Laboratory Accreditation at Tertiary Institutions

“Improving the quality of results”

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INTRODUCTION

The South African National Accreditation System (SANAS) and various academic institutions established a partnership programme. The aims of the partnership programme are:

- To promote awareness of laboratory accreditation and the use of relevant standards;
- To develop skills of laboratory personnel, researchers and lecturers to apply international standards applicable to laboratories;
- To jointly develop a programme that provides practical and work experience that will expose staff and students to the operations of an accreditation body;
- To train and monitor selected potential technical assessors for the SANAS assessors pool; and
- To continue provide any technical expertise to SANAS for its accreditation activities.

This brochure profiles laboratories at several academic institutions that are implementing international standards.

The international standards applied are recognised as best international practice as they improve the quality and consistency of laboratory results. Other identified benefits are improved efficiency, increased productivity and improved bottom line. There has been noticeable improvement in customer focus and customer service. Personnel that work in the laboratories noticed an improvement in staff morale and enhanced team awareness.

Where laboratories provided commercial testing services, they benefited from an increased confidence to be able to provide credible evidence of good practices and to produce results that are accurate, traceable and reproducible. They are also in a position to demonstrate that a prescribed level of technical competence has been achieved.

Certificates issued by a SANAS accredited laboratories are accepted and recognised throughout the world by other accreditation bodies, that are signatories to the International Laboratory Accreditation Co-operation.
WHAT IS AN INTERNATIONAL STANDARD?

An international standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

WHICH INTERNATIONAL STANDARDS ARE USED BY LABORATORIES?

The International Standards used by laboratories are: ISO 17025 and ISO 15089. ISO 17025 applies to test and calibration laboratories and ISO 15089 to medical laboratories.

WHAT ARE THE REQUIREMENTS OF THE ABOVEMENTIONED STANDARDS?

Some of the key requirements are the following:

- A documented management system that gives direction to the laboratory activities and directives to the staff to achieve effectiveness and efficiency in the laboratory;
- The qualifications, training and on-going competence monitoring of staff of the laboratory is important. The technical competence of the staff has to be relevant in terms of experience and sector expertise;
- The laboratory has access to all the necessary equipment or facilities that is maintained and calibrated;
- The laboratory uses the correct methods that is repeatable, reproducible and demonstrate correct performance in terms of accuracy, precision, detection limits and robustness;
- The laboratory carefully manages the handling, storing protection, transport, etc of test items;
- The laboratory controls and monitors the environmental conditions in order to maintain at a level that is conducive to laboratory work; and
- The laboratory observes professional secrecy with regard to all information gained in carrying out its tasks.
Department of Chemistry
FORENSIC TOXICOLOGY LABORATORY

Services of the laboratory:
The Forensic drug testing laboratory at the University of Pretoria is equipped with state-of-the-art technology and is accredited to perform analysis for illicit compound body fluids namely (urine/blood/saliva). This facility is also the first forensic laboratory in South Africa that can perform hair analysis to test for the presence of drugs-of-abuse.

Accreditation date: 14 August 2012

Period of Accreditation: Eight months

Technical Signatories:
• Dr T Laurens
• Ms M Jordaan
• Ms H Kruger

Activities in the laboratory:
• Laboratory output: Approximately 10 000 analyses have been performed since inception of the Forensic Laboratory.

Research impact:
• The UP Forensic Laboratory specializes in the analysis of “Internet” and designer drugs as well as hair analysis.
Department: Veterinary Tropical Diseases  
FACULTY OF VETERINARY SCIENCES  
BACTERIOLOGY

Services of the laboratory:

Isolation and identification of:
- Aerobic and facultative anaerobic bacteria;
- Anaerobic bacteria;
- Mycoplasma;
- Yeasts and fungi;
- Antimicrobial sensitivity testing;
- Selective isolation of Salmonella species;
- Serotyping of Salmonella species;
- Minimum Inhibitory Concentration testing (only for large numbers of isolates and by prior arrangement); and
- Testing of disinfectant efficacy against bacteria (by prior arrangement – not routine testing).

