PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN (PERUBATAN)
KEMENTERIAN KESIHATAN MALAYSIA
ARAS 7, BLOK E1, PARCEL E, PRESINT 1,
PUSAT PENTADBIRAN KERAJAAN PERSEKUTUAN
62590 PUTRAJAYA

Tel : 03-88831034
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Ruj. Kami : KKM.600-27/4/15 Jld. 3 (15)
Tarikh : 22Mei 2020

SEPERTI SENARAI EDARAN

YBhg. Dato' Indera / Datuk / Dato' / Datin / Tuan / Puan,

EDARAN "GUIDELINE ON COVID-19 TESTING USING ANTIGEN RAPID TEST KIT (RTK-Ag) FOR THE HEALTH FACILITIES, MINISTRY OF HEALTH VERSION 2.0"

Dengan segala hormatnya saya merujuk kepada perkara di atas.

2. Untuk makluman, ujian pengesanan wabak COVID19 boleh dilakukan dengan menggunakan kaedah *Rapid-Test Kit Antigen* (RTK-Ag) yang mana ujian dapat dijalankan dengan cepat dan dalam kuantiti yang banyak. RTK-Ag yang telah dikenalpasti ini telah melepasi evaluasi oleh IMR yang mana mempunyai tahap sensitiviti 84.4% dan spesifisiti 100%.

3. Jawatankuasa Garispanduan Pelaksanaan Penggunaan COVID-19 RTK-Ag telah mengemaskini dan menambah baik garispanduan sedia ada kepada *"Guideline on COVID-19 Testing using Antigen Rapid Test Kit (RTK-Ag) for the Health Facilities, Ministry of Health version 2.0"*.

4. Antara perkara yang dikemaskini adalah senarai indikasi kegunaan ujian RTK-Ag, carta alir ujian serta interpretasi ujian RTK-Ag. Bagi sebarang ujian RTK-Ag yang didapati warna jalur pada *control line* dan *test line* pudar dengan kebarangkalian yang rendah bagi jangkitan COVID-19, ujian pengesahan dengan RT-PCR mungkin diperlukan. Sekiranya ujian RT-PCR dilakukan, keputusan RTK-Ag tersebut perlu didaftarkan sebagai *indeterminate.* Keputusan muktamad adalah berdasarkan ujian RT-PCR.

5. Sehubungan dengan itu, diharapkan garispanduan yang diedarkan dapat memberi gambaran jelas mengenai pelaksanaan ujian COVID-19 menggunakan RTK-Ag di fasiliti KKM. YBhg. Dato' Indera / Datuk / Dato' / Datin / Tuan / Puan juga dimohon untuk memanjangkan perkara ini kepada fasiliti kesihatan di bawah seliaan masing-masing. Segala kerjasama dan keprihatinan yang diberikan amat dihargai.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATUK DR. HJ. ROHAIZAT BIN HJ. YON) (MMC: 26029)
Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

DATUK. DR. HJ. ROHAIZAT BIN HJ. YON (MMC : 26029)
MD, MHP, PhD, AM (Malaysia)
Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

s.k.: Ketua Setiausaha
Kementerian Kesihatan Malaysia

Ketua Pengarah Kesihatan Malaysia

Timbalan Ketua Pengarah Kesihatan (Kesihatan Awam)

Timbalan Ketua Pengarah Kesihatan (Penyelidikan dan Sokongan Teknikal)

Pengarah
Bahagian Perkembangan Perubatan

Pengarah
Bahagian Kawalan Penyakit

Pengarah
Bahagian Pembangunan Kesihatan Keluarga

Pengarah
Bahagian Amalan Perubatan

Pengarah
Bahagian Perkembangan Kesihatan Awam

Pengarah
Pusat Perubatan Universiti Kebangsaan Malaysia

Pengarah
Pusat Perubatan Universiti Malaya

Pengarah
Hospital Angkatan Tentera Malaysia

Ketua Pegawai Eksekutif
Institut Jantung Negara

Presiden
Persatuan Hospital Swasta Malaysia (APHM)

Timbalan Pengarah
Cawangan Perkembangan Perkhidmatan Perubatan
Bahagian Perkembangan Perubatan

Dr Arni binti Talib
Ketua Perkhidmatan Patologi

SENARAI EDARAN

Pengarah Kesihatan Negeri
Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur/ Putrajaya

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Perlis

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Kedah

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Pulau Pinang

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Perak

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Selangor

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Negeri Sembilan

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Melaka

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Johor

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Pahang

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Terengganu

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Kelantan

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Sarawak

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Sabah

Pengarah Kesihatan Negeri
Jabatan Kesihatan Wilayah Persekutuan Labuan

Pengarah
Hospital Kuala Lumpur

GUIDELINE ON COVID-19 TESTING USING ANTIGEN RAPID TEST KIT (RTK-Ag) FOR THE HEALTH FACILITIES, MINISTRY OF MALAYSIA VERSION 2.0

1. OBJECTIVE

This revised guideline is aimed to enhance the previous Guideline on "Guideline on COVID-19 Testing Using Antigen Rapid Test Kit (RTK-Ag) for The Health Facilities, Ministry of Malaysia" dated 6th May 2020.

