

COVID-19 Rapid Test Kit Antigen (RTK-Ag) Testing for Professional Use

1. OBJECTIVE

This document provides guidance to testing facilities performing COVID-19 rapid test kit antigen (RTK-Ag) testing for professional use.

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 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 With the development this guideline, the previous document is no longer applicable.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 approved 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 The testing is encouraged to be carried out using Biosafety Cabinet in the laboratory. When performing rapid antigen test **without Biosafety Cabinet** it is suggested that the test is performed on large paper towel in a well-ventilated area, free of clutter and appropriate PPE worn by well-trained staff following good microbiological practice and procedure.

3.3 Preparation and test procedure

- 3.3.1 Type of specimen to be taken is based on the kit insert.
- 3.3.2 Test cartridge/card must be stored according to kit insert.
- 3.3.3 Test procedure shall be done as per manufacturer's recommendation.
- 3.3.4 Operator shall minimize the risks of cross-contamination during procedures. Proper infection control measures should be in place.
- 3.3.5 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.
- 3.3.6 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 personnel.
- 3.4.2 **Positive RTK-Ag** shall be interpreted as per Annex 1: Case definition that is updated from time to time. (<http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm>)
- 3.4.3 A negative results may warrant RT-PCR/rapid molecular testing if clinically indicated at discretion of clinician.
- 3.4.4 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 All results shall be keyed into *Sistem Informasi Makmal Kesihatan Awam Outbreak* (SIMKA Outbreak) or E-Covid according to the current directive by Ministry of Health.
- 3.5.3 It is mandatory to report all results into SIMKA Outbreak or E-Covid within 24 hours. All results shall be keyed into the *SIMKA* or E-COVID.

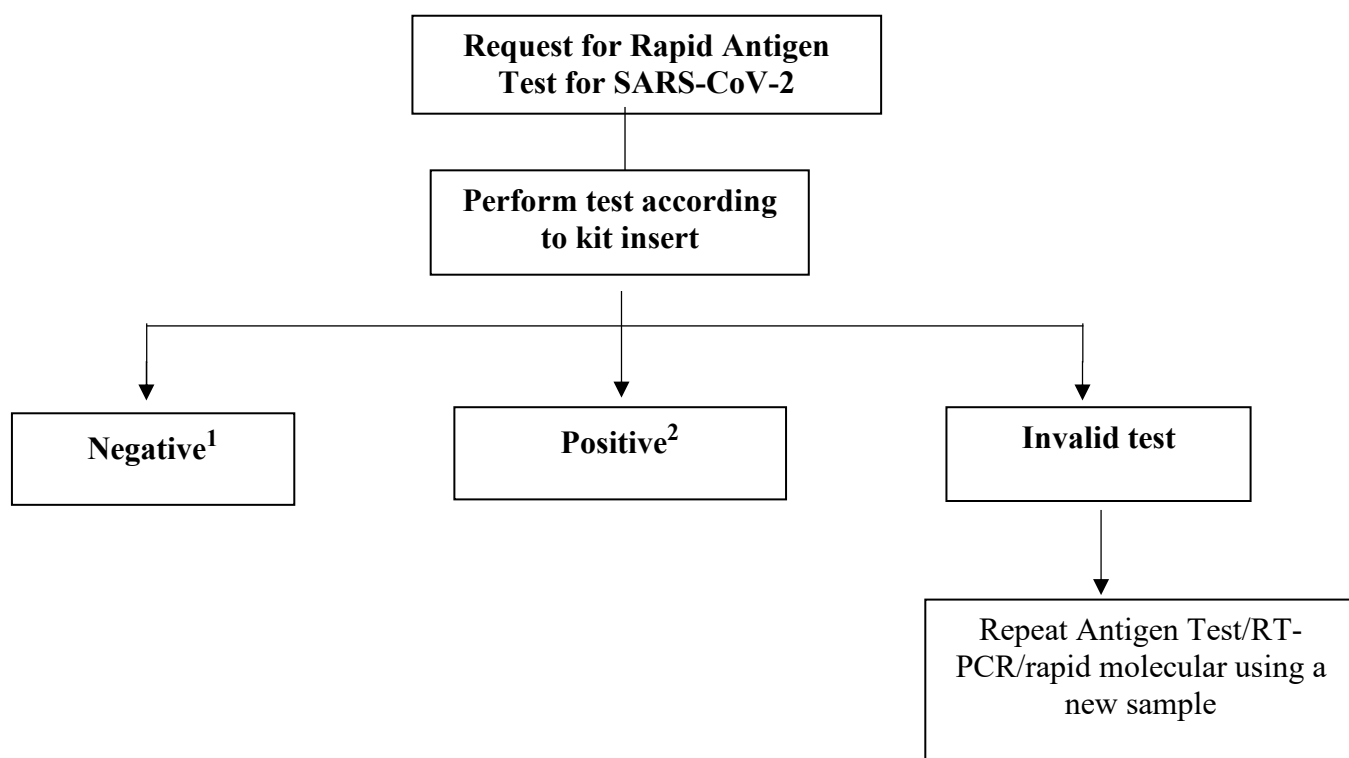
4. Waste management

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. Please refer to Laboratory Safety for Handling and Processing Specimen.

FLOW CHART FOR SARS-CoV-2 RAPID ANTIGEN TESTING



Note:

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

² Inform result to requesting doctor.

All results must be keyed-in into SIMKA or E-COVID within 24 hours.