Technical Signatories:
- Mr J Gouws
- Ms D Landman
- Mr E Kapp
- Ms H Bunge
- Ms J Greyling

Participants in the SANAS accreditation assessments in your laboratory:
- Prof A Michel
- Mr J Gouws
- Mr E Kapp
- Miss D Landman

Activities in the Laboratory:
- Delivery of a diagnostic service to the Onderstepoort Veterinary Academic Hospital (OVAH), Section of Pathology, Section: Poultry Health and other Departments in the Faculty of Veterinary Science.
- Generation of research information
- Training of post-graduate students in laboratory techniques needed to perform and complete their research projects.

Research impact:
- The DVT&D is a research intensive department and the laboratory is an important pillar to both Departmental and Faculty Research Projects on an ongoing basis.
Commercial impact
• Testing of disinfectants for efficacy against bacteria by prior arrangement.
• Service to the OVAH and the poultry industry through the Section: Poultry Health.

Figure 1. Training in the Bacteriology laboratory
Laboratory Accreditation at Tertiary Institutions

**Department: Veterinary Tropical Diseases**

**FACULTY OF VETERINARY SCIENCES**

**HELMINTHOLOGY**

**Services of the laboratory:** Diagnosing parasites of veterinary importance

**Accreditation date:** N/A

**Period of Accreditation:** N/A

**Technical Signatory in the laboratory:** Dr EV Schwan

**Participants in the SANAS accreditation assessments:**
- Ms D Durand
- Mr LCF Taljaard
- Dr EV Schwan

**Laboratory output:**
The laboratory delivers a diagnostic service to veterinarians both abroad and within the Southern African region.

**Research impact:**
- Training of the occasional post graduate student in various diagnostic techniques
- Providing bench space (at predetermined cost) to perform acquired techniques

**Providing Commercial impact:**
The main income of the laboratory is generated from the diagnostic testing of canines destined for import into South Africa or export to various other countries. The laboratory also provides general diagnostic services to local veterinarians, in the fields of helminthology, protozoology and ectoparasitology.

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**Fig 1. Mr Louis Taljaard at work in the Helminthology laboratory**

**Fig 2. Parascaris equorum nematodes from a horse**
Department: Production Animal Studies
FACULTY OF VETERINARY SCIENCES
MILK LABORATORY

Services of the Laboratory:
Diagnostic, research, clinical trials and student training.

Accreditation date:
Aiming for first SANAS application in 2014 DAFF Approved.

Period of Accreditation:
SANAS accreditation not yet applicable. Department of Agriculture, Forestry and Fisheries (DAFF) approved from 2010 to January 2015

Technical signatories:
Reports: Dr I Petzer and Ms J Karzis (Proxy)

Participants in accreditation assessments:
Dr I Petzer (Laboratory Manager), T van Der Schans (Quality Manager) and Ms J Karzis (Deputy Quality Manager)

Activities in the Laboratory:
• Diagnostic and research laboratory offering both microbiology and cytology on individual cow and herd basis, as well as bulk milk and water analysis;
• Two PhD and one MedVet student are utilising data from the laboratory for their degrees. Five students completed the final year of their Diploma in Veterinary Technology successfully from 2009 to 2013. Two obtained their B. Tech degree (2012 and 2013);
• The average output per year from the Milk laboratory over the past 5 years was 140 000 samples, representing 560 clients.

Research Impact for period 2009 to date (professional personnel: 2)
• The milk laboratory performs research utilising routine milk samples;
• Publications in peer reviewed journals: 6;
• Published full length conference papers/keynote addresses: 7;
• Papers presented at scientific meetings: 15;
• Poster presented at scientific meetings: 5;
• Guideline for anti-mastitis medicine 2013;
• Udder health and milking machine guideline book published 2010;
• Non-refereed publications or popular articles: 17; and
• Continuing education course/congresses national and international: 17

Commercial Impact for period 2009 to date:
• The laboratory assists the industry with trials when requested;
• Participate in national and international congresses;
- Co-presenter of the Production Animal Studies in Dairy Herd Health course.
Veterinary Tropical Disease Department
FACULTY OF VETERINARY SCIENCES
MOLECULAR BIOLOGY

Services of the laboratory:
Reverse line blot (RLB) hybridization assay for the detection of Theileria/Babesia and Ehrlichia/Anaplasma species. Real-time Polymerase Chain Reaction (RT-PCR) for detection of Mycoplasma gallisepticum (MG) and Mycoplasma synoviae (MS). Polymerase Chain Reaction (PCR) for the detection of Lumpy Skin Disease. PCR for the detection of Salmonella Enteritidis (SE) in faecal and environmental samples (development in progress).