2. BACKGROUND

2.1 RTK-Ag has the advantage of detecting COVID-19 outbreaks quickly and in large quantities.The RTK-Ag used has undergone the evaluation by the IMR and has a sensitivity of at least 80%.

2.2 MOH's facilities has started using RTK-Ag since 6th May 2020 along with the circulation of existing guideline. In view of this, several hospitals have carried out validation studies between RTK-Ag and RT-PCR.

2.3 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). At the same time, 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. Thus, they remain as important requirements in performing this test.

2.4 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.

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 COVID-19 testing for healthcare workers (HCW) shall remain using RT-PCR as it is regarded as one of the high risk group. It is important to reduce the risk of having an outbreak within MOH's facitilies which may cause a great impact to healthcare deliveries. This is also in line with 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.

3.1.4 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 laboratory will receive RTK-Ag testing kit which consists of :

i. Test device (individually in a foil pouch with desiccant)
ii. Extraction buffer tube
iii. Nozzle cap
iv. Sterile swab
v. Paper stand
vi. Instructions for use

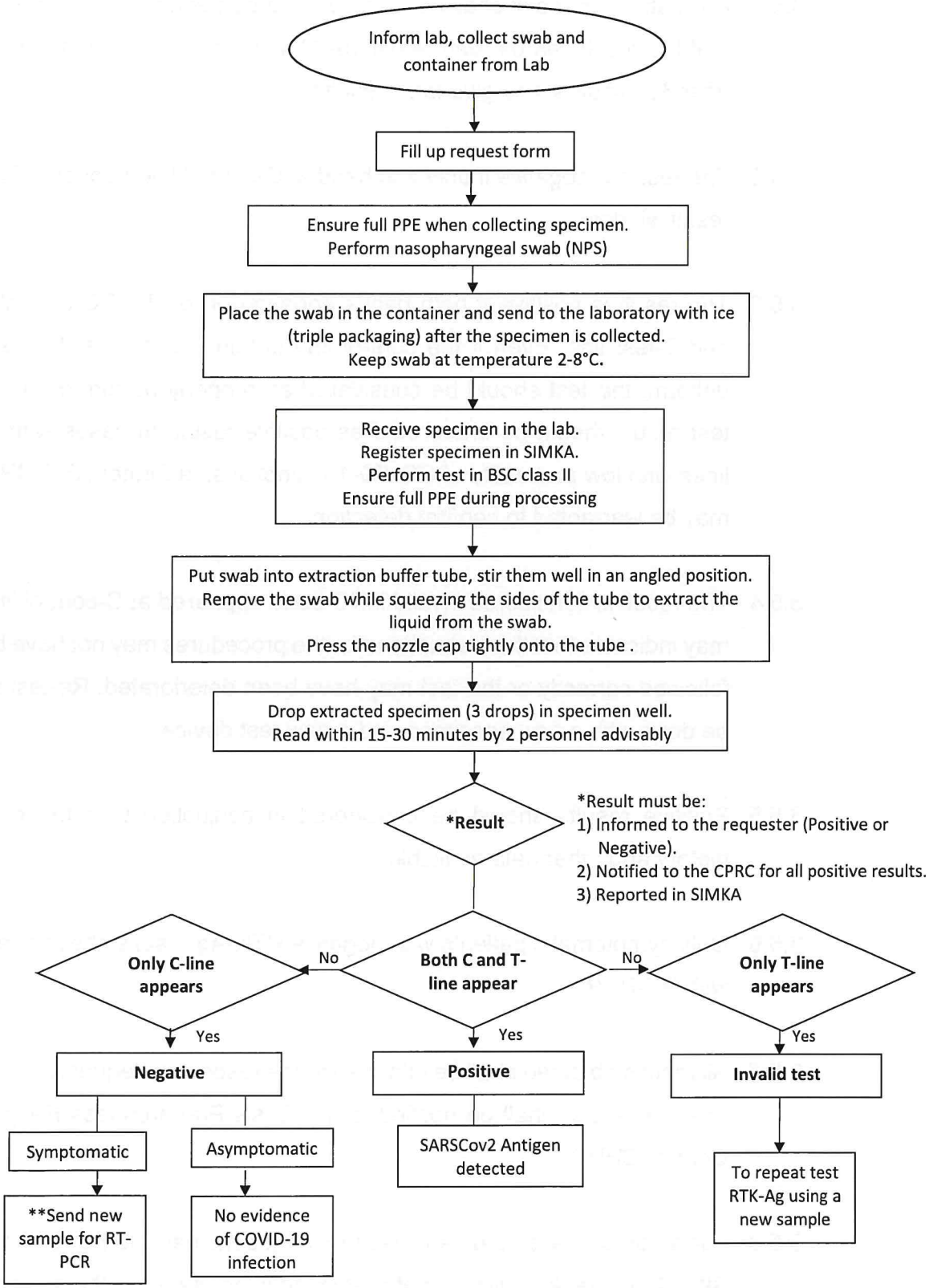
3.3.2 The laboratory personnel shall carefully check the expiry date at the back of the foil pouch. Do not use the kit if expiry date has passed. The test device and the desiccant shall as well be checked. Yellow coloured desiccant indicates valid test device while green coloured desiccant indicates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

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

3.3.4 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 HEALTH FACILITIES



**Refer to Disclaimer Box

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.

