

# CERTIFICATE OF ACCREDITATION

## DIAGNOFIRM MEDICAL LABORATORIES - GABORONE

*Registration No. CO89/1221*

**Facility Accreditation Number: MED 012**

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, HISTOPATHOLOGY,  
MICROBIOLOGY, 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*

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**Eve C Gadzikwa**  
**SADCAS Chief Executive Officer**

**Date of renewal of Accreditation: 23 July 2020**  
**Effective Date (Issue No: 4): 18 September 2023**  
**Certificate Expires: 22 July 2025**

## ANNEXURE A

### SCHEDULE OF ACCREDITATION

Laboratory Accreditation Number: **MED 012 (ISO 15189:2012)**

<p><b>Permanent Address of Laboratory</b> Diagnofirm Medical Laboratories Gaborone Plot 12583 Nyerere Drive, Middle Star Gaborone Botswana</p> <p><b>Postal Address:</b> Private Bag 283 Gaborone Botswana</p> <p><b>Tel</b> : +267 395 0007 <b>Cell</b> : +267 77583859 <b>Fax</b> : +267 395 7980 <b>Email</b> : <a href="mailto:mohammed@diagnofirm.co.bw">mohammed@diagnofirm.co.bw</a> <a href="mailto:gcmanger@diagnofirm.co.bw">/gcmanger@diagnofirm.co.bw</a></p>		<p><b>Technical Signatories</b> : As Authorized by the Head of Laboratory</p> <p><b>Nominated Representative</b> : Dr Mohamed Chand</p> <p><b>Issue No</b> : 05 <b>Date of Issue</b> : 18 September 2023 <b>Expiry Date</b> : 22 July 2025</p>
DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<b>CLINICAL CHEMISTRY</b>		
Serum	Alanine Aminotransferase (ALT)	Abbott Alinity
Serum	Albumin	Abbott Alinity
Serum	Alkaline Phosphatase	Abbott Alinity
Serum	Amylase	Abbott Alinity
Serum	Aspartate Aminotransferase (AST)	Abbott Alinity
Serum	Bicarbonate (CO <sub>2</sub> )	Abbott Alinity
Serum	Bilirubin Direct	Abbott Alinity
Serum	Bilirubin Total	Abbott Alinity
Serum	Calcium (Total)	Abbott Alinity
Serum	Chloride	Abbott Alinity
Serum	Cholesterol (HDL)	Abbott Alinity
Serum	Cholesterol (LDL) Calculated	Abbott Alinity
Serum	Cholesterol (Total)	Abbott Alinity
Serum	Cholesterol (Total) / Cholesterol (HDL) Ratio calculated	Abbott Alinity
Serum	C-Reactive Protein (CRP)	Abbott Alinity
Serum	Creatine Kinase (CK)	Abbott Alinity
Serum	Creatine Kinase MB (CKMB)	Abbott Alinity
Serum, Urine	Creatinine	Abbott Alinity
Serum	Ferritin	Abbott Alinity
Serum	Gamma Glutamyl Transferase (GGT)	Abbott Alinity
Serum	Globulins (calculated)	Abbott Alinity
Plasma, CSF, Urine	Glucose	Abbott Alinity
Whole blood	Glycosylated Haemoglobin HbA1c	Tosoh G8

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Issue No: 05

Date of Issue: 18 September 2023

Date of Expiry: 25 July 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<b><u>CLINICAL CHEMISTRY (cont'd)</u></b>		
Serum	Iron	Abbott Alinity
Serum	Lactate Dehydrogenase (LDH)	Abbott Alinity
Serum	Magnesium	Abbott Alinity
Serum	Phosphate	Abbott Alinity
Serum	Potassium	Abbott Alinity
Serum	Protein (Total)	Abbott Alinity
Serum	Sodium	Abbott Alinity
Serum	Transferrin	Abbott Alinity
Serum	Triglycerides	Abbott Alinity
Serum	Urate (Uric acid)	Abbott Alinity
Serum	Urea	Abbott Alinity
Urine	Protein	Abbott Alinity
<b><u>ENDOCRINOLOGY</u></b>		
Serum	Alpha Feto Protein	Bio Merieux Mini Vidas
Serum	Beta Human Chorionic Gonadotropin ( $\beta$ HCG)	Abbott Alinity
Serum	CA 125	Bio Merieux Mini Vidas
Serum	CA 19.9	Bio Merieux Mini Vidas
Serum	Carcinoembryonic Antigen (CEA)	Bio Merieux Mini Vidas
Serum	Estradiol (E2)	Abbott Alinity
Serum	Folate	Abbott Alinity
Serum	Follicle Stimulating Hormone	Abbott Alinity
Serum	Free T3	Abbott Alinity
Serum	Free T4	Abbott Alinity
Serum	Insulin	Abbott Alinity
Serum	Luteinizing Hormone	Abbott Alinity
Plasma	Pro Brain Natriuretic Peptide (pro BNP)	Bio Merieux Mini Vidas
Serum	Progesterone	Abbott Alinity
Serum	Prolactin	Abbott Alinity
Serum	Prostate Specific Antigen (PSA)	Abbott Alinity
Serum	Sex Hormone Binding Globulin (SHBG)	Abbott Alinity
Serum	Total testosterone	Abbott Alinity
Serum	Thyroid Stimulating Hormone (TSH)	Abbott Alinity
Serum	Vitamin B12	Abbott Alinity
Serum	Vitamin D250H	Abbott Alinity
Serum	Cortisol	Abbott Architect
Serum	DHEA-S	Abbott Architect
Serum	Free PSA	Abbott Architect

