

CERTIFICATE OF ACCREDITATION

PATHCARE – WINDHOEK MAIN LABORATORY

Company Registration No. Co. Reg. No.: 93/302

Practice No.: 0520000006238

Facility Accreditation Number: MED 129

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, CYTOLOGY, ENDOCRINOLOGY, HAEMATOLOGY,
HISTOLOGY, MICROBIOLOGY, MOLECULAR BIOLOGY, MYCOBACTERIOLOGY,
MYCOLOGY, PARASITOLOGY 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 C Gadzikwa
SADCAS Chief Executive Officer

Effective Date (issue No:1): 29 March 2023
Certificate Expires: 05 December 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 129 (ISO 15189:2012)**

<p><u>Permanent Address of Laboratory</u> Dr Shaw Roux and Partners Windhoek Main Laboratory 155 Nelson Mandela Avenue Eros Windhoek, Namibia</p> <p><u>Postal Address</u> P.O Box 5355 Ausspannplatz Windhoek Namibia</p> <p><u>Tel</u> : +2721 5963400 <u>Cell</u> : +2774 5858910 <u>Fax</u> : - <u>Email</u> : stephan.marias@pathcare.net</p>		<p><u>Technical Signatories</u> : As Authorized by the Head of Laboratory</p> <p><u>Nominated Representative</u> : Mr Stephan Marais</p> <p><u>Issue No</u> : 01 <u>Date of Issue</u> : 29 March 2023 <u>Expiry Date</u> : 05 December 2025</p>	
DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD	
<u>CLINICAL CHEMISTRY</u>			
Serum	Acetaminophen/Paracetamol	Abbott Alinity CI	
Serum	Albumin	Abbott Alinity CI	
Serum	Alkaline Phosphatase (ALP)	Abbott Alinity CI	
Serum	Alanine Aminotransferase (ALT)	Abbott Alinity CI	
Serum	Aspartate Aminotransferase (AST)	Abbott Alinity CI	
Serum	Amikacin	Abbott Alinity CI	
Serum	Amylase	Abbott Alinity CI	
Serum	Beta – 2-microglobulin	Abbott Alinity CI	
Serum	Bicarbonate (CO ₂)	Abbott Alinity CI	
Serum	Calcium	Abbott Alinity CI	
Serum	Carbamazepine	Architect	
Serum/ CSF/ Urine/Sweat	Chloride	Abbott Alinity CI	
Serum	Cholesterol (HDL)	Abbott Alinity CI	
Serum	Cholesterol (Total)	Abbott Alinity CI	
Serum	Creatinine	Abbott Alinity CI	
Serum	Creatinine Kinase - Total	Abbott Alinity CI	
Heparinised Whole Blood	Creatinine Kinase MB (CKMB)	Abbott Alinity CI /Cardiac Reader	
Serum	C-Reactive Protein	Abbott Alinity CI	
Serum	Direct Bilirubin	Abbott Alinity CI	
Serum	Total Bilirubin	Abbott Alinity CI	

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<u>CLINICAL CHEMISTRY cont'd</u>		
Serum	Gamma Glutamyl Transferase (GGT)	Abbott Alinity Ci
Serum	Gentamycin	Abbott Alinity Ci
CSF/Plasma/Urine	Glucose	Abbott Alinity Ci
Whole Blood	HBA1C	Trinity Premier
Serum	Iron	Abbott Alinity Ci
Serum	Lactate Dehydrogenase (LDH)	Abbott Alinity Ci
Serum/Urine	Magnesium	Abbott Alinity Ci
Urine	Microalbumin	Abbott Alinity Ci
Serum/ Urine	Osmolality	Osmometer
Serum / Urine	Phosphate - Inorganic	Abbott Alinity Ci
Serum / Urine	Potassium	Abbott Alinity Ci
CSF / Urine	Protein (Micro)	Abbott Alinity Ci
Serum	Protein, Total	Abbott Alinity Ci
Serum / Urine / Sweat	Sodium	Abbott Alinity Ci
Serum	Transferrin	Abbott Alinity Ci
Serum	Triglycerides	Abbott Alinity Ci
Serum	Urate	Abbott Alinity Ci
Serum / Urine	Urea	Abbott Alinity Ci
<u>CYTOLOGY</u>		
Pleural, NDN, Gynae Fluid, Bronchial Smear, Brushing and Washing. Fine Needle aspiration, Gastric Brushing, Impression Smear, Oesophageal Brushings, Scrapings Cytology, Sputum Cytology, Urine Cytology	Special Stains	Manual Method
Liquid Based Cytology (LBC) Specimens	Papaniculou Stains	LBC Method
Conventional Gynaecological	Papaniculou Stains	Convectional Method
<u>ENDOCRINOLOGY</u>		
Serum	Alpha Fetoprotein (AFP)	Abbott Alinity Ci
Serum	Beta Human Chorionic Gonadotrophin	Abbott Alinity Ci
Serum	(βHCG) Quantitative	Abbott Alinity Ci

