

# **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  
GEORGE LABORATORY  
Co reg no: 2007/018337/21  
Practice no: 052 000 5200431**

Facility Accreditation Number: **M0347**

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, HAEMATOLOGY AND MICROBIOLOGY**

*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  
Chief Executive Officer**

**Effective Date: 01 February 2010  
Certificate Expires: 31 January 2014**

ANNEXURE A

**SCHEDULE OF ACCREDITATION**

Testing Laboratory Number: M0347

<p><b>Permanent Address of Laboratory:</b>                  Ampath National Laboratories                  George Laboratory                  Shop 8A                  Prince Vincent Building                  Langehoven Street                  George</p> <p><b>Postal Address:</b>                  Same as above</p> <p>Tel : (044) 884-1946                  Fax : (044) 874-3572</p>	<p><b>Signatories:</b>                  Signatories as authorised by the                  Head of Laboratory</p> <p><b>Contact Person:</b>                  Mr R Gilmore <span style="float: right;">Area Manager</span></p> <p>Issue No. : 05                  Date of issue : 22 July 2010                  Expiry date : 31 January 2014</p>
---	---

Discipline/ Sample Type	Types of Test	Equipment/ Method
<b>CHEMISTRY</b>		
Serum	Alanine Aminotransferase (ALT)	CX9
Serum	Albumin	CX9
Serum	Alkaline Phosphatase (ALP)	CX9
Serum	Amylase	CX9
Serum	Aspartate Aminotransferase (AST)	CX9
Serum	Beta Human Chorionic Gonadotrophin (βHCG) Quantitative	Access 2
Serum	Bicarbonate (CO <sub>2</sub> ) (Total)	CX9
Serum	Bilirubin, Direct	CX9
Serum	Bilirubin, Total	CX9
Whole Blood	Blood Gasses: Glucose	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: Ionised Calcium	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: Lactate	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: pCO <sub>2</sub>	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: pH	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: pO <sub>2</sub>	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: Potassium	Gem Premier 3000 Ilex
Whole Blood	Blood Gasses: Sodium	Gem Premier 3000 Ilex
Serum	CA 125	Access 2
Serum	CA 15.3	Access 2
Serum	CA 19.9	Access 2
Serum	Calcium (Total)	CX9
Serum	Carcinoembryonic Antigen (CEA)	Access 2
Serum, CSF	Chloride	CX9
Serum	Cholesterol (HDL)	CX9
Serum	Cholesterol (Total)	CX9
Serum	C-Reactive Protein (CRP)	CX9
Serum	Creatine Kinase (CK)	CX9
Serum	Creatine Kinase MB (CKMB)	Access 2
Serum, Urine	Creatinine	CX9
Serum	Estradiol (E2)	Access 2
Serum	Follicle Stimulating Hormone (FSH)	Access 2
Serum	Free Thyroxine (F-T4)	Access 2
Serum	Free Triiodothyronine (F-T3)	Access 2
Serum	Gamma Glutamyl Transferase (GGT)	CX9
Serum, CSF	Glucose	CX9
Serum	HIV	Access 2

## ANNEXURE A

Laboratory No: M0347  
Date of issue: 22 July 2010  
Expiry date: 31 January 2014

Discipline/ Sample Type	Types of Test	Equipment/ Method
<b><u>CHEMISTRY</u></b>		
<b><u>(CONTINUED)</u></b>		
Serum	Lactate Dehydrogenase (LDH)	CX9
Serum	Luteinising Hormone (LH)	Access 2
Serum	Magnesium	CX9
Serum	Myoglobin	Access 2
Serum	Paul Bunnel	Manual Method-Microgen Kit
Serum	Phosphate	CX9
Serum	Potassium	CX9
Serum	Progesterone	Access 2
Serum	Prolactin	Access 2
Serum	Prostate Specific Antigen (PSA) (Free)	Access 2
Serum	Prostate Specific Antigen (PSA) (Total)	Access 2
Urine, CSF	Protein (Micro)	CX9
Serum	Protein (Total)	CX9
Serum	Sodium	CX9
Serum	Thyroid Stimulating Hormone (TSH)	Access 2
Serum	Triglycerides	CX9
Whole Blood	Troponin T	Cardiac Reader
Serum	Troponin I	Access 2
Serum	Urate	CX9
Serum	Urea	CX9
Serum	Weil Felix	Manual Method-Sep Scient
<b><u>HAEMATOLOGY</u></b>		
Plasma	Activated Partial Thromboplastin Time (APTT)	Coatron M2
Plasma	D-Dimer	Cardiac Reader
Whole Blood	Differential Cell Count	Manual Method
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Westergren
Plasma	Fibrin Monomer	Manual Method
Whole Blood	Full Blood Count and Platelets	Cell-Dyne 3500R
Whole Blood	Malaria Antigens	Manual Method-Now-Binax
Whole Blood	Malaria Smears	Manual Method
Plasma	Prothrombin Index (PI)	Coatron M2
Whole Blood	Reticulocyte Count	Manual Method
<b><u>MICROBIOLOGY</u></b>		
Urine, Stool	Microscopy Including Parasites	Manual Method
Urine, Stool	Iodine Wet Preparation	Manual Method
Urine, Stool	Saline Wet Preparation	Manual Method
Body Fluids, Swabs, Tissue, Sputum	Gram Stains – Including Detection of Yeast	Manual Method
Body Fluids, Swabs, Tissue, Sputum	Differential Counts	Manual Method
Body Fluids, Swabs, Tissue, Sputum	AFB	Manual Method
Semen	Wet Preparation	Manual Method
Semen	Count	Manual Method
Semen	Motility	Manual Method
Urine Biochemistry	Dipstick	Manual Method

Original date of accreditation: 01 December 2003

Page 2 of 3

**Senior Manager**

## ANNEXURE A

Laboratory No: M0347  
Date of issue: 22 July 2010  
Expiry date: 31 January 2014

Discipline/ Sample Type	Types of Test	Equipment/ Method
<b>MICROBIOLOGY (CONTINUED)</b>		
Stool, Urine, Body Fluids, Genital Tract, Upper Respiratory Tract, Blood Cultures, Superficial Sites, Sputum	Aerobic, Anaerobic & Micro-aerophilic Cultures Cultures for Sterility	Manual Method Cultures on Media Bactec 9050
Genital Swabs	Urea Plasma & Mycoplasma	Manual Method-kit
	Antimicrobial Susceptibility Testing: Disk diffusion	Manual Method
	Micro-organism Identification Techniques: Organisms are Identified up to Species Level (except urines), Using Various i.d. Systems e.g. API, Satellitism, DNase, Bile Esculin, Catalase, Beta Lactamase, Spot Indole Test, 6.5% Sodium Chloride Agar, Germ Tube, Staphylococcus Streak Technique, S.Aureus Latex Agglutination Test, Optochin, Bacitracin, Novobiocin, Oxacillin Disc Susceptibility Testing, DNase	Manual Method
Sputum	RSV Detection	Manual Method-kit
Stool	Adenovirus	Manual Method
Stool	Occult Blood	Manual Method-kit
Stool	Rotavirus	Manual Method
Stool	Salmonella Serotyping	Polyvalent
Stool	Shigella Serotyping	Polyvalent
CSF	Bacterial Antigen	Manual Method-kit
CSF, Urine	Group B Antigen	Manual Method-kit
Swabs	Influenza A & B Rapid Test	Manual Method-kit

Original date of accreditation: 01 December 2003

Page 3 of 3

ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

**Senior Manager**