

Maharashtra Association Of Practicing Pathologists & Microbiologists

Reg. No. MAH / 11167/Str.

MAPPM ; 126/20
Date : 06.07.20

To
Dr. Balram Bhargava,
Secretary DHR &
Director General ICMR,
New Delhi..

Subject : Permission to conduct Antigen testing of COVID-19 by 'Standard Q Covid-19 Ag detection kit', by SD Biosensor, South Korea, to all Pathologists/ Microbiologists run Laboratories- withdraw clause of NABL accreditation.

Dear sir ,

Government of India and ICMR are making best possible efforts to Contain the COVID - 19 Pandemic. The success of these efforts reflect in low Case fatality Rate and percentage infectivity in India as compared to the world statistics. We would like to make some suggestions regarding present criteria prescribed by ICMR for Rapid Antigen testing.

Many Private pathology laboratories from Maharashtra, run by duly qualified and Medical Council registered pathologists have applied for permission to conduct Rapid Antigen testing of COVID-19 by 'Standard Q Covid-19 Ag detection kit', by SD Biosensor, South Korea on email ag-pvthosp-nabh@icmr.gov.in.

Many of these laboratories have been denied Permission based on the argument that these laboratories are not Accredited by NABL. The reason for rejection being " **requirement of NABL accreditation for private labs is as per ICMR advisory and we are bound to abide by them**".

There is a letter from ICMR dated 01.07.2020 to all the states. I would like to quote some part of it that is relevant in the present context.

' Since "test-track-treat" is the key strategy for early detection and containment of the pandemic, it is important to augment testing for SARS-CoV-2 in all parts of the country. This is the only way to detect the Infection early and prevent its spread. To ramp up testing in the

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country, ICMR has so far approved a total of 1,049 public and private laboratories for COVID-19 testing. Of this, 761 labs are in the public sector and 288 are in the private sector. Further, ICMR has also recommended use of a rapid point-of-care antigen test kit for diagnosis and more such kits are being validated to increase the available options to the citizens.

3. However, it has been observed that in some States/ UTs, the capacity utilization of the testing labs, particularly the ones In the private sector, is grossly sub-optimal. It is strongly advised that you should take all possible steps to ensure full capacity utilization of all COVID-19 testing laboratories in the State/UT.

4. It has also been observed that some States/UTs have mandated the need of a prescription from a Government doctor for making an individual eligible to undergo COVID-19 test. In view of the increased load on government healthcare facilities, this mandatory requirement may at times pose an Impediment for an individual to get tested and lead to unnecessary delays. At this juncture, it is absolutely necessary to facilitate testing at the earliest by enabling all qualified medical practitioners including private practitioners to prescribe COVID test any Individual fulfilling the criteria for testing as per ICMR guidelines. In fact, ICMR strongly recommends that laboratories should be free to test any Individual in accordance with the ICMR guidelines and State authorities must not restrict an Individual from getting tested, as early testing will help in containing the virus and saving lives.

I would like to draw your attention towards the available modalities for testing. While RT PCR Is the gold standard for diagnosis of COVID-19, ICMR has recently approved the use of a point-of-care rapid antigen test for early detection of COVID-19. The test is quick, simple, safe and can be used as a point-of-care test in containment zones as well as hospitals, as per criteria specified by ICMR for testing.

6. In view of the above, it is requested that impediments, which restrict testing may be removed forthwith. Further, to facilitate testing:

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Efforts should be made in 'campaign mode' by setting up camps/using mobiles vans in high incidence areas to collect samples of all symptomatic Individuals as well as their contacts, and get those samples tested by using rapid antigen tests. The positive Individuals should be treated according to the treatment protocol and the negative ones should be tested for RT-PCR"

The intent of letter and the insistence on NABL accreditation criteria for Antigen testing are contradictory to each other.

