


Schedule

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LABORATORY LOCATION: (PERMANENT LABORATORY) 	StemLife Berhad B-0-14, B-1-14 & B-8-14, Megan Avenue II 12 Jalan Yap Kwan Seng, 50450 WP Kuala Lumpur. , 50450, WILAYAH PERSEKUTUAN KUALA LUMPUR MALAYSIA
ACCREDITED SINCE :	19 MARCH 2025
FIELD(S) OF MEDICAL TESTING :	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	StemLife Berhad B-0-14, B-1-14 & B-8-14, Megan Avenue II 12 Jalan Yap Kwan Seng, 50450 WP Kuala Lumpur. , 50450, Wilayah Persekutuan Kuala Lumpur
FIELD(S) OF MEDICAL TESTING :	HAEMATOLOGY, MEDICAL MICROBIOLOGY

SCOPE OF MEDICAL TESTING : HAEMATOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Mobilized Peripheral Blood	Full Blood Count	XN-1000 Manual
	(HSC)	documented in CD45 FITC/CD34 PE
	(HSC)	package insert, Trucount?
	(HSC)	package insert
	(HSC)	(single platform) and BD Stem Cell
	(HSC)	Enumeration Application Guide for
	(HSC)	BDFACsCanto II Flow Cytometers.
	Cell Viability	cells in flowcytometric assay, based on light
	Cell Viability	scatter and uptake of nucleic acid dye, 7-
Peripheral Blood	Cell Viability	Amino-actinomycin D (7-AAD) as documented in BD Via Probe? package
	Cell Viability	insert
	Full Blood Count	Sysmex XN-1000 based on counting and
	Hemopoietic Stem Cell	BD FACSCanto II three-colour flowcytometry

SCOPE OF MEDICAL TESTING : MEDICAL MICROBIOLOGY

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used
Cord Blood	Full Blood Count	sizing method as documented in Sysmex
	(HSC)	fluorescence detection method as
	Cell Viability	BD Via Probe? for exclusion of non-viable

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Plasma	ABO Grouping	Diamed-ID micro typing system gel card
	ABO Grouping	method as documented in Diamed Diaclon
	ABO Grouping	ABO/Rh for newborns package insert
	Blood Culture	BACTEC blood culture system (BACTEC
	Blood Culture	9240) fluorescent method as documented in
	Blood Culture	SL/LAB/S3.1 and BD BACTEC 9240 Manual
	HIV Genotypic Resistance -"	Polymerase Chain Reaction (PCR) and
	Protease and Reverse	Population-based Genome Sequencing /
	Transcriptase	Eppendorf Mastercycler X50s thermal cycler
	Transcriptase	as documented in
	Transcriptase	IMR/IDRC/VIRO/SOP/HIV/10
	HIV Genotypic Resistance -"	Polymerase Chain Reaction (PCR) and
	Integrase	Population-based Genome Sequencing /
	Integrase	Eppendorf Mastercycler X50s thermal cycler
	Integrase	as documented in
	Integrase	IMR/IDRC/VIRO/SOP/HIV/11
	Homocysteine (Total)	Documented in IMR/SDC/BC/SOP-4 / Agilent 1260 HPLC
	Homocysteine (Total)	with Fluorescence Detector
	Carnitine (Total & Free)	Enzymatic end-point as documented in
	Carnitine (Total & Free)	IMR/SDC/BC/SOP-3/ Spectrophotometer
	Glycosaminoglycans	Complex with Dimethylmethylene Blue (DMB)
	(GAG) Quantitation	as documented in IMR/SDC/BC/SOP-5/ Spectrophotometer
	GAG Separation	High Resolution Electrophoresis as
	GAG Separation	documented in IMR/SDC/BC/SOP-6/ Multiphor
	GAG Separation	II Electrophoresis System