Accreditation date: N/A

Period of Accreditation: N/A

Technical Signatories:
• Prof E Venter
• Prof M Oosthuizen

Participants in the SANAS accreditation assessments:
• Prof E Venter
• Prof M Oosthuizen
• Miss A-M Bosman
• Mrs M Troskie
• Miss I Vorster
• Mr K Ledwaba

Activities in the Laboratory:
• Perform RLB hybridization assay to detect Theileria/Babesia and Ehrlichia/Anaplasma species as a diagnostic test and for research projects;
• Perform MG/MS RT-PCR for the poultry industry through the Section: Poultry Health at the Faculty;
• Perform RT-PCR for detection of SE for the Veterinary Academic Hospital and for the poultry industry through the Section: Poultry Health at the Faculty (development in progress).

Research impact:
• Training and assistance of post-graduate students during their research projects:
  ◦ Assistance of researchers during their research projects.
  ◦ Generation of research material through diagnostic services.

Commercial impact:
• Supporting the poultry industry by providing a diagnostic service.
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Fig 1. Reverse line blot (RLB)

Fig 2. Molecular Biology laboratory
Veterinary Tropical Disease Department
SEROLOGY

Services of the laboratory:
ELISA tests for Avian Influenza (AI), Newcastle Disease (NDV), Mycoplasma gallisepticum (MG), Mycoplasma synoviae (MS), Infectious Bronchitis Virus (IBV), Infectious Bursal Disease Virus (IBD) Haemagglutination-inhibition tests for AI, NDV Plate agglutination tests for Salmonella Enteritidis, BWD, MG and MS. Indirect Immunofluorescent tests for Ehrlichia canis, Canine Distemper Virus and other canine and feline viruses. Snap ELISA test for Feline Immunodeficiency Virus (FIV) and Feline Leukemia Virus (FeLV).

Accreditation date: N/A

Period of Accreditation: N/A

Technical Signatory:
• Ms J Greyling
• Mr M Khoza
• Ms R Mahlare
• Ms K Sefara

Participants in the SANAS accreditation assessments:
• Dr J Crafford
• Mr J Gouws
• Miss J Greyling
• Mr M Khoza
• Mrs E Cornelius
• Miss R Mahlare
• Miss K Sefara

Activities in the Laboratory:
• Delivery of a diagnostic service to the Onderstepoort Veterinary Academic Hospital regarding serological testing on small animal diseases;
• Delivery of a service to the poultry industry through the Poultry Health Section in the Faculty; and
• Testing of canine sera from Quarantine Stations for antibodies to Ehrlichia canis for immigration to New Zealand, Australia and certain other countries if required.

Research impact:
• Training and assistance of post-graduate students in applicable techniques used in their research projects; and
• Assistance of research personnel in research projects.
Commercial impact:
- Service rendering to the poultry industry; and
- Service rendering to Quarantine Stations regarding immigration of dogs (E. canis testing).
Veterinary Tropical Disease Department
VIROLOGY

Services of the laboratory:
• Preparation and maintenance of tissue cultures for diagnostic and research purposes.
• Isolation of mammal viruses on tissue culture.
• Isolation of poultry viruses on embryonated chicken eggs.
• Perform Serum Neutralization Tests (SNTs) to determine virus and or antibody titers.
• Perform testing for the determination of disinfectant efficacy against viruses.

Accreditation date: N/A

Period of Accreditation: N/A

Technical Signatory:
• Ms C Lourens
• Ms K Ebersohn
• Ms P Wambulawaye

Who participates in the SANAS accreditation assessments in your laboratory:
• Prof M van Vuuren
• Mr J Gouws
• Miss J Greyling
• Mrs C Lourens
• Miss K Ebersohn

Laboratory output:
• Preparation and supply of tissue cultures;
• Virus isolation on tissue culture and embryonated eggs;
• SNT tests for virus and antibody level determination; and
• Testing of disinfectant efficacy.

