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Date)

DDG, NHSL,
DDG, NH Kandy,
Directors of All Hospitals,
Provincial and Regional Directors of Health Service,
Heads of Institutions of dedicated COVID-19 treatment facilities,
All other Heads of Institutions

Guideline for Use of Ag-RDT in Testing Policy for COVID-19

The Guideline for the use of COVID-19 Antigen–Rapid Diagnostic Test in the control of COVID-19 transmission and management which has been developed by the Ministry of Health is now recommended to use in state sector health institutes and public health outbreak management work.

Ag-RDT is strongly recommended to be used in teaching hospitals, tertiary level special care institutes, provincial hospitals and district general hospitals, essentially under the guidance and supervision of a microbiologist or a virologist available onsite.

Further review of the guideline will take place with information gathered through ongoing usage and evidence.

The guideline is annexed herewith, and you are kindly requested to disseminate the said guideline in view of facilitating Ag-RDT in specified clinical settings.

Dr Asela Gunawardena,
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- Hon. Minister of Health
- Secretary
- Additional Secretaries
- All DDGs
- Chairman, NMRA
- Director, LS
- Chief Epidemiologist
- Director, MRI
- Technical heads of designated laboratories

Guideline for Use of Ag-RDT (Rapid Diagnostic Test) for COVID-19

This guideline is for the use of locally validated and NMRA registered COVID 19 Ag RDT in state sector health institutions and public health outbreak management work with ongoing review by Consultant Virologists/Microbiologists and Consultant Epidemiologists.

Guiding principles for use of Ag-RDT in the control of COVID-19 transmission and management

1. Ag-RDT is supplementary to RT-PCR assay in an outbreak situation and not replacing PCR assay.
2. To urgently isolate infectious individuals to prevent further transmission.
3. To rapidly test high risk groups with potential transmission of the virus during an outbreak.
4. Not to be used as a freely available screening or diagnostic assay in low risk situations or on demand without risk assessment.

Indications for COVID 19 Ag RDT

1. Clinically suspected COVID 19 patients admitted to isolation units of the hospitals can be tested with Ag RDT, in addition to the RT PCR assay to diagnose COVID 19. Samples for both tests should be obtained simultaneously. Patients testing positive on Ag RDT should be transferred to a COVID treatment unit and the sample taken for RT PCR testing be discarded. Patients testing negative on Ag RDT should remain in the isolation unit for the results of the RT PCR assay. *Manage to take swabs for both Ag RDT and RT PCR assays simultaneously. Nasopharyngeal swab for Ag RDT can be obtained through one nostril and the combined nasopharyngeal and throat swab for RT PCR assay can be obtained through the other nostril and throat at the same time.*

Do the Ag RDT immediately according to the kit instructions. If it is positive, swab taken for the RT PCR assay can be properly discarded. If the Ag result is negative, the combined nasopharyngeal and throat swab in VTM should be sent for COVID 19 RT PCR assay.

2. Ag-RDT can be performed on asymptomatic close contacts of a known COVID-19 patient after the verified exposure.

Identification of asymptomatic close contacts for infection screening should be done by the Regional Epidemiologists under the supervision of Epidemiology Unit during any outbreak situation (the test characteristics of the approved Ag-RDT clearly states that positive predictive value of the test declines below 78% when the expected prevalence of the disease is less than 10% in the selected population). Hence, the risk groups for possible infection transmission should be identified to make this strategy effective.

3. Patients admitted without any COVID-19 related symptoms to the hospitals for therapeutic procedures from a locality with an ongoing outbreak.

This decision needs to be taken in consultation with consultant virologists/ microbiologist.

4. When urgent decisions need to be made to quarantine or/and isolate healthcare workers (with verified exposure to a COVID 19 patient) in preventing transmission

The decision should be made after exposure assessment made by the COVID cell, in consultation with consultant virologists/ microbiologist.

5. Samples of dead bodies can be tested with Ag-RDT and if positive, COVID death can be confirmed and follow the recommended protocol for COVID deaths with further action according to the quarantine guidelines; if negative, should be followed by RT PCR where parallel sampling must be performed anticipating a follow up PCR.

6. Symptomatic patients with influenza like illness (ILI) presenting to OPD of hospitals (when they are not categorized as COVID 19 suspected patients for admission) can be tested with Ag RDT, in addition to the RT PCR assay to screen for COVID 19. Samples for both tests should be obtained simultaneously. Patients testing positive on Ag RDT should be transferred to a COVID treatment unit and the sample taken for RT PCR testing be discarded. Patients testing negative on Ag RDT can be sent home (if he/she is not a COVID 19 suspected patient for admission) with proper infection prevention and control advice and pending further communication of RT PCR assay results when available.

Manage to take swabs for both Ag RDT and RT PCR assays simultaneously. Nasopharyngeal swab for Ag RDT can be obtained through one nostril and the combined nasopharyngeal and throat swab for RT PCR assay can be obtained through the other nostril and throat at the same time.

Do the Ag RDT immediately according to the kit instructions. If it is positive, swab taken for the RT PCR assay can be properly discarded. If the Ag result is negative, the combined nasopharyngeal and throat swab in VTM should be sent for COVID 19 RT PCR assay.

* Ag-RDT will be conducted by special teams established at district level under the Regional CCPs/ Regional Epidemiologists. Factors to be considered are mentioned in Box- 1.

Practical considerations on conducting Ag-RDT at field settings

Box-1

1. A medical officer designated as the team leader for each team to supervise and certify the test results.
2. A team will comprise of medical officers, MLTs, nursing officers, and other para medical and supportive staff.
3. The team should inform the results to the individual and to the epidemiology unit in order to provide specific instructions.
4. Patient information and all test results, including positives should be provided to relevant heads of institutions, MOHs and Epidemiology unit.
5. The Epidemiology Unit and the Medical Officer of Health of the area (MOH) need to be notified immediately for tracing the close contacts of the positive patient.
6. Safe transport and discarding of test material should be arranged according to biosafety guidelines.

Sample collection and testing Procedure

The COVID 19 Ag RDT can be done in hospitals (for the indications 1, 3, 4, 5 and 6) or by trained medical staff at a field settings (for the indication 2) immediately after collecting the samples (within 1 hour) while adhering to appropriate infection prevention and control measures.

Sample collection and the test will be performed by qualified trained medical staff. Certification of the results will be done by a trained medical officer under the guidance from a Consultant Microbiologist/ Virologist designated for the special team.

Test results should be immediately informed to the regional epidemiologist and the Epidemiology Unit by the team leader according to a prescribed format.

***Special Note:**

This guideline was developed based on currently available epidemiological and scientific evidence and may subject to further review.