

CERTIFICATE OF ACCREDITATION

MBEYA ZONAL REFERRAL HOSPITAL LABORATORY - TANZANIA

Company Registration No. MOHSW Ref: HB 295/446/01

Facility Accreditation Number: MED 003

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
BLOOD BANK, CLINICAL CHEMISTRY, HAEMATOLOGY, IMMUNOPHENOTYPING,
MICROBIOLOGY, MOLECULAR BIOLOGY, MYCOBACTERIOLOGY,
PARASITOLOGY AND SEROLOGY**

The facility is accredited in accordance with the recognized International Standard

ISO 15189:2022

*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: 26 March 2020
Effective Date (Issue No: 3) 31 July 2024
Certificate Expires: 25 March 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 003 (ISO 15189:2022)**

<p>Permanent Address of Laboratory Mbeya Zonal Referral Hospital Laboratory Hospital Hill Sissimba Mbeya Tanzania</p> <p>Postal Address P.O Box 419 Mbeya Tanzania</p> <p>Tel : +255 252503577 Cell : +255 712166180 Fax : +255 252500057 Email : isackelias@gmail.com</p>			<p>Technical Signatories : As Authorized by the Head of Laboratory</p> <p>Nominated Representative : Mr Isack Elias Nyangi</p> <p>Issue No : 03 Date of Issue : 31 July 2024 Expiry Date : 25 March 2025</p>		
DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD			
<p>BLOOD BANK Whole Blood/Serum Whole Blood</p> <p>CLINICAL CHEMISTRY Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Plasma Serum Serum Serum Serum Serum Serum</p>	<p>ABO Grouping & Rhesus Crossmatch</p> <p>Albumin Amylase ALP ALT AST Calcium Creatine kinase (CK) Cholesterol (HDL) Cholesterol (LDL) Chloride Creatinine Total Bilirubin Direct Bilirubin Gamma Glutamyl Transferase (GGT) Glucose Potassium Sodium Total Protein Triglycerides Urea</p>	<p>Manual Method Manual Method</p> <p>Cobas Integra 400 Plus Cobas Integra 400 Plus</p>			

ANNEXURE A

Laboratory Accreditation No: MED 003 (ISO 15189:2022)

Issue No: 03

Date of Issue: 31 July 2024

Date of Expiry: 25 March 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>HAEMATOLOGY</u>		
Whole Blood	WBC	Sysmex XN 330
Whole Blood	RBC	Sysmex XN 330
Whole Blood	HB	Sysmex XN 330
Whole Blood	HCT	Sysmex XN 330
Whole Blood	MCV	Sysmex XN 330
Whole Blood	MCH	Sysmex XN 330
Whole Blood	MCHC	Sysmex XN 330
Whole Blood	RDW	Sysmex XN 330
Whole Blood	Platelet Count	Sysmex XN 330
Whole Blood	Differential Count	Sysmex XN 330
Whole Blood/Serum	ABO Grouping & Rhesus	Manual Method
Whole Blood	Crossmatch	Manual Method
<u>IMMUNOPHENOTYPING</u>		
Whole Blood	CD4 Count	BD Facs Presto
Whole Blood	CD4 %	BD Facs Presto
<u>MICROBIOLOGY</u>		
Isolates, Swabs, CSF	Gram Stain	Manual – Microscopy
Urine	Culture/Identification/Sensitivity	Manual Method – Kirby Bauer
Blood	Culture/Identification/Sensitivity	BD Bactec FX 200
<u>MOLECULAR BIOLOGY</u>		
Dried Blood Spot	Qualitative HIV -EID	CAP/CTM 96
Plasma	HIV Viral Load	Cobas 8800
Plasma	HIV Drug Resistance Test	ABI Genetic Analyser 3500XL
<u>MYCOBACTERIOLOGY</u>		
Sputum	AFB-Ziehl Neelsen	Manual – Microscopy
Sputum	AFB-Auramine	Manual – Microscopy
Sputum	MTB/RIF	GeneXpert
<u>PARASITOLOGY</u>		
Blood	Malaria	Manual – Microscopy

ANNEXURE A

Laboratory Accreditation No: MED 003 (ISO 15189:2012)

Issue No: 03

Date of Issue: 31 July 2024

Date of Expiry: 25 March 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>SEROLOGY</u> Blood CSF, Blood Urine	Rapid HIV Cryptococcal Meningitis Pregnancy Test	Rapid Test Rapid Test Rapid Test

Original date of accreditation: 14 May 2014

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Mrs Pinkie J Malebe
SADCAS Technical Manager