

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 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 Pinkie J Malebe
For Chief Executive Officer**

**Original Date of Accreditation: 09 August 2022
Certificate Expires: 08 August 2027**

ANNEXURE A

SCHEDULE OF ACCREDITATION

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

| <p><u>Permanent Address of Laboratory</u> Namibia Institute of Pathology NIP Windhoek Reference Laboratory Windhoek Central Hospital Complex Windhoek Namibia</p> <p><u>Postal Address:</u> P O Box 277 Windhoek Namibia</p> <p><u>Tel</u> : +264 61 295 4001 <u>Cell</u> : +264 81 2772809 <u>Fax</u> : - <u>Email</u> : douglas.chiwara@nip.com.na</p> | | <p><u>Technical Signatories</u> : As Authorized by the Head of Laboratory</p> <p><u>Nominated Representative</u> : Mr Douglas Chiwara</p> <p><u>Issue No</u> : 01 <u>Date of Issue</u> : 09 August 2022 <u>Expiry Date</u> : 08 August 2027</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DISCIPLINE/SAMPLE TYPE | TYPES OF TESTS | EQUIPMENT/METHOD |
| <p><u>CLINICAL CHEMISTRY</u></p> <p>Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Serum Plasma Serum Serum Serum</p> | <p>Albumin ALP ALT AST Amylase Chloride Cholesterol Creatinine Compliment C3 Compliment C4 CRP Direct Bilirubin Total Bilirubin GGT Glucose Iron LDH Magnesium</p> | <p>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</p> |

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Issue No: 01

Date of Issue: 09 August 2022

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| 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 | IGA | Alinity CI |
| Serum | IgG | Alinity CI |
| Serum | IgM | Alinity CI |
| Whole Blood | Blood Gas pH | Radiometer ABL 80 |
| Whole Blood | Blood Gas PCO ₂ | Radiometer ABL 80 |
| Whole Blood | Blood Gas PO ₂ | Radiometer ABL 80 |
| <u>ENDOCRINOLOGY</u> | | |
| Serum | HCG | Alinity CI |
| Serum | Estradiol | Alinity CI |
| Serum | TSH | Alinity CI |
| Serum | LH | Alinity CI |
| Serum | Progesterone | Alinity CI |
| Serum | TSH | Alinity CI |
| Serum | T-PSA | Alinity CI |
| Serum | Prolactin | Alinity CI |
| Serum | FT3 | Alinity CI |
| Serum | FT4 | Alinity CI |
| Serum | Testosterone | Alinity CI |
| Serum | SHBG | Alinity CI |
| Serum | AFP | Alinity CI |
| Serum | CA-153 | Alinity CI |
| Serum | CA-125 | Alinity CI |
| Serum | CA-199 | Alinity CI |
| Serum | CEA | Alinity CI |
| Serum | Free PSA | Alinity CI |
| Serum | Ferritin | Alinity CI |
| Serum | Vitamin B12 | Alinity CI |
| Serum | FSH | Alinity CI |

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|------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------|
| <u>HAEMATOLOGY</u> | | |
| Whole Blood | WBC | Sysmex XN 1000i |
| Whole Blood | RBC | Sysmex XN 1000i |
| Whole Blood | HB | Sysmex XN 1000i |
| Whole Blood | HCT | Sysmex XN 1000i |
| Whole Blood | MCV | Sysmex XN 1000i |
| Whole Blood | MCH | Sysmex XN 1000i |
| Whole Blood | MCHC | Sysmex XN 1000i |
| Whole Blood | RDW | Sysmex XN 1000i |
| Whole Blood | Platelet Count | Sysmex XN 1000i |
| Plasma | APTT | ACL Elite |
| Plasma | 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 | EID | Cobas Ampliprep/Taqman 96 |
| <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 Pathogenic Organisms, Aerobic | Manual Method |
| Faecal Samples | 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 |
| Sputum/Bronchial/Tracheal | Macroscopy Gram Stain Culture and Isolation of Pathogenic Organisms, Aerobic | Manual Method |
| Cultures | Bacterial Identification Testing | Automated: Vitek 2XL |
| | Agglutination Testing | |
| | Wellcolex Salmonella | Manual Method |
| | Wellcolex Shigella | Manual Method |
| Cultures | Staphaurex | Manual Method |
| | Prolex Staph Latex | Manual Method |
| | Streptex | Manual Method |
| | API Identification | Manual Method |
| | <ul style="list-style-type: none"> • 20 E • 10 S | Manual Method Manual Method Manual Method |
| Cultures | Bacterial identification Techniques | Manual Method |
| | Antimicrobial Susceptibility Testing: | Automated: Vitek 2XL |
| | Disc Diffusion Kirby Bauer | 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 | CMV 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 | RPR | Manual Method |
| Serum | TPHA | Manual Method |

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Eva Muronda
For Technical Manager