

LABORATORY ACCREDITATION (SAMM NO.537)

INTRODUCTION:

Driven by the institute's vision to become a leading in molecular medicine and achieve global recognition and excellence, TMC made the timely decision to comply with international standards, MS ISO 15189 through accreditation to MS ISO 15189 by SAMM (STANDARD MALAYSIA) would certainly lend credence the institute's testing and vision services.

LABORATORY ACCREDITATION:

The accreditation of the laboratory involved is Level 6 Bioanalytical (Hematology and Chemical Pathology), UMBI under the Biobank & Bioanalytical Division.

SCOPE:

1. Haematology (Full Blood Count)
2. Chemical Pathology (Full Lipid Profile, Renal Profile, Urine Analysis, Haemoglobin A1c (HbA1c)

TIMELINE:

2011	2015	2017	2021	2023	2025
<ul style="list-style-type: none">• MS ISO 15189:2007• Granted Accreditation• Date: 1 Nov. 2011	<ul style="list-style-type: none">• MS ISO 15189:2014• Renewal of Accreditation (1) + Upgrade version• Date : 23 Jan. 2015	<ul style="list-style-type: none">• MS ISO 15189:2014• Renewal of Accreditation (2)• Date : 24 July 2017	<ul style="list-style-type: none">• MS ISO 15189:2014• Renewal of Accreditation (3)• Date: 8 Feb. 2021	<ul style="list-style-type: none">• MS ISO 15189:2014• Renewal of Accreditation (4)• Date: 11 Oct. 2023	<ul style="list-style-type: none">• MS ISO 15189:2022• Renewal of Accreditation (5) + Upgrade version• Date : 11 Jun 2025

SCOPE OF MEDICAL TESTING

Scope of Medical Testing	Specimen Tested	Type of Test/Properties Measured	Test Methods, Specifications/Equipment/Techniques Used
Chemical Pathology	Plasma (1000µl) from 2.0 ml Fluoride Vacutainer	Glucose	COBAS 6000 (c501) Document No. TMC – C – 1 (SOP 9)
	Serum (200 µl) from SST II vacutainer	Full Lipid Profile (Total Cholesterol, LDL Cholesterol, HDL Cholesterol, Triglycerides)	COBAS 6000 (c501) Document No: TMC – C – 1 (SOP 9)
		Renal Profile (Calcium, Potassium, Urea, Creatinine, Phosphate, Sodium)	
	Urine (1000 µl) from plain random urine (EOS)	Urine analysis	
	Haemoglobin A1c (HbA1c) From 3.0 ml EDTA vacutainer	HbA1c	Variant II Turbo, Bio-Rad Document No: TMC – C – 1 (SOP 11)
Haematology	Whole Blood from 3.0 ml EDTA vacutainer	Full Blood Count	UniCel DxH 800 Coulter from Beckman Coulter Document No: TMC – C – 1 (SOP 10)

The latest certificate and scope can be found on the Department of Standards Malaysia website
<https://cab.jsm.gov.my/cab-directories/resultSamm>