

CERTIFICATE OF ACCREDITATION

In terms of section 22(2)(b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-

**AMPATH NATIONAL LABORATORIES
DRS DU BUISSON, KRAMER, SWART, BOUWER INC
DURDOC CENTRE
IMMUNOCHEMISTRY LABORATORY
Co reg no: 2007/018337/21
Practice no: 052 000 5200431**

Facility Accreditation Number: **M0147C**

is a South African National Accreditation System accredited laboratory
provided that all SANAS conditions and requirements are complied with

This certificate is valid as per the scope as stated in the accompanying schedule of accreditation,
Annexure "A", bearing the above accreditation number for

**MEDICAL TESTING LABORATORY
CHEMISTRY, ENDOCRINOLOGY AND SEROLOGY**

The facility is accredited in accordance with the recognised International Standard

ISO 15189:2007

*The accreditation demonstrates technical competency for a defined scope and the operation of a
laboratory quality management system*

While this certificate remains valid, the Accredited Facility named above is authorised to
use the relevant SANAS accreditation symbol to issue facility reports and/or certificates

**Mr R Josias
Acting Chief Executive Officer**

**Effective Date: 01 April 2010
Certificate Expires: 31 October 2013**

ANNEXURE A

SCHEDULE OF ACCREDITATION

Testing Laboratory Number: M0147C

<p><u>Permanent Address of Laboratory:</u> AMPATH National Laboratories Durdoc Centre Laboratory 9th Floor Durdoc Centre 460 Smith Street Durban</p> <p><u>Postal Address:</u> P O Box 62700 Bishopsgate 4008</p> <p>Tel : (031) 327-7500 Fax : (031) 327-7590</p>	<p><u>Signatories:</u> Signatories as authorised by the Head of Laboratory</p> <p><u>Contact Person:</u> Ms S Lambris Laboratory Manager</p> <p>Issue No. : 10 Date of issue : 19 April 2010 Expiry date : 31 October 2013</p>
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Discipline/ Sample Type	Types of Tests	Equipment/ Method
CHEMISTRY		
Serum, Plasma	Alanine Aminotransferase (ALT)	Modular
Serum, Plasma	Albumin	Modular
Serum, Plasma	Albumin (Micro)	Modular
Serum, Plasma	Alcohol	Axsym
Serum, Plasma	Alkaline Phosphatase (ALP)	Modular
Serum, Plasma, Urine, Fluid	Amylase	Modular
Serum, Plasma	Aspartate Aminotransferase (AST)	Modular
Serum, Plasma	Bence Jones Protein	Manual Method
Serum, Plasma	Bicarbonate (CO ₂)	Modular
Serum, Plasma	Bilirubin, Direct	Modular
Serum, Plasma	Bilirubin, Total	Modular
Serum, Plasma, Urine	Calcium (Total)	Modular
Serum, Plasma, Urine, CSF	Chloride	Modular
Whole Blood	Cholesterol (HDL)	Modular
Serum, Plasma	Cholesterol (LDL) Calculated	Modular
Serum, Plasma	Cholesterol (Total)	Modular
Serum, Plasma	Cholinesterase	Modular
Serum	Cotinine	Immulite 2000
Serum, Plasma	C-Reactive Protein (CRP)	Modular
Serum, Plasma	Creatine Kinase (CK)	Modular
Serum, Plasma, Urine	Creatinine	Modular
Stool	Faecal Electrolytes	Modular
Stool	Faecal Fat	Manual Method
Serum, Plasma	Gamma Glutamyl Transferase (GGT)	Modular
Plasma, CSF	Glucose	Modular
Plasma	Glucose Tolerance Test (GTT)	Modular
Whole Blood	HbA1c	Modular
Serum, Urine	Immunofixation Electrophoresis (IFE)	Sebia System
Serum, Plasma	Immunoglobulin A (IgA)	Modular

