Annex 4c

GUIDELINE ON COVID-19 TESTING USING ANTIGEN RAPID TEST KIT (RTK-Ag) FOR THE HEALTH FACILITIES, MINISTRY OF MALAYSIA VERSION 3.0

1. OBJECTIVE

This revised guideline is aimed to replace the previous Guideline on "Guideline on COVID-19 Testing Using Antigen Rapid Test Kit (RTK-Ag) for The Health Facilities, Ministry of Malaysia, Version 2.0" dated 22nd May 2020.

2. BACKGROUND

2.1 RTK-Ag has the advantage of detecting COVID-19 outbreaks quickly and in large quantities. Malaysia has been using RTK-Ag since 6th May 2020. The RTK-Ag used has undergone re-evaluation by the IMR and the results are satisfactory and within the Ministry of Health's (MOH) minimum sensitivity and specificity values.

2.3 Limit of detection for RTK-Ag is currently at Cycle Treshold (Ct) value of 30. Any Ct value above 30 is unable to be detected by RTK-Ag. Ct value of 30 is equivalent to about 300-400 viral copy numbers on the Nasopharyngeal Sample (NPS). As compared to RT-PCR, it involves amplification step and it's limit of detection is about 4-5 viral copy numbers.

2.5 An evaluation on specifity was also carried out using other respiratory viruses including influenza A pdm01, influenza A H3, Influenza B and Adenovirus. The RTK-Ag is specific enough towards COVID-19 as the RTK-Ag did not detect any of those viruses. However, other respiratory viruses such as parainfluenza, metapneumovirus and community associated coronavirus were unable to be performed in this evaluation.

2.6 Both RTK-Ag and RT-PCR are different platform. Setting up RTK-Ag is to provide an alternative to RT-PCR where results can be obtained within a shorter time and services is beneficial where there is no molecular testing available. Nevertheles, testing using RTK-Ag shall be complimented with RT-PCR in some instances for a comprehensive patient and public health management.

2.7 A local unpublished study has shown that the **same buffer solution of RTK-Ag** can be used for RT-PCR testing. This study was done on 91 known positive samples. All of them were previously positive with lower ct values of 13-22 on 26th May 2020 and when re-tested with RTK-Ag and RT-PCR (using same buffer solution of RTK-Ag) 2 weeks apart showed valid results.

2.8 Since the sample used is from the Nasopharyngeal Swab (NPS)- an area with high potential for viral content, sampling should be performed by fully trained health personnel using appropriate Personal Protective Equipment (PPE). The test should be conducted in the Biological Safety Cabinet (BSC) class II as there is a high risk of spilling the specimen during the mixing process between the swab and extraction buffer solution.

2.9 This guideline therefore is aimed at enhancing the previous guideline on testing COVID-19 using RTK-Ag. Due to the dynamic nature of the COVID-19 pandemic, recommendations are meant to be refined 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 3.0 guideline, the previous document is no longer applicable**.

3. IMPLEMENTATION

3.1 Indication

3.1.1 The use of RTK-Ag is made priority in cases or samples that require urgent result for a prompt patient management to be given.

3.1.2 The list of appropriate cases / samples using RTK-Ag is as follows :

i. Emergency and semi-emergency procedures or surgical cases with high probability of COVID-19 infection.
(Garis Panduan Versi 2.0: Pengendalian Prosedur atau Pembedahan Semasa Wabak COVID19 di Hospital Kementerian Kesihatan Malaysia).

ii. Brought in dead (BID) cases with high probability or high suspicion of COVID-19.

iii. 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.

iv. A wider coverage for screening in the area of Enforced Movement Control (EMCO).

v. Screening at the country's entry point .

vi. Screening identified or determined by MOH.

3.1.3 However, any pre-procedure or pre-operation related to transplant cases will be screened using RT-PCR instead of RTK-Ag.

3.1.4 COVID-19 testing for healthcare workers (HCW) shall remain using RT-PCR as it is regarded as one of the high risk groups. It is important to reduce the risk of having an outbreak within MOH's facilities which may cause a great impact to healthcare deliveries. This is also in line with the current policy of two sampling (on day 3 and day 5 after contact) for HCW, in which the test can be done using paired-sample testing.

