GUIDELINE ON COVID-19 TESTING USING ANTIGEN RAPID TEST KIT (RTK-Ag) FOR THE HEALTH FACILITIES, VERSION 6.0

1. OBJECTIVE

This document provides guidance to testing facilities performing COVID-19 rapid antigen testing. It replaces the previous Guideline on “Guideline on COVID-19 Testing Using Antigen Rapid Test Kit (RTK-Ag) for The Health Facilities, Ministry of Malaysia (MOH), Version 5.0” dated 11th January 2021.

2. BACKGROUND

2.1 RTK-Ag directly detects SARS-CoV-2 viral proteins and has the advantage of providing fast result, inexpensive and can be used as point of care testing.

2.2 In Malaysia, RTK-Ag has been used since 6th May 2020 to provide an alternative to RT-PCR where results can be obtained within a shorter time and services is beneficial where molecular testing is not readily available.

2.3 RTK-Ag testing is considered as a screening test currently while RT-PCR / Rapid Molecular shall be used as diagnostic test to define a COVID-19 case. However, RTK-Ag can be used as diagnostic test for targeted group/confirmed clusters when prevalence $\geq$ 10% identified by the local level or check positivity rate by PCR (on rolling 7 days) or any situational analysis decided by MOH (Appendix 2).

2.4 Due to the dynamic nature of the COVID-19 pandemic, recommendations will be updated based on the latest available evidence and should be evaluated by respective experts over the duration of the crisis. With the development of this guideline, the previous document is no longer applicable.
3. IMPLEMENTATION

3.1 General requirement

3.1.1 The testing facility shall use RTK-Ag test kit that have been listed by the Medical Device Authority (MDA). Please refer to MDA for updated list from time to time. (https://www.mda.gov.my/)

3.1.2 Sampling procedure should be done or supervised by a trained personnel and usage of appropriate PPE shall be ensured.

3.1.3 Type of specimen to be taken is based on the test kit.

3.1.4 The testing is encouraged to be carried out using Biosafety Cabinet in the laboratory. However, in places where biosafety cabinet is not available, the test can be conducted with proper infection prevention control measures in place. (Please refer to Appendix 2)

3.3 Preparation and test procedure

3.3.1 Test cartridge/card must be stored according to kit insert.

3.3.2 Test procedure shall be done as per manufacturer’s recommendation.

3.3.3 Operator shall minimize the risks of cross-contamination during procedures. Proper infection control measures should be in place.

3.3.4 Read the test result according to specified time especially if processing multiple specimens in a batch. Preferably, not to do more than 10 specimens in a batch to prevent cross contamination and false positive. Reading the test before or after specified time may result in false positive or false negative results.

3.3.5 The work area must be cleaned after procedure with approved disinfectant.
3.4 Interpretation of test result

3.4.1 Interpretation of test results shall be as per the manufacturer’s insert kit. Advisably, the result should be read by 2 lab personnel.

3.4.2 **Positive RTK-Ag** shall be interpreted as a probable or confirmed COVID-19 cases based on the latest case definition. Refer to Annex 2 for patient management.


3.4.3 Positive results should be considered in conjunction with the clinical history and epidemiological history.

3.4.4 A negative result may warrant RT-PCR / Rapid Molecular testing if clinically indicated at discretion of clinician.

3.4.5 Invalid test shall be repeated using a new specimen.

3.5 Reporting of results

3.5.1 Positive results shall be informed to requesting doctor as soon as possible.

3.5.2 Requesting doctor must notify positive results to the patient and PKD as soon as possible within 24 hours. Refer to Annex 2 for patient management.


3.5.2 All results shall be keyed into *Sistem Informasi Makmal Kesihatan Awam Outbreak* (SIMKA Outbreak) within 24 hours.

4. Waste management

The testing facility shall have waste management procedure in place.

5. Risk Management

The testing facility shall have risk assessment activities before offering the test *(Appendix 2).*
FLOW CHART FOR SARS-CoV-2 RAPID ANTIGEN TESTING

Request for Rapid Antigen Test for SARS-CoV-2

Perform test according to kit insert

- Negative¹
- Positive²
- Invalid test

RT-PCR/Rapid Molecular test required?³

YES

Send new sample for RT-PCR/Rapid Molecular test within 24 hours

- Positive
- Negative¹

Note:

¹ Repeat testing with RT-PCR/Rapid molecular within 24-48 hours if clinically indicated.

