## **CERTIFICATE OF ACCREDITATION**

#### TROPICAL DISEASES RESEARCH CENTRE LABORATORY - ZAMBIA

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, HAEMATOLOGY, IMMUNOLOGY, MICROBIOLOGY, MOLECULAR BIOLOGY, MYCOBACTERIOLOGY AND PARASITOLOGY

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

**Eve Christine Gadzikwa SADCAS Chief Executive Officer** 

Date of Renewal of Accreditation: 15 July 2024 Effective Date (Issue No: 01): 15 July 2024

**Certificate Expires: 05 December 2025** 



### **ANNEXURE A**

#### SCOPEOF ACCREDITATION

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

**Technical Signatories** 

: As Authorized by the Head of

Laboratory

**Permanent Address of Laboratory** 

Tropical Diseases Research Centre (TDRC) 6<sup>th</sup> & 7<sup>th</sup> Floors, Ndola Teaching Hospital

Email : kenshimpindu@gmail.com

Corner Broadway/Nkhana Roads

Ndola Zambia

<u>Postal Address:</u> : Mr Kenny Situtu

P.O Box 71769

Ndola Zambia

<u>Tel</u> : +260 212620737 | <u>Issue No</u> : 01

<u>Cell</u> : +260973732949 <u>Date of Issue</u> : 15 July 2024

Fax : Expiry Date : 05 December 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
CLINICAL CHEMISTRY		
Serum/Plasma	Albumin	Cobas C111
Serum/Plasma	Alkaline Phosphatase (ALP)	Cobas C111
Serum/Plasma	Alanine Aminotransferase (AST)	Cobas C111
Serum/Plasma	Aspartate Aminotransferase	Cobas C111
Serum/Plasma	Bilirubin, Total	Cobas C111
Serum/Plasma	Cholesterol	Cobas C111
Serum/Plasma	Creatinine	Cobas C111
Serum/Plasma	Glucose	Cobas C111
Serum/Plasma	Total Protein	Cobas C111
Serum/Plasma	Triglycerides	Cobas C111
Serum/Plasma	Urea	Cobas C111
Serum/Plasma	Uric Acid	Cobas C111
<u>IMMUNOLOGOGY</u>		
Serum/Plasma	HIV	Manual - Rapid
Serum	RPR	Manual - Rapid
PARASITOLOGY		
Blood	Malaria Microscopy- Giemsa	Manual - Microscopy

Original date of accreditation: 12 August 2019



## **ANNEXURE A**

Laboratory Accreditation No: MED 032 (ISO 15189:2012)

Issue No: 01

Date of Issue: 15 July 2024 Date of Expiry: 05 December 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
MOLECULAR BIOLOGY Nasopharyngeal Swab/ Nasal Swab	SARS-CoV-2	QuantStudio 5 Real -time PCR
MICROBIOLOGY		
Urine	Culture and Isolation of Pathogenic Organisms	Manual Method
Pus swabs	Gram stain Culture and Isolation of Pathogenic Organisms: Aerobic and Anaerobic	Manual Method- Microscopy Manual Method
Cultures	Bacterial Identification Testing	Manual Method
MYCOBACTERIOLOGY Sputum	AFB Microscopy TB Culture and DST Line Probe Assay (1 <sup>st</sup> and 2 <sup>nd</sup> Line)	Manual - Fluorescent Microscopy BD Bactec MGIT 960 PCR/LPA – Hain Lifesciences Platform

Original date of accreditation: 12 August 2019



## **ANNEXURE A**

Laboratory Accreditation No: MED 032 (ISO 15189:2012)

Issue No: 01

Date of Issue: 15 July 2024

Date of Expiry: 05 December 2025

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	MCH	ABX Micros 60
Whole Blood	MCHC	ABX Micros 60
Whole Blood	Platelets	ABX Micros 60

Original date of accreditation: 12 August 2019 Page 3 of 3

Mrs Pinkie J Malebe SADCAS Technical Manager