

Shri Narendra Modi
Hon'ble Prime Minister of India
South Block, Raisina Hill
New Delhi 110011

25 March 2020

Dear Modi ji,

Access to Free Testing and Free Treatment for COVID-19

The number of people infected with COVID-19 has steadily been increasing globally. As is well recognized, access to screening test and confirmatory diagnostics is an important element of our response to the COVID-19 pandemic. We note that 119 government laboratories that are either operational or in the process of operationalization have been approved for conducting COVID-19 testing. We appreciate that ICMR has also started approving private labs to carry out testing and so far has approved 26 labs in 7 states. The labs network is to cover 15,000 collection points.

Efforts in high burden countries have shown a correlation between extensive screening and control of the epidemic, and even of mortality. Testing can also pinpoint "hot spots", where timely prevention and treatment efforts can be implemented to address the pandemic.

We, therefore, welcome the amendments to the testing strategy through which the eligibility criteria for undergoing diagnostic tests for COVID-19 were expanded to include all hospitalized patients with Severe Acute Respiratory Illness, all symptomatic healthcare workers, and asymptomatic direct and high-risk contacts of a confirmed case (between day 5 and day 14 of coming in contact). The testing strategy needs to be further expanded to all patients with Severe Acute Respiratory Illness or Influenza like illness and not restricted to only hospitalized patients with Severe Acute Respiratory Illness. Further, at specific well chosen sentinel sites within each state, there should be adequate population wide testing with an adequate sampling design so as to understand the actual spread of the disease - and the proportion of infected who are severe, or with mild symptoms and who are asymptomatic.

The Government first diagnosed COVID-19 by Reverse Transcriptase polymerase chain reaction (RT-PCR), a molecular technique performed in centralized labs. More portable versions of these molecular diagnostic machines are required to decentralize testing.

We therefore welcome that ICMR has established a fast-track mechanism for validation of non-US FDA/CE approved commercial test kits at ICMR NIV, Pune and is permitting the use of the test kits that are subsequently approved by CDSCO. Further studies to validate the accuracy and quality of these kits should be continued in parallel.

Laboratories in public health systems across the world have had delays in securing reagents. We would in this context like to draw your attention to the absence of local production of reagents and raw materials of reagents, necessary to secure availability of laboratory confirmation and RT-PCR test kits for COVID-19 and other diseases. We request you to mobilize the domestic capacity available with national and the domestic industry for securing the local supply.

Only 3 mass-produced test kits – Altona Diagnostics, Mylab and Seegene–have been approved to date through this process. We understand that several more applications are pending validation by ICMR NIV or will soon seek such validation. Accelerated approval of the test kits is critical to ensure sufficient availability of kits to meet the growing need of testing.

We understand that currently testing is being carried out in the government laboratories through home brewed kits. This is relatively time consuming and expensive too. Many commercial test kits have the potential to deliver faster results and at significantly lower costs. Therefore it is important to ensure the availability of cheaper and quicker tests that have passed strict validation. Moreover, private labs, where testing has been restricted to only commercial test kits, also require access to the kits. However, the mere availability of tests kits and lab facilities alone will not enable the scale-up of testing under the current testing strategy.

We have serious concerns and question the approach to make patients pay up to Rs. 4500 for testing in private labs because it negates the public health response to the pandemic and creates inequitable access to testing for people who meet the testing criteria. We further understand that test kits developed by Indian companies may significantly reduce costs, and therefore urge appropriate support for scaling up of domestic production to further reduce costs. The ICMR's call for private labs to provide free testing is unrealistic. **Irrespective of whether an individual is tested in a public or a private lab, the Government needs to bear the cost.**

The constraints of public health infrastructure will make the use of the private sector necessary for testing as well as treatment. As infection spreads, and particularly at the stage of community spread, it is inevitable that more private sector hospitals and laboratories will be pressed into action.

We appreciate that the Government has already instructed for COVID-19 related expenses to be covered under government-sponsored insurance schemes such as Ayushman Bharat. However, the majority of the population is outside the purview of government schemes and lacks access to health insurance that would cover COVID-19, and would be vulnerable to catastrophic expenditure and potential exploitation in the private sector.

Therefore, we urge the Government to announce and follow a **free test and free treatment policy** in dealing with this public health emergency, and make the necessary cost-sharing arrangements with the private sector for its services. Such a responsible approach would enable the Government to fulfill its duty in protecting peoples' health and also ease any overwhelming burden on the public sector, enhancing our collective efforts to contain the disease.

We request you to instruct the relevant Government ministries and offices to:

- immediately ensure testing for COVID-19 as per the testing protocol in private laboratories free of charge to patients, with reporting of test data to appropriate centres
- mandate all test results should be made publicly accessible and put in an open repository
- make necessary arrangements to extend treatment for COVID-19 even in private healthcare institutions at no cost to patients
- provide for full disclosure of the prices at which test kits are being supplied by each manufacturer as well as the costs of testing in public and private laboratories
- accelerate the evaluation of pending applications of RT-PCR test kits for COVID-19 and subsequent approval by CDSCO of kits passing validation, and provide appropriate support for scaling up production to reduce costs
- ensure timely procurement and supply of test kits approved by CDSCO for supply to Government and approved private laboratories for testing
- take urgent steps to secure supplies and to promote local production of reagents, raw material of reagents, and other physical components used such as swabs which are used in testing

We urge you to expedite the action of the Government on our proposals provided through this letter.

Sincerely,

Jan Swasthya Abhiyan (JSA)

All India Drug Action Network (AIDAN)

All India Peoples Science Network (AIPSN)

Copy to:

Dr. Harsh Vardhan, Hon'ble Minister, Ministry of Health and Family Welfare (MOHFW)

Dr. Balram Bhargava, Secretary DHR & Director General ICMR, MOHFW

Dr. Priya Abraham, Director, ICMR National Institute of Virology (NIV)

Ms. Preeti Sudan, Secretary, MOHFW

Dr. V. G. Somani, Drugs Controller General of India, Central Drugs Standard Control Organization (CDSCO), MOHFW

Dr. S. Eswara Reddy, Joint Drugs Controller (India), CDSCO

Shri D. V. Sadananda Gowda, Hon'ble Minister, Ministry of Chemicals and Fertilizers

Dr. P. D. Vaghela, Secretary, DOP, Ministry of Chemicals and Fertilizers

Smt. Shubhra Singh, Chairperson, NPPA, Ministry of Chemicals and Fertilizers

Dr. Vinod K. Paul, Member, Niti Aayog

Prof. K VijayRaghavan, Principal Scientific Adviser to the Government of India

Dr. P K Mishra, Principal Secretary to Prime Minister, PMO

Shri P. K. Sinha, Principal Advisor to Prime Minister, PMO

Dr. ShrikarPardeshi, Joint Secretary, PMO

For further information, contact:

Prof. T. Sundararaman, 9971415558, sundararaman.t@gmail.com

Dr. Sulakshana Nandi, 9406090595, sulakshana.nandi@gmail.com

K. M. Gopakumar, 9372927647, kumargopakm@gmail.com

Malini Aisola, 7838381185, malini.aisola@gmail.com