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<b><u>HAEMATOLOGY</u></b>		
Whole Blood	Blood Grouping (ABO and Rh(D))	Manual Method
Whole Blood	CD3	Beckman Coulter Aquios
Whole Blood	CD4	Beckman Coulter Aquios
Whole Blood	CD4%	Beckman Coulter Aquios
Whole Blood	CD8	Beckman Coulter Aquios
Whole Blood	CD4:CD8 ratio Calculated	
Plasma	D-Dimer (Fibrin Degradation Product)	Bio Merieux Mini Vidas
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Beckman Coulter Alifax
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Manual Method
Whole Blood	Full Blood Count	Abbott Emerald
Whole Blood	Malaria antigens	Manual Method
Whole Blood	Malaria Smears	Manual Method
<b><u>HISTOPATHOLOGY</u></b>		
Human Tissue Samples (Formalin fixed)	Grossing	Manual Method
	Tissue Processing	Diapath Tissue Processor
	Embedding	Kedee Embedding Centre & Cold Plate
	Sectioning	Manual Method
	H & E Routine Staining	Manual Method
	Special Stains	Manual Method
<b><u>MICROBIOLOGY</u></b>		
Urine	Wet preparation: <ul style="list-style-type: none"> <li>• Cells</li> <li>• Casts</li> <li>• Crystals</li> <li>• Parasites</li> </ul>	Manual Method-Microscopy
Pus Swabs, Ear, Eye, Throat Wound, Nasal, HVS	Gram Stain	Manual Method-Microscopy
Sputum	Ziehl Neelsen	Manual Method-Microscopy
Urine	Macroscopy	Manual Method
Pus Swabs, Ear, Eye, Throat, Wound, HVS, Urine	Culture on Selective and General Medium Antimicrobial Sensitivity Testing	Manual Method Manual Method- Modified Kirby Bauer/ Vitek 2 Compact
	Bacterial Identification Techniques Biochemical Tests: <ul style="list-style-type: none"> <li>• Catalase</li> <li>• Coagulase</li> <li>• Oxidase</li> </ul>	
	Electronic Rapid Compendium (ERIC)	

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<b><u>MOLECULAR BIOLOGY</u></b>		
Plasma	Molecular Amplification (HIV Viral Load)	Roche COBAS 5800
<b><u>SEROLOGY</u></b>		
Serum	Antistreptolysin O Titre (ASOT)	Manual Method
Serum, Urine	Beta Human Chorionic Gonadotropin ( $\beta$ HCG) Screen	Manual Method
Serum	Cytomegalovirus (CMV) IgG	Abbott Architect
Serum	Cytomegalovirus (CMV) IgM	Abbott Architect
Serum	<i>Helicobacter pylori</i>	Manual Method
Serum	Hepatitis A IgG	Abbott Architect
Serum	Hepatitis A IgM	Abbott Architect
Serum	Hepatitis B Core Antibody	Abbott Architect
Serum	Hepatitis B Surface Antigen (HBsAg)	Manual Method
Serum	Hepatitis B Surface Antibody (AUSAB)	Abbott Architect
Serum	Hepatitis C Virus antibody	Abbott Architect
Serum	HIV Rapid	Manual Method
Serum	Rheumatoid Factor (RF)	Manual Method
Serum	Rubella IgG	Abbott Architect
Serum	Rubella IgM	Abbott Architect
Serum	Rapid Plasma Reagin (RPR)	Manual Method
Serum	Toxoplasma IgG	Abbott Architect
Serum	Toxoplasma IgM	Abbott Architect
Serum	<i>Treponema pallidum</i> Haemagglutination (TPHA)	Manual Method
Whole Blood	Tropinin I Quantative	Manual Method

Original date of accreditation: 25 June 2015

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**Mrs Pinkie J Malebe**  
**SADCAS Technical Manager**