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<u>ENDOCRINOLOGY cont'd</u>		
Serum	CA 19.9	Abbott Alinity CI
Serum	CA 15.3	Abbott Alinity CI
Serum	CA 125	Abbott Alinity CI
Serum	Carcinoembryonic Antigen (CEA)	Abbott Alinity CI
Serum	Digoxin	Abbott Alinity CI
Serum	Ferritin	Abbott Alinity CI
Serum	Folate	Abbott Alinity CI
Serum	Follicle Stimulating Hormone (FSH)	Abbott Alinity CI
Serum	Free Thyroxine (F-T4)	Abbott Alinity CI
Serum	Free Triiodothyronine (F-T3)	Abbott Alinity CI
Serum	Luteinising Hormone (LH)	Abbott Alinity CI
Serum	Oestradiol	Abbott Alinity CI
Serum	Phenytoin	Abbott Alinity CI
Heparinised Whole Blood	Pro Brain Natriuretic Peptide (proBNP)	Abbott Alinity CI/ Cardiac Reader H232
Serum	Procalcitonin	Abbott Alinity CI
Serum	Progesterone	Abbott Alinity CI
Serum	Prolactin	Abbott Alinity CI
Serum	Prostate Specific Antigen (PSA) Free	Abbott Alinity CI
Serum	Prostate Specific Antigen (PSA) Total	Abbott Alinity CI
Serum	Theophylline	Abbott Alinity CI
Serum	Thyroid Stimulating Hormone (TSH)	Abbott Alinity CI
Heparinised Whole Blood	Troponin - T	Cardiac Reader H232
Serum	Troponin – I	Abbott Alinity CI
Serum	Valproic – Acid	Abbott Alinity CI
Serum	Vancomycin	Abbott Alinity CI
Serum	Vitamin B12	Architect
<u>HAEMATOLOGY</u>		
Whole Blood	Full Blood Count and Differential Count	Sysmex XN 10
Whole Blood	Differential Count	Manual Method
Whole Blood	Blood Grouping (ABO and Rh (D))	Manual Method
Whole Blood	Coombs (Direct /Indirect)	Manual Method
Whole Blood	CD4	Aquios
Whole Blood	Activated Partial Thromboplastin Time (APTT)	Siemens CA660
Whole Blood	Prothrombin Time (PT)	Siemens CA660

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<u>HAEMATOLOGY cont'd</u>		
Whole Blood	International Normalised Ratio (INR)	Siemens CA660
Whole Blood	D- Dimer (Fibrin Degradation Product)	Mini Vidas
Whole Blood	Fibrinogen	Siemens CA660
Whole Blood	Malaria Smears	Manual Method
Whole Blood	Sickle Cell Screen	Manual Method
<u>HISTOLOGY</u>		
All Biological specimens	Decalcification Frozen sections Special Stains, H & E stain	Manual Method
All Biological Specimens	IHC	Ventana Method
<u>MICROBIOLOGY</u>		
CSF	Macroscopy Cryptococcal Antigen Gram Stain Culture and isolation of pathogenic organisms Antimicrobial sensitivity	Manual Method Manual Method Manual Method Manual Method / Vitek
Urine	Microscopy Culture and isolation of pathogenic organisms Antimicrobial sensitivity	Manual Method Manual Method / Vitek Manual Method
Swabs (Ear, Nose, Throat, genital)	Gram Culture and isolation of pathogenic organisms, aerobic Antimicrobial sensitivity	Manual Method Manual Method / Vitek Manual Method
Fluids ((Vitreous, ascites, pleural, Peritoneal dialysis fluid, Pericardial, synovial, Peritoneal)	Macroscopy Gram Stain Culture and isolation of pathogenic Organisms, aerobic Antimicrobial sensitivity	Manual Method Manual Method Manual Method / Vitek Manual Method
Pus/Wound/Abscess/Soft Tissue/ Sputum/ Aspirates (Bartholin Cyst) Tips	Gram Stain Culture and isolation of pathogenic organisms, aerobic	Manual Method Manual Method / Vitek

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<u>MICROBIOLOGY cont'd</u>		
Stool	Macroscopy Culture and isolation of pathogenic organisms excluding <i>Campylobacter</i> species, <i>Yersinia</i> species and <i>Vibrio</i> species and Enteropathogenic <i>Escherichia coli</i> , aerobic	Manual Method / Vitek
Blood Culture	Culture and isolation of pathogenic organisms, aerobic	BactAlert / Vitek
<u>MOLECULAR BIOLOGY</u>		
Whole Blood	HIV -1 Viral Load	Abbott m2000/Alinity M
LBC Samples	HPV	Abbott m2000 / Alinity M
Respiratory	SARS-Cov-2	Abbott m2000/Alinity M /GXP
Respiratory	Biofire Respiratory panel	Biofire Film Array
Respiratory	TB	GPX
CSF	Meningitis Panel	Biofire Film Array
Stool	C. difficile	GPX
<u>MYCOBACTERIOLOGY</u>		
CSF, Urine, Stool, Sputum, Swabs Pleural Fluids, Joint aspirates, Abscess, Pus aspirate, Tissue, Endotracheal aspirate, Ascitic fluid, Pericardial fluid, Peritoneal dialysis fluid, Peritoneal fluid, Bronchial aspirates, Tips	Microscopy	Manual Method
Urine	TB LAM	Manual Method

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<p><u>MYCOLOGY</u> CSF, Urine, Stool, Sputum, Swabs Pleural Fluids, Joint aspirates, Abscess, Pus aspirate, Tissue, Endotracheal aspirate, Ascitic fluid, Pericardial fluid, Peritoneal dialysis fluid, Peritoneal fluid, Bronchial aspirates, Tips</p>	Yeast -Microscopy	Manual Method
<p><u>PARASITOLOGY</u> Stool/Urine/Blood</p>	Parasitology	Manual Method
<p><u>SEROLOGY</u> Serum Serum Serum Serum Serum Serum Serum</p>	<p>Cotinine Hepatitis A IgM Hepatitis B Surface Antigen (HBsAg) HIV Immunoglobulin E SARS CoV-2 IgM Rubella IgG</p>	<p>Abbott Alinity CI Abbott Alinity CI Abbott Alinity CI Abbott Alinity CI Phadia 250 Manual Method Abbott Alinity CI</p>

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Mrs Pinkie J Malebe
SADCAS Technical Manager