

Current Event

PCR Testing for MERS-CoV

Command and Control Center reviewed the current molecular testing for MERS-CoV in Saudi Arabia.

Editorial Notes

Molecular tests are used to diagnose active infection (presence of MERS-CoV) in people who are thought to be infected with MERS-CoV based on their clinical symptoms and/or presence of an epidemiological links.

The Ministry of Health (MoH) recognizes the laboratory results for testing MERS-CoV run by five Public Health Laboratories (PHL) in Riyadh, Jeddah, Dammam, Makkah, and Madinah regional laboratories. MERS-CoV is diagnosed using reverse transcriptase Real-Time PCR (rRT-PCR) for testing MERS-CoV. Two kits are currently used: Altona Diagnostics-Real Star Kit and Tib Molbiol Primers and Probes with Roche Master Mix. The related cut-off points for CT value of a valid run is 37 (Figure 1). A valid run is when both positive and negative controls are working fine and the data has been analyzed using appropriate method of analysis (Second Derivative Maximum Method). The Limit of Detection (LOD) for Tib MolBiol is 10 copies of DNA per 5 µl, and for Real Star Altona Orf1a 0.93 copies/µl; and for UpE gene is 0.54 copies/µl. The test has a sensitivity of 95%.

A negative result does not exclude the possibility of infection as viral load could be very low to be detected by the assay in very early infection. There are many factors can affect the result of the assay and give false negative result such as contamination of the sample by some PCR inhibitors (e.g. gloves powder or alcohol used as disinfectant), wrong collection of the

Figure 1: Interpretation of Molecular Testing for MERS-CoV

UP-E gene	ORF1a gene	Interpretation
Ct value <37	Ct value <37	MERS CoV detected ^a
Ct value <37	Ct value ≥37 or Negative	Probable, please repeat ^b
Ct value ≥37	Regardless of Ct value	Equivocal, please repeat ^b

^a Result will be reported as a confirmed MERS-CoV case (either new case or follow up case).

^b After laboratory test repetition (twice), preferably with the other kit rather than the one used for testing initially e.g. if Tib MolBiol kit was used then Altona Real Star is preferable for repetition, another (2nd) sample will be asked from the patient through his clinician to confirm the result of the patient and to rule out the possibility of low viral load or sampling error. The 2nd requested sample should preferably be from lower respirator tract e.g. a probable or equivocal result obtained with NP swab requires preferably a sputum, Broncho-alveolar Lavage (BAL), tracheal aspirate...etc. as per situation of the patient.

Cases of MERS-CoV: International Week (IW) No. 22: 29 May – 4 June 2016

Total	1
Symptomatic (S)	1
Asymptomatic (AS)	0
Healthcare worker (S)	0
Healthcare Worker (AS)	0

sample and highly mucoid sample (which need to be properly liquefied before RNA extraction). Therapeutic success or failure cannot be determined using this PCR assay.

The success of rRT-PCR testing depends on several factors, including the experience and expertise of laboratory personnel, laboratory environment (e.g., avoidance of contamination), and the type and condition of specimens being tested.

MoH considers a known MERS patient to be negative for active MERS-CoV infection following two consecutive negative rRT-PCR tests on all specimens. If symptom onset for a patient under investigation with an ongoing respiratory tract infection, especially lower, was 14 or more days ago, a single serum specimen for serologic testing in addition to a lower respiratory specimen and an nasopharyngeal/oropharyngeal (NP/OP) specimen are recommended.

Recent Publications:

Algahtani H, Subahi A, Shirah B. Neurological Complications of Middle East Respiratory Syndrome Coronavirus: A Report of Two Cases and Review of the Literature. *Case Rep Neurol Med.* 2016;2016:3502683.doi:10.1155/2016/3502683. Epub 2016 Apr 28.

MERS-CoV in KSA 2016*

Region	Case	Primary	Secondary	U.C.
Qassim	36	10	23	3
Riyadh (1)	31	20	9	2
Hail	7	6	0	1
Jeddah	5	4	0	1
Asir	5	4	1	0
Taif	4	3	1	0
Najran	4	3	0	1
Al-Ahsaa	3	3	0	0
Madinah	2	2	0	0
Eastern Region	2	2	0	0
Al-Baha	1	0	0	1
Bisha	1	1	0	0
Makkah	0	0	0	0
Tabuk	0	0	0	0
Al-Joaf	0	0	0	0
Jazan	0	0	0	0
Northern Borders	0	0	0	0
Qunfotha	0	0	0	0
Hafr Al-Batin	0	0	0	0
Qurayyat	0	0	0	0
Total	101	58	34	9

Case: Confirmed Symptomatic. U.C.: Unclassified cases

*Period: Form 3 Jan to 4 June 2016

Regions with new cases of this week are highlighted in yellow.

