

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 15189:2012

*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*

**Mrs Maureen P Mutasa
SADCAS Chief Executive Officer**

**Effective Date (Issue No: 3): 24 March 2022
Certificate Expires: 18 June 2024**

ANNEXURE A

Laboratory Accreditation No: MED 031 (ISO 15189:2012)

Issue No: 03

Date of Issue: 24 March 2022

Date of Expiry: 18 June 2024

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	BD FACS Calibur
Blood	CD4	Beckman Coulter Aquios
Blood	Full Blood Count	Sysmex XT-2000i
Blood	Differential Count	Manual Method
Blood	Peripheral Blood Mononuclear Cells (PBMC preservation)	Hemocytometer
<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
Urine/Cervical	Chlamydia Trachomatis/Neisseria Gonorrhoea (CT/NG)	Abbott/M2000sp/rt
Plasma	HIV Drug Resistance Sequencing	Applied Biosystems Thermo Fisher Scientific
Nasopharyngeal/Oropharyngeal	SARS – CoV-2/COVID -19	MGSIP 960 and Line Gene 9600 Analyzers using DanAn Gene Assay
<u>SEROLOGY</u>		
Serum	HIV 1 Western Blot	Manual Method
Serum	Rapid Plasma Reagin (RPR)	Manual Method
	Treponema Pallidum Particle Agglutination Assay (TPPA)	Manual Method
Serum/Plasma	HIV -1/2 Ag/Ab	Abbott Architect
Serum/Plasma	HIV-1/2	Murex HIV -1.2.0
Serum/Plasma	HIV-1/2	GS Biorad HIV-1/2
Serum/Plasma	Hepatitis B Virus	Murex HBs Ag
Serum/Plasma	Hepatitis C Virus	Murex HCV

Original date of accreditation: 19 June 2019

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