COVID-19 RAPID MOLECULAR TESTING

1. Objectives

1.1 This document describes the requirements to be complied by the testing facilities offering rapid molecular test for SARS-CoV-2 virus detection.

2. Background

2.1 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.

3. Procedures

3.1 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 and the proof of training must be kept by the health facilities.

3.2 Authorized signatory

The testing facilities shall have qualified signatory to validate the result

a) Pathologists

b) Medical Officer

c) Science 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**, handling of suspected SARS-CoV-2 positive samples should include additional precautions to provide a protective barrier between specimen manipulation and personnel performing the test. Refer to Annex 4c (Risk assessment).

4.2 Reagents shall be stored at the appropriate storage and temperature as recommended by the manufacturer. There shall be an inventory onthe 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 operated andmaintained according to manufacturer's instructions.

6. Sample Management

6.1 Specimens shall be collected as recommended by the manufacturer.

6.2 The traceability of the specimen 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 approved by Medical Device Authority (MDA).

7.2 Result correlation shall be performed before offering the test.

i. To obtain 5 positive and 5 negative samples from any recognized COVID-19 lab (private testing facilities can obtain their samples from non-MOH COVID-19 laboratory). At least 90% concordance must be achieved.

ii. 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 before 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 per kit insert.

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.**

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) or E-Covid according to the current directive by Ministry of Health within 24 hours. Each facility is required to choose "Rapid Molecular" as the method of testing in the SIMKA or E-Covid.

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

12. Clinical waste management

The testing facility shall have clinical waste management procedure inplace.

13. 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.