Government of Karnataka

No. HFW/246/ACS/2020

Karnataka Government Secretariat
Vikasa Soudha,
Bengaluru, dated: 10.07.2020

CIRCULAR

Subject: Guidelines on the use of Rapid Antigen Testing Kits for COVID-19

Reference:
1. ICMR-GOI advisory on newer additional strategies for COVID 19 testing dated 23/06/2020
2. Order No. HFW 205 CGM 2020 regarding revised lab testing protocol –Karnataka dated 08.06.2020
3. Addendum to revised lab testing protocol dated 09.06.2020

In view of evolving situation of COVID-19 in Karnataka, testing protocol has been revised from time to time. There is a need to enhance testing using a reliable point-of-care (PoC) rapid antigen detection test with good sensitivity and specificity for early detection of infection. Based on the advisory issued by ICMR on rapid antigen detection test kits, the following guidelines are issued.

A. The COVID-19 antigen detection tests are recommended as mentioned in the flowchart in Annexure-1

B. All hospitals, laboratories, medical establishments (both government and private) intending to perform rapid antigen tests **'should mandatorily register with ICMR,** and enter positive and negative results of each person on ICMR portal (Annexure-2). Failure to register with ICMR or uploading COVID-19 results of each person on portal will be liable for action under Epidemic Diseases Act.

C. Brief description and video guide link for PoC Rapid Antigen Test as mentioned in Annexure-3 shall be followed.

D. The testing protocol issued by Government of Karnataka in reference (2) & (3) vide above should be strictly followed.

E. The following categories shall be given priority for Rapid Antigen testing: ILI in containment zones and fever clinics, SARI, suspected COVID-19 deaths, healthcare workers, international travellers and asymptomatic patients undergoing chemotherapy, immunosuppressed patients including those who are HIV positive, patients diagnosed with cancer, transplant patients, elective and emergency surgical procedures, etc.

10/7/20
(Jawaid Akhtar)
Additional Chief Secretary to Government
Health and Family Welfare Department

