Date: 1 July 2020
Document Code: 01-03
Version: 03

Guidelines

National Testing Guidelines

Real-Time Polymerase Chain Reaction (RT-PCR) Diagnostic Test

Objective

To provide public health and health care professionals the guidelines regarding the persons who should be undergoing the diagnostic (RT-PCR) testing for COVID-19.

Rationale

The current incidence of the COVID-19 disease in Pakistan is identified by a positive test result and reported at the national and international levels. The Ministry of National Health Services, Regulations & Coordination (MNHSR&C) encourages everyone to adhere to the National Testing guidance.

Of all the available tests for COVID-19 in Pakistan, Real-time Polymerase Chain Reaction (RT-PCR) is currently the most reliable test/assay for the detection of SARS-CoV-2 infection. The antibody testing is still not considered appropriate for diagnosing COVID-19 infection and fresh guidelines will be formulated once new evidence surfaces for their use.

RT-PCR detects virus from the nasopharynx or oropharynx in the individual and is usually positive as early as the first or second day of infection even in an asymptomatic individual. However, there may be variation in the sensitivity of detection due to sampling technique or technical processing of tests and testing kits. Therefore, there may be a false negative rate associated with it as well.

In view of rising cases of COVID-19 it is imperative to expand the testing capacity. It is essential to identify infected cases to isolate and treat in order to prevent transmission to others. To improve the capacity of testing it is also appropriate to consider block testing in asymptomatic individuals where prevalence is low. Two approaches are advised; Smaller blocks with fewer samples (e.g 3-5), for areas with a case positivity rate of 10% and larger blocks with >5 samples for areas with a case positivity rate of 5%.

Public health and health care professionals are advised to prioritize testing for COVID-19 using the following guidelines.

