GOVERNMENT OF NAGALAND DIRECTORATE OF HEALTH AND FAMILY WELFARE NAGALAND::KOHIMA

ADVISORY ON RAPID ANTIGEN TEST COVID-19 TESTING

Dated Kohima, the ______ th July 2020.

No: DHFW/COVID-19/2019-20/55/9-19 :: ICMR has approved use of Rapid Antigen Test for quick detection of COVID-19 patients and accordingly the following Guidelines are to be strictly adhered to by all users:

 Only ICMR validated Rapid Antigen Test shall be used. The details of validated Test kits List of Companies / Vendors of Rapid Antigen Test Kits for COVID-19 can be downloaded from:

https://www.icmr.gov.in/pdf/covid/kits/List_of_rapid_antigen_kits_22072020.pdf

- 2. As recommended by ICMR, the deployment of the rapid antigen Point of Care (PoC) test for COVID-19 testing is permissible in the following setting:
 - a. All containment zones identified by the State Governments,
 - b. All Central & State Government Medical Colleges and Government hospitals
 - c. All private hospitals approved by National Accreditation Board for Hospitals & Healthcare (NABH).
 - d. All private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs.
- 3. A positive test should be considered as a "true positive" whereas all symptomatic cases testing negative through rapid antigen test should be confirmed with a real-time PCR test. The detail advisory issued by ICMR can be downloaded from:
 - a. https://www.icmr.gov.in/pdf/covid/strategy/Advisory for rapid antigen test1406 2020.pdf
 - b. https://www.icmr.gov.in/pdf/covid/strategy/New additional Advisory 23062020
 3.pdf
- 4. Rapid antigen PoC test is recommended for use subject to the following conditions:
 - a. All hospitals, labs, State Govts intending to perform the PoC antigen test need to register with ICMR to obtain the login credentials for data entry. Interested Institutions may send their request on the following email id's:
 - For Govt Hospitals

: ag-govthosp@icmr.gov.in

For Private Hospitals

: ag-pvthosp-nabh@icmr.gov.in

- b. All data of testing needs to be entered into the ICMR portal on a real time basis.
- c. All labs/hospitals initiating testing through the rapid antigen PoC test need to ensure that all symptomatic negative patients should be essentially referred to a real-time RT-PCR test for COVID19. This is particularly essential as the rapid antigen PoC test has a moderate sensitivity.
- d. All the entities using antigen PoC test are expected to tie up with the nearest RT-PCR COVID-19 testing lab to ensure that all symptomatic who are negative by the rapid antigen test get tested at the nearest facility.
- e. The data of individuals tested by RT-PCR will need to be entered through the lab performing the RT-PCR test.





The recommended use of Standard Q COVID-19 Ag a point of care diagnostic assay is given at ANNEXURE: 1.

5. All hospital/ labs initiating testing through the rapid antigen PoC test are to mandatorily register with ICMR for data entry into the ICMR portal on a real time basis and are to send their details to the State Nodal Officer for COVID-19 Testing, Dr. Robin Lotha, Joint Director by email to stong@rntcp.org and to contact Mob. No: 8119000484 for any queries. Detailed video is available on ICMR website at:

http://www.icmr.gov.in/video/Data Entry Antigen v4.mp4.

6. Registered Private Hospitals within the State is allowed to charge user's fee for COVID-19 Testing through Rapid Antigen Test at the rate fixed by the Government.

This of Advisory is subject to revision from time to time.

(Dr. VIZOLIE Z SUOKHRIE)

Principal Director Directorate of Health & Family Welfare

No: DHFW/COVID-19/2019-20/55/4-19

Dated Kohima, the _____ 31 th July 2020

Copy To:

- 1. The Deputy Secretary to the Chief Secretary, Government of Nagaland for kind information.
- 2. The Principal Secretary to the Government of Nagaland, Home Department for kind information.
- 3. The Commissioner & Secretary to the Government of Nagaland, Health & Family Welfare Department for kind information.
- 4. The Director, IPR Department for wide publicity.
- 5. The Mission Director (NHM)/ Director (H)/ Jt Director (Store)/ Jt Director & SPO (NTEP) for information and necessary action.
- 6. The Deputy Commissioner/ Chief Medical Officer/ Medical Superintendent of all districts for information and necessary action.

7. Guard file/ Office copy.

(Dr. VIZOLIÈ Z SUOKHŘIE)

Principal Director Directorate of Health & Family Welfare



Use of Standard Q COVID-19 Ag a point of care diagnostic assay is recommended in the following settings in combination with the gold standard RT-PCR test:

A. Containment zones or Clustering of Cases in a defined geographic area/ place (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):

i. All symptomatic ILI/ SARI.

- ii. Asymptomatic direct and high-risk contacts with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.
- B. Healthcare settings (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):
 - All symptomatic ILI/ SARI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
 - ii. Asymptomatic patients who are hospitalized or seeking hospitalization, in the following highrisk groups:
 - Patients undergoing chemotherapy
 - Immunosuppressed patients including those who are HIV+;
 - Patients diagnosed with malignant disease;
 - Transplant patients;
 - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
 - iii. Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
 - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures etc.
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis etc.

*ILI case is defined as one with acute respiratory infection with fever ≥ 38°C AND cough.

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- a. Should be interpreted between 15 to 30 minutes with a naked eye. No interpretation should be made before 15 minutes of after 30 minutes.
- b. Symptomatic individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.
- c. Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.
- d. The test should be conducted onsite under strict medical supervision and within one hour of sample collection in extraction buffer.

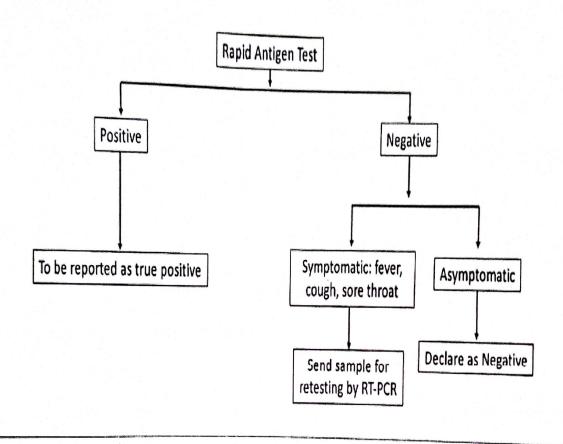
The algorithm attached herein for interpreting the antigen test should be followed wherein all positives can be labeled as true positives and symptomatic negatives should be subjected to RT-PCR.

(Dr. VIZOLIE Z SUOKHRIE)

Principal Director
Directorate of Health & Family Welfare

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ALOGORYTHM FOR COVID-19 TESTING USING RAPID ANTIGEN POINT-OF-CARE TEST



- All positive and negative results should be entered into the ICMR portal on a real time basis after performing the antigen test.
- Results of samples subjected to RT-PCR should be entered after the RT-PCR results are available.

(Dr. VIZOLIE Z SUOKHRIE)

Principal Director
Directorate of Health & Family Welfare

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