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National Health Mission  
SDA Complex, Kasumpti, Shimla-9  
Himachal Pradesh

Dated: Shimla-171009, \_\_\_\_ July 2020

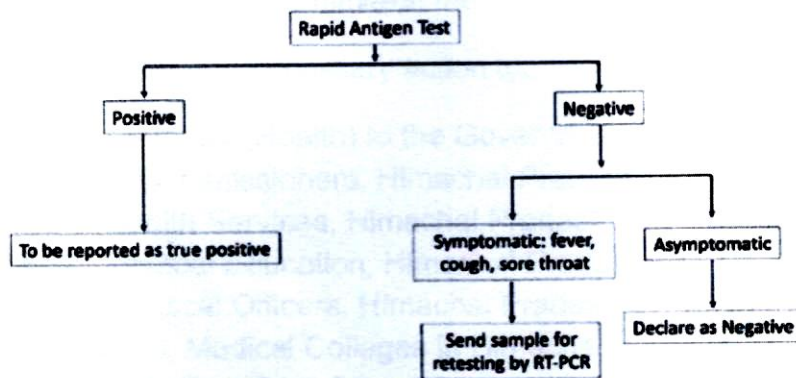


### NOTIFICATION

Real time RT-PCR is the gold standard test for diagnosis of COVID-19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for diagnosis of COVID-19 in the State. All these platforms require specialized laboratory facilities in terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours and the time taken for sample transportation. These issues limit the widespread use of the RT-PCR test and also impede quick augmentation of testing capacity in various settings. Government of India has issued guidelines from time to time for use of antigen-based assays as point-of-care tests for early detection of SARS-CoV-2 and to increase testing so as to achieve the objective of test, track & treat and thereby prevent and control the spread of COVID-19 infection.

ICMR has recently allowed private NABH/NABL hospitals/Labs to initiate antigen testing vide letter no. ECD/COVID-19/Misc./2020 dated July 16, 2020 and several requests are being received from the NABL Laboratories in the State for permission to start COVID-19 Rapid Antigen Tests. The request has been carefully considered keeping in view the advisories being issued from time to time by Ministry of Health and Family Welfare, Government of India and ICMR, New Delhi. The following guidelines are laid down for conducting the Rapid Antigen Tests by the private NABH/NABL hospitals/Labs in the State of Himachal Pradesh:

1. RT-PCR tests including CBNAAT and TrueNat (molecular based diagnostics) remain the gold standard for diagnosis of COVID-19. The Antigen tests have high specificity and relatively low sensitivity.
2. The results of the Rapid Antigen Kits shall be interpreted as per the following algorithm:



3. For testing the symptomatic negatives, the samples shall be sent to the RT-PCR Lab which is conducting the COVID-19 Samples for the particular area in which private NABH/NABL hospital/Lab is located. It shall be the responsibility of the private NABH/NABL hospital/Lab to get the sample of symptomatic negative (by Antigen Assay) tested by RT-PCR at no extra cost.
4. Only those Antigen based assays shall be used which are validated and approved by ICMR. The Present list is annexed with this notification and the updated list can be seen at [www.icmr.gov.in](http://www.icmr.gov.in) from time to time.
5. Sample collection, transportation and testing will be the sole responsibility of the private NABH/NABL hospitals/Labs. The diagnostic lab/hospital should have requisite strength of Medical and Paramedical Staff for the purpose. The prescribed guidelines issued for sample taking, transport, testing (including the biosafety precautions) and biomedical waste management shall be adhered to, by the concerned hospital/lab.
6. It has to be ensured that the details of sample collected and results of samples be entered on the ICMR portal for which a formal letter of request shall be sent by the hospital/lab to the concerned Chief Medical Officer. The State Surveillance Officer shall issue login credentials for the hospital/lab upon the recommendations of the concerned Chief Medical Officer.
7. The rates to be charged by the authorized hospitals/labs for conducting Rapid Antigen Test shall not exceed Rs. 700/- per sample inclusive of all charges.

  
 Additional Chief Secretary (Health) to the  
 Government of Himachal Pradesh





Endst no. As Above, Dated: Shimla-9, the

Copy for information and necessary action to:

1. Special Secretary (Health) to the Government of Himachal Pradesh
2. All Deputy Commissioners, Himachal Pradesh
3. Director Health Services, Himachal Pradesh
4. Director Medical Education, Himachal Pradesh
5. All Chief Medical Officers, Himachal Pradesh
6. All Principals, Medical Colleges in Himachal Pradesh
7. All Senior Medical Superintendents in Himachal Pradesh
8. State Surveillance Officer, NHM, Himachal Pradesh
9. All Private NABH/NABL Hospitals/Labs

  
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