

DECODING LAB DIAGNOSTICS IN COVID PANDEMIC

20 AUGUST 2021



DR. BARNALI DAS
CHAIR, AACC INDIA SECTION

MESSAGE FROM THE CHAIR:

It is a great honour to serve as the chair of the AACC India Section. The AACC India Section was established as a first international pilot project of the American Association for Clinical Chemistry (AACC). Its objective is to connect with global leaders in clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, laboratory management and other frontier areas of laboratory medicine. AACC India Section activities have included: i) granting 30 AACC trainee memberships to postgraduates in India ii) organizing two symposiums, in conjunction with national conferences iii) holding two AACC India Section CMEs at AIIMS, New Delhi and Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Mumbai with international and national speakers, and clinicians, and iv) hosting a Meet and Greet at the 71st AACC Annual Scientific Meeting & Clinical Lab Expo in Anaheim, California, US.

The COVID-19 pandemic has notably underscored the essential role that we as diagnosticians play not only in identifying SARS-COV-2 infections, but also in supporting clinicians working strenuously to effectively manage patients with COVID-19 who exhibit a considerable spectrum of illness.

Therefore, we conducted an AACC India Section webinar on “Decoding Lab Diagnostics in COVID Pandemic” on 20th August 2021 with Dr. Stephen R. Master, AACC President and other esteemed national faculty. We had three outstanding speakers along with Dr. Master and distinguished special guests who attended the event. The speakers and guests included laboratory experts, clinical chemists, management experts, accreditation authorities and IVD specialists. During the event, we also facilitated our speakers with AACC full Memberships.

Topics discussed during this webinar on 20th August 2021 included:

AACC’s Perspective on the COVID-19 Pandemic

Dr. Stephen R. Master
American Association for Clinical Chemistry (AACC) President
Chief, Division of Laboratory Medicine
Director, Michael Palmieri Laboratory for Metabolic and Advanced Diagnostics
Children’s Hospital of Philadelphia
Associate Professor of Pathology and Laboratory Medicine,
Perelman School of Medicine at the University of Pennsylvania

ICMR Journey and Testing Protocol for COVID-19

Dr. Nivedita Gupta
Scientist ‘F’ & In-charge Virology Unit,
Division of Epidemiology & Communicable Diseases
Indian Council of Medical Research
Department of Health Research
(Ministry of Health & Family Welfare)

What Did We Learn from the Genomes of SARS-CoV-2 from India?

Dr. Vinod Scaria

Senior Scientist,

CSIR Institute of Genomics and Integrative Biology (CSIR-IGIB)

COVID-19 Protocol: Clinical Perspective

Dr. Randeep Guleria

Director, AIIMS New Delhi

Member, National Task Force on COVID-19

So, I end, quoting Robert Frost,

“Miles to go.”

With our distinguished executive committee members, we expect another great year for the AACC India Section and our valued members.

We will have many more such events in future and hopefully we will have the opportunity of meeting all of you in person soon.

Thanks & Warm Regards,

Barnali

Dr. Barnali Das, MD, DNB, PGDHHM.

Chair, AACC India Section

Consultant, Biochemistry & Immunology Division.

Laboratory Medicine,

Kokilaben Dhirubhai Ambani hospital & medical research institute,

Four Bungalows, Andheri (West), Mumbai - 400053, India.

- Adjunct Faculty, Kasturba Medical College, Manipal, MAHE.

- Executive Member, Scientific Division, IFCC.

**COVID-19 PROTOCOL:
CLINICAL PERSPECTIVE****Dr. Randeep Guleria***Director, AIIMS New Delhi**Member, National Task Force on Covid-19*

COVID-19 is a novel respiratory viral illness which has acquired pandemic proportions and claimed over 4 million lives over the past 20 months. As the pandemic has resulted in a global health crisis, development of treatment protocols was an utmost priority. With this in consideration, the Ministry of Health & Family Welfare (Government of India) has issued guidelines on the clinical management protocol of COVID-19. These guidelines have been periodically updated as new scientific evidence has accrued, with the latest version being released in May 2021.

In this talk, we discussed the status and what the predictions are for the future. Also, what the previous pandemic has taught us. The classification of COVID-19 into mild, moderate, and severe disease was presented. We specified the important laboratory investigations for COVID-19 along with their indications. We elaborated upon the home management of mild COVID-19 illness and the indications for hospitalization.

Next, we discussed the hospital management of moderate and severe COVID-19. Herein, we reviewed the current evidence and recommendations for common therapeutic agents including corticosteroids, Remdesivir, and Tocilizumab. Steroid therapy has been found to have survival benefit in patients with moderate to severe COVID-19 who require supplemental oxygen or mechanical ventilation. However, the rampant use of steroids in patients with mild COVID-19 may be harmful and should be avoided. Use of Remdesivir in selected patients with moderate illness may reduce the time to clinical recovery. Tocilizumab may improve outcomes when used in patients with severe disease who worsen despite steroid therapy. However, the benefit of Tocilizumab is seen only when the drug is started within 24-48 hours of initiation of intensive care or mechanical ventilation, and superadded infection has been excluded. We also examined the role of supplemental oxygen, non-invasive ventilation, and invasive mechanical ventilation in COVID-19 along with their respective indications. Prone positioning has also emerged as a useful clinical modality in hypoxemic patients: both self-pronation for patients on supplemental oxygen and prone positioning for patients on mechanical ventilation. As more scientific evidence emerges on various aspects of the management of COVID-19, protocol will undergo further modifications in the future.

