

Guideline for Rapid Antigen Diagnostic Testing (Ag-RDT) for COVID-19

This document offers recommendations and advice on SARS-CoV-2 Rapid antigen tests (Ag-RDT), based on current evidence and recommendations by WHO

The clinical performance of rapid antigen diagnostic tests largely depends on the circumstances in which they are used. SARS-CoV-2 Rapid antigen tests (Ag-RDT) perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest.

A. General recommendations:

1. Ag-RDT testing is recommended to be performed only on symptomatic persons, within the first 7 days of symptoms onset (when the viral load is high), in a community transmission setting. In such a setting, if the test result is positive this should be counted as a valid result.
2. Any Ag-RDT negative for high risk category should be confirmed with a RT-PCR test.
3. The Ag-RDT should be performed by registered health professionals, in a health facility that has been approved by Quality Assurance Regulation Division, Ministry of Health to conduct SARS-Cov2 Antigen testing, and under strict infection control and prevention measures.
4. The SARS-CoV-2 Ag-RDT test should have > 90 % sensitivity and > 97% specificity.
5. The Ag-RDT test should be one that has Emergency Use Authorization of US FDA or included in the Emergency Use Listing of WHO.
6. Results of Ag-RDT test done in the country should be reported to Health Protection Agency.

Use of Ag-RDTs is not recommended in settings or populations with low expected prevalence of disease (e.g. screening at points of entry, blood donation, and elective surgery). Such use will not be possible until there are more data from high-quality studies confirming high specificity (>99%) of one or more of the commercialized Ag-RDT test kits.

B. Ag-RDT is recommended to be performed in the following situations:

1. In clinical settings of a locality with ongoing community transmission, where patient symptoms are compatible with COVID-19. This includes designated flu clinics and hospital settings. To conduct Ag-RDT for such patients in health care setting further approval of HPA is not required if the facility has approval of Ministry of Health mentioned above.
2. In other settings, any Ag-RDT testing will require prior approval of HPA. The conditions where Ag-RDT will be used in other settings are only for COVID-19 outbreak investigation purposes and will be done by HPA. These include, amongst others;

- a. To respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities (e.g. in care-homes, safaris and cruise ships, prisons, rehabs, factories and dormitories, etc.)
- b. To detect cases among front line workers and health workers early, in localities where there is an outbreak and or ongoing community transmission.