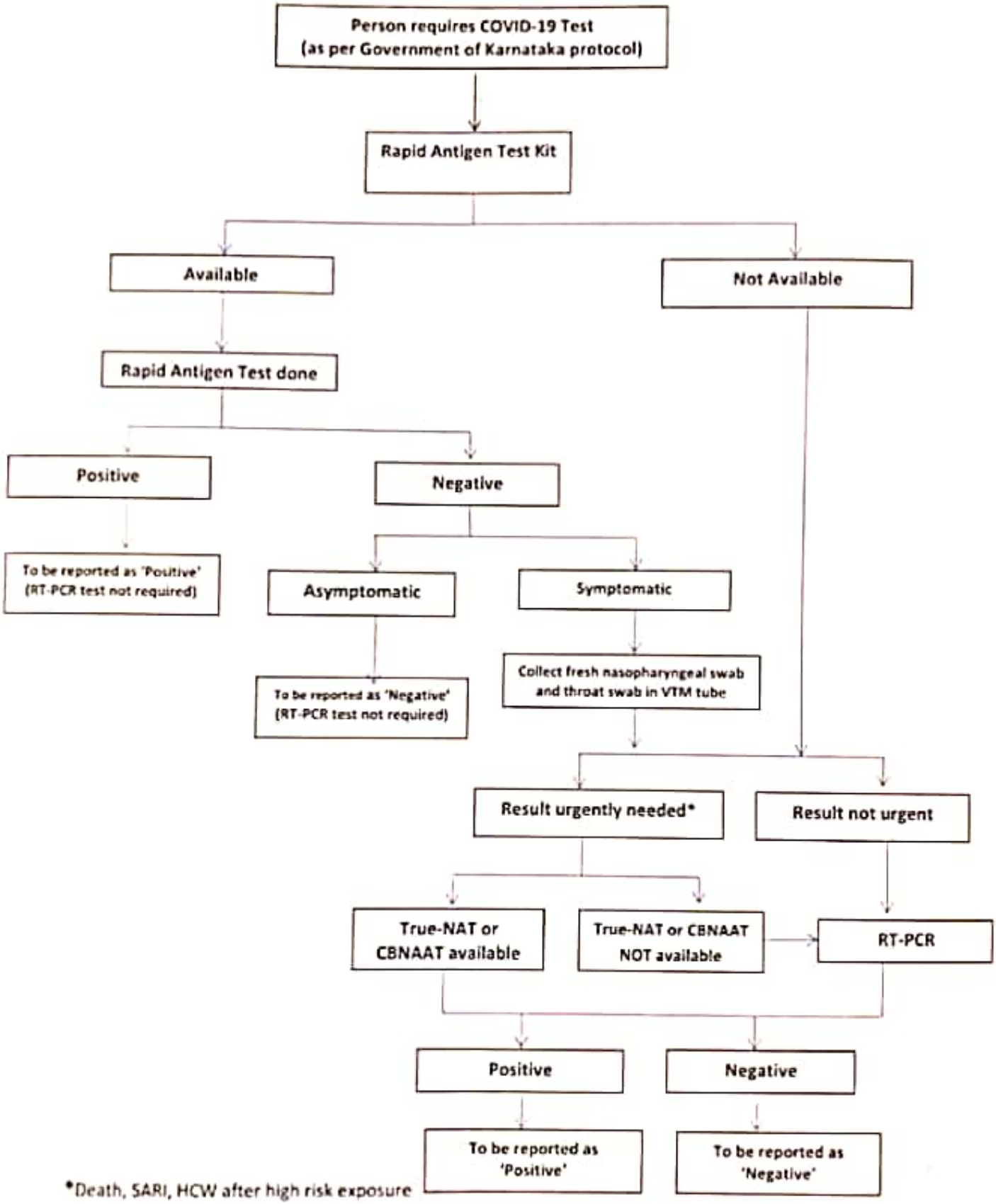
Copy to,

1. Commissioner-BBMP
3. Commissioner-Health and Family welfare services, Bengaluru
3. Mission Director-NHM, Bengaluru
4. Deputy Commissioners of all districts
5. CEOs of ZP of all districts
6. Director- HFWS, Bengaluru
7. Director, Medical Education Department
8. District Health and Family welfare officers/ District Surgeons of Bengaluru Urban
9. All COVID-19 testing labs in the state

Copy for kind information to:

1. Chief Secretary to GoK, Vidhana Soudha
2. ACS to Hon. Chief Minister, Vidhana Soudha
3. Principal Secretary, Medical Education

Annexure-1: Flow chart for COVID-19 testing



*Death, SARI, HCW after high risk exposure

Annexure-2

Rapid antigen PoC test is recommended for use subject to the following conditions:

i) All hospitals, laboratories, medical establishments (both government and private) intending to perform Rapid antigen tests '**should mandatorily register with ICMR**, and enter positive and negative results of each person on ICMR portal. Failure to register with ICMR or uploading COVID-19 results of each person on portal will be liable for action under epidemic diseases Act.

For registration with ICMR and to obtain the login credentials for data entry, send request on the following email id's:

ag-pvthosp-nabh@icmr.gov.in

ag-govthosp@icmr.gov.in

ii) All data of testing needs to be entered into the ICMR portal on a real time basis. The ICMR portal has been modified to include a component on antigen testing. Detailed video is available on ICMR website at:

http://www.icmr.gov.in/video/Data_Entry_Antigen_v4.mp4

iii) 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 RT-PCR/CBNAAT/True-NAAT test for COVID-19. This is particularly essential as the rapid antigen PoC test has a moderate sensitivity. Fresh nasopharyngeal swab and throat swab shall be collected in VTM tube for such patients requiring RT-PCR/CBNAAT/True-NAAT test

Annexure 3: Brief description on the COVID-19 Rapid Antigen detection kit

- Samples **(only nasopharyngeal swab)** shall be collected by a trained healthcare worker following full infection control practices including the use of full PPE kit.

- The test should be conducted on-site under strict medical supervision with maintaining kit temperature between 2° to 30° C and within one hour of sample collection in extraction buffer Standard Q COVID-19 Ag detection

- Each **Standard Q COVID-19 Ag detection** kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.

- One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, broncho-alveolar lavage or sputum) should be used.

- After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

- Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.

- Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.

- The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes. After that the test strip should be discarded.

- The test kit should be stored between 2° to 30° C.

- Detailed instructions for use can be accessed through the video link:

https://youtu.be/mBdaOHJWxI4