KETUA PENGARAH KESIHATAN MALAYSIA
DIRECTOR GENERAL OF HEALTH MALAYSIA
Kementerian Kesihatan Malaysia
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Email: anhisham@moh.gov.my

Ruj. Kami : KKM.600-27/4/2 Jld.3 (74)
Tarikh : 13 Ogos 2020

SEPERTI SENARAI EDARAN

YBhg. Datuk/Dato'/Dato' Indera/Datin/Tuan/Puan,

EDARAN STANDARD OPERATING PROCEDURE (SOP) FOR SARS-CoV-2 REAL-TIME RT-PCR TESTING LABORATORY DAN CARTA ALIR PERMOHONAN MENJALANKAN UJIAN SARS-CoV-2 RT-PCR

Dengan segala hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa satu dokumen "Standard Operating Procedure (SOP) for SARS-CoV-2 Real-Time RT-PCR Testing Laboratory" telah berjaya dihasilkan oleh Kementerian di bawah Jawatankuasa Pasukan Khas Makmal COVID-19.

3. Dokumen ini bertujuan mengawal selia dan memastikan makmal yang terlibat di dalam pelaksanaan ujian COVID-19 RT-PCR memenuhi standard, kualiti dan kaedah yang seragam dalam pengujian COVID-19 yang mana memainkan peranan utama di dalam pencegahan dan pengawalan penularan wabak COVID-19 negara.

4. Dokumen ini antaranya menjelaskan mengenai keperluan asas yang diperlukan bagi sesuatu makmal COVID-19, proses permohonan dan pentauliahan serta keperluan keterlibatan makmal-makmal tersebut di dalam aktiviti audit selepas pentauliahan.

5. Sehubungan itu, dilampirkan dokumen-dokumen berkaitan bagi rujukan dan kegunaan pihak YBhg. Datuk / Dato' / Datin / Tuan / Puan. Dokumen-dokumen ini juga boleh didapati di laman sesawang http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm bagi kemudahan semua.

6. Sukacita dimohon YBhg. Datuk / Dato' / Dato' Indera / Datin / Tuan / Puan untuk memanjangkan perkara ini kepada fasiliti di bawah seliaan masing-masing. Keprihatinan dan kerjasama yang diberikan oleh YBhg. Datuk / Dato' / Dato' Indera / Datin / Tuan / Puan dalam hal ini amat kami hargai.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATUK DR. NOOR HISHAM BIN ABDULLAH)

s.k. Ketua Setiausaha
Kementerian Kesihatan Malaysia

Timbalan Ketua Pengarah Kesihatan (Perubatan)
Kementerian Kesihatan Malaysia

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Bahagian Dasar dan Hubungan Antarabangsa

Penasihat Undang-undang
Pejabat Penasihat Undang-undang

Pengarah
Bahagian Perkembangan Perubatan

Pengarah
Bahagian Kawalan Penyakit

Pengarah
Bahagian Amalan Perubatan

Pengarah
Bahagian Pembangunan Kesihatan Keluarga

Pengarah
Bahagian Perkembangan Kesihatan Awam

Pengarah
Institut Penyelidikan Perubatan (IMR)

Ketua Pegawai Eksekutif
Pihak Berkuasa Peranti Perubatan

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Jabatan Kesihatan Negeri Perlis

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Kedah

Pengarah Kesihatan Negeri
Jabatan Kesihatan Pulau Pinang

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Perak

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Selangor

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Sembilan

Pengarah Kesihatan Negeri
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Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Kelantan

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Sabah

Pengarah Kesihatan Negeri
Jabatan Kesihatan Negeri Sarawak

KEMENTERIAN

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STANDARD OPERATING PROCEDURE (SOP)

FOR

SARS-CoV-2 REAL-TIME RT-PCR TESTING LABORATORY

Version 1.0

2020

STANDARD OPERATING PROCEDURE (SOP) FOR SARS-CoV-2 REAL-TIME RT-PCR TESTING LABORATORY

CONTENTS

STANDARD OPERATING PROCEDURE (SOP) FOR SARS-CoV-2 REAL-TIME RT-PCR TESTING LABORATORY

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1. Scope

1.1 This document describes the requirements to be complied by the laboratories offering Real-time RT-PCR 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.