² Inform result to requesting doctor. Refer to Annex 2h for management of probable cases.

³ Confirmatory testing may not be necessary in certain circumstances. (Appendix 1). All results must be keyed-in into SIMKA within 24 hours.
FLOW CHART FOR SARS-CoV-2 RAPID ANTIGEN TEST KIT FOR DIAGNOSTIC TESTING

State to decide on usage of RTK-Ag as a diagnostic test for targeted group/confirmed clusters as when Prevalence ≥ 10%

Check positivity rate by PCR (on rolling 7 days)

- Positivity rate by PCR < 10%
  - Use RTK-Ag as a screening test only.
- Positivity rate by PCR ≥ 10%
  - RTK-Ag can be used as a diagnostic test

State to inform National CPRC on decision to use RTK-Ag as a diagnostic test for specific group or cluster.

Once the positivity rate become < 10%, a concordance test must be done at state/PKD level.

Concordance Test
5% of the samples of the week (both positive & negative) should be sent for both RTK-Ag and PCR*

Concordance Test Result

- < 85%
  - Use RTK-Ag as a screening test.
- ≥ 85%
  - RTK-Ag still can be used as a diagnostic test.

*For PCR test: use either the buffer of the RTK-Ag or another swab should be taken (at least 2 hours apart).

Ministry of Health Malaysia
Updated on 11 June 2021
RTK-Ag as confirmatory testing:

- Specific cluster/cohort with prevalence ≥ 10%
- New cluster with high positivity rate, suggest doing the concordance study using RTK-Ag.
- RTK-Ag can be used as confirmatory test when the concordance study shows high PPV, high specificity and high agreement with RT-PCR.
Appendix 2

RISK ASSESSMENT FOR COVID-19 RAPID ANTIGEN TESTING

Before starting a procedure, local risk assessment is needed to prevent workplace incidents, for example, getting infected during the procedure. Risk assessment is carried out by identifying hazards in a situation that may expose operators to infections when conducting test. The risk assessment should prioritize those potential negative outcomes, or risks, based on an evaluation of the likelihood and consequences of each of those identified risks. Risks can be determined using a two-dimensional graph as below:

![Risk Assessment Graph]

The risk assessment should determine the most appropriate control measures, and how the system will measure the effectiveness of those control measures. Very low or low risk level indicates that existing controls are sufficient to protect operators from infection during the testing. For moderate, high or very high-risk level, additional control measures should be carried out.

For rapid antigen testing, specific hazards can be identified such as aerosol exposure / eye splash during sample processing, or chances of spills, especially when staff are not adequately trained and at the same time are under immense pressure to deliver rapid results. The risk can be high thus there is need for hazards control measures such as to employ an aerosol containment box (acrylic box) or Biosafety Cabinet (BSC).

However, performing rapid antigen test without BSC and such can be carried out when the local risk assessment dictates so, in which, test is performed on large paper towel in a well-ventilated area, free of clutter, appropriate PPE worn by well-trained staff on good microbiological practice and procedure with no rush or increased pressure for test turnaround time and have a waste management in place. Laboratory ventilation, where provided (including fans/local cooling split-system air-conditioning units – specifically when retrofitted) should ensure airflows do not compromise safe working environment. Consideration must be made for resultant airflow speeds and directions, and turbulent airflows should be avoided; this applies also to natural ventilation.

Risk assessment should be a continuous process and should be performed whenever changes take place i.e. personnel, facility, equipment, methods and regulations. An example of risk assessment template can be assessed at https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1
References

2. Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil. 3/2021 bertarikh 17 Januari 2021
3. Laboratory biosafety guidance related to coronavirus disease (COVID-19) Interim guidance, WHO 28 January 2021
4. Laboratory Biosafety, Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories, CDC, Updated 10 March 2021
5. Laboratory Biosafety Manual. 3rd. 1983
8. COVID-19 MOH Guidelines, Annex 7: Notification Form
9. Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Sandia National Laboratory and International Federation of Biosafety Associations