

CERTIFICATE OF ACCREDITATION

CERBA LANCET ZAMBIA LIMITED

Registration No: - TPIN 100179905

Facility Accreditation Number: MED 177

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, ENDOCRINOLOGY, HAEMATOLOGY, MICROBIOLOGY,
MOLECULAR BIOLOGY AND SEROLOGY**

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

Effective Date (Issue No: 1): 01 August 2024
Certificate Expires: 5 December 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 177 (ISO 15189:2012)**

<u>Permanent Address of Laboratory</u> Cerba Lancet Zambia Limited 2404 Kabelenga Road Lusaka Zambia <u>Postal Address:</u> 2404 Kabelenga Road Lusaka Zambia <u>Tel</u> : +260 211374800 <u>Cell</u> : +260 968278573 <u>Fax</u> : - <u>Email</u> : Alzera.hussein@cerbalancetafrica.com		<u>Technical Signatories</u> : As Authorized by the Head of Laboratory <u>Nominated Representative</u> : Ms Alzera Hussein <u>Issue No</u> : 01 <u>Date of Issue</u> : 01 August 2024 <u>Expiry Date</u> : 05 December 2025
DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY</u> Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum/CSF Serum Serum Serum Serum Serum Serum Serum Serum Serum/CSF Serum	Albumin Alkaline Phosphatase (ALP) Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Amylase Bicarbonate (CO ₂) β-Lactate Calcium (Corrected) Calcium (Total) Chloride Cholesterol (HDL) Creatinine Creatinine Kinase (CK) C-Reactive Protein Direct Bilirubin Total Bilirubin Gamma Glutamyl Transferase (GGT) Glucose Magnesium	Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus Cobas Integra 400 plus

ANNEXURE A

Laboratory Accreditation No: MED 177 (ISO 15189:2012)

Issue No: 01

Date of Issue: 01 August 2024

Date of Expiry: 05 December 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY contd'</u>		
Serum	Phosphate	Cobas Integra 400 plus
Serum	Potassium	Cobas Integra 400 plus
Serum	Sodium	Cobas Integra 400 plus
Serum/CSF	Total Protein	Cobas Integra 400 plus
Serum	Triglycerides	Cobas Integra 400 plus
Serum	Urea	Cobas Integra 400 plus
Serum	Urate	Cobas Integra 400 plus
Serum	Creatine Kinase - MB (CK-MB)	Cobas H232
Whole Blood	Troponin T	Cobas H232
Whole Blood	Human Chorionic Gonadotropin (β HCG)	Manual Method
	Qualitative	
<u>ENDOCRINOLOGY</u>		
Serum	Alpha Feto Protein (AFP)	Elecsys E411
Serum	Beta Human Chorionic Gonadotropin (β HCG)	Elecsys E411
	Quantitative	
Serum	Estradiol E2	Elecsys E411
Serum	Ferritin	Elecsys E411
Serum	Free Triiodothyronine (FT3)	Elecsys E411
Serum	Free Thyroxine (FT4)	Elecsys E411
Serum	Follicular Stimulating Hormone (FSH)	Elecsys E411
Serum	Luteinizing Hormone (LH)	Elecsys E411
Serum	Progesterone	Elecsys E411
Serum	Prolactin	Elecsys E411
Serum	Prostate Specific Antigen (PSA) Total	Elecsys E411
Serum	Sex Hormone Binding Globulin (SHBG)	Elecsys E411
Serum	Thyroid Stimulating Hormone (TSH)	Elecsys E411
Serum	Total Testosterone	Elecsys E411
<u>HAEMATOLOGY</u>		
Whole Blood	Full Blood Count (FBC)	Sysmex XNL 330
Whole Blood	D-Dimer (Fibrin Degradation Product)	Cardiac Reader H232
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Manual Method
Whole Blood	Prothrombin Time (PI-INR)	Sysmex CA104
Whole Blood	Malaria Antigens (Immuno-chromatograph Testing)	Manual Method

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DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>MICROBIOLOGY</u>		
Fluids, Urine, Pus swabs, Genital swabs, Sputum, Ear, nose and throat swabs, CSF, Stool	• Microscopy • Culture • Identification • Sensitivity	Manual method Manual method Manual method Manual method
Fluids	Cell count – body fluids	Manual method
CSF	• Bacterial antigen • Cryptococcal antigen • India Ink	Manual/kit
Urine	Chemistry	Manual/Dipstick
Urine, Stool	Stool parasitology	Manual Method
Blood culture	• Microscopy • Culture • Identification • Sensitivity	Manual Method
Sputum, CSF	Ziehl Neelsen stain	Manual Method
<u>MOLECULAR BIOLOGY</u>		
Plasma	HIV Viral Load	Cobas Ampliprep/Taqman 48
<u>SEROLOGY</u>		
Serum	Beta Human Chorionic Gonadotropin (βHCG) Qualitative	Manual Method
Serum	<i>Helicobacter pylori</i>	Manual Method
Serum	Rapid HIV	Manual Method
Serum	Rheumatoid Factor (RF)	Manual Method
Serum	Rapid Plasma Reagin (RPR)	Manual Method
Serum	<i>Treponema pallidum</i> Hemagglutination (TPHA)	Manual Method
Serum	Widal	Manual Method

Original Date of Accreditation: 01 August 2024

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Mrs Pinkie J Malebe
SADCAS Technical Manager