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ENHANCING INDIA'S TESTING CAPACITY

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INTRODUCTION

On 18 May India reached a landmark in its fight against COVID-19 by performing 100,000 tests in one day. Starting from less than 100 tests per day just two months ago, a 1000 fold increase in just 60 days was made possible by dedicated teams from research institutions, medical colleges, testing laboratories, ministries, airlines and postal services working together. In January 2020, India had only one laboratory testing for COVID-19, at the Indian Council of Medical Research's National Institute of Virology, Pune. Today there are 555 laboratories across the country, performing molecular tests for diagnosis of COVID-19 - an unparalleled achievement in the history of the Indian health system.

THE REMARKABLE STORY



Location of Laboratories across India

The remarkable story of how India became fully self-reliant in its testing capabilities, despite starting from scratch just a few months ago, is one about the steely resolve of multiple agencies, working together round-the-clock to save lives.

Faced with an unprecedented challenge, both in terms of technicalities and scale, Indian scientists had to innovate extensively, health workers had to train and learn on the job, administrators had to coordinate multiple actions round the clock amid the challenges of nationwide lockdown, and civil and defence aviation personnel had to fly at the shortest of notices.



The fundamental principle to counter any infectious epidemic is to detect/isolate/treat/manage cases early and prevent the occurrence of new cases. In the absence of an effective treatment, prevention is the best strategy, which revolves around testing. In a diverse country like India, for inclusive and equitable access to testing, optimization of resources, based on the evolving epidemic was an essential part of sustainable scaling up. As the epidemic evolved, India's testing strategy underwent iterative calibration to keep pace with the changing epidemiology and extent of infection. This ensured that access to tests was assured for risk groups that needed it the most; wasteful, unnecessary testing was avoided; and testing infrastructure was optimally scaled up without taking away resources from other key public health interventions.

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Sample collection using throat or nasal swabs, which are then kept in a special fluid called viral transport medium (VTM). This is transported to the laboratory, where the genetic material of the virus is separated from the swab and transport medium using a RNA extraction kit.

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Using another kit, an RT-PCR machine detects the virus. In order to do this test, a constant supply of swabs, VTM, viral extraction kits and PCR kits are required, for use by trained personnel wearing proper personal protection equipment (PPE) in quality assured laboratories

This is evidenced by the fact that for every positive test more than 20 negative tests have been done throughout the course of the epidemic. However, before this, an even more primary requirement was to have the expertise, materials, staff and capacity to carry out testing safely, successfully and reliably. The RT PCR test for COVID-19, although increasingly available around the country today, involves multiple, complex steps (Mentioned in the left box)



With the pandemic soaring, there were severe constraints for procuring COVID 19 diagnostic material. Empowered groups set up by the Government of India, cutting across ministries, were tasked with the objective of increasing procurement and ensuring regular supplies. Indian missions and embassies abroad helped identify global suppliers in a highly competitive seller's market. At the same time, the government partnered with domestic industry to work towards self sufficiency in testing. Because of the nationwide lockdown, industries faced severe operational challenges related to movement of human resources and procurement of material and machinery. A task force was set up principally to ease out these challenges and handhold the industry to accelerate production.

THE INCREASE IN NUMBERS

A case in point being the development of swabs for COVID 19, which was initiated within 6 days locally. Three companies can now manufacture upto 200,000 swabs/day. Despite the lockdown, the production of VTM was upscaled from 500,000 units per year to 500,000 units per day. After expedited approval from the Central Drug Standard Control Organization, a private company has developed 10 million PCR tests and 5 million viral extraction kits. Another indigenous manufacturer has developed a viral extraction kit. These RT-PCR testing kits should be validated before mass testing. Initially, these tests were validated only at NIV, Pune. To expedite kits produced by the industry and reduce the burden of NIV, 14 validation centers have been approved. 71 kits have been evaluated till date and 28 have been approved for use. Out of these, 14 kits were indigenous ones, paving the way for self-sufficiency in testing.



THE LOGISTICS OF TESTING

In order to ensure that the supplies reached every laboratory in a timely manner amid the nationwide lockdown, the services of the Ministry of Civil Aviation and their airline partners in government and private sector under 'Mission Lifeline Udan' were availed. They carried ICMR consignments of COVID 19 diagnostic material across the country. In the last 2 months, despite the lockdown, approximately 40 tonnes of testing material was transported in more than 150 flight operations, reaching out to the remotest corners of the nation. Doorstep deliveries were coordinated with several courier companies and state governments. As the lab network expanded, a need was felt to rope in India Post, which has country wide operations, to streamline the flow of supplies to the last mile. To cut down transit times, logistic complications and risks of stock outs, decentralized storage of these supplies has been done by building a network of 16 storage depots in a phased manner across the country.

SETTING UP A LABORATORY

RT-PCR tests also require handling of viral samples that carries the risk of infecting laboratory personnel. Laboratory operationalization is a 4-step process that ensures the quality of testing and safety of laboratory staff. The first step is availability of proper infrastructure as per WHO guidelines, including a cabinet to ensure safety from the virus. The next step is to review the documentation using photo and videographic evidence. The third step is to train the staff at a VRDL. In the fourth step a trial run is done to ensure independent functioning of the laboratory. To hasten the operationalisation of laboratories, 14 mentor institutes were identified to guide testing sites through these 4 steps. The risk of infection associated with PCR testing limits it to only laboratories in medical colleges which have proper infrastructure.



TRUENAT TESTING

Another modality of testing, called TrueNAT, an indigenous testing developed for tuberculosis, can also be used for COVID 19 testing. The advantage of TrueNAT is that the virus is lysed during the testing process, minimising the risk of infection and contamination by the virus. While RT-PCR is limited to well equipped hospitals, TrueNAT can be deployed at district hospitals across the country, addressing the last mile barrier for COVID-19 testing. Currently, 77 TrueNAT machines are already in use for COVID and there are a total of 1,800 TrueNAT machines across the country which can be deployed by states when needed for COVID 19 testing.

COORDINATED EFFORT

The scale up of testing laboratories started with a network of 106 ICMR-funded Viral Research and Diagnostic Laboratories, (VRDLs), which already had the capacity to conduct testing for viruses similar to SARS-CoV-2. Subsequently, the testing was initiated in partnership with laboratories in DST, DBT, ICAR, CSIR, DRDO, MHRD, medical colleges and private laboratories. Private laboratories that had approval from the National Accreditation Board for Testing and Calibration Laboratories (NABL) were accepted. With its testing capabilities now matching the most advanced countries in the world, Indian institutions have risen to the occasion in an emergency situation. In the days ahead their contributions will be required even more as India continues to grapple with the clear and present danger still posed by COVID-19.



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