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. Even if the control 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. In cases with faint lines with low probabilty of COVID-19 infections, a further RT-PCR test may be warranted to confirm detection.

3.5.4 The result is considered invalid if NO band appeared at C-control line. It may indicates 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.

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

3.5.6 Only symptomatic patients with negative RTK-Ag results shall be tested with RT-PCR.

3.5.7 All results obtained shall be informed to the respective requester. And all positive results shall be notified to the Crisis Preparedness Response Centre (CPRC).

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Interpretation of Test Result

* "C" Control Line | "T" Test Line

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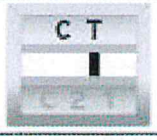
Invalid	 
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RTK-Ag negative but tested by RT-PCR to be positive (in symptomatic patients) is possible as the sensitivity rate for this test device is only 84.4%.

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Medical Development Division

Level 5-7, Block E, Parcel E,

Federal Government Administrative Centre

62590 Putrajaya

Tel : 03-8883 1489

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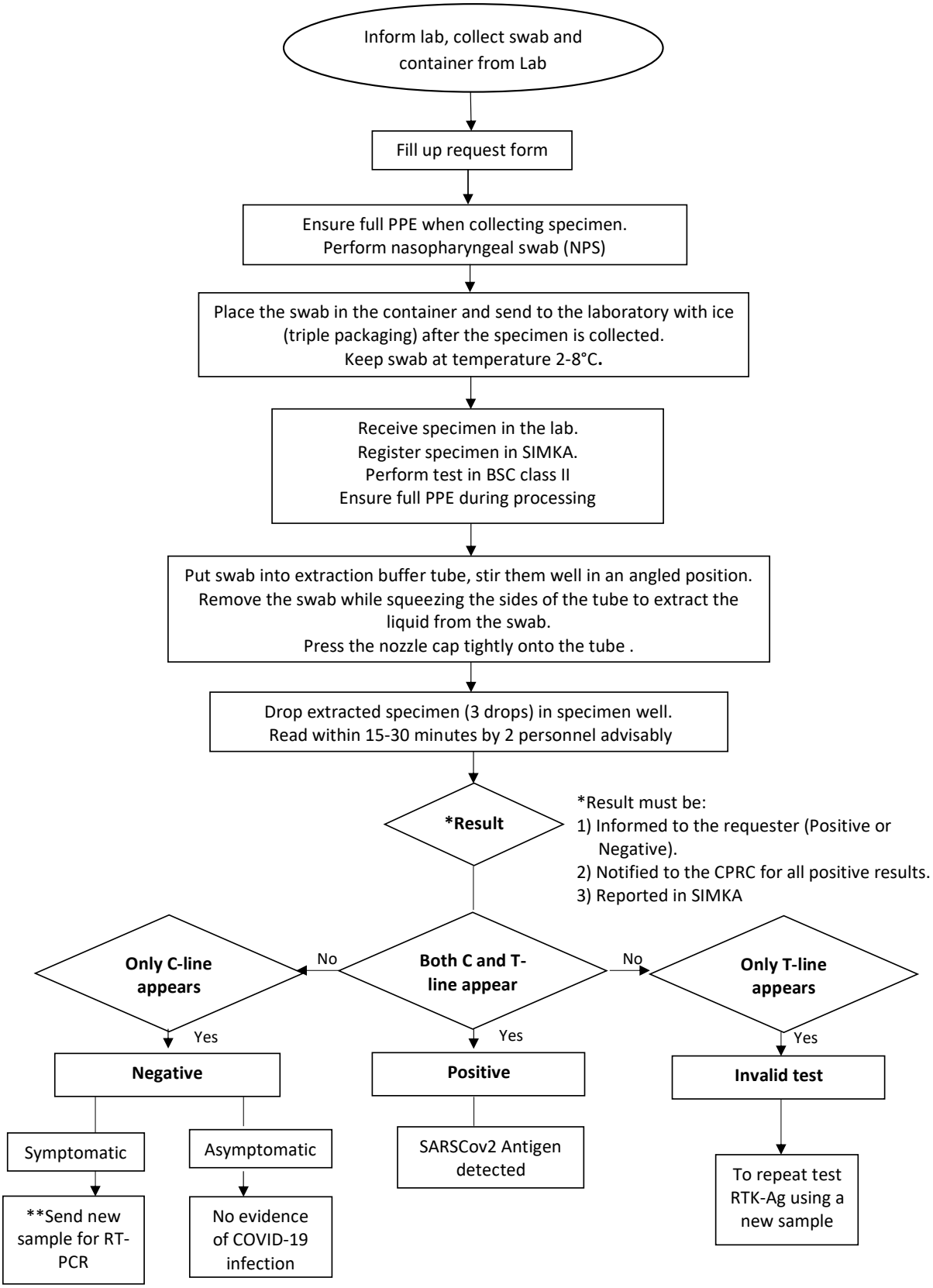

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