3.1.5 The usage of rRT-PCR is also recommended to screen for Severe Acute Respiratory Illness (SARI) cases as the severe symptoms and presentations in SARI patients is highly suspicious of COVID-19.

3.2 **Requirements**

3.2.1 Sampling procedure should be done by a trained personnel and usage of appropriate PPE shall be ensured. *(Recommended PPE to be used when managing Patient Under Investigation (PUI) / Confirmed COVID-19 & Severe Acute Respiratory Infection (SARI) / Influenza Like Illness (ILI) Patients in Healthcare Facilities 21 April 2020)*

3.2.2 Request for RTK-Ag testing should be informed to the Lab Personnel. Laboratory is responsible to provide suitable swab for NPS and empty container upon request. Usage of Falcon tube is preferable or any empty container with a length of at least 9 cm can be considered as alternative.

3.2.3 The testing shall be carried out using BSC in the laboratory due to safety reasons. The testing shall be done by a trained laboratory staff with appropriate PPE.

3.2.4 Testing using RTK-Ag and its result needs to be registered in *Sistem Informasi Makmal Kesihatan Awam* (SIMKA) Outbreak.

3.3 Preparation and Test Procedure

3.3.1 The sample should be sent in plain container and not in VTM.

3.3.2 Heavily blood stained swab shall be rejected as it may give false results.

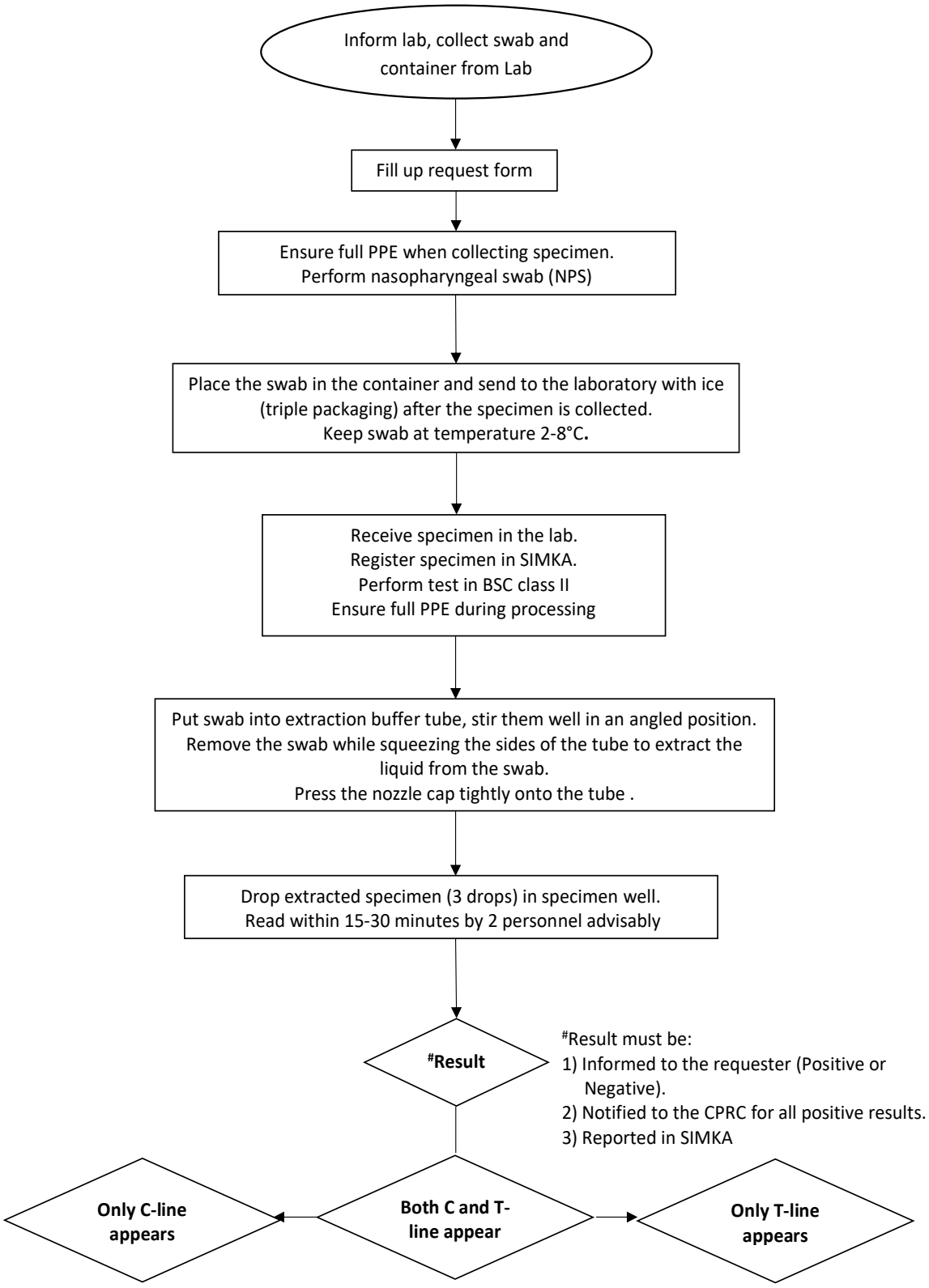
3.3.3 The laboratory personnel shall carefully check the expiry date at the back of the foil pouch. Do not use the kit if expiry date has passed. The test device and the desiccant shall as well be checked. Yellow coloured desiccant indicates valid test device while green coloured desiccant indicates invalid test device.

