

CERTIFICATE OF ACCREDITATION

BOTSWANA HARVARD HIV REFERENCE LABORATORY

Company Registration No.00000108A

Facility Accreditation Number: MED 031

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 15189:2022

*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 C Gadzikwa
SADCAS Chief Executive Officer

Date of Renewal of Accreditation 21 February 2024
Effective Date (Issue No: 1): 21 February 2024
Certificate Expires: 20 February 2029

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 031 (ISO 15189:2022)**

<p>Permanent Address of Laboratory Botswana Harvard HIV Reference Laboratory Plot 1836 Northring Road Gaborone Botswana</p> <p>Postal Address Private Bag 320 Gaborone Botswana</p> <p>Tel : +267 390 2671 Ext 2112 Cell : +267 77628715 Fax : - Email : tntalabgwe@bhp.org.bw</p>		<p>Technical Signatories : As Authorized by the Head of Laboratory</p> <p>Nominated Representative : Ms Tshenolo Ntalabgwe</p> <p>Issue No : 01 Date of Issue : 21 February 2024 Expiry Date : 20 February 2029</p>	
DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD	
CLINICAL CHEMISTRY			
Serum	Albumin	Cobas Integra 400 plus	
Serum	Alkaline Phosphate (ALP)	Cobas Integra 400 plus	
Serum	Alanine Aminotransferase (ALT)	Cobas Integra 400 plus	
Serum	Amylase	Cobas Integra 400 plus	
Serum	Aspartate Aminotransferase (AST)	Cobas Integra 400 plus	
Serum	Bicarbonate (CO ₂)	Cobas Integra 400 plus	
Serum	Bilirubin, Direct	Cobas Integra 400 plus	
Serum	Bilirubin, Total	Cobas Integra 400 plus	
Serum	Calcium	Cobas Integra 400 plus	
Serum	Chloride	Cobas Integra 400 plus	
Serum	Cholesterol	Cobas Integra 400 plus	
Serum	Cholesterol (HDL) Measured	Cobas Integra 400 plus	
Serum	Cholesterol (LDL) Measured	Cobas Integra 400 plus	
Serum	Cholesterol (LDL) Calculated	Cobas Integra 400 plus	
Serum	Creatinine	Cobas Integra 400 plus	
Serum	Creatinine Kinase (CK)	Cobas Integra 400 plus	
Serum	Gamma Glutamyl Transferase (GGT)	Cobas Integra 400 plus	
Plasma	Glucose	Cobas Integra 400 plus	
Serum	Lactate Dehydrogenase (LDH)	Cobas Integra 400 plus	
Serum	Lipase	Cobas Integra 400 plus	
Serum	Phosphate	Cobas Integra 400 plus	
Serum	Potassium	Cobas Integra 400 plus	
Serum	Protein (Total)	Cobas Integra 400 plus	

ANNEXURE A

Laboratory Accreditation No: MED 031 (ISO 15189:2022)

Issue No: 01

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DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY cont'd</u>		
Serum	Sodium	Cobas Integra 400 plus
Serum	Triglycerides	Cobas Integra 400 plus
Serum	Urea	Cobas Integra 400 plus
<u>HAEMATOLOGY</u>		
Blood	CD4	Beckman Coulter Aquios
Blood	Full Blood Count	Sysmex XN1000
Blood	Differential Count	Manual Method
Blood	Peripheral Blood Mononuclear Cells Preservation (PBMC)	Hemocytometer
Blood	Peripheral Blood Mononuclear Cells Preservation (PBMC)	Muse
<u>MOLECULAR BIOLOGY</u>		
Dry Blood Spot	HIV- DNA PCR	Roche CAP/CTM Qual
Blood	HIV- DNA PCR	Roche CAP/CTM Qual
Plasma	HIV- 1 RNA PCR Viral Load	Abbott/M2000sp-rt
Plasma	HIV- 1 RNA PCR Viral Load	Roche CAP/CTM
Plasma	HIV- 1 RNA PCR Viral Load	Panther Hologic
Urine/Cervical	<i>Chlamydia Trachomatis/Neisseria Gonorrhoea</i> (CT/NG)	Abbott/M2000sp/rt
Plasma	HIV Drug Resistance Sequencing	Applied Biosystems Thermo Fisher Scientific
Nasopharyngeal/Oropharyngeal	SARS – CoV-2/COVID -19	Line Gene 9600 Analyzers using DanAn Gene Assay
<u>SEROLOGY</u>		
Serum	Rapid Plasma Reagin (RPR)	Manual Method
Serum	Treponema Pallidum Particle Agglutination Assay (TPPA)	Manual Method
Serum	HIV -1/2 Ag/Ab	Manual Method
Serum/Plasma	HIV -1/2 Ag/Ab	Abbott Architect
Serum/Plasma	Hepatitis B Virus	Murex HBs Ag
Serum/Plasma	Hepatitis B Virus	Abbott Architect
Serum/Plasma	Hepatitis C Virus	Murex HCV
Serum/Plasma	Hepatitis C Virus	Abbott Architect

Original date of accreditation: 19 June 2019

Page 2 of 2

Mrs Pinkie J Malebe
SADCAS Technical Manager