

ANNEX 4h: GUIDELINE FOR COVID-19 RAPID MOLECULAR TESTING

**GUIDELINE
FOR COVID-19 RAPID MOLECULAR TESTING
Version 1.0**

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1. Background

- 1.1 Recent advancements in rapid molecular testing allow faster case detection, diagnosis and management of COVID-19 patients using rapid, robust, point-of-care test with results available in less than an hour. The components are often self-contained, requiring fewer laboratory resources (i.e., hands-on personnel) with minimum requirement of specialized equipment than other laboratory-based instruments.

2. Scope

- 2.1 This document describes the requirements to be complied by the testing facilities offering rapid molecular test for SARS-CoV-2 virus detection. The guideline, requirement and performance criteria outlined in this document are intended for comparable, accurate and reproducible results.
- 2.2 Testing facilities include Ministry of Health Malaysia (MOH) Facilities or Private Healthcare Facilities and Services registered or licensed under Act 586 at the premises or elsewhere that has been approved by MOH.

3. Personnel

3.1 Personnel taking the samples

Refer to Arahan Am Menteri Bilangan 2/2020 for “Self-Declaration Bagi Menyediakan Healthcare Screening Booth oleh Klinik Perubatan Swasta yang Berdaftar di Akta 586.”

3.2 Personnel conducting the tests

Operators must be registered health personnel (i.e. Medical Lab Technologist, Science Officer, Medical Officer) with minimum

Diploma in related medical field who have been trained to do the testing. Personnel conducting the tests shall be trained by supplier and facilities must keep the proof of training by supplier.

3.3 Authorized signatory

The testing facilities shall have qualified, skilled and experienced signatory to validate the result i.e. Medical Officers or Scientific Officer.

4. Accommodation and environmental conditions

- 4.1 It is recommended that all SARS-CoV-2 samples are be handled in a class II or higher biosafety cabinet. If a biosafety cabinet is **unavailable**, handing of suspected SARS-CoV-2 positive samples should include additional precautions to provide a protective barrier between specimen manipulation and personnel performing the test. The area to conduct the test must be a dedicated room/space/area, free of clutter with good ventilation system.
- 4.2 Reagents shall be stored at the appropriate temperature as recommended by the manufacturer. There shall be an inventory on the date of receive, lot number, expiry date and date opened of the kit in use.

5. Equipment

- 5.1 All refrigerator and freezer shall have daily temperature chart monitoring
- 5.2 All equipment including biosafety cabinet class II shall be maintained according to the planned preventive maintenance (PPM).

6. Sample Management

- 6.1 Staff shall be trained for appropriate personal protective equipment (PPE) usage, specimen collection, storage, packaging and transport before collecting the samples.
- 6.2 Specimens shall be collected from upper respiratory tract specimens such as nasopharyngeal / oropharyngeal swabs or as recommended by the manufacturer.
- 6.3 The traceability of all sampling activities from receipt through preparation, proper analysis, reporting of results, storage to disposal of the samples shall be documented.

7. Test method and method verification

- 7.1 The testing facility shall use rapid molecular kit and instrument that have been listed by Medical Device Authority (MDA).
- 7.2 Verification shall be performed before offering the test
 - i. Test **one known positive** sample on the analyser. This sample can be obtained from any recognized COVID-19 private laboratory for private testing facilities.
 - ii. Once acceptable, send the **first 5 patients' samples** to any recognized COVID-19 lab (private testing facilities to non-MOH COVID-19 laboratory) for confirmation. (Refer Annex 4a at <http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm> website)
- 7.3 Records of all verifications shall be safely stored for future reference.

8. Testing procedure

8.1 Test procedure to be done as per manufacturer's recommendation. All result records shall be kept and maintained for retrieval purpose.

9. Assuring the quality of test results

9.1 Regular quality control and instrument calibration shall be performed according to the manufacturer's instructions. If quality control or calibration fails, identify and correct issues prior to proceeding with patient testing.

9.2 All testing facility can be subjected to random check by the Ministry of Health.

10. Interpretation

10.1 The interpretation of results shall be as **Appendix 1**

10.2 All results shall be reviewed and validated by authorized personnel (approved signatories) prior to release.

11. Reporting of results

11.1 **Positive results** shall be informed to the referring doctor **as soon as possible**. (Please refer to **Annex 2f** at <http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm> website)

11.2 **Requesting doctor** must notify positive results to the PKD **as soon as possible within 24 hours**.