3.3.4 Detailed test procedure is as explained in the flow chart of RTK-Ag Testing for COVID-19 for health facilities.

3.3.5 Swab, swab container, test device, extraction buffer tube and nozzle cap shall be discarded into biohazard bag once they are used and sealed properly to avoid exposure to other staff.

3.4 Flow Chart Using COVID-19 RTK-Ag Testing

FLOW CHART OF COVID-19 RAPID TEST KIT (RTK) ANTIGEN TESTING FOR MOH'S HEALTH FACILITIES AND RESULT INTERPRETATION



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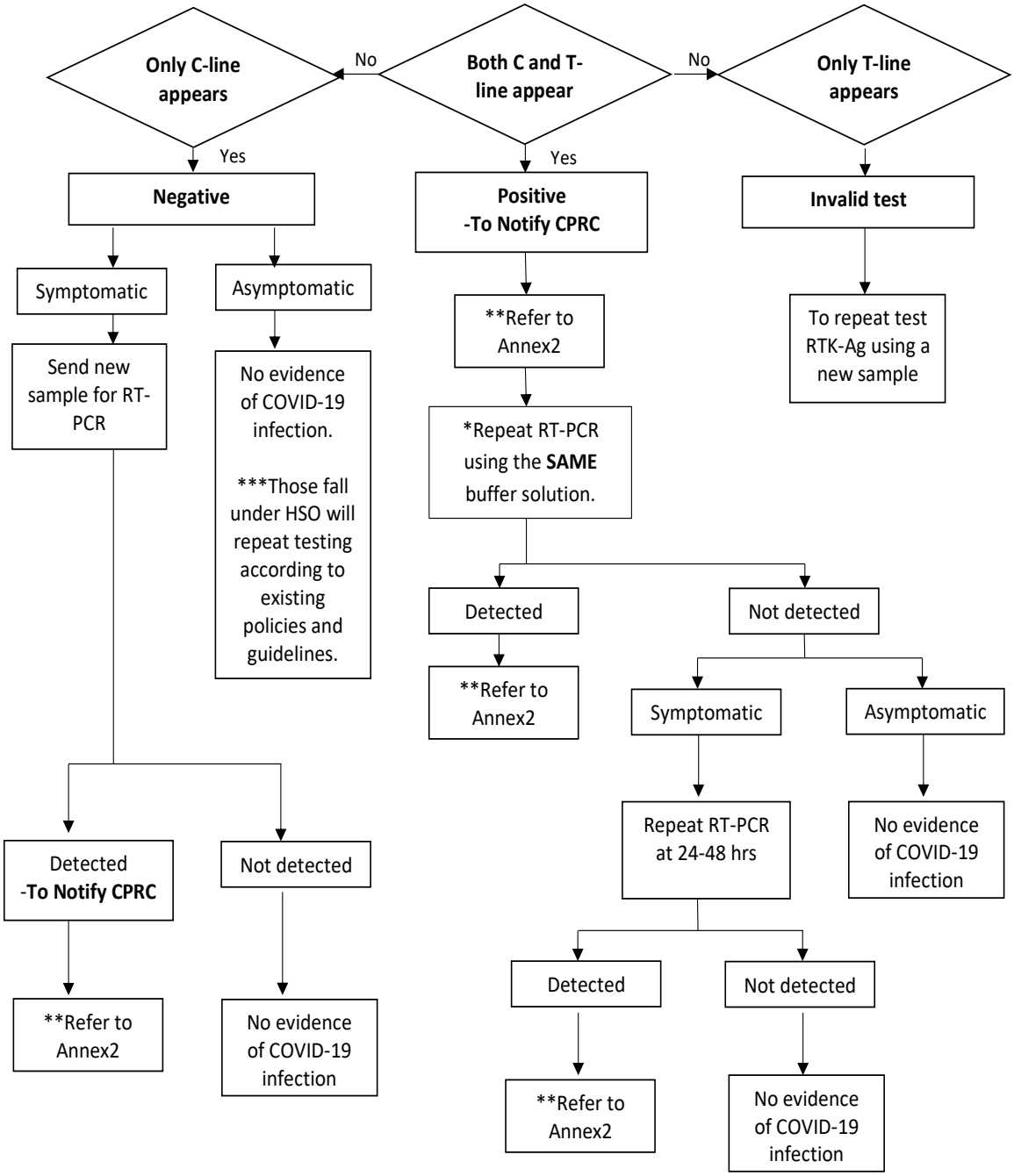


*Repeat RT-PCR using same buffer solution
- the leftover buffer solution should be sent to hospital's laboratory where the positive subject is referred to.
- the "floc" of the swab need to be squeezed as much as possible to ensure most buffer is released into the tube,
- the buffer tube must be labelled with name, IC number of subject
- the lid of the buffer tube must be sealed with parafilm and placed in biohazard bag and packed in triple packaging, and send on ice 2^{o} – 8^{o} C
- the package must be enclosed with a copy of the request form.

** Guidelines COVID-19 Management in Malaysia No.5/2020

3.5 Interpretation of Test Result

3.5.1 Advisably, the result shall be read by 2 lab personnel. This is to ensure that the result can be read within 15-30 minutes. Results that are read after 30 minutes may give false results. Results are interpretated as **negative**, **positive** or **invalid test** (referring to the kit insert) and reported in SIMKA accordingly.

3.5.2 The result is negative if only one band at C-control line appeared in the result window.

3.5.3 The result is positive if both bands appeared in each of C-control line and T-test line. Supported by a local study, **even if the T-test line is faint**, or the test line is not uniform, the test should be considered as properly performed and **the test result should be interpreted as positive** result.

3.5.4 However, for a comprehensive patient and public health management, all positive RTK-Ag cases will be tested with RT-PCR using the ***same buffer solution** of RTK-Ag. The buffer solution should be kept at 2^{o} – 8^{o} celcius and be sent to the hospital of COVID-19 testing laboratory where the patient is referred to (in triple packaging) as soon as possible. The test shall be carried out immediately. If the samples were unable to be sent within the same day, the sample need to be stored at 2^{o} – 8^{o} celcius at all time and to maintain cold chain during transportation.