Research impact:
• Training and assistance of post-graduate students during their research projects;
• Assistance of researchers during their research projects; and
• Generation of research material through diagnostic services.

Commercial impact:
• Disinfectant testing for the industry.
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Fig 2. Molecular Biology laboratory

Fig 2. Ms Carina Lourens and Ms Karen Ebersohn in the Virology laboratory
Vision:
The UPBRC is committed to assist the University of Pretoria in becoming a leading research University.

Services of the UPBRC:
• Platform for testing of efficacy of new chemicals in treatment of human and animal diseases;
• Platform for studying infectious diseases to derive vaccines and technologies to improve human and animal health;
• Provide an accredited platform for evaluation of toxicity of chemicals used in crop science, to improve plant productivity while promoting human health and safety;
• Provide a platform for the evaluation of new medical devices and surgical techniques in animal models, prior to implementation in people;
• Provide a platform for testing of new foods to demonstrate their nutritional benefit in the absence of toxicity; and
• Provide a platform for undergraduate and post-graduate student training.

The UPBRC is working towards accreditation in terms of the Organisation for Economic Development and Cooperation Good Laboratory Practices (OECD GLP) and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products Good Clinical Practice (VICH GCP).
The UPBRC is an interfaculty multi-purpose animal facility that can house and maintain animals of various sizes and species under various controlled housing conditions. We support controlled laboratory and domestic animal research projects and/or biomedical training courses with a medical, veterinary or natural science focus.
Department: Paraclinical Sciences  
FACULTY OF VETERINARY SCIENCES  
VETERINARY HISTOPATHOLOGY

Services of the laboratory:  
• Histopathology Services;  
• Immunohistochemistry on paraffin blocks e.g. Rabies, RVF (Rift Valley Fever), BVDV (Bovine Viral Diarrhea Virus), Heartwater; and  
• Special stains, e.g. Ziehl-Neelsen, Reticulin fibres stain, Gram stain

Accreditation date: N/A; currently approved by DAFF

Period of Accreditation: N/A

Technical Signatory:  
• Prof L Prozesky  
• Prof MC Williams  
• Prof NM Duncan  
• Dr JH Williams  
• Dr SJ Clift  
• Dr JCA Steyl

Participants in the SANAS accreditation assessments:  
• Ms RM Phaswane  
• Ms N Timmerman  
• Mr P Mokonoto  
• Ms J Breedt  
• Prof L Prozesky  
• Dr SJ Clift  
• Dr JCA Steyl

Laboratory output:  
• Delivery of a diagnostic service to the Onderstepoort Veterinary Academic Hospital (OVAH), as well as private clients and other Departments at the Faculty of Veterinary Science;  
• Generation of research material through the diagnostic service offered; and  
• The laboratory also acts as a training facility for both veterinary and technical student.

Research impact:  
• The immunohistochemistry laboratory is an important resource for both Departmental and Faculty Research Projects on an on-going basis.  
• Training of postgraduate students in laboratory techniques required for their research projects.
Commercial impact:
• high quality diagnostic service is crucial for agriculture and the Republic of South Africa, particularly for production animals, poultry and the game industry. The Histopathology laboratory contributes immensely in that regard.

Fig 1. Loading the tissue processor
Fig 2. Mounting stained slides
FACULTY OF VETERINARY SCIENCES
VETERINARY GENETICS LABORATORY

Services of the laboratory:
• Genotyping and Parentage analysis of domestic and wild animals;
• Species identification by means of sequencing analysis;
• Population analysis for breeding and conservation management;
• Forensic DNA testing;
• Supply of routine and forensic DNA collection kits;
• RhODIS: an international rhino DNA profile database; and
• Animal identification: specifically internationally recognised horse ID system.

