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 4.0” dated 17th August 2020.

2. BACKGROUND

2.1 RTK-Ag has the advantage of providing fast result, inexpensive and can be used as point of care testing. This method directly detects SARS-CoV-2 viral proteins in nasopharyngeal swabs and the result is available in a short time (< 30 minutes).

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 Due to its limitation in sensitivity compared to molecular testing like RT-PCR RTK-Ag testing is considered as a screening test and RT-PCR shall be used as confirmatory test to define a COVID-19 case. However, RTK-Ag can be used as confirmatory test in certain circumstances where there are confirmed COVID-19 clusters or outbreaks or areas identified by National Crisis Preparedness Response Centre (CPRC), MOH.

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 With the development of the version 5.0 guideline, the previous document is no longer applicable.

Ministry of Health Malaysia
Updated 27 January 2021
3. IMPLEMENTATION

3.1 General requirement

3.2.1 The testing facility shall use RTK-Ag test kit that have been listed by the Medical Device Authority (MDA).

3.2.2 For private healthcare facilities involved in sampling and testing of RTK Ag, please refer to Annex 4g: Garis Panduan Penggunaan RTK Ag di Fasiliti Swasta, at http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm website

3.2 Indications for usage

3.2.1 The use of RTK-Ag in MOH facilities is made priority in cases that require urgent result for a prompt patient management and to support outbreak investigations.

The appropriate usage of RTK-Ag include the following:

i. Screening for emergency and semi-emergency procedures or surgical cases with high probability of COVID-19 infection;

ii. Screening for brought in dead (BID) in low probability cases when indicated;

iii. Screening for symptomatic person in a confirmed cluster/outbreak management;

iv. Screening for close contact in a confirmed cluster/outbreak management;

v. Screening for Acute Respiratory Infection (ARI) following Guideline on Management of Patient Suspected COVID-19 in Health Clinic by Family Health Development Division and Disease Control Division, MOH;

vi. Other screening identified by MOH.

3.2.3 RTK-Ag is not recommended to be used for COVID-19 screening in
i. Any pre-procedure or pre-operation related to transplant cases;
ii. Elective surgery;
iii. Healthcare workers;
iv. Severe acute respiratory illness (SARI).

3.3 Preparation and test procedure

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

3.3.2 The testing is encouraged to be carried out using Biosafety Cabinet in the laboratory due to safety reasons. However, in places where biosafety cabinet is not available, the test can be conducted with proper infection prevention control measures in place.

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

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

3.3.5 Laboratory staff shall minimize the risks of cross-contamination during procedures.

3.3.6 The work area must be cleaned after procedure with approved disinfectant.

3.3.7 Read the test result according to specified time especially if processing multiple specimens in a batch. Reading the test before or after specified time may result in false positive or false negative results.

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 is regarded as probable COVID-19 and shall be followed by RT-PCR to confirm as COVID-19 case (Refer Annex 2).
3.4.3 RTK-Ag can be used as confirmatory test in certain circumstances approved by National CPRC (Refer to 2.3). In this situation, a representative samples of positive and negative samples using buffer must be send for RT-PCR testing for quality assurance.

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

3.4.5 A negative results may warrant RT-PCR testing if clinically indicated at discretion of clinician.

3.4.6 Invalid test shall be repeated using a new specimen.

3.5 Reporting of results

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

3.5.2 Requesting doctor must notify positive results to the PKD and patient as soon as possible within 24 hours. Refer to Annex 2h: Management of Probable COVID-19 Case.

3.5.2 All results shall be entered into Sistem Informasi Makmal Kesihatan Awam (SIMKA) within 24 hours.
FLOW CHART FOR SARS-CoV-2 RAPID ANTIGEN TESTING

Request for Rapid Antigen Test for SARS-CoV-2

Perform test according to kit insert

- **Negative**
  - Repeat testing with RT-PCR within 48 hours if clinically indicated.

- **Positive**
  - Send new NPS/OPS for RT-PCR within 24 hours

- **Invalid test**
  - Repeat Antigen Test using a new sample

- **Detected**
  - Repeat RT-PCR at 24 - 48 hours

- **Not Detected**
  - Not Detected

Note:

1. All positive results must be entered into SIMKA within 24 hours

2. Confirmatory RT-PCR may not be necessary in certain circumstances following decision by National CPRC, MOH.
INQUIRIES

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### List of Recommended RTK-Ag Kit

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<th>Officer In-charge</th>
<th>Telephone No.</th>
<th>Email</th>
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<tr>
<td>1.</td>
<td>Medical Device Authority, Ministry of Health</td>
<td>Pn. Aidahwaty binti Ariffin @ M.Olaybal</td>
<td>03-83200341</td>
<td><a href="mailto:aidahwaty@mda.gov.my">aidahwaty@mda.gov.my</a></td>
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### COVID-19 Case Notification and Management

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<tr>
<td>1.</td>
<td>Infection Control Division, Ministry of Health</td>
<td>Dr. Asiah binti Ayob</td>
<td>03-88834118</td>
<td><a href="mailto:drasiahayob@moh.gov.my">drasiahayob@moh.gov.my</a></td>
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