1.2 The laboratory intending to apply for SARS-CoV-2 RT-PCR testing shall be a under supervision by a clinical microbiologist officially appointed by the laboratory **and** :

a) have been accredited for medical testing under ISO15189 for microbiology molecular testing **or**

b) have offered medical microbiology molecular testing on human samples as one of the testing scopes.

2. Personnel

2.1 Personnel taking the samples

The personnel taking the samples of nasopharyngeal and oropharyngeal swabs must be a registered medical practitioner who has attended training and has a certificate of attendance for Sample Taking and Handling Training for COVID-19 for General Practitioners and Paramedics from Private Health Facilities issued by the Family Health Development Division, MOH or State / Federal Health Department.

Sampling can only be done by the Private Healthcare Facilities and Services registered or licensed under Act 586 at the premises or

elsewhere that has been approved for the facilities by the Medical Practice Division, Ministry of Health Malaysia.

2.2 Personnel conducting the tests

The personnel conducting the test procedure shall have the qualifications, training, and experience appropriate to the tasks performed. The personnel shall have a minimum Diploma in Medical Laboratory Technology with experience of performing nucleic acid testing of at least 3 months. Training and competency in nucleic acid testing methods shall also be documented.

2.3 Authorized signatory

The laboratory shall have qualified, skilled and experienced signatory (ies) to validate data and troubleshoot problems. Approved signatory (ies) 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. For those with less than 1-year laboratory working experience shall have at least 6 months working experience in the current laboratory. Trained and competent Pathologist or Scientific Officer in Nucleic Acid Testing are also allowed to validate the result.

3. Accommodation and environmental conditions

The laboratory shall have dedicated areas for specimen reception, pre and post analysis to minimize cross-contamination. There shall be separate room for pre-PCR, reagent preparation and PCR amplification. The laboratory that has fully automated system, such as from extraction to master-mix preparation, need not have separate room.

3.1 Specimen storage

There shall be a designated space for storage of specimens, as specified in the Guidelines on COVID-19 Management in Malaysia.

Specimens shall not be placed in the same storage as the reagents. Pre-testing samples shall not be kept together with post-testing samples.

3.2 Reagents storage

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 of the kit in use.

Each new lot of the kit or any changes in reagents or procedures shall be verified for performance before use in testing and documented.

4. Equipment

4.1 All freezers and chillers shall have daily temperature chart monitoring.

4.2 All equipment including biosafety cabinet class II shall be maintained according to the planned preventive maintenance (PPM).

4.3 Autoclaves shall be operated by trained personnel.

5. Test method and method verification

5.1 The laboratory shall use kits that have been validated by Institute for Medical Research (IMR) or National Public Health Laboratory (NPHL). The list of recommended kits can be obtained from Medical Device Authority (MDA).

5.1 The laboratory shall perform verification of the test method before offering the test. Records of all verifications shall be safely stored for future reference.

5.3. The procedure for offering SARS-CoV-2 Real Time RT-PCR test are as follows:

i. To completely fill up an application form to conduct the test and to submit the form to the Secretariat of Jawatankuasa Pasukan Khas Makmal COVID-19 (JPKMCOVID-19) at *covid19makmal@moh.gov.my* (Attachment 1). This form is available at *http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm.*

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

iii. Laboratory shall be given 14 working days to take and submit corrective actions to the Secretariat for the non-conformity found during the site visit.

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

v. The testing assay shall have at least two (2) different targets on the COVID-19 virus genomes, of which at least one target is confirmatory for COVID-19 virus, following the recommendations and updates by WHO from time to time.[1]

vi. Upon completion of PCR, e-mail the report containing the Ct value and image of the PCR amplification curve of each sample, as well as the interpretation of the results to evaluating laboratory accordingly (IMR or MKAK).

vii. Approval shall be given to the requesting laboratory by the Chairman of JPKMCOVID-19 after a successful technical evaluation process.

viii. Once approved to conduct the test, the laboratory may proceed to test using actual clinical samples. The laboratory shall email the PCR images of the first 5 positive and 5 negative clinical samples and send those samples (minimum 500 µl) to IMR/MKAK for verification.

ix. All positive samples shall be kept at -80^{0}C for retesting if necessary.

x. 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 date of un-approved notice.

xi. The authorized list of laboratories shall be kept by the Secretariat and updated regularly.

