Rapid Molecular Point of Care Testing for COVID-19

Rapid NAAT (Nucleic-Acid Amplification Tests) are to be utilized as a screening test for symptomatic persons for COVID19 within first 7 days of onset of symptoms. The test is to be used for the detection of SARS-CoV2 viral RNA, from direct nasal, nasopharyngeal and throat swabs, from patients referred by a healthcare worker for suspicion of having COVID19 (Viet Loan Dao Thi, 2020).

The use of Rapid-NAAT (Rapid Nucleic-Acid Amplification Tests) and RT-LAMP (Rapid-Loop-Mediated Isothermal Amplification Assay) are limited to persons having symptoms for SARS-CoV2 infection in an area of high community spread of SARS-CoV2 infection (CDC, Interim Guidance for Antigen Testing for SARS-CoV-2, 2020)

A positive result is indicative of SARS-CoV2 Viral RNA, and shall be correlated with clinical history.

A negative result shall be regarded as a presumptive diagnosis, and shall be confirmed with routine RT-qPCR assay. It is important to note that a negative result does not eliminate the possibility of infection with SARS-CoV2 and shall not be used as a sole basis for patient management decisions. The test shall not be used as a method for diagnosis of infective status of an asymptomatic person, or shall not be used in areas of low incidence of SARS-CoV2 infection.

The test shall be performed in a clinical setting authorized to perform molecular testing by Quality Assurance and Regulation Division, Ministry of Health.

General recommendations:

i) The rapid POC testing should be done in a RT PCR (**R**eal **T**ime **P**olymerise **C**hain **R**eaction laboratory registered at Ministry of Health
   a. Each laboratory would need to submit the manufacturers instruction, instruments and methods they propose to utilize

ii) The laboratory testing should be conducted by trained laboratory technicians or by a trained medical practitioner registered at the relevant professional bodies.

iii) POC testing should be done according to HPA COVID-19 testing guideline and in coordination with HPA.

iv) POC testing can only be approved where the registered facility agrees to use 'Sampler' application as per the guideline

v) Testing should be conducted according to the manufacturer's instructions

vi) All results of POC tests should be entered into the national COVID-19 surveillance system.

vii) The rapid POC molecular tests should have > 90 % sensitivity and > 97% specificity

   a. Documents pertaining to these should be submitted to the regulating body (Quality Assurance and Regulatory Division of the Ministry of Health)

viii) The COVID-19 tests used in the country will have to be WHO or US FDA approved tests or those with at least an emergency use authorization from WHO or US FDA

ix) All tests deemed 'not-detected' from a POC test had to re-run a RT-PCR test

Recommendation on POC testing:

1. POC testing can be done in those with symptoms within the first 7 days of symptoms onset.
   a. High risk person
      i. E.g: a close contact of a case should get a PCR done if the result of the initial test is negative.
   b. Low risk person
      i. Low risk people with an initial negative POC testing should get a PCR test done if the symptoms persist or worsen.
2. In situation where the result of the test is required urgently as in contact tracing investigation in outbreaks or for urgent travel requirements, asymptomatic people may be tested with the rapid POC testing.
   a. All positive results in a low prevalence or low risk exposure setting have to be confirmed with PCR testing
   b. During the investigation of an outbreak a subset of initial positive samples would need to be confirmed with PCR testing.

Reference:

World Health Organization, 2020. *Diagnostic testing for SARS-CoV-2: interim guidance, 11 September 2020* (No. WHO/2019-nCoV/laboratory/2020.6). World Health Organization

Centers for Disease Control and Prevention (CDC). 2020. Interim laboratory biosafety guidelines for handling and processing specimens associated with coronavirus disease 2019 (COVID-19). *Available from: Original URL: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html [Last accessed on 2020 October 13].*

CDC. (2020). Interim Guidance for Antigen Testing for SARS-CoV-2.

Viet Loan Dao Thi, K. H. (2020). A colorimetric RT-LAMP assay and LAMP-sequencing for detecting SARS-CoV-2 RNA in clinical samples. Science Translational Medicine.

Quality Assurance and Regulation Division

Ministry of Health