

NO: SAMM 1139

Page: 1 of 1

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

FIELD OF MEDICAL TESTING: MOLECULAR

The standard used for assessment of this laboratory is MS ISO 15189:2014 (ISO 15189:2012 IDT).

A medical laboratory's fulfillment of the requirements of ISO 15189:2012 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 (Section 4) are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008 Quality management systems - Requirement and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2015).

SCOPE OF MEDICAL TESTING: MOLECULAR

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
COVID-19 Molecular – PCR Inactivated Oropharyngeal Swab and Nasopharyngeal Swab samples	COVID-19 Genes: - S Gene - N Gene - Orf 1 a/b Gene - E Gene	Polymerase Chain Reaction / Quant Studio 5 Real Time PCR System / As documented in MG-SOP-PCR Polymerase Chain Reaction / qTower3 G Real Time PCR System / As documented in MG- SOP-PCR

Laboratory Key Personnel:

	Name	Designation
1.	Dr Heilly Chong	Laboratory Director
2.	Roshani Vijaya Kumar	Quality Manager
3.	Zeinabsadat	Technical Manager
4.	Dr. Norhazwani	Document Controller