11.3 All results shall be entered into the *Sistem Informasi Makmal Kesihatan Awam* (SIMKA) within 24 hours. Each facility is required to choose "Rapid Molecular" as the method of testing in the SIMKA system.

11.4 The access to SIMKA can be obtained by emailing the details of the health personnel performing the testing to it.mkak@moh.gov.my

12. Clinical waste management

The testing facility shall have clinical waste management procedure in place.

13. Risk Management

The testing facility shall have risk assessment activities before offering the test (**Appendix 2**).

14. Notification to Offer Rapid Molecular Testing

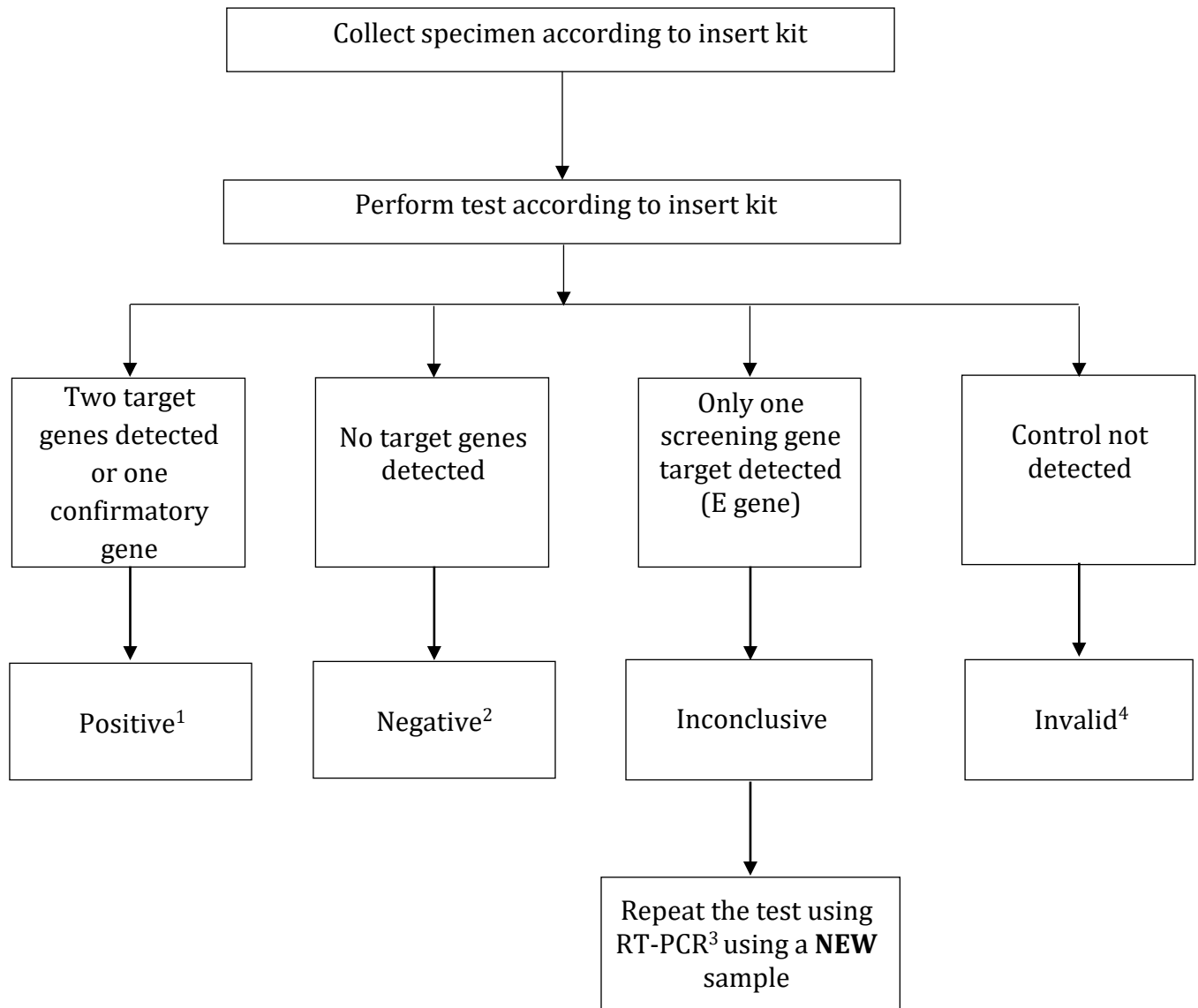
Facilities intend to offer rapid molecular testing need to fill in the Online Notification Form: <https://forms.gle/Wc5hRS9AnpY8XRxA8>

As this is a **notification form**, facilities can start performing the test once all the SOP are followed and notification form are submitted.

