Annex 5c. Flow Chart for Laboratory Diagnosis of SARS-CoV-2 using Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) in Suspected Case of COVID-19

Suspected Case of COVID-19

Collect specimen (refer to Annex 5b)

Place combined Nasopharyngeal(NP) and Oropharyngeal(OP) swabs in VTM

OR
Deep throat saliva, saliva, nasal, bronchoalveolar lavage, tracheal aspirate, pleural fluid or nasopharyngeal aspirate / wash, sputum in sterile container

OR
Tissue in VTM or normal saline

Send specimen on ice to maintain temperature at 2-8°C as soon as possible to the designated laboratory (refer to Annex 4a) in triple packaging (refer to Annex 5b)

Perform RT-PCR test

SARS-CoV-2 DETECTED

INCONCLUSIVE

INVALID

SARS-CoV-2 NOT DETECTED

Repeat RT-PCR on same specimen

Repeat RT-PCR after 48 – 72 hours if clinically indicated

SARS-CoV-2 DETECTED

INCONCLUSIVE

INVALID

SARS-CoV-2 NOT DETECTED

Repeat RT-PCR on new specimen within 24 hours
1 Refer to Annex 1: Case definition of COVID-19 (Refer to the latest KKM guideline).
2 Selected tissues from post mortem cases. Send specimens to IMR, National Institute of Health (NIH).
3 If transportation of sample is within 72 hours, store at 2-8°C. If transportation of sample is after 72 hours, store at -80°C.
4 Use Medical Device Authority (MDA) approved RT-PCR kit. The assay shall have minimum of 2 different targets on SARS-CoV-2 genome, of which at least one target confirmatory for SARS-CoV-2 (following the recommendations and updates by WHO from time to time). A correlation study is needed if the assay has only one target gene. Follow manufacturer’s kit insert for procedure.
5 A positive laboratory result must be interpreted taking into consideration the clinical history, presentation and/or post mortem findings.
6 Inconclusive – only one target gene is detected.
7 For post mortem cases, inconclusive result need to be interpreted on case to case basis.
8 Internal control of the results are not detected.
9 The negative result does not conclusively rule out these viruses as the causative agent of the disease for the following reason: a. Specimens were not collected at the time when the virus present, b. Specimens were not collected, stored or transported in a proper manner.

All results must be reported in SIMKA OUTBREAK.