Annex 4e

APPLICATION PROCEDURE FOR LABORATORIES OFFERING RT PCR COVID-19 TESTING

The procedure for offering real time RT-PCR tests for COVID -19 are as follows:

a. Write request to conduct the test to the Secretariat of Jawatankuasa Pasukan Khas Makmal COVID-19(JPKMCOVID-19) at covid19makmal@moh.gov.my.

b. A site visit shall be carried out by the committee, to determine the feasibility of the laboratory to offer the service.

c. Blinded samples shall be provided to the laboratory that has passed the site visit.

d. The laboratory shall conduct the testing using the assay that include minimum one confirmatory target gene. The kit must be approved by the MDA.

e. Upon completion of PCR, e-mail the file containing the ct value and image of the PCR amplification curve of each sample, as well as the interpretation of the results to the Secretariat of JPKMCOVID-19 at covid19makmal@moh.gov.my.Approval shall be given by the Chairman of JPKMCOVID-19 within 14 working days from the submission of results via email to the requesting laboratory.

f. Once approved to conduct the test, the laboratory may proceed to test using actual clinical samples.

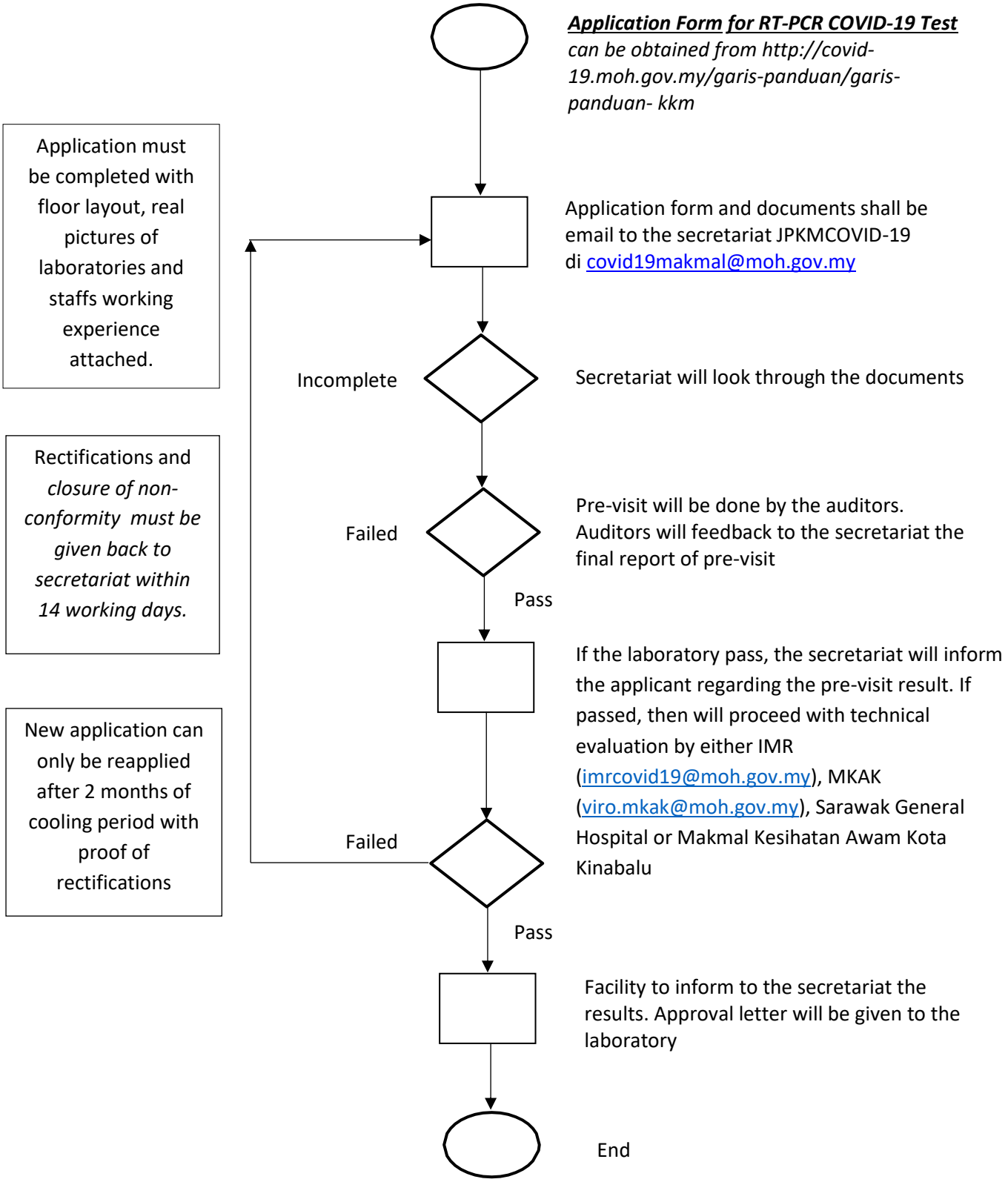
g. The approved laboratory shall email the PCR images of the first 5 positive and 5 negative clinical samples (minimum 500 µl) to IMR/MKAK/MKAKK/HUS for verification.

h. If the laboratory is not approved to conduct the test, re-application for offering SARS-CoV-2 Real Time RT-PCR testing to the JPKMCOVID-19 can only be made **after 2 months** from the un-approved notice with proof of rectifications done during the period.

i. The authorized list of laboratories shall be kept by the Secretariat and updated regularly. (Annex 4a)

FLOW CHART OF APPLICATION PROCEDURE FOR LABORATORIES TO PERFORM RT-PCR COVID-19 TEST

WORKFLOW



APPLICATION PROCEDURE FOR LABORATORIES TO PERFORM RT-PCR COVID-19 TEST

LABORATORY NAME:

Clause	Requirement	Yes	No	COMMENTS
1. Scope	a. be under supervision by a Clinical Microbiologist or pathologist with molecular training/experience officially appointed by the laboratory. CM/Pathologist must do a visit twice a month with proof of documentation. (Refer to TOR for more details) b. Shall register for ISO15189 within 1 year of running the test to ensure the quality of test results			
2. Personnel	a. The personel conducting the test procedure shall have a minimum Diploma in Medical Laboratory Technology. b. Training and competency in nucleic acid testing methods are documented. c. The laboratory have qualified, skilled and experienced signatory (ies) to validate data and troubleshoot problems, thus shall have a degree or higher in the medicine or basic science, trained and competent in the nucleic acid method, with at least one year or more laboratory working experience and at least 3 months working experience in molecular testing. d. Result validated by trained and competent Pathologist, medical officer, scientific Officer or Research Officer. e. The lab should have at least one personnel that have qualifications in microbiology.			
3. Accommodation and environmental conditions	a. Dedicated areas for specimen reception, pre and post analysis to minimize cross-contamination. b. A separate room for pre-PCR, reagent preparation and PCR amplification. c. The laboratory that has fully automated system, from extraction and master-mix preparation, need not have separate room.			

Clause	Requirement	Yes	No	COMMENTS
	d. A designated space for storage of specimens e. Specimens are not be placed in the same storage as the reagents. f. Pre-testing and post samples not kept in the same place g. appropriate temperature for reagents storage as recommended by the manufacturer. h. An inventory on the date of received, lot number, expiry date and date of the kit in use are available. i. Each new lot of the kit or any changes in reagents or procedure are verified for performance before use in testing and documented.			
4. Equipment	a. Daily temperature chart monitoring for all freezers and chillers. b. All equipment including biosafety cabinet class II are maintained according to the planned preventive maintenance (PPM). c. Autoclaves are operated by trained personnel.			