

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,
MICROBIOLOGY 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

Date of Renewal of Accreditation: 23 July 2020
Effective Date (Issue No: 3): 22 May 2023
Certificate Expires: 22 July 2025

ANNEXURE A

SCHEDULE OF ACCREDITATION

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

<p>Permanent Address of Laboratory: Diagnofirm Medical Laboratories Gaborone Plot 12583 Nyerere Drive, Middle Star Gaborone Botswana</p> <p>Postal Address: Private Bag 283 Gaborone Botswana</p> <p>Tel : +267 395 0007 Cell : +267 77583859 Fax : +267 395 7980 Email : mohammed@diagofirm.co.bw</p>	<p>Technical Signatories : As authorized by the Head of the Laboratory</p> <p>Nominated Representative : Dr Mohammed Chand</p> <p>Issue No : 04 Date of issue : 22 May 2023 Expiry Date : 22 July 2025</p>
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DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
CLINICAL CHEMISTRY		
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 ₂)	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) ratiocalculated	Abbott Alinity
Serum	C-Reactive Protein (CRP) High Sensitive	Abbott Alinity
Serum	Creatine Kinase (CK)	Abbott Alinity
Serum	Creatine Kinase MB (CKMB)	Abbott Alinity
Serum, Urine	Creatinine	Abbott Alinity

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Laboratory Accreditation No: MED 012 (ISO 15189:2012)

Issue No: 04

Date of Issue: 22 May 2023

Date of Expiry: 22 July 2025

DISCIPLINE/SAMPLE TYPE	TYPES OF TESTS	EQUIPMENT/METHOD
<u>CLINICAL CHEMISTRY (cont'd)</u>		
Serum	Ferritin	Abbott Alinity
Serum	Gamma GlutamylTransferase (GGT)	Abbott Alinity
Serum	Globulins (calculated)	Abbott Alinity
Plasma, CSF, Urine	Glucose	Abbott Alinity
Whole blood	Glycosylated Haemoglobin HbA1c	Tosoh G8
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
<u>ENDOCRINOLOGY</u>		
Serum	Alpha Feto Protein	Bio Merieux Mini Vidas
Serum	Beta Human Chorionic Gonadotropin (β 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

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<u>ENDOCRINOLOGY (cont'd)</u>		
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
<u>HAEMATOLOGY</u>		
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	Full Blood Count and Differential Count	Abbott Emerald
Whole Blood	Malaria antigens	Manual Method
Whole Blood	Malaria Smears	Manual Method
Whole Blood	ESR	Manual Method
<u>MICROBIOLOGY</u>		
Urine	Wet preparation: <ul style="list-style-type: none"> Cells, casts, crystals, parasites 	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

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<u>MICROBIOLOGY cont'd</u>		
Pus Swabs, Ear, Eye, Throat, Wound, HVS, Urine	Culture on Selective and General Medium Antimicrobial Sensitivity Testing Bacterial Identification Techniques Biochemical Tests Catalase Coagulase Oxidase Electronic RapID Compendium(ERIC)	Manual Method Manual Method- Modified Kirby Bauer/ Vitek 2 Compact
<u>SEROLOGY</u>		
Serum	Antistreptolysin O Titre (ASOT)	Manual Method
Serum, Urine	Beta Human Chrionic Gonadotropin (β HCG) Screen	Manual Method
Serum	Cytomegalovirus (CMV) IgG	Abbott Architect
Serum	Cytomegalovirus (CMV) IgM	Abbott Architect
Serum	Helicobacter Pylori	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	RPR	Manual Method
Serum	Toxoplasma IgG	Abbott Architect
Serum	Toxoplasma IgM	Abbott Architect
Serum	Treponema Pallidum 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