

CERTIFICATE OF ACCREDITATION

NAMIBIA INSTITUTE OF PATHOLOGY - WINDHOEK CENTRAL REFERENCE LABORATORY

Company Registration No. 2000/41

Facility Accreditation Number: MED 108

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, MOLECULAR
BIOLOGY, MICROBIOLOGY, MYCOBACTERIOLOGY 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): 14 August 2024
Certificate Expires: 5 December 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 108 (ISO 15189:2012)**

<u>Permanent Address of Laboratory</u> Namibia Institute of Pathology NIP Windhoek Reference Laboratory Windhoek Central Hospital Complex Ooievaart Street Windhoek Namibia <u>Postal Address:</u> P O Box 277 Windhoek Namibia <u>Tel</u> : +264 61 295 4001 <u>Cell</u> : +264 81 2772809 <u>Fax</u> : - <u>Email</u> : douglaschiwara@nip.co.na		<u>Technical Signatories</u> : As Authorized by the Head of Laboratory <u>Nominated Representative</u> : Mr Douglas Chiwara <u>Issue No</u> : 02 <u>Date of Issue</u> : 14 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 Serum Serum Serum Serum Serum Plasma Serum Serum Serum	Albumin Alkaline Phosphatase (ALP) Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Amylase Chloride Cholesterol Creatinine Compliment C3 Compliment C4 C-Reactive Protein (CRP) Direct Bilirubin Total Bilirubin Gamma Glutamyl Transferase (GGT) Glucose Iron Lactate Dehydrogenase (LDH) Magnesium	Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI Alinity CI

ANNEXURE A

Laboratory Accreditation No: MED 108 (ISO 15189:2012)

Issue No: 02

Date of Issue: 14 August 2024

Date of Expiry: 05 December 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY cont'd</u>		
Serum	Phosphorus	Alinity CI
Serum	Potassium	Alinity CI
Serum	Sodium	Alinity CI
Serum	Total CK	Alinity CI
Serum	Total Protein	Alinity CI
Serum	Triglycerides	Alinity CI
Serum	Transferrin	Alinity CI
Serum	Urea	Alinity CI
Serum	Uric Acid	Alinity CI
Serum	Calcium	Alinity CI
Serum	Immunoglobulin A (IgA)	Alinity CI
Serum	Immunoglobulin G (IgG)	Alinity CI
Serum	Immunoglobulin M (IgM)	Alinity CI
<u>ENDOCRINOLOGY</u>		
Serum	Human Chorionic Gonadotropin (HCG)	Alinity CI
Serum	Estradiol	Alinity CI
Serum	Thyroid Stimulating Hormone (TSH)	Alinity CI
Serum	Luteinising Hormone (LH)	Alinity CI
Serum	Progesterone	Alinity CI
Serum	TSH	Alinity CI
Serum	T-PSA	Alinity CI
Serum	Prolactin	Alinity CI
Serum	Free Triiodothyronine (FT3)	Alinity CI
Serum	Free Thyroxine (FT4)	Alinity CI
Serum	Testosterone	Alinity CI
Serum	SHBG	Alinity CI
Serum	Alpha Fetoprotein (AFP)	Alinity CI
Serum	CA-153	Alinity CI
Serum	CA-125	Alinity CI
Serum	CA-199	Alinity CI
Serum	Carcinoembryonic Antigen (CEA)	Alinity CI
Serum	Free PSA	Alinity CI
Serum	Ferritin	Alinity CI
Serum	Vitamin B12	Alinity CI
Serum	Follicle Stimulating Hormone (FSH)	Alinity CI

