Issue date: 09 May 2026
Valid until: 16 October 2028

NO: SAMM 1139
(Issue 03, 09 May 2026 replacement
of SAMM 1139 dated 07 May 2025)

LABORATORY LOCATION:
(PERMANENT LABORATORY)

MYGENOME SDN BHD
SUITE NO. 03-04, GROUND FLOOR
MENARA SEE HOY CHAN
NO. 374, JALAN TUN RAZAK
50400 KUALA LUMPUR

FIELDS OF MEDICAL TESTING: **MOLECULAR**

The standard used for assessment of this laboratory is MS ISO 15189:2022 (ISO 15189:2022, IDT)

A medical laboratory's fulfilment of the requirements of ISO 15189 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results. The management system requirements in ISO 15189 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001. (See Joint IAF-ILAC-ISO Communiquè dated November 2021).

SCOPE OF MEDICAL TESTING: MOLECULAR

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Inactivated Oropharyngeal Swab and Nasopharyngeal Swab samples	COVID-19 Genes: - N Gene - Orf 1 a/b Gene - E Gene	Polymerase Chain Reaction by using Quant Studio 5 Real Time PCR System, as documented in MG-SOP-PCR
		Polymerase Chain Reaction by using qTower3 G Real Time PCR System, as documented in MG-SOP-PCR
EDTA Whole Blood	Type of Test: Whole Genome Sequencing (WGS) Properties measured: DNA sequence (A, G, T, C), genome coverage 30x read depth, Genome coverage (breadth and depth), Read quality (Q30 scores, error rate), Insert size and fragment length distribution. Range of Measurement: Read length: 150 bp paired-end, Data output: 480 Gb per flow cell, Accuracy: > 99.9% (Q30 bases), Coverage depth: 30x	Standard Test Method: Qiagen DNA extraction Kit protocols, MGI Easy FS DNA Library Prep Kit Protocol, DNBSEQ-G400RS User Manual protocol / Equipment: Sequencing platform: MGISEQ-2000 (DNBSEQ technology, DNA nanoball sequencing), DNA extraction system (e.g., Qiagen, Nanodrop/Qubit for quantification), Quality control equipment: TapeStation, Qubit. Techniques: DNA extraction, Library preparation (enzymatic fragmentation, adapter ligation, PCR amplification), Circularization and DNB formation (MGI technology), Sequencing-by-synthesis with fluorescently labeled nucleotides, Data processing (base calling, alignment, variant calling, QC filtering)

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