6. Sampling

6.1 Staff shall be trained for appropriate personal protective equipment (PPE) usage, specimen collection, storage, packaging and transport before collecting the samples.

Specimens

Specimens shall be collected from:

a) lower respiratory tract such as sputum (if produced) or tracheal aspirate or bronchoalveolar lavage

or

b) upper respiratory tract specimens such as nasopharyngeal AND oropharyngeal swabs or nasopharyngeal wash / aspirate

6.2 All swab samples shall be placed in viral transport media (VTM) or universal transport media and kept at 2-8°C before processing.

6.3 Request forms and specimens shall be labelled with at least 2 unique identifiers to ensure traceability of the specimens.

6.4 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. Specimen Management

7.1 Packaging and Transportation

Specimens shall be packed in triple packaging and transported at 2-8°C. The request forms shall be placed separately on the outside package. Refer to Guidelines on COVID-19 Management in Malaysia.

7.2 Handling of specimens

Specimens shall be processed in biosafety cabinet class II and handled by staff wearing proper PPE.

8. Examination procedure

The laboratory shall have a standard operating procedure for conducting the real-time RT-PCR. All worksheets related to the testing shall be kept and maintained for retention of record.

9. Assuring the quality of test results

9.1 Each test run shall include positive and negative control.

9.2 The laboratory shall also participate in the External Quality Assurance Programme. The laboratory shall achieve at least 80% overall correct results. If the result is unsatisfactory, the laboratory shall give evidence of corrective actions taken.

9.3 The laboratory shall conduct internal audit of the test at least once a year and corrective actions taken where necessary and documented.

9.4 All SARS-CoV-2 RT-PCR testing laboratories shall be audited at least once a year by the committee.

10. Interpretation and Reporting of results

10.1 The interpretation of results shall be based on manufacturer's instruction as outlined in the kit insert.

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

10.3 All results shall be keyed into the *Sistem Informasi Makmal Kesihatan Awam* Outbreak (SIMKA Outbreak).

10.4 It is mandatory to report all positive results into SIMKA Outbreak within 24hrs.

10.5 All negative results shall be reported into SIMKA Outbreak within 48hrs.

11. Waste management

The laboratory shall have waste management procedure in place. All clinical samples and consumables used shall be autoclaved or incinerated.

12. Risk Management

The laboratory shall have risk assessment activities for performing SARS-CoV-2 RT-PCR testing.

References

1. https://www.frontiersin.org/articles/10.3389/fcell.2020.00468/full
2. WHO recommendation for testing specimens for COVID-19.
3. Laboratory testing for coronavirus disease (COVID-19) in suspected human cases. Interim guidance 19th March,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.

Acknowledgements

Dr. Hishamshah bin Mohd Ibrahim

Deputy Director General of Health (Research and Technical Support)

Institute for Medical Research

Dr Norazah Ahmad

Dr Ravindran Thayan

Dr Rozainanee Mohd Zain

Dr Rohaidah Hashim

National Public Health Laboratory

Dr Hani Mat Husin

Dr Donal Huda Nasril

Dr Wan Amani Wan Abdul Azim

MOH Hospitals

Dr Arni Talib

Dr Tengku Norita Tengku Yazid

Dr Noraini Ismail

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Dr Nur Izati Mustapa

National Cancer Institute

Dr Suhaila Md Hanapiah

Medical Development Division

Dr Mawaddah Ghazali

Dr Olivia Tan Yen Ping

INQUIRIES

Any inquiries about this document can be referred to:

