



Dr Siti Salwa Mohd Nazri KPJ Ampang Puteri Specialist Hospital No: 1, Jalan Mamanda 9, Taman Dato Ahmad Razali Ampang Ampang Selangor DE



Patient Name : MIOR DANIEL IBRAHIM BIN MIOR MOHD ADIB									
Ward / Clinic	: ACCIDENT & EMERGENCY	(DEPARTMENT	Lab No. : 0222616884						
Age	: 3Y	Sex : Male	Date Received : 14/02/2022 11:58						
IC No.	: 180524-10-0813	MRN : 593304	Date Reported : 15/02/2022 07:11						
		DOB: 24/05/2018	Report Status : Final						
		Result U	Unit Reference range						
PCR for COVID-19 / SARS-CoV-2 DETECTION									
Sample ty	/pe	Nasopharyngeal and	Nasopharyngeal and Oropharyngeal Swab						
** Sarbecov	irus Envelope, E gene	Detected							

	Sample type	Nasopharyngeal and Oropharyngeal Swab
**	Sarbecovirus Envelope, E gene	Detected
		(ct value:20.54)
**	COVID-19 Nucleocapsid, N gene	Detected
		(ct value:21.38)
**	COVID-19 RdRp gene & S gene	Detected
		(ct value:21.55)
**	COVID-19 S gene mutations	Detected
		(ct value:20.95)
**	COVID-19/SARS-CoV-2 RNA	Detected

Probable Omicron variant detected.

Note:

Covid-19 rRT-PCR assay unable to differentiate between viable and non-viable virus. Please correlate clinically.

Methodology:

By Seegene Allplex SARS-CoV-2 Master Assay

This multiplex real-time RT-PCR assay simultaneously detects four wild-type SARS-CoV-2 genes (E gene, RdRP gene, N gene, and S gene) and five notable S-gene mutations: HV69/70 deletion, Y144 deletion, E484K, N501Y, and P681H.

A false negative result may occur if a specimen is improperly collected, transported, handled, inadequate material in quality or volume, the presence of interfering substances or PCR-inhibitor in the sample, and sampling & testing being carried out outside the diagnostic window. A single negative COVID-19 test (especially if from upper respiratory tract specimen) does not exclude COVID-19 infection. The rate of PCR positivity in different biological sources collected from patients with COVID-19 are as follows: BAL >90%, sputum 70-80%, nasopharyngeal & oropharyngeal swabs 70-80%, nasal swab 40-70%, and pharyngeal swab 30-50%. If there is a strong clinical, radiological, and/or epidemiological suspicion of COVID-19 infection, the submission of a new specimen is highly recommended.

Positive result indicates active SARS-CoV-2 infection, or the detection of non-viable/ dead fragments of SARS-CoV-2 specific genes, but does not rule out other viruses and/or bacterial co-infection. The positive result should be interpreted in correlation with clinical history, signs and symptoms, epidemiologic evidence and other relevant diagnostic information.

References:

1. World Health Organization. Novel Coronavirus (2019-nCoV) technical guidance.

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance (Accessed on January 04, 2022). 2. Corman V, Bleicker T, Brünink S, Drosten C, Landt O, Koopmans M, et al. Diagnostic detection of Wuhan coronavirus 2019 by real-time RTPCR 2020 [17 January 2020]. Available from: https://www.who.int/docs/default-source/coronaviruse/wuhan-virusassay-v1991527e5122341d99287a1b17c111902.pdf

3. G. Lippi et al. Vulnerabilities in the diagnosis of COVID-19. Clin Chem Lab Med 2020 58(7):1070-1076.

4. US Food and Drug Administration (US FDA). SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. 2021.

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viralmutations-impact-covid-19-tests

Validated by Dr. Muhammad Nazri Aziz (Medical Microbiologist) on 15/02/2022 7:11:45 AM

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Consultant Pathologist:-

Dr. Muhammad Nazri Bin Aziz; MD (USM), MPath. Med. Microbiology (UKM), Consultant Medical Microbiologist

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