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<u>HAEMATOLOGY</u>		
Whole Blood	Full Blood Count (FBC)	Sysmex XN 1000i
Plasma	Activated Partial Thromboplastin Time (APTT)	ACL Elite
Plasma	Prothrombin Time (PT)	ACL Elite
Plasma	D - dimer	ACL Elite
Plasma	Fibrinogen	ACL Elite
<u>MOLECULAR BIOLOGY</u>		
Plasma	HIV Viral Load	Cobas Ampliprep /Taqman 96 Abbott M2000rt/Cobas 4800
DBS	Early Infant Diagnostic	Cobas Ampliprep/Taqman 96
DBS	Early Infant Diagnostic	GeneXpert
Swab	SARS-CoV-2	GeneXpert
Urine	Neisseria gonorrhea	GeneXpert
Urine	Chlamydia trachomatis	GeneXpert
Swab	Influenza	Bioer/Light Cyclor 480
<u>MICROBIOLOGY</u>		
CSF	Macroscopy Gram Stain Culture and Isolation of Pathogenic Organisms	Manual Method
Urine	Culture and Isolation of Pathogenic Organisms	Manual Method
Swabs (Ear, Nose, Throat, Genital)	Gram Culture and Isolation of Pathogenic Organisms, Aerobic	Manual Method Manual Method
Fluids ((Vitreous, Ascites, Pleural, Peritoneal, Synovial)	Macroscopy Gram Stain Culture and Isolation of Pathogenic Organisms, Aerobic	Manual Method
Catheter Tips	Culture and Isolation of Pathogenic Organisms, Aerobic	Manual Method

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<u>MICROBIOLOGY cont'd</u>		
Pus, Wound, Abscess, Soft Tissue, Aspirates (Bartholin Cyst)	Gram Stain Culture and Isolation of aerobic Pathogenic Organisms	Manual Method
Faecal Samples	Macroscopy Culture and Isolation of aerobic Pathogenic Organisms excluding <i>Campylobacter</i> Species, <i>Yersinia</i> species and <i>Vibrio</i> Species and Enteropathogenic <i>Escherichia coli</i>	Manual Method
Sputum/Bronchial/Tracheal	Macroscopy Gram Stain Culture and Isolation of Pathogenic Organisms, Aerobic	Manual Method
Cultures	Agglutination Testing Wellcolex Salmonella Wellcolex Shigella Staphaurex Prolex Staph Latex Streptex	Manual Method Manual Method Manual Method Manual Method Manual Method
Cultures	API Identification 20 E 10 S Bacterial identification Techniques Antimicrobial Susceptibility Testing: Disc Diffusion Kirby Bauer	Manual Method Manual Method Manual Method Manual Method Manual Method Manual Method Manual Method Automated: Vitek 2XL Manual/CLSI
<u>MYCOBACTERIOLOGY</u>		
Sputum	TB Direct Microscopy	Manual (Fluorescence Auramine O)
Sputum	TB Direct Microscopy	Manual (Ziehl Neelsen Stain)
Sputum	MTB/RIF	Infinity
Sputum	TB Culture	BACTEC MGIT 960
Sputum	LPA 1 st and 2 nd	GT Blot/Twincubator
Sputum	Rapid Identification (MPT64) Antigen	Manual

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<u>SEROLOGY</u>		
Serum	Hepatitis A IgM	Alinity CI /Architect i2000
Serum	Hepatitis C	Alinity CI /Architect i2000
Serum	Hepatitis B Surface Antigen	Alinity CI /Architect i2000
Serum	Hepatitis B Surface Ab	Alinity CI /Architect i2000
Serum	Hepatitis B Core IgM	Alinity CI /Architect i2000
Serum	Hepatitis B Core Ab	Alinity CI /Architect i2000
Serum	HIV 1 & 2	Alinity CI /Architect i2000
Serum	Cytomegalovirus IgG and IgM	Alinity CI /Architect i2000
Serum	Toxoplasma IgG and IgM	Alinity CI /Architect i2000
Serum	Rubella IgM and IgM	Alinity CI /Architect i2000
Serum	Rapid Plasma Reagin (RPR)	Manual Method
Serum	<i>Treponema pallidum</i> Hemagglutination (TPHA)	Manual Method

Original date of accreditation: 09 August 2022

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Mrs Pinkie J Malebe
SADCAS Technical Manager