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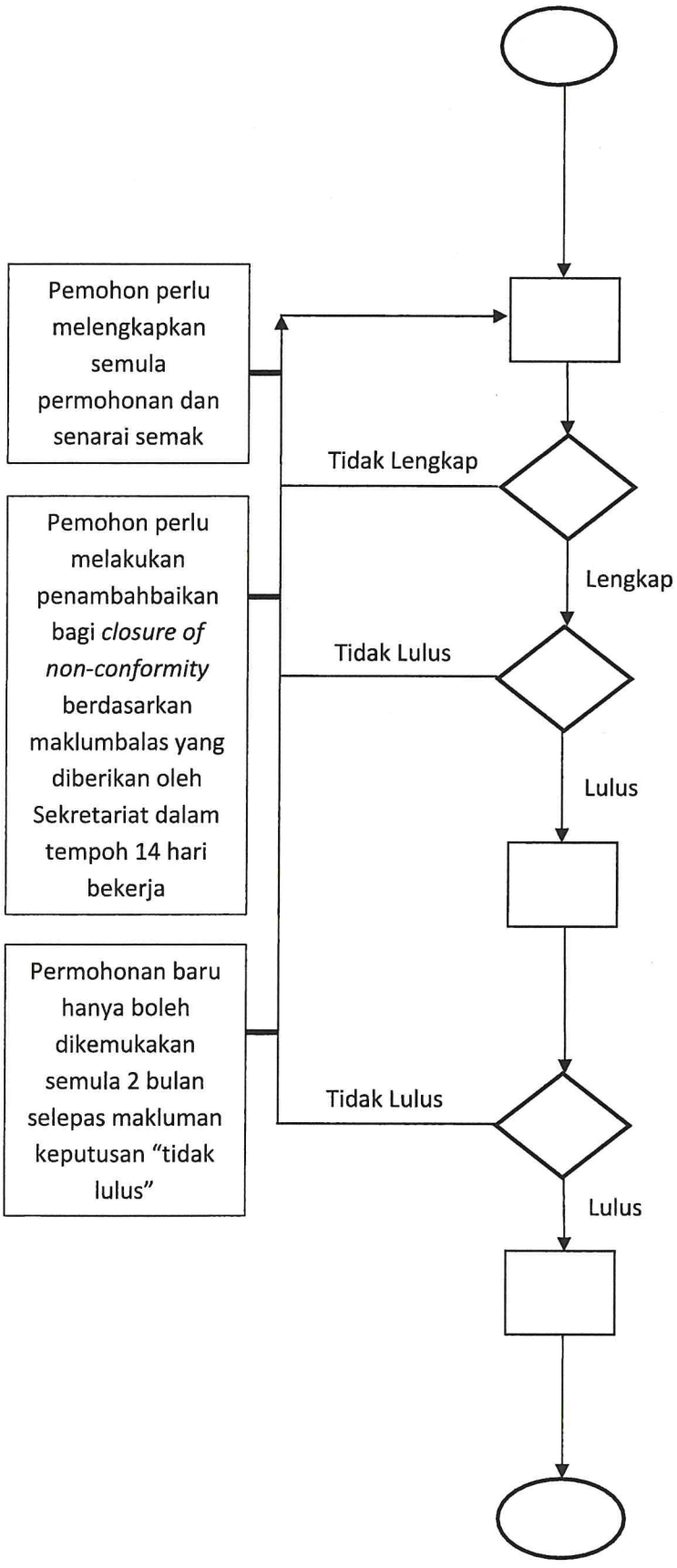
Medical Development Division
Level 5, Block E, Parcel E,
Federal Government Administrative Centre
62590 Putrajaya
Tel : 03-8883 1489 / 03-8890 6028
Email : covid19makmal@moh.gov.my

CARTA ALIR PERMOHONAN MENJALANKAN UJIAN SARS-COV-2 RT-PCR

PROSES KERJA



Permohonan menggunakan ***Application Form for SARS-CoV-2 Real-Time RT-PCR Testing Laboratory*** di laman sesawang *http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm.*

Permohonan dan senarai semak yang lengkap dikemukakan kepada sekretariat JPKMCOVID-19 di covid19makmal@moh.gov.my.

Sekretariat membuat semakan permohonan

Lawatan bagi penilaian fizikal makmal. Pasukan lawatan perlu memaklumkan hasil lawatan kepada Sekretariat.

Sekretariat akan memaklumkan kepada pemohon mengenai keputusan lawatan. Sekiranya lulus, proses penilaian teknikal akan diteruskan oleh badan penilai yang ditentukan samada oleh IMR (imrcovid19@moh.gov.my) atau MKAK (viro.mkak@moh.gov.my).

Penilaian teknikal oleh MKAK /IMR

Pemakluman keputusan penilaian teknikal kepada Sekretariat. Kelulusan bagi makmal yang melepasi penilaian teknikal akan diputuskan dalam mesyuarat JPMKCOVID-19 yang bersidang setiap awal bulan. Surat kelulusan akan diberikan kepada pemohon.

Tamat

Attachment 1

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**