Activities within the laboratory:
• Wildlife DNA evidence collection training;
• Supply animal DNA evidence in forensic court cases;
• Optimise genotyping tests in various species;
• Training of post graduate students;
• On-going research to improve current protocols within the laboratory;
• Presentations for schools and special interest groups;
• Collaboration with conservation organisations and international scientists;
• Regular interviews for local and international media;
• Participate in international comparison tests; and
• Electronic field data collection systems.

Research Impact:
• Publications in prominent scientific journals;
• Hosting and supervising post graduate and internal students; and
• Various current research projects in molecular diagnostics; forensic DNA testing and genetic testing.

Commercial Impact:
• Identification and micro chipping of thoroughbred race horses; and
• Commercial DNA genotyping and parentage of wildlife and domestic species.

Global Impact:
• Assisting in fighting international wildlife crime; and
• Raising poaching awareness through local and international media.
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Fig 1. RHODIS App launch

Fig 2. Wildlife crime workshop

Fig 3. Rhino capturing
PLANT PATHOLOGY LABORATORIES
MICROBIOLOGY AND PLANT PATHOLOGY

Services of the laboratory:
• Detecting plant pathogens using PCR i.e. citrus black spot;
• Total microbial counts of agricultural samples;
• Identification of bacteria using the API system;
• Identification of bacteria using the BIOLOG system; and
• Detecting coliform bacteria in packhouse water using the colilert system.

Accreditation date: 2001-2006

Period of Accreditation: 5 years

Who is the Technical Signatory in your laboratory:
• Ms A Lombard
• Ms Z Zulu

Who participates in the SANAS accreditation assessments in your laboratory:
• Please advise on the Laboratory output:
  Plant Pathology Laboratories output for commercial diagnostic testing can be considered low primarily due to the non-commercial status of the unit and its mandate to focus on research and training. Due to this and other financial constraints it was decided to discontinue accreditation in 2006. However, we have been able to retain most of the laboratory quality elements of ISO 17025 and run six laboratories on these principles. The elements of the standard retained within the academic environment have enabled us to train more than 60 postgraduate students and 18 staff members in ISO 17025 laboratory practices over the past 10 years. We have also been able to identify the critical elements of the ISO management system that best fit and support best practices in academic research laboratories.

• Research impact:
The Plant Pathology Laboratories was the first of its kind in South Africa (SA) to establish a diagnostic facility for plant disease identification and for screening biocontrol products for the agricultural sector. The unit fulfilled an important role in establishing a national diagnostic framework for citrus black spot (CBS) detection in soil, leaves and stems collected from citrus nurseries or orchards and on fruit from packhouses and in the export market. The test methods developed and originally accredited in this laboratory constituted a world first and is still used by several leading research institutions and government bodies to test for one of the most important pathogens of citrus i.e. Phyllosticta citricarpa. The outcomes of the CBS research project resulted in two important international publications describing the PCR test methods. Four other
peer reviewed papers followed and one masters and three PhD students graduated through this research project. These methods are also officially used by the Department of Agriculture, Forestry and Fisheries (DAFF) in testing suspect fruit samples destined for export. This method is also used in international export consignments to verify the presence or absence of the CBS pathogen in fruit intercepted at the ports. Currently CBS is one of the most important challenges that the more than 100 year old export industry has faced and may result in market access loss to the European Union (EU). Citrus black spot can be considered as a typical example of a disguised barrier to trade and will most likely be challenged at the World Trade Organization and the International Plant Protection Convention level as a technical barrier to trade.

The diagnostic laboratory has also been able to develop a set of food safety test methods for water and fresh produce in 2002. These methods have extensively been used in research programmes for the Water Research Commission Project no K5/1875//4: “An investigation into the link between water quality and microbiological safety of fruit and vegetables from the farming to the processing stages of production and marketing” and project no K5/2175 “Evaluation of the risks associated with the use of rain-water harvested from roof-tops for domestic use and homestead food gardens; and groundwater for domestic use and livestock watering”, as well as for the European Union 7th Framework project Veg-i-trade “Impact of climate change and globalization on safety of fresh produce governing a supply chain of uncompromised food sovereignty”. Food safety test methods are currently being reviewed, improved and adapted to new technologies to improve sensitivity and accuracy.