References

1. WHO recommendation for testing specimens for COVID-19.
2. Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. Interim guidance 19th March, WHO.
3. Laboratory biosafety guidance related to coronavirus disease (COVID-19) Interim guidance 13th May, WHO.
4. Guidelines on Management of COVID-19 Management in Malaysia. covid-19.moh.gov.my
5. Medical laboratories – Requirements for quality and competence. MS ISO 15189:2014.
6. Specific Technical Requirements 1.6 (STR 1.6). Specific Technical Requirements for Accreditation of Nucleic Acid Testing Laboratories. Jabatan Standard Malaysia.
7. Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19), CDC

Recommended result interpretation using rapid molecular testing



¹ Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient's infection status.

² Negative results do not preclude SARS-CoV-2 infection. If clinically indicated, repeat PCR after 48 hours – 72 hours.

³ Repeat PCR test using other RT-PCR or rapid PCR platform, based on local setting.

⁴ To follow manufacturer recommendation/ troubleshooting.

Appendix 2

RISK ASSESSMENT FOR COVID-19 RAPID MOLECULAR TESTING

Risk assessment is a systematic process of gathering information and evaluating the likelihood and impact of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk.



Diagram 1: Risk assessment process

Risk assessment is carried out by gathering information and identifying hazards (**Diagram 1**) in a situation that may expose operators to infections when conducting test. Factors to be taken into account are the use of personnel protective equipment, facility design, ventilation of testing area, level of health of personnel conducting tests, standard operating procedures in place and operators' competency. After information are gathered, risks are evaluated.

In rapid molecular testing, for example; hazard is identified when operators transfer patients' samples to the cartridge before being analyzed by machine in which there is a probability of spillage or production of aerosols that may expose operators to infections as well as lead to contamination to the environment.

After considering the above factors, the inherent risk can be qualitatively determined using a two-dimensional graph as below:

Consequences of exposure/ release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium
		Unlikely	Possible	Likely
Likelihood of exposure/release				

The likelihood of exposure will depend on control measures that are already in place. 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 mitigation measures should be carried out. Risk should be reduced to a level that is acceptable.

A control strategy must be developed but must take in consideration sufficient resources to secure and maintain potential risk control measures. Additional mitigation, for example, is to provide engineering controls such as the addition of ventilation exhaust fans to increase room ventilation, use of additional personal protective devices or any other strategy considered feasible.

Risk assessment should be a continuous process and should be performed whenever changes take place i.e. personnel, facility, equipment, methods and regulations.

INQUIRIES

Any inquiries about this document can be referred to:

General Inquiry				
No.	Institution/Division/ Department	Officer In-charge	Telephone No.	Email
1.	Medical Development Division, Level 5, Block E, Parcel E, Federal Government Administrative Centre 62590 Putrajaya	Jawatankuasa Pasukan Khas Makmal COVID-19 (JPKMCOVID-19)	03-8890 6028	covid19makmal @moh.gov.my

Testing facilities				
No.	Institution/Division/ Department	Officer In-charge	Telephone No.	Email
1.	Private Healthcare Facilities and Services	Dr Mohamed Ahsan	drmdahsan@ moh.gov.my	bap@moh.gov.m y

Training on Nasopharyngeal and Oropharyngeal Sampling and Sample Handling				
No.	Institution/Division/ Department	Officer In-charge	Telephone No.	Email
1.	Family Health Development Divison	Dr Siti Khadijah Binti Ahmad Tajuddin	03-88832265	sitikhatijah@moh. gov.my
		Dr Naning Sachiman	03-88835370	naning@moh.gov .my

Reporting of Results, SIMKA Outbreak and Risk assessment				
No.	Institution/Division/ Department	Officer In- charge	Telephone No.	Email
1.	National Public Health Laboratory, Ministry of Health	Dr Wan Amani binti Wan Abdul Azim	03-61261200	mkak_careline @moh.gov.my

List of Recommended RTK-Ag Kit				
No.	Institution/Division/ Department	Officer In- charge	Telephon e No.	Email
1.	Medical Device Authority, Ministry of Health	Pn Aidahwaty Ariffin @ M.Olaybal	03-83200341	aidahwaty@mda. gov.my

COVID-19 Case Notification and Management				
No.	Institution/Division/ Department	Officer In- charge	Telephone No.	Email
1.	Infection Control Division, Ministry Of Health	Dr Asiah binti Ayob	03-88834118	drasihayob@ moh.gov.my