APPLICATION PROCEDURE FOR LABORATORIES TO PERFORM MOLECULAR TEST

Risk Groups for pathogens are classifications that describe the relative hazard posed by infectious agents or toxins in the laboratory. The risk group to which an infectious agent or toxin is assigned is the primary, but not only, consideration used in a biological risk assessment to determine the appropriate biosafety level in which a worker can handle the infectious agent or toxin. Risk groups are designated from 1 (the lowest risk) to 4 (the highest risk). **This document is applicable for risk group pathogen 3 and 4.**

"Laboratory" is used to include all types of laboratories that are relevant in public and private health provision. Molecular methods have played critical roles in the discovery, monitoring, and clinical diagnostics of emerging pathogens. In the setting of emerging infectious diseases, rapid and accurate identification of the causative agent is critical to facilitate effective patient management and enable prompt initiation of infection controls.

National and international stakeholders have increasingly embraced Public-Private-Partnerships (PPP) as an effective way to boost health system performance and in turn improve health outcomes. This engagement is very crucial in curbing any novel, emerging or re-emerging diseases in the country, lesson learnt from the recent pandemic COVID-19. This document is designed for any laboratories applying for molecular testing in line to ensure the standardization of the requirements across the country.

LABORATORY REQUIREMENT FOR MOLECULAR TESTING (DRY EVALUATION PURPOSES)

The procedure for offering molecular test are as follows:

a. Write request to conduct the test to the Secretariat (MKAK) at it.mkak@moh.gov.my

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

c. The kit **used by the laboratory** must be approved by the MDA.

d. Assessment to be completed within 14 days by the commitee and approval shall be given by *TKPK (KA)* or *Pengarah BKP* via official letter to the requesting laboratory. Once approved to conduct the test, the laboratory may proceed to test using clinical samples.

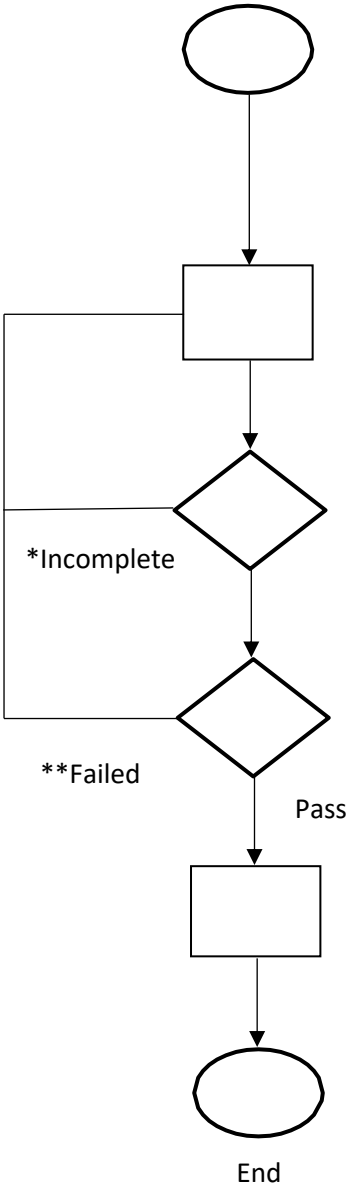
e. The approved laboratory shall **send their first positive case sample to the reference laboratory, MKAK** for verification. **Verification by reference laboratory not required for subsequent positive results(s).**

f. If the laboratory is not approved to conduct the test, re-application for offering **molecular** testing to the Secretariat can only be made **after 2 months** from the un-approved notice with proof of rectifications done during the period.

g. The authorized list of laboratories shall be kept by the Secretariat and updated regularly in the guidelines.

FLOW CHART OF APPLICATION PROCEDURE FOR LABORATORIES TO PERFORM MOLECULAR TEST

WORKFLOW



Application Form for Molecular Test *(via email)*

Checklist and documents shall be email to the secretariat

Secretariat will look through the documents

*Incomplete

If needed, Pre-visit will determined based on the checklist.
Auditors will be identified
Auditors will feedback to the secretariat visit

**Failed

Pass

If the laboratory pass, the secretariat will inform the applicant regarding the result within 2 weeks after completion of documents/audit.

Approval letter will be given to the laboratory

End

**Rectifications and *closure of non-conformity must be given back to secretariat within 14 working days.*

Note:

- New application can only be reapplied after 2 months with proof of rectifications
- This flow is applicable to other relevant government, private and academia laboratories.

LABORATORY REQUIREMENT FOR MOLECULAR TESTING (DRY EVALUATION PURPOSES)

NAME OF TEST :

LABORATORY NAME :

LABORATORY ADDRESS :

TECHNICAL REQUIREMENTS :

***if you answer yes, please provide comments and/or evidence**

Related SOP /Clause	Requirement	Tick the box (Yes ✔, No ✘)	COMMENTS
1. Scope (general molecular testing)	a. i. Have offered any molecular testing as one of the testing scopes. ii. Have offered any microbiology testing as one of the testing scopes. (If yes, please specify the type of test)	☐ ☐	
	b. Have been accredited for medical testing under MS ISO15189 for any molecular testing. (If yes, please state the accreditation date and scope)	☐	
	c. Have an approval letter issued for administering COVID-19 tests during the pandemic. (If yes, please provide the letter's reference number and approval date)	☐	

2. Personnel	a. The personnel conducting the test procedure shall have a minimum of Diploma in Medical Laboratory Technology at least one-year experience in molecular testing. b. The laboratory has 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 molecular testing with at least one year or more laboratory working experience. c. Training and competency in molecular testing are documented.	☐ ☐ ☐	
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. A designated space for storage of specimens (pre and post testing) and reagents.	☐ ☐ ☐	

4. Equipment	a) All laboratory equipment including biosafety cabinet class II and micropipette are maintained. b) Clinical waste disposal procedure is available.	☐ ☐	
5. Test method	a. Kits use must have MDA approval. b. Please state the name of the kit.	☐	

Comments:

NAME OF AUDITOR : DATE :