• Commercial impact:
The CBS story is an important example of how research and technology can support a countries development and growth. SA is one of the major citrus producing and exporting countries in the world with more than 60% of the fresh produce being exported with an approximate value of R6.6 billion. South Africa ranks as the world’s second largest exporter of fresh citrus fruit by volume behind Spain, and is ranked 14th in the world citrus production. The citrus industry is also labour intensive and it is estimated that it employs more than 100 000 people, with large numbers of workers in the orchards and packing houses. Providing a diagnostic service to the industry that supports market access is thus crucial and the value of the outputs from the Plant Pathology Laboratories should therefore be considered in this context.
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Fig. 2 Plant Pathology Laboratories get the official SANAS certificate in 2002. Mr Mike Peet from SANAS (left) Prof Lise Korsten and Prof Callie Pistorius (University of Pretoria Vice Chancellor and Principle).

Figure 2 Ms Amelita Lombard, Ms Zama Zulu and Prof Lise Korsten in 2012 working towards accreditation.

Plant to Food
Research Group for Plant Health and Food Safety
Research Institute for Industrial Pharmacy, Incorporating the Centre for Quality Assurance of Medicines (RIIP®/CENQAM®)
Part of the Centre for Pharmaceutical and Biomedical Services Faculty of Health Sciences at the North-West University

Services of the laboratory:
RIIP®/CENQAM® is a globally recognised provider of analytical and related services to the pharmaceutical industry, non-governmental organisations (NGO’s), procurement agencies and medicines regulatory authorities.

Services include:
• Stability testing;
• Final products release control (FPRC);
• Drug release testing;
• Solid state physico-chemical studies;
• Method development and validation;
• Consultation;
• Literature searches and interpretation;
• Assistance with regulatory issues;
• Training; and
• Research.

Research activities are focused mainly on the following:
• Physico-chemical properties of active pharmaceutical ingredients (APIs) (BCS classification, polymorphism, etc.);
• Comparative release studies from semi-solid and solid dosage forms (biowaver dissolution);
• Development of monographs for the International Pharmacopoeia. These include monographs for APIs and dosage forms used in the treatment of HIV/AIDS, malaria and tuberculosis.

Accreditation date: 13 November 2011
Period of accreditation: 2 years
Technical Signatories:
• M Nieman
• AS van der Walt
• CS Botha
• I Brits
• A Koster
• D Maasdorp
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- A Joubert
- S Nieman

Nominated representative: Dr A Wessels

SANAS STC member: Dr A Wessels

SANAS STC member:
Dr A Wessels

NIIF®/CENQAM® staff members
Faculty of Health Sciences
NATIONAL HEALTH LABORATORY SERVICES (NHLS)
UNIVERSITAS ACADEMIC LABORATORIES

Services of Laboratory:
Tertiary-level Medical Diagnostics, Research and Training

Accreditation date:
2000 (Haematology), October 2009 (All Disciplines at NHLS Universitas Academic Laboratories)

Period of Accreditation:
One of the first academic laboratories to be accredited in South Africa in 2000 (Haematology). Haematology accreditation remained in place for about 5 years.

Signatories:
Pathologists, Medical Technologists, Medical Scientists, as authorised by the Head of Laboratory Prof H Pieters.

Activities in the Laboratory:

• Laboratory output:
  Staff that contribute towards, or support, the quality of final laboratory results include laboratory assistants, laboratory clerks, phlebotomists, technologists, technicians, registrars, pathologists, medical scientists, heads of departments and the quality coordinator. Students (intern technicians, intern technologists, intern scientists, student laboratory assistants, registrars) also play a role in the laboratory diagnostic processes and quality assurance procedures.

• Research impact:
  Most contract research and clinical trial bodies require internationally recognised accreditation. Opportunities for research exist, with accreditation adding credibility of testing for research projects. Projects in drug-development are conducted in collaboration with international partners, mainly the European union(EU) and NHLS Laboratory tests are used, which may be as a result of being accredited by SANAS.

