

CERTIFICATE OF ACCREDITATION

UNIVERSITY OF ZIMBABWE CLINICAL TRIALS RESEARCH CENTRE

Company Registration No: Lab115

Facility Accreditation Number: MED 086

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, 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 subsidiary 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: 2): 05 April 2024
Certificate Expires: 05 December 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 086 (ISO 15189:2012)**

<u>Permanent Address of Laboratory</u> University of Zimbabwe – Clinical Trials Research Centre Parirenyatwa Hospital Department of Obstetrics & Gynaecology Mazowe Street, Avondale Harare Zimbabwe		<u>Technical Signatories</u> : As Authorized by the Head of Laboratory
<u>Postal Address:</u> 15 Phillips Avenue Belgravia Harare Zimbabwe		<u>Nominated Representative</u> : Mr Nicholas Dhibi
<u>Tel</u> : +263 242 2706127 <u>Cell</u> : +263 779653650 <u>Fax</u> : +263 242 2704897 <u>Email</u> labqc@uz-ctrc.org		<u>Issue No</u> : 02 <u>Date of Issue</u> : 05 April 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 Serum Serum Serum Serum Serum Serum Serum Serum Serum	 Albumin Alkaline Phosphatase (ALP) Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Amylase Bicarbonate (CO ₂) Bilirubin, Direct Bilirubin, Total Calcium Cholesterol (HDL) Cholesterol (LDL) Cholesterol (Total) Chloride Creatinine Kinase (CK) Creatinine Gamma Glutamyl Transferase (GGT) Glucose	 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 086 (ISO 15189:2012)

Issue No: 02

Date of Issue: 05 April 2024

Date of Expiry: 05 December 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY (Cont'd)</u>		
Serum	Lipase	Cobas Integra 400 Plus
Serum	Magnesium	Cobas Integra 400 Plus
Serum	Inorganic Phosphate (PO ₄)	Cobas Integra 400 Plus
Serum	Potassium	Cobas Integra 400 Plus
Serum	Protein (Total)	Cobas Integra 400 Plus
Serum	Sodium	Cobas Integra 400 Plus
Serum	Triglycerides	Cobas Integra 400 Plus
Serum	Urate	Cobas Integra 400 Plus
Serum	Urea	Cobas Integra 400 Plus
<u>HAEMATOLOGY</u>		
Whole Blood	WBC	Sysmex XN550
Whole Blood	RBC	Sysmex XN550
Whole Blood	HCT	Sysmex XN550
Whole Blood	HB	Sysmex XN550
Whole Blood	MCV	Sysmex XN550
Whole Blood	MCH	Sysmex XN550
Whole Blood	MCHC	Sysmex XN550
Whole Blood	Platelets	Sysmex XN550
Whole Blood	Lymphocytes	Sysmex XN550
Whole Blood	Neutrophils	Sysmex XN550
Whole Blood	Eosinophils	Sysmex XN550
Whole Blood	Monocytes	Sysmex XN550
Whole Blood	Basophils	Sysmex XN550
Whole Blood	CD4	BD FacsCanto 11 / BD FacsVia
Whole Blood	CD8	BD FacsCanto 11 / BD FacsVia
<u>MOLECULAR BIOLOGY</u>		
Whole blood	HIV DNA PCR	GeneXpert 4 and 16 Module
Plasma	HIV RNA PCR	Abbott m 2000rt
Urine/Swab	<i>Chlamydia trachomatis</i>	GeneXpert 16 Module
Urine/Swab	<i>Neisseria gonorrhoeae</i>	GeneXpert 16 Module
Swab	<i>Trichomonas vaginalis</i>	GeneXpert 4 and 16 Module

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DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>SEROLOGY</u>		
Serum	Hepatitis B Surface Antigen (HBsAg)	Architect i1000SR
Serum	Hepatitis C Antibody (Anti-HCV)	Architect i1000SR
Serum	HIV Ag/Ab Combo	Architect i1000SR
Serum	Rapid Plasma Reagin Test (RPR)	Manual Method
Serum	<i>Treponema pallidum</i> Hemagglutination (TPHA)	Manual Method

Original date of accreditation: 28 February 2022

Page 3 of 3

Mrs Pinkie J Malebe
SADCAS Technical Manager