYUSH related treatments, the Government of India in 2014, formed the Ministry of AYUSH and consequently brought in the National Accreditation Board for Hospitals & Healthcare Providers (NABH) to start implementing quality healthcare standards for hospitals providing AYUSH treatments as well.

In the recent years, there has been a paradigm shift from allopathy system to traditional healthcare. To support this trend, health insurers have started offering AYUSH treatment covers as part of their health insurance policies. NABH Ayush Entry Level Certification Standards provide an objective system of empanelment by insurance and other third parties. These standards also address the need for quality control and quality monitoring in AYUSH healthcare as required by the Pradhan Mantri Jan Arogya Yojana (PM-JAY) under the Ayushman Bharat Scheme.

NABH AYUSH Entry Level Certification standards are easily downloadable from NABH website.

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