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Guidelines

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

Objective

To provide public health and health care professionals the guidelines regarding the priorities recommended for the purpose of diagnostic testing for COVID-19, including block testing.

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.

RT-PCR detects viremia in the individual and is usually positive as early as the first day of infection even in an asymptomatic individual. However, due there may be variation in the sensitivity of detection due to sampling or technical processing of tests. 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 prioritize the testing methodologies. It is essential to identify infected cases to isolate and treatment to prevent transmission to others. To improve the capacity of testing it is necessary 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

Priority 1: For individual 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 who also 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 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;
- Mandatory testing of all unexplained death due to respiratory illness, efforts to be made to obtain X-Ray/CT Thorax

Priority 2: For block testing with fewer samples (in high-risk districts*)

- Individuals identified through influenza-like symptoms surveillance;
- Individuals with contact with a positive COVID-19 patient or recent travel to areas with community transmission

Priority 3: For block testing with bigger samples (in low-risk districts*)

- All those who fall in priority 2 but reside in a **low-risk district***;
- Individuals traveling to Pakistan from countries with local transmission;
- Individuals who have been self-checking and are asymptomatic;
- 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}

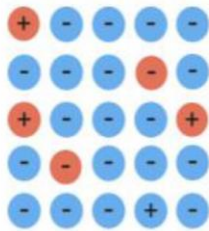
¹ Analysis and Applications of Adaptive Group Testing Methods for COVID-19; Cassidy Mentus, Martin Romeo, Christian DiPaola doi: <https://doi.org/10.1101/2020.04.05.20050245>

² Figure adapted from Mentus, C. 2020. medRxiv <https://doi.org/10.1101/2020.04.05.20050245>

COVID-19 Bulk Testing Strategy

Steps

① Clinically screen out symptomatic members



+ Symptomatic Positive

- Symptomatic Negative

+ Asymptomatic Positive

- Asymptomatic Negative

② Test symptomatic cases individually



③ Test asymptomatic people in batches. If test positive divide batch in half & test again



④ If bulk sample is **negative**, people can return to population



⑤ If bulk sample is **positive**, divide batch in half & test again



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 HSA/ HPSIU/ NIH team to compile these guidelines.

For more information, please contact:

HSA/ HPSIU/ NIH, PM National Health Complex, Islamabad

<http://covid.gov.pk/>

<http://nhsrco.gov.pk/>

<https://www.facebook.com/NHSRCOOfficial>

<http://www.hsa.edu.pk/>

<https://twitter.com/nhsrcoofficial>

<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