Annex 4f

APPLICATION FORM FOR SARS-CoV-2 RT-PCR TESTING LABORATORY

DATE :
NAME OF REQUESTOR :
ORGANIZATION :
ADDRESS OF REQUESTING FACILITY :

STATUS OF REQUESTING FACILITY :Standalone / Part of a Private Healthcare Facility Licenced under ACT 586

TO COMPLETE THE APPLICATION CHECKLIST BELOW :

Requirement		Yes	No	COMMENTS
1. Scope	a. Must be under supervision by a Clinical Microbiologist that is officially appointed by the laboratory. b. Have been accredited for medical testing under ISO15189 for microbiology molecular testing c. Have offered microbiology molecular testing as one of the testing scope			
2. Personnel	a. A minimum Diploma in Medical Laboratory Technology with experience of performing nucleic acid testing of at least 3 months. 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 microbiology field, 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 the current laboratory. d. Result validated by trained and competent Pathologist or Scientific Officer in Nucleic Acid Testing			
3.Handling of specimens	a. Samples are packed in triple packaging and transported at 2-8 ^{0}C. b. The request forms are placed separately on the outside package c. Processing of specimen in Biosafety Cabinet class II and handled by staff wearing proper PPE.			
4.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. 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.			
5 .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.			
6. Record and reporting system	a. All data are kept confidential and in safe computer system and access to the result are limited to authorised personel b. Required data are keyed into the Sistem Informasi Makmal Kesihatan Awam Outbreak (SIMKA Outbreak).			
7. Waste Management	a. Waste management procedure in place b. All clinical samples and consumables are autoclaved or incinerated			

REQUESTOR'S
SIGNATURE :
POSITION :
TELEPHONE :
EMAIL :

***TO SUBMIT THE COMPLETE FORM TO covid19makmal@moh.gov.my**