COVID-19 TESTING AT SCALE – HOW INDIA DID IT

Dr. Nivedita Gupta

Scientist 'F' & In-charge Virology Unit,
Division of Epidemiology & Communicable
Diseases

Indian Council of Medical Research
Department of Health Research
(Ministry of Health & Family Welfare)

Before the COVID-19 pandemic, India had 100 NABL accredited private laboratories and 75 medical and research laboratories in public sector for molecular testing of RNA viruses. Additionally, 106 virus research & diagnostic laboratories (VRDLs), established by the government after the 2009 H1N1 pandemic had state-of-art diagnostic facility. Following key steps were taken for expeditiously augmenting COVID-19 testing in India:

- **Strengthening the available infrastructure:** The National Institute of Virology (NIV), Pune, the apex virology institute of the Indian Council of Medical Research (ICMR), standardized diagnosis of SARS-CoV-2¹ and provided reagents and standard operating protocols to the VRDLs². Through virtual trainings and daily interactions, from January to mid-March 2020, all the 106 VRDLs initiated testing for COVID-19.
- **Engaging with the private sector:** In view of increased testing demand, ICMR partnered with NABL for onboarding all laboratories accredited for molecular testing of RNA viruses. NABL also evaluated and accredited mobile testing laboratories, which were later deployed in underserved areas with high caseloads.
- **Setting up Mentor Institutes:** ICMR laid down standard guidance on space, infrastructure, equipment, human resource and training requirements for molecular virology laboratories and established fourteen mentor institutes to support equipped public and private laboratories to undertake COVID-19 testing³. Testing was also successfully established in North-Eastern states, Andaman & Nicobar and Lakshwadeep Islands and Ladakh.
- **Political commitment:** Testing was also commissioned at many institutes of ICMR, animal husbandry, science ministries and defense. Evacuated Indian Nationals were tested and quarantined. As per gazette notification of June 2020, Medical Council of India (MCI) mandated existence of operational Biosafety Level 2 laboratory in all medical colleges for registration⁴. With concerted efforts, COVID-19 testing laboratories increased from 1 in January 2021 to 2868 laboratories with testing capacity of 25 lakhs/day and more than 480 million cumulative tests in August, 2021.
- **Outside help to the path of self-reliance:** Till early 2020, India was importing most of the diagnostic materials. Soon, demand far surpassed supplies and India focussed on in-country manufacturing through multi-stakeholder engagement. Validation protocols were laid down, panels were created, and forty validation centres were commissioned. By mid-August 2021, more than 1400 diagnostics were validated wherein 70% of the approved kits were indigenous, resulting in approximately twenty-fold cost reduction.
- **Increasing outreach and access to testing:** Indigenous COVID-19 screening and confirmation test were expeditiously validated by ICMR^{5,6} and along with GeneXpert were partially redeployed from TB to COVID-19 testing. In June 2020, India became the first country to successfully validate and introduce Rapid Antigen Test (RAT), in its national testing program. Home testing solutions were approved in May 2021. These strategies together increased

downstream access to COVID-19 testing.

- *Inter-Laboratory-Quality Control (ILQC) program:* Quarterly interlaboratory quality control (ILQC) program for RTPCR laboratories was established since April 2020⁷. A tiered structure was created with a National QC laboratory at ICMR-NIV, Pune followed by 38 designated regional QC laboratories. WHO designated the National QC laboratory as the Global COVID-19 Reference laboratory and 1100 Proficiency Testing panels were provided by WHO as part of External Quality Assurance Program.
- *Calibrated expansion of testing:* In February 2020, only China returnees were tested, followed by symptomatic contacts of laboratory confirmed cases, healthcare workers and patients of sub-acute respiratory illness followed by community Influenza like illness (ILI) clusters, hospitalised/symptomatic ILI in returnees and migrants and pooled testing^{8,9}. With inclusion of RAT, immunocompromised individuals and patients undergoing surgery were included. Finally, testing in India was fully liberalised in September, 2020 by including testing on demand. The testing strategy was calibrated to match the size and capacity of the laboratory network, availability of kits and disease spread^{10,11}.
- *Single source of data entry:* Since inception, Government of India created a single source of data entry at ICMR which is shared downstream with several stakeholders¹². A common sample referral form was deployed in the field, filled through a mobile RTPCR application developed by the National information Centre (NIC) in partnership with ICMR. The data entry portal was diversified to accommodate direct inflow of data from state governments, private and public laboratories.

Overall, the multipronged strategy deployed by India to augment COVID-19 testing has been exemplary¹³. India has showcased its immense strength to fight the odds and emerge as a self-reliant country with one of the largest COVID-19 testing networks globally.

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