• Commercial impact:
  NHLS is a public entity with a mandate to serve state health facilities and is thus a not-for-gain organisation. A small percentage of work is for private sector patients or research / clinical trial contracts.
Services of the laboratory:
QuantiFERON –TB Gold In-Tube Assay and T SPOT.TB ELISpot Assay

Accreditation Date: 01 August 2012

Period of Accreditation: 4 Years

Technical Signatory: Belinda Kriel

Activities in the Laboratory:

Laboratory output:
The SUN-IRG focuses on the immunology of Mycobacterium tuberculosis (MTB) infection and in particular hosts biomarkers. These include diagnostic markers, markers of TB treatment response and markers of protective immunity against MTB. Their research spans the divide between clinical and basic (laboratory) sciences in a high TB prevalence area.

The SUN-IRG is part of several international consortia and it processes samples from large cohorts of participants with well characterized MTB infection and disease phenotypes to search for biomarkers of TB. A range of sample types including serum, urine, saliva, sputum, exhaled breath condensate, bronchoalveolar lavage, pleural fluid and cerebrospinal fluid, depending on specific studies.

Sample storage takes place in minus 80°C freezers (alarmed with back-up electricity via a diesel-powered generator) and in liquid nitrogen tanks, and sample management is performed through customized databases. We routinely perform Quantiferon and T-SPOT.TB tests, cryopreserve PMBCs, perform short- and long term whole blood culture assays stimulated with a range of mycobacterial antigens), conduct whole blood and PBMC flow cytometric analysis (8-colour), including phenotyping and intracellular cytokine production, extract RNA for quantitative real-time PCR and perform multiplex cytokine arrays (Luminex platform) and ELISA tests.

The SUN-IRG serve as an immunology specialist laboratory on TB vaccine trials and are part of the IMPAACT International TB Reference Laboratory.

Research Impact:
The SUN-IRG is a leading international player in TB biomarker discovery, in particular in the field of TB treatment response evaluation. Its funders include the Bill and Melinda Gates Foundation, the European Union (FP7 and EDCTP), the NIH, the South African
MRC, the South African Department of Science and Technology, the German Research Foundation and several private companies. Group members serve on international scientific advisory boards and are regular keynote speakers at international conferences. The group has published approximately 24 research papers in international peer reviewed journals in 2012 (69 since 2003) and has graduated 12 PhD students and 4 MSc students since 2005. 10 post-doctoral fellows have undergone training in the group since 2002. We host many international students, including researchers from Africa and Europe.

**Commercial Impact:**
The group holds two patents and works closely with several international pharmaceutical and biotechnology companies, and leads a large international consortium that is developing host-based diagnostic tests for active tuberculosis.

Their income is growing steadily from research grants and contract research with a gross income of over R 14 million in 2012.

The QuantiFERON test is an alternative to the Tuberculin skin test (TST). It is more precise than TST in predicting progression to active TB disease in infected people. It is significantly more sensitive than TST and >99% specific, thereby virtually eliminating false-positive readings. The T-SPOT.TB test has very few false negative results (sensitivity ~95%) which results in reliable detection of truly infected individuals. It is a simple and robust test with virtually no repeat testing and results available the next day.

Both these tests can be performed in people with HIV/AIDS, as well as people taking immunosuppressive therapy, students, health care worker screening, children and travellers. This tests also minimise costs associated with onward transmission of TB disease by eliminating unnecessary treatment and costs involved in monitoring of patients.
Business Unit
TYGERBERG HOSPITAL

Services at the laboratory:
- Virology (M0196)
- Chemistry, Haematology, Immunology, Microbiology, Molecular Biology, Cytology, Histology, Tuberculosis (M0390)

Accreditation Date:
- M0196 – 01 July 2002
- M0390 – 11 December 2009

Period of Accreditation:
- M0196 – July 2010 to 30 June 2014
- M0390 – 11 December 2009 to 10 December 2013

Technical Signatories are:
Authorized by the Head of the laboratory
Department of Clinical Laboratory

**Services in the Laboratory:**
Clinical and Anatomical Pathology

**Accreditation Date:** 01 March 2012

**Period of Accreditation:** 01 year

**Technical Signatory:** Kangelani Bantwini

**Activities in the laboratory:**
- Laboratory output: Clinical Diagnosis
- Commercial impact: Ability to attract trial