


Schedule

Issue date: 08 December 2023
Valid Until: 30 December 2028



NO: SAMM 687

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LABORATORY LOCATION: (PERMANENT LABORATORY) 	Quantum Diagnostics Malaysia Sdn. Bhd No.19, Level 2, Galeri Empire, Jalan Empayar, Off Persiaran Sultan Ibrahim/KU1, 41150 Klang, Selangor Darul Ehsan. , 41150, SELANGOR MALAYSIA
ACCREDITED SINCE :	30 DECEMBER 2014
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY HAEMATOLOGY MEDICAL MICROBIOLOGY

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 Communiqué, November 2021)

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CENTRAL LOCATION	Quantum Diagnostics Malaysia Sdn. Bhd No.19, Level 2, Galeri Empire, Jalan Empayar, Off Persiaran Sultan Ibrahim/KU1, 41150 Klang, Selangor Darul Ehsan. , 41150, Selangor
FIELD(S) OF MEDICAL TESTING :	CHEMICAL PATHOLOGY, HAEMATOLOGY MEDICAL MICROBIOLOGY

SCOPE OF MEDICAL TESTING : CHEMICAL PATHOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Serum	Cholesterol	Colourimetry - Cholesterol Oxidase / Peroxidase as documented electronically in Roche COBAS LINK/COBAS 8000
	Creatinine	Colourimetry - Alkaline Picrate - Jaffe as documented electronically in Roche COBAS LINK/COBAS 8000
	High Density Lipoprotein	Colourimetry - Non sep DxSo4/PEG mod enzymes as electronically in Roche COBAS LINK/COBAS 8000
	Potassium	Indirect ISE as documented electronically in Roche COBAS LINK/COBAS 8000
	Sodium	Indirect ISE as documented electronically in Roche COBAS LINK/COBAS 8000
	Triglycerides	Colourimetry – Lipase / Glycerol kinase / GPOPAP as documented electronically in Roche COBAS LINK/COBAS 8000
	Urea	Colourimetry – Urease – Rate as documented electronically in Roche COBAS LINK/COBAS 8000
Immunoassay Serum	?-hCG	Immuno-electrochemiluminescence as documented electronically in Roche COBAS LINK/COBAS 8000

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Immunoassay Whole Blood	HbA1C	Turbidimetric Inhibition Immunoassay (TINIA) as documented electronically in Roche COBAS LINK/COBAS 6000
Toxicology Urine	Urine Cannabinoids	Kinetic interaction of microparticles in a solution as documented electronically in Roche COBAS 8000
	Urine Opiates	Kinetic interaction of microparticles in a solution as documented electronically in Roche COBAS LINK/COBAS 8000

SCOPE OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Whole Blood	Blood Grouping	Immune agglutination as documented in GPQD/QD-HAE/SOP-1 for manual method and Galileo Neo Instrument Manual for Auto Method/Galileo Neo
	Full Blood Count	Multi-Angle Polarized Scatter Separation, optical laser light scatter and colourimetry as documented in CellDyn Ruby Instrument Manual/CellDyn Ruby
	Malarial Parasites	CellDyn Ruby based on MAPSS technology as documented in CellDyn Ruby Instrument Manual/CellDyn Ruby and Manual microscopy as documented in GPQD/QD-HAE/SOP-2

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Urine	Urine Chemistry - UFEME	Reflectance Photometry as documented in GPQD/QD-MI/SOP-1

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Serum	Urine Microscopy	Manual method documented in GPQD/QD-MI/SOP-2
	Urine Pregnancy test	Chromatographic immunoassay method as documented in GPQD/QD-MI/SOP-3
	TPHA	Passive particle agglutination as documented in GPQD/QD-MI/SOP-4
	RPR	Immunoturbidimetric assay in ROCHE Cobas LINK/Cobas 8000
	Hepatitis B Surface Antigen / Antibody	Immunoelectrochemiluminescence as documented in electronically in Roche COBAS LINK/COBAS 8000
	Anti HIV / HIV Ag (Combo)	Immunoelectrochemiluminescence as documented in electronically in Roche COBAS LINK/COBAS 8000

NOTE :

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