



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:-

**NATIONAL HEALTH LABORATORY SERVICE (NHLS)
GROOTE SCHUUR HOSPITAL
SEROLOGY & VIROLOGY LABORATORY
Practice No.: PR 5200296**

Facility Accreditation Number: **M0199D**

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
MOLECULAR VIROLOGY 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
Chief Executive Officer

Effective Date: 01 July 2010
Certificate Expires: 30 June 2014



ANNEXURE A

SCHEDULE OF ACCREDITATION

Facility Number: M0199D

Permanent Address of Laboratory: National Health Laboratory Service (NHLS) Grootte Schuur Hospital Serology & Virology Laboratory C17 / C 18, Grootte Schuur Hospital Observatory 7925		Signatories: Signatories as authorised by the Head of Laboratory	
Postal Address: Grootte Schuur Hospital Serology & Virology Laboratory Observatory 7935		Contact Person: Dr D Roditi	
Tel: (021) 404-5280 Fax: (021) 404-5281 E-mail: leigh.johnson@nhls.ac.za		Issue No.: 07 Date of Issue: 14 September 2012 Expiry Date: 30 June 2014	
Discipline / Sample Type	Type of Tests	Equipment / Method	
MOLECULAR VIROLOGY Serum, Urine Urine, Whole Blood, Aspirates, Biopsy Whole Blood Whole Blood, Biopsy Whole Blood Serum, CSF, Stool, Throat Swab Serum Serum Serum Plasma CSF, Serum, Swabs, Aspirates, Biopsy Whole Blood, Dried Blood Spot Plasma Biopsy Whole Blood, CSF Plasma, CSF Whole Blood, Aspirates, Biopsy CSF Urine, Whole Blood, Respiratory Sample Respiratory Sample Pericardial Fluids, Aspirates Serum, Amniotic Fluid, Bone Marrow Urine, Amniotic Fluid Aspirates, Amniotic Fluid, CSF CSF, Serum, Swabs, Aspirates, Biopsy	BK Virus Cytomegalovirus (CMV) Cytomegalovirus (CMV) Viral Load Epstein-Barr Virus (EBV) Epstein-Barr Virus (EBV) Viral Load Enterovirus Hepatitis B Hepatitis B Viral Load Hepatitis B Drug Resistance (Lamivudine) Hepatitis C Genotyping Herpes Simplex Virus HIV-1 HIV-1 Viral Load HPV HTLV-1 HHV-6 HHV-8 JC Virus Measles Multiple Respiratory Virus Mycobacterium Tuberculosis Parvovirus Rubella Toxoplasma Gondii Varicella-Zoster	In-house PCR In-house PCR CMV R-Gene Kit In-house PCR LC Kit In-house PCR In-house PCR Cobas TaqMan In-house PCR & Sequencing Line Probe Assay In-house PCR Amplicor v1,5 PCR / Cobas TaqMan HIV-1 Qual Test M2000SP / RT In-house PCR In-house PCR In-house PCR In-house PCR In-house PCR In-house PCR Seeplex RV-7 Kit (Seegene) PCR In-house PCR In-house PCR In-house PCR In-house PCR In-house PCR	

Original Date of Accreditation: 01 July 2006

Page 1 of 2

Cleball
 Senior Manager

ANNEXURE A

Facility No.: M0199D
 Date of Issue: 14 September 2012
 Expiry Date: 30 June 2014

Discipline / Sample Type	Type of Tests	Equipment / Method
SEROLOGY		
Stool	Adenovirus 40/41	Immunochromatographic Strip Test
Serum	Cytomegalovirus IgM	Mini Vidas
Serum	Cytomegalovirus IgG	Architect
Serum	Epstein Barr Virus (EBV) Monospot	Manual Method
Serum	Epstein Barr Virus (EBV) EBNA (IgG)	Mini Vidas
Serum	Epstein Barr Virus (EBV) VCA IgM	Mini Vidas
Serum	Hepatitis A IgG	Architect
Serum	Hepatitis A IgM	Architect
Serum	Hepatitis B Core Antibodies (Total)	Architect
Serum	Hepatitis B Core IgM	Architect
Serum	Hepatitis B Early Antibody	Architect
Serum	Hepatitis B Early Antigen (HbE)	Architect
Serum	Hepatitis B Surface Antibody (AUSAB)	Architect
Serum	Hepatitis B Surface Antigen (HBsAg)	Architect
Serum	Hepatitis C Antibody	Architect / Manual Method-Elisa
Serum	Herpes Simplex 1 IgG	Manual Method-Elisa
Serum	Herpes Simplex 1/2 IgM	Manual Method-Elisa
Serum	Herpes Simplex 2 IgG	Manual Method-Elisa
Serum, Dried Blood Spot	HIV 1 & 2 Antibody	Manual Method-Elisa
Serum	HIV 1 p24 Antigen	Mini Vidas
Serum, Dried Blood Spot	HIV 1/2 Ab/p24 Antigen Combo	Architect
Serum	HIV Rapid	Manual Method
Serum	Measles IgG	Mini Vidas
Serum	Parvovirus B19 IgM and IgG	Manual Method-Elisa
Stool	Rotavirus Direct Detection on Stool	Immunochromatographic Strip Test
Serum	Rubella IgG	Architect
Serum	Rubella IgM	Mini Vidas
Serum	Toxoplasma Gondii IgG and IgM	Mini Vidas
Serum	Varicella-Zoster IgG	Mini Vidas

Original Date of Accreditation: 01 July 2006

Page 2 of 2

ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

Cleballo
 Senior Manager