CERTIFICATE OF ACCREDITATION

TROPICAL DISEASES RESEARCH CENTRE LABORATORY

Company Registration No. HPCZ/101/3/0637

Facility Accreditation Number: MED 032

is a SADCAS accredited Medical Laboratory provided that all SADCAS conditions are complied with

This certificate is valid as per the scope stated in the accompanying schedule of accreditation, Annexure "A", bearing the above accreditation number for

MEDICAL TESTING LABORATORY CLINICAL CHEMISTRY, IMMUNOLOGY, PARASITOLOGY, MYCOBACTERIOLOGY, MICROBIOLOGY, HAEMATOLOGY AND MOLECULAR BIOLOGY

The facility is accredited in accordance with the recognized International Standard

ISO 15189:2012

The accreditation demonstrates technical competency for a defined scope and the operation of a laboratory quality management system

SADCAS is a subsidiarity organization of SADC. A memorandum of understanding between SADC and SADCAS serves as the basis for the recognition of SADCAS by SADC Member States as a multi-economy accreditation body

> Mrs Pinkie J Malebe For Chief Executive Officer

Effective Date (Issue No: 3): 05 August 2022 Certificate Expires: 11 August 2024



ANNEXURE A

SCOPEOF ACCREDITATION

Laboratory Accreditation Number: MED 032 (ISO 15189:2012)

Permanent Address of Laboratory Tropical Diseases Research Centre (TDRC) 6 th & 7 th Floors, Ndola Teaching Hospital Corner Broadway/Nkhana Roads Ndola		Technical Signatories	: As Authorized by the Head of Laboratory
Zambia <u>Postal Address:</u> P.O Box 71769 Ndola Zambia		Nominated Representative	: Mr Ephraim Chikwanda
Tel : +260 212620737 Cell : +2600979241426 Fax : +260212620737 Email : chikwandaephraim@gn	nail.com	<u>Issue No</u> <u>Date of Issue</u> <u>Expiry Date</u>	: 03 : 05 August 2022 : 11 August 2024
DISCIPLINE/SAMPLE TYPE		TYPES OF TESTS	EQUIPMENT/METHOD
CLINICAL CHEMISTRY			
Serum/Plasma	Albumin		Cobas C111
Serum/Plasma	Alkaline	Phosphatase (ALP)	Cobas C111
		Aminotransferase (AST)	Cobas C111
Serum/Plasma Aspartate		e Aminotransferase	Cobas C111
Serum/Plasma Bilirubin,		, Total	Cobas C111
Serum/Plasma Choleste		rol	Cobas C111
Serum/Plasma Creatinin		ie	Cobas C111
Serum/Plasma Glucose			Cobas C111
Serum/Plasma Total Pro			Cobas C111
Serum/Plasma Triglyceri		ides	Cobas C111
Serum/Plasma Urea			Cobas C111
Serum/Plasma	Uric Acid		Cobas C111
IMMUNOLOGOGY			
Whole Blood CD4			Fab-BD Facs Count
Serum/Plasma	HIV		Manual - Rapid
Serum	RPR		Manual Rapid
PARASITOLOGY			
		Vicroscopy- Giemsa	Manual - Microscopy
		d Concentrated Microscopy	Manual - Microscopy
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Original date of accreditation: 12 August 2019



ANNEXURE A

Laboratory Accreditation No: MED 032 (ISO 15189:2012) Issue No: 03 Date of Issue: 05 August 2022 Date of Expiry: 11 August 2024

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
MOLECULAR BIOLOGY Nasopharyngeal Swab/ Nasal Swab	SARS-CoV-2	ABI 7500 Fast Real time PCR
MICROBIOLOGY		
Urine	Culture and Isolation of Pathogenic Organisms	Manual Method
Fluids/Pus swabs	Gram stain	Manual Method- Microscopy
	Culture and Isolation of Pathogenic Organisms: Aerobic and Anaerobic	Manual Method
Cultures	Bacterial Identification Testing Optochin Bacitracin Novobiocin API 20E Catalase Coagulase (Slide and Tube) Triple Sugar Iron (TSI) Lysine Iron Agar Sulfur, Indole, Motility (SIM) Urease Citrate Oxidase Antimicrobial Susceptibility Testing:	Manual Method Manual Method
MYCOBACTERIOLOGY Sputum	AFB Microscopy TB Culture and DST Line Probe Assay (1 st and 2 nd Line)	Manual - Fluorescent Microscopy BD Bactec MGIT 960 PCR/LPA – Hain Lifesciences Platform

Original date of accreditation: 12 August 2019

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ANNEXURE A

Laboratory Accreditation No: MED 032 (ISO 15189:2012) Issue No: 03 Date of Issue: 05 August 2022 Date of Expiry: 11 August 2024

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
HAEMATOLOGY		
Whole Blood	WBC	ABX Micros 60
Whole Blood	RBC	ABX Micros 60
Whole Blood	НСТ	ABX Micros 60
Whole Blood	НВ	ABX Micros 60
Whole Blood	MCV	ABX Micros 60
Whole Blood	МСН	ABX Micros 60
Whole Blood	МСНС	ABX Micros 60
Whole Blood	Platelets	ABX Micros 60
Whole Blood	Lymphocytes	ABX Micros 60
Whole Blood	Neutrophils	ABX Micros 60
Whole Blood	Eosinophils	ABX Micros 60
Whole Blood	Monocytes	ABX Micros 60
Whole Blood	Basophils	ABX Micros 60
Whole Blood	ESR	ABX Micros 60
Whole Blood	DIFF	Manual Method

Original date of accreditation: 12 August 2019

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Eva Muronda For Technical Manager