



सत्यमेव जयते



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सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक, आई सी एम आर

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Addl.Chief Secretaery/Secretary/Principal Secretary Health (All States)

Sub: Protocol for using 'Rapid antibody test' in Hot area – epidemiological studies and surveillance

I am writing to you with reference to the rapid antibody test kits for COVID-19 testing. It is understood that many States intend to use these kits in affected areas.

2. The National Task Force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID-19 has been revised further. The revised document is enclosed for your reference.

3. It is critical to understand the following key facts while using the rapid antibody tests:

- Gold standard frontline test for COVID-19 diagnosis is **real time PCR based molecular test**, which is aimed at early virus detection.
- The rapid antibody test cannot replace the frontline test.
- The rapid Antibody test is a **supplementary tool** to assess the prevalence of the diseases within a specific area / perimeter.
- The rapid antibody test will **only be of utility after a minimum of 7 days of onset of symptoms**.
- Data about these rapid tests is emerging and understanding of their utility for diagnosis is still evolving.
- The rapid tests are useful for **epidemiological studies and surveillance purposes**.
- **THE TEST HAS TO BE DONE UNDER STRICT MEDICAL SUPERVISION.**


4. The enclosed ICMR advisory is for Hot spots. In case your state does not have a Hot spot, these tests may be used for:-

- a) Any hotspot which may emerge in future
OR
- b) As a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far.

5. Before starting the rapid test, it should be registered on covid19cc.nic.in/ICMR and data related to the test should be reported on the same.

With best regards

Yours sincerely


(Balram Bhargava)

Enclosed: As above

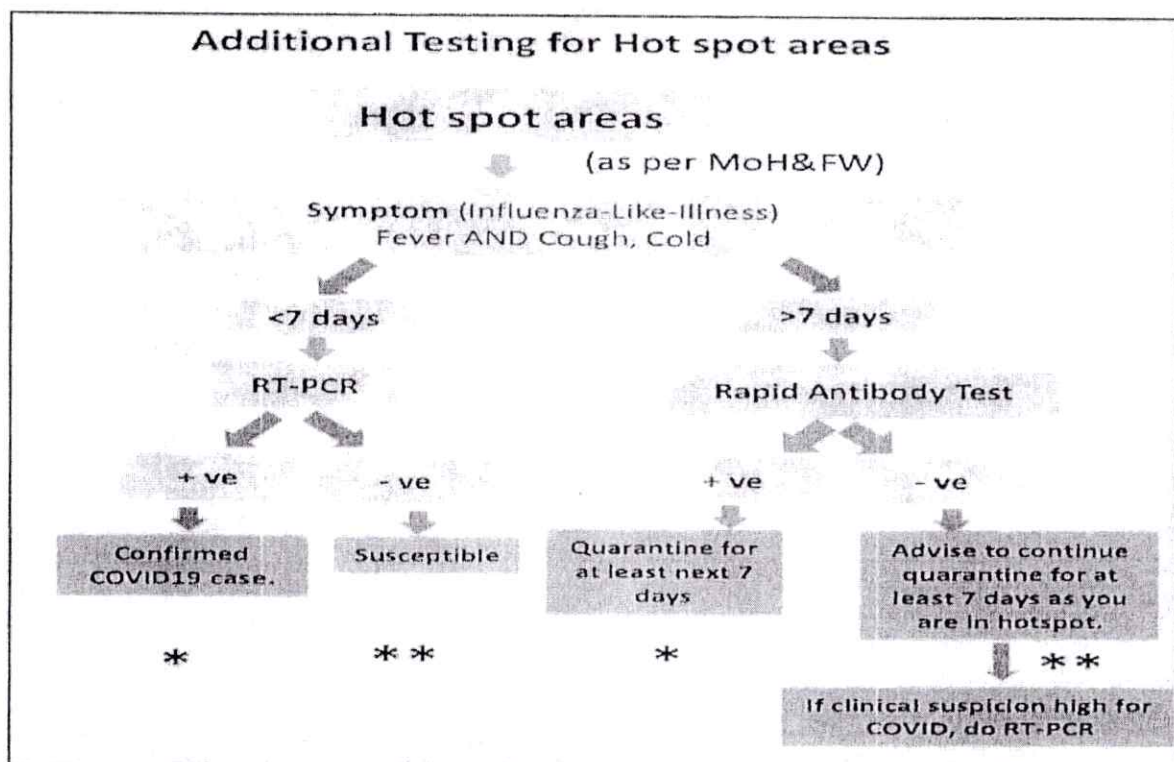
CC: Chief Secretary/Administrators

A. COVID-19 Testing Strategy for India (Recommended for the entire country)

Real-Time PCR (RT-PCR) test and Point-of-Care molecular diagnostic assays are recommended for diagnosis of COVID-19 among individuals belonging to the following categories:

- All symptomatic individuals who have undertaken international travel in the last 14 days
- All symptomatic contacts of laboratory confirmed cases
- All symptomatic health care workers
- All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)
- Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact

B. Additional (in addition to A) Testing recommended in hot spots



- * Refer to Hospital if symptoms appear / worsen
- ** Follow precautions, social distancing, use masks, frequent hand washing, avoid unnecessary travel)

Balran Shalgaon

**INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH**

Advisory on feasibility of using pooled samples for molecular testing of COVID-19

Background: Number of COVID-19 cases in India is rising exponentially. In view of this, it is critical to increase the numbers of tests conducted by laboratories. Positivity rate in cases is still low. Hence, it may help to use the pooled samples for screening. A pooled testing algorithm involves the PCR screening of a specimen pool comprising multiple individual patient specimens, followed by individual testing (pool deconvolution) only if a pool screens positive. As all individual samples in a negative pool are regarded as negative, it results in substantial cost savings when a large proportion of pools tests negative.

Objectives: To increase capacity of the laboratories to screen increased numbers of samples using molecular testing for COVID-19 for the purpose of surveillance.

Methods & Results: A feasibility study was conducted at DHR/ICMR Virus Research & Diagnostic Laboratory (VRDL) at King George's Medical University (KGMU), Lucknow. It has been demonstrated that performing real-time PCR for COVID-19 by pooling 5 samples of TS/NS (200 ul/sample) is feasible when the prevalence rates of infection are low. All individual samples in a negative pool to be regarded as negative. Deconvoluted testing is recommended if any of the pool is positive. Pooling of more than 5 samples is not recommended to avoid the effect of dilution leading to false negatives.

Recommendations for sample pooling for real-time RT-PCR screening for COVID-19 are as follows (based on the KGMU study):

1. Use only in areas with low prevalence of COVID-19 (initially using proxy of low positivity of <2% from the existing data. Still a watch should be kept on increasing positivity in such areas
2. In areas with positivity of 2-5%, sample pooling for PCR screening may be considered only in community survey or surveillance among asymptomatic individuals, strictly excluding pooling samples of individuals with known contact with confirmed cases, Health Care Workers (in direct contact with care of COVID-19 patients). Sample from such individuals should be directly tested without pooling
3. Pooling of sample is not recommended in areas or population with positivity rates of >5% for COVID-19

Preferable number of samples to be pooled is five, though more than two samples can be pooled, but considering higher possibility of missing positive samples with low viral load, it is strongly discouraged to pool more than 5 samples, except in research mode.