- A. In this letter the need of extensive testing , tracking and treatment is rightly stressed . It has also suggested to set up camps and mobile vans to collect samples of all symptomatic individuals and their contacts and use of Rapid Antigen test. It is not possible to set NABL accredited laboratories in all nooks and corners of our country where there are Hot Spots.
- B. With the Unlock process travelers have increased. In Maharashtra the increase in covid cases in rural areas is due to travelers only. We can think of starting rapid antigen tests at inter-district Check posts.
- C. Now as the rainy season has begun we anticipate a rise in vector borne and waterborne diseases with Dengue likely to raise its head amongst other diseases . Dengue treatment needs platelets. Plateletpheresis is a procedure that takes around one hour. During this period there is a chance of transmission of the Corona virus if the donor happens to be an asymptomatic carrier . We can prevent this by testing The SDP donor by Rapid antigen test prior to the procedure along with other tests.
- D. Doctors have made up their mind to work with COVID . They are attending regular OPDS But with unlock many patients are getting detected as COVID positive. Many registered medical practitioners are in confusion whether to treat common non covid ailments and emergencies and surgical procedures without knowing Covid-19 status of the patient. Many of these clinicians want Rapid antigen tests to be done but they don't have access to NABL accredited laboratories nearby.

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E. Rapid Antigen test is quick, simple, safe and can be used as a point-of-care test in containment zones as well as hospitals and in preoperative settings. But the rider of NABL accreditation being mandatory is a major hurdle to ramp up testing and contain the SARS – cov2 virus and treatment of Non Covid ailments.

F. NABL Accreditation Vs laboratory run under supervision of MCI/ State medical Council registered Pathologists/ Microbiologists:

1. In India NABL Accreditation is a voluntary process. Going through 112 of NABL documents, which are the norms for the personnel in the laboratory/ signatory authority, keeps on changing and many times it was contradictory to Hon. Supreme Court order dated 12.12.2017 regarding certifying Pathology reports. So NABL itself is biased and does not obey the law of the land . Many laboratories initially accredited didn't apply for renewal.
2. **NABL accreditation is the only norm for quality and accurate reports :**
There are 761 ICMR approved COVID testing labs in the public sector , the majority of whom are not accredited by NABL. These non accredited labs are also giving standard and quality reports. So NABL accreditation cannot be said to be the only criteria for quality and accurate reports. Otherwise these laboratories in the public sector need to be stopped from functioning.

G. **Availability of Pathologists/ Microbiologists run Labs:** There are almost 5000 Pathology Laboratories in Maharashtra in which MMC registered Pathologists / Microbiologists are supervising the process of testing , preparing and certifying reports. These laboratories are distributed across the state including metro cities to municipal council areas at taluka places. All quality norms are taken care of. They are diagnosing diseases and on the basis of their reports which patients are being treated with favorable clinical outcome.

H. **Scarcity of NABL accredited Labs :** In Maharashtra there are only 48 NABL accredited laboratories , majority of them are located in metro cities like Pune, Bombay, Nagpur, Aurangabad. Many of the districts in the country don't have a single NABL accredited lab. This is because Many Pathologists and Microbiologists' don't want to go for accreditation just

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because NABL does not obey Hon. Supreme Court order dated 12.12.2017 and other laws of land.

I. **Many non accredited pathologists laboratories** are providing laboratory services required for treatment of to covid positive patients admitted in covid centre.

J. **Majority of Corona Care hospitals are not NABH accredited.**

Sir,

Considering the need of the hour in containing Pandemic, I humbly request you to withdraw the clause of NABL accreditation for the Rapid Antigen test and permit this test to Laboratories willing to do this test , where full time Pathologists or Microbiologists are working and abiding by guidelines of ICMR and State govt .

Refraining non-NABL accredited , Pathologists or Microbiologists run laboratories from conducting Rapid Antigen tests will be contradictory to the intentions of the govt. to contain SARS- CoV-2 and will be refraining common man from medical treatment and violation of basic human right of health .

Thanking You,

Yours,



DR. Sandeep Yadav. MD

President,

Maharashtra Association of Practising pathologists and microbiologists.

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