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Organic Acids	Derivatisation with BSTFA as documented in
Organic Acids	IMR/SDC/BC/SOP-9/GCMS Agilent 7890B
Orotic Acids	Reverse-phase Chromatography as
Orotic Acids	Documented in IMR/SDC/BC/SOP-10/ Agilent 1200 HPLC
Orotic Acids	with Diode Array Detector
Coagulation:	Clotting (optical) Method/Sysmex CS1600 As documented in
Prothrombin time (PT)	HSNI/PAT/HM/TPM/VER3/2019/02 HSNI/PAT/HM/AK/VER3/2019/04
Activated Partial	HSNI/PAT/HM/TPM/VER3/2019/03
Thromboplastin Time (APTT)	HSNI/PAT/HM/AK/VER3/2019/04
Ammonia	GLDH ? UV on Beckman Coulter AU5800 as documented in HS/JP/W1 (CP;07)-024 Test on Beckman Coulter AU5800
Lactate	Enzymatic LOD-POD on Beckman Coulter AU5800 as documented in HS/JP/W1 (CP;07)- 024 Test on Beckman Coulter AU 5800
Mycophenolic Acid	EMIT on Viva E (Siemens) as documented in HS/JP/W1 (CP;07)- 014 Test on VIVA E (Siemens)
Prothrombin Time (PT)	Clotting Activity HS/JP/W1(HM:08)- 007
Activated Partial Thromboplastin Time (APTT)	Clotting Activity HS/JP/W1(HM:08)- 007
Fibrinogen Estimations (FIB)	Clotting Activity HS/JP/W1(HM:08)- 007
International Normalised Ratio (INR)	Clotting Activity HS/JP/W1(HM:08)- 007
D-Dimer Quantitative	Change in turbidity of a microparticle suspension measured by photometry
Coagulation Mixing Test: APTT/PT	Clotting Activity HS/JP/W1(HM:08)- 017
Ammonia	Glutamate Dehydrogenase as documented in Arahan Kerja Pengendalian Ujian Pada Alinity (HTPG/JP/CHM/AK-02)

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	Lactate (LacticAcid)	Lactic Acid to Pyruvate (L to P) as documented in Arahan Kerja Pengendalian Ujian Pada Alinity (HTPG/JP/CHM/AK-02)
	PT/ INR	Mechanical clot detection
	PT/ INR	Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-04
	APTT	Mechanical clot detection
	APTT	Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-05
	Fibrinogen	Clauss method Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-06
	D-Dimer	Turbidimetry Analyser: Stago Compact/ Max All methods and specifications as documented in HTPG/JP/HEM/AK-07
	Glucose (Plasma)	Hexokinase Method. Analyzer Beckman Coulter AU680 (labelled as AU680-A and AU680-B) as documented in SASMEC@IIUM/PALM/INT-WI0203
	Serum Or Plasma	HBsAg Qualitative
		HBsAg Qualitative
	HBsAg Qualitative	Abbott Architect HBsAg chemiluminescent
	HBsAg Qualitative	microparticle immunoassay (CMIA) for the
	HBsAg Qualitative	qualitative detection of antigen as documented
	HBsAg Qualitative	in Architect HBsAg package insert
	Anti ? HCV	Abbott Architect Anti-HCV chemiluminescent
	Anti ? HCV	microparticle immunoassay (CMIA) for the
	Anti ? HCV	qualitative detection of antibodies as
	Anti ? HCV	documented in Architect HCV package insert
	Anti ? HIV 1 & 2 Ab / p24	Abbott Architect HIV Ag/Ab Combo
	Ag	chemiluminescent microparticle immunoassay
	Ag	(CMIA) for detection of antibodies and p24

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	Ag	antigen as documented in Architect HIV
	Ag	package insert
	CMV IgM	Abbott Architect CMV IgM chemiluminescent
	CMV IgM	microparticle immunoassay (CMIA) for
	CMV IgM	qualitative detection of antibodies as
	CMV IgM	documented in Architect CMV IgM package
	CMV IgM	insert.
	Syphilis	Abbott Architect Syphilis TP chemiluminescent
	(Treponema palladium)	microparticle immunoassay (CMIA) for
	(Treponema palladium)	detection of antibodies to TP as documented in
	(Treponema palladium)	Architect Syphilis TP package insert
	CMV IgG	Abbott Architect CMV IgG chemiluminescent
	CMV IgG	microparticle immunoassay (CMIA) for
	CMV IgG	qualitative detection of antibodies as
	CMV IgG	documented in Architect CMV IgG package
	CMV IgG	insert
	HTLV I/II	Abbott Architect rHTLV I/II chemiluminescent
	HTLV I/II	microparticle immunoassay (CMIA) for
	HTLV I/II	qualitative detection of antibodies as
	HTLV I/II	documented in Architect rHTLV I/II package
	HTLV I/II	insert
Virology	Blood Culture	None

NOTE :