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Discipline/ Sample Type	Types of Tests	Equipment/ Method
<u>CHEMISTRY</u>		
<u>(CONTINUED)</u>		
Serum, Plasma	Immunoglobulin M (IgM)	Modular
Serum, Plasma	Immunoglobulin G (IgG)	Modular
Serum, Plasma	Iron	Modular
Serum, Plasma	Lactate	Modular
Serum, Plasma	Lactate Dehydrogenase (LDH)	Modular
Serum, Plasma	Lipase	Modular
Serum, Plasma, Urine	Magnesium	Modular
Urine, Stool	pH	pH Meter
Serum, Plasma, Urine	Phosphate	Modular
Urine	Porphobilinogen	Manual Method
Serum, Plasma, Urine	Potassium	Modular
Serum, Plasma, Urine, CSF	Protein (Total)	Modular
Serum, Plasma	Rheumatoid Factor (RF)	Modular
Serum, Urine	Serum Protein Electrophoresis (SPE)	Sebia Systems
Serum, Plasma, Urine	Sodium	Modular
Sweat	Sweat Test	Sweat Conductivity Analyser
Serum, Plasma	Transferrin	Modular
Serum, Plasma	Triglycerides	Modular
Serum, Plasma, Urine	Urate	Modular
Serum, Plasma, Urine	Urea	Modular
Urine	Urine Dipstick	Manual Method
<u>ENDOCRINOLOGY</u>		
Serum, Plasma	Acetaminophen	Integra
Serum, Plasma	Alpha fetoprotein (AFP)	Architect
Serum, Plasma	Amikacin	Integra
Urine	Amphetamines	Axsym
Serum, Plasma	Anti Thyroglobulin-antibodies (ATG)	Modular
Serum, Plasma	Anti Thyroid Peroxidase (ATPO)	Modular
Urine	Barbiturates	Axsym
Urine	Benzodiazepine	Axsym
Serum, Plasma	Beta Human Chorionic Gonadotrophin (β HCG) Qualitative	Manual Method / Commercial Kit
Serum, Plasma	Beta Human Chorionic Gonadotrophin (β HCG) Quantitative	Modular
Serum, Plasma	CA 125	Modular
Serum, Plasma	CA 15.3	Architect
Serum, Plasma	CA 19.9	Modular
Urine	Cannabinoids	Axsym
Serum, Plasma	Carbamazepine	Integra
Serum, Plasma	Carcinoembryonic Antigen (CEA)	Modular
Urine	Cocaine Metabolite	Axsym
Serum, Plasma	Cortisol	Modular
Whole Blood	Cyclosporin	Axsym
Serum, Plasma	Dehydroepiandrosterone Sulphate (DHEAS)	Modular
Serum, Plasma	Digoxin	Integra

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ENDOCRINOLOGY		
(CONTINUED)		
Amniotic Fluid	Fetal Lung Maturity (FLM)	IMX
Serum, Plasma	Ferritin	Modular
Serum, Plasma	Folate	Modular
Serum, Plasma	Follicle Stimulating Hormone (FSH)	Modular
Serum, Plasma	Free Thyroxine (F-T4)	Modular
Serum, Plasma	Free Triiodothyronine (F-T3)	Modular
Serum, Plasma	Gentamicin	Integra
Serum, Plasma	Homocystine	Axsym
Serum, Plasma	Immunoglobulin E (IgE) Specific	Immunocap 250
Serum, Plasma	Immunoglobulin E (IgE) Total	Immunocap 250
Serum, Plasma	Insulin	Architect
Serum	Lithium	Integra
Serum, Plasma	Luteinising Hormone (LH)	Modular
Serum, Plasma	Methotrexate	TDX
Serum, Plasma	Oestradiol (E2)	Modular
Serum	Oestriol, Unconjugated	Immulite 2000
Urine	Opiates	Axsym
Serum, Plasma	Phadiatop	Immunocap 250
Serum, Plasma	Phenobarbitone	Integra
Serum, Plasma	Phenytoin	Integra
Serum, Plasma	Progesterone	Modular
Serum, Plasma	Prolactin	Modular
Serum	Prostate Specific Antigen (PSA) Free	Calculation
Serum	Prostate Specific Antigen (PSA) Total	Architect
Serum, Plasma	Salicylate	Integra
Serum, Plasma	Sex Hormone Binding Globulin (SHGB)	Modular
Serum, Plasma	Sirolimus	Architect
Serum, Plasma	Tacrolimus	Architect
Serum, Plasma	Theophylline	Integra
Serum, Plasma	Thyroid Stimulating Hormone (TSH)	Modular
Serum, Plasma	Tobramycin	Integra
Serum, Plasma	Valproic Acid	Integra
Serum, Plasma	Vancomycin	Integra
Serum, Plasma	Vitamin B12	Modular