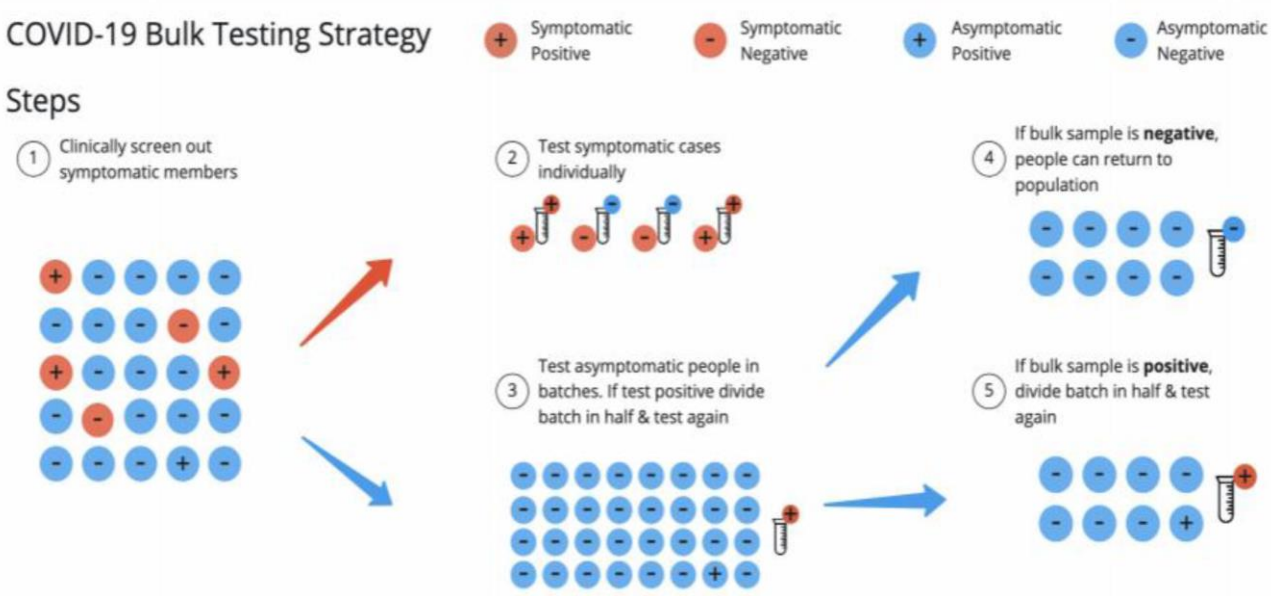
Priorities for the RT-PCR Testing

- Critically ill patients requiring hospitalization with unexplained symptoms of viral pneumonia or respiratory failure, including patients identified through SARI surveillance;
- Patients with fever or lower respiratory tract infections requiring hospitalization and those who are immune-compromised (including those with HIV), elderly or have underlying chronic conditions;
- Patients in outpatient settings who meet the updated COVID-19 case definition, including those with select co-morbid conditions like diabetes, COPD, congestive heart failure; pregnant women; and symptomatic children with additional risk factors;
- Testing of all Health Care Workers, particularly individuals who experience respiratory symptoms (ILI) and are critical to the pandemic response, such as first responders, health care workers including laboratory staff, and public health officials, housekeeping staff who are handling bedding and waste of patients in general (Institutions should develop SOPs to monitor the COVID-19 status of HCWs by regular testing cycles)
- Mandatory testing of all unexplained death due to respiratory illness (in such situations **dead body should not be retained while awaiting results**)
- Individuals identified through Influenza Like Illness (ILI) and Severe Acute Respiratory Illness (SARI)
- Individuals with contact with a positive COVID-19 patient or recent travel to areas with community transmission
- Individuals traveling to Pakistan from countries with local transmission and presenting with signs / symptoms compatible with COVID-19 infection;
- Individuals who self report for possible suspicions and maybe asymptomatic at this time
- Individuals in communities being monitored by public health authorities, such as quarantine facilities, extended contact tracing, research or other purposes

Block testing strategy

Process of block testing. First samples will be tested in a block and if it is 'Negative' then all samples will be reported as such. However, if the pool is 'Positive', it will be 'resolved' by individual testing of each sample.[1,2]

[1] Analysis and Applications of Adaptive Group Testing Methods for COVID-19; Cassidy Mentus, Martin Romeo, Christian DiPaola doi: https://doi.org/10.1101/2020.04.05.20050245
[2] Figure adapted from Mentus, C. 2020. medRxiv https://doi.org/10.1101/2020.04.05.20050245



Note: The above recommendations are being regularly reviewed by the Ministry of National Health Services, Regulations & Coordination and will be updated based on the international recommendations and best practices.

The Ministry acknowledges the contribution of Dr Usman, Dr Salman, Dr Faisal and HSA/ HPSIU/ NIH team to compile these guidelines.

For more information, please contact:

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http://covid.gov.pk/
http://nhsrc.gov.pk/ https://www.facebook.com/NHSRCOfficial
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https://www.nih.org.pk/ https://www.youtube.com/channel/UCdYuzeSP4Ug1f__ZZ

Annex 'A'

Current Case Definitions of ILI & SARI

Definition of Influenza Like Illness (ILI)
Acute respiratory infection with:

1. Measured fever of 38.0 C or more, AND cough
2. With onset within past 10 days

Definition of Severe Acute Respiratory Infection (SARI)
Acute respiratory infection with:

1. History of fever or measured fever of 38.0 C or more, AND cough
2. With acute onset within past 10 days
3. Requires hospitalization

Implementation Guidelines for Policy Makers

Breaking the COVID19 disease transmission requires effective testing, tracing, isolating and quarantining of cases and suspected cases. Testing and tracing are the first two crucial steps. Operationalizing the revised testing guidelines would provide planners an opportunity to understand the spread, transmission patterns of COVID19 and together with enforcement of other Non-Pharmaceutical Interventions, help flatten the curve at the local and provincial level.

Implementing the revised guidelines requires following:

1. Clear communication to the general public, health care workers and administrators.
    a. And why it is important for the public to get tested?
    b. Who should get tested?
    c. Where should they get tested?
2. Considerably strengthen local tracing capacity by increasing HR to trace all relevant contacts of COVID19 patients
3. Put in place logistical arrangements to connect SARI and ILI surveillance with sampling facilities (testing)
4. Implement Expanding Sensitivity/Passive surveillance
    a. Increasing the cohort of suspected would require;
        i. Access to health facilities:
        ii. Tehsil level Fever Clinics

iii. District level Fever Clinics.
iv. Tehsil Level sampling facility

5. Rapidly Increasing testing capacity by:
    a. Estimating local testing capacity and future demand
    b. Implementation of lab referral mechanism

Implementation Guidelines for Healthcare Workers

Implementing the revised guidelines requires testing for people who have a high risk for bad outcomes from COVID-19 infection, such as elderly or immunosuppressed patients, and those with high risk of exposure and transmission of the disease to other people, such as health care workers.
Deploying diagnostic tests more broadly can generate critical information about the presence of SARS-CoV-2 in the population, and therefore likely patterns of transmission and propagation.

Message to the General Public

The possibility of coronavirus disease 2019 (COVID-19) should be considered primarily in patients with compatible symptoms, in particular fever and/or respiratory tract symptoms, who reside in or have traveled to areas with community transmission or who have had recent close contact with a confirmed or suspected case of COVID-19.

The public health and medical communities should recognize the need to alter policy to fit changing circumstances and support consistent and compassionate messaging that recognizes both the benefits and limitations of testing