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TEST	RESULT	FLAG	UNIT	REFERENCE RANGE
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MOLECULAR

CORONAVIRUS DISEASE 2019 RNA (RT-PCR)

Nature of Specimen	Nasopharyngeal and Oropharyngeal Swab			
SARS-CoV-2 RNA	DETECTED			
Detection cut-off Ct value	=<40 (Detected)			
	Genes Detected:	Ct value		
	S gene	Not Detected		
	ORF1ab gene	18.33		
	N gene	17.82		

Interpretation: Positive for Coronavirus disease 2019 (COVID-19). Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

This assay is in vitro diagnostic medical device designed for qualitative detection of SARS-CoV-2 that cause the respiratory coronavirus disease 2019 (COVID-19). This assay is a multiplex real-time reverse transcription polymerase chain reaction (RT-qPCR) and able to detect multiple target genes related to SARS-CoV-2 simultaneously in one single reaction. Limit of detection (LOD) studies determined by the lowest detectable concentration of SARS-CoV-2 is 10 to 100 (Genomic Copy Equivalents or GCE)/reaction. Detectable Ct value for analyte targets is below and equal to 40 cycle threshold (=< 40 Ct). The assay is CE-IVD certified.

Reference: 1. COVID-19 Management Guidelines in Malaysia No.5 / 2020

Reported by: MOHD FALIHIN BIN MD LAZI
 Medical Laboratory Scientist

Verified by: Dr. Rohani Md Yassin (Consultant Medical Microbiologist)

Reported by : MOHD FALIHIN BIN MD LAZI

Report Completed, Please File.

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