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Discipline/ Sample Type	Types of Tests	Equipment/ Method
SEROLOGY		
Serum	Antinuclear Factor (ANF)	Manual Method / Commercial Kit
Serum	Autoantibodies Screen	Manual Method / Commercial Kit
Serum	Bilharzia IgA	Manual Method / Commercial Kit
Serum	Bilharzia IgG	Manual Method / Commercial Kit
Serum	Bilharzia IgM	Manual Method / Commercial Kit
Serum	Brucella Coombs	Manual Method / Commercial Kit
Serum	Brucella IgM	Manual Method / Elisa
Serum	Brucella Coombs	Manual Method / Commercial Kit
Serum	Cellognost Amoebiasis	Manual Method / Commercial Kit
Serum	Chlamydia Trachomatis Detection	Manual Method / Commercial Kit
Serum, Plasma	Cytomegalovirus (CMV) IgG	Architect
Serum, Plasma	Cytomegalovirus (CMV) IgM	Architect
Serum	DNA IgG and IgM Antibodies	Manual Method / Commercial Kit
Serum	Epstein-Barr Virus (EBV) Early Antibodies	Manual Method / Commercial Kit
Serum	Epstein-Barr Virus (EBV) IgG and IgM	Manual Method / Commercial Kit
Serum	Epstein-Barr Virus (EBV) Nuclear Antibody	Manual Method / Commercial Kit
Serum	Extractable Nuclear Antigen Antibodies (ENA)	Manual Method / Commercial Kit
Serum, CSF	FTA	Manual Method / Commercial Kit
Serum, Plasma	Hepatitis A IgG Antibodies (HAVAB)	Architect
Serum, Plasma	Hepatitis A Virus Antibodies (HAVAB-M)	Architect
Serum, Plasma	Hepatitis B Core Antigen	Architect
Serum, Plasma	Hepatitis B Core M (CORE-M)	Architect
Serum, Plasma	Hepatitis B Early Antigen (HbE)	Architect
Serum, Plasma	Hepatitis B Surface Antibody	Architect
Serum, Plasma	Hepatitis B Surface Antigen (HbSAB)	Architect
Serum, Plasma	Hepatitis B Surface Antigen Confirmatory	Architect
Serum, Plasma	Hepatitis C Virus (HCV)	Architect
Serum	Herpes Simplex Virus (HSV) 1 and 2 IgG	Manual Method / Commercial Kit
Serum	Herpes Simplex Virus (HSV) 1 and 2 IgM	Manual Method / Commercial Kit
Serum, Plasma	HIV	Manual Method / Commercial Kit
Serum	Mycoplasma IgG and IgM	Manual Method / Commercial Kit
Serum, Plasma	Rubella IgG	Architect
Serum, Plasma	Rubella IgM	Architect
Serum, Plasma	Syphilis IgG	Manual Method / Commercial Kit
Serum, Plasma	Toxoplasma IgG	Axsym
Serum, Plasma	Toxoplasma IgM	Axsym
Serum	VDRL	Manual Method / Commercial Kit
Serum	Weil-felix Test	Manual Method / Commercial Kit
Serum, Plasma	Western Blot	Autoblot
Serum	Widal Test	Manual Method / Commercial Kit

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