3.5.5 Symptomatic patients with negative RTK-Ag results shall be tested with RT-PCR.

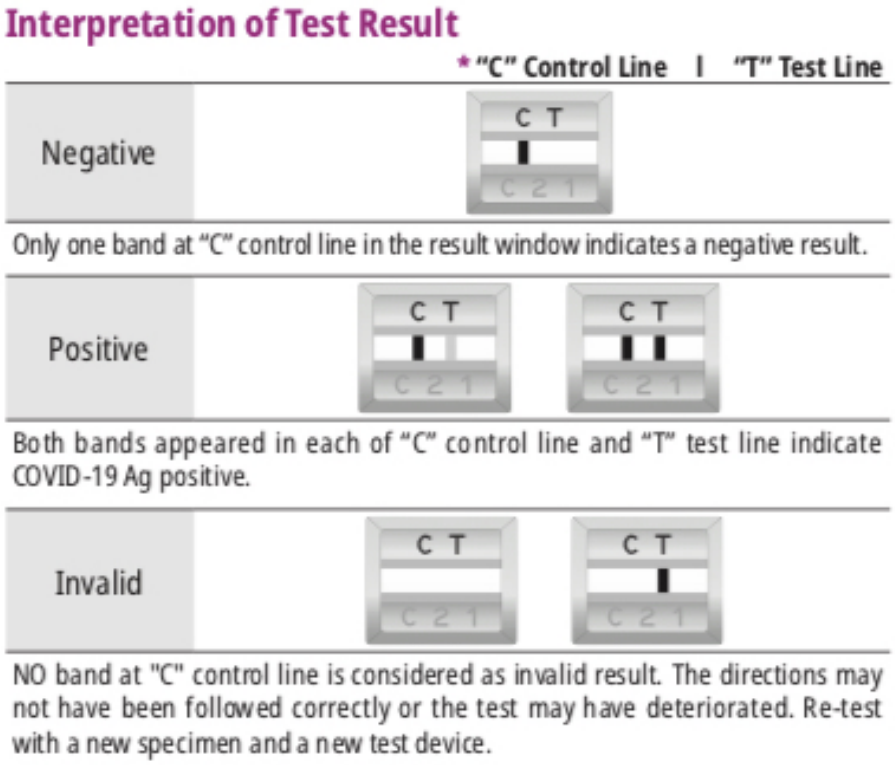
3.5.6 Positive results should be considered in conjuction with the clinical history and other data available.

3.5.7 The result is considered invalid if NO band appeared at C-control line. It may indicate~~s~~ that the instructions for the procedures may not have been

followed correctly or the test may have been deteriorated. Re-test shall be done with a new specimen and a new test device.

3.5.8 All results obtained shall be informed to the respective requester. All positive results of RTK-Ag or RT-PCR following negative RTK-Ag shall be notified to the Crisis Preparedness Response Centre (CPRC). Negative result of RT-PCR following RTK-Ag positive shall not change the notifications however will help in further patient management.

3.5.9 For a comprehensive data collection, all results need to be reported in SIMKA outbreak.



*Repeat RT-PCR using same buffer solution :

1) The leftover buffer solution should be sent to hospital's laboratory where the positive subject is referred to.
2) The "floc" of the swab need to be squeezed as much as possible to ensure most buffer is released into the tube.
3) The buffer tube must be labelled with name and IC number of the subject
4) The lid of the buffer tube must be sealed with parafilm, placed in biohazard bag, packed in triple packaging, and send on ice 2^{o} – 8^{o} C
5) The package must be enclosed with a copy of the request form.

In the laboratory:

1) To ensure there is minimum of 50µl of the buffer. If anything less that 50µl, there is no need to proceed with PCR testing. New sample shall be taken for PCR testing.

3) VTM solution will be added to the buffer solution to reach maximum 150µl in total and the testing shall proceed with manual extraction ONLY.
4) Do not perform auto extraction as this process requires higher volume of 200 -300µl and thus not suitable for testing with the leftover buffer solution

Disclaimer:

RTK-Ag negative but tested by RT-PCR to be positive (in symptomatic patients) is possible as the sensitivity rate for this test device is only 90%.

4. INQUIRIES

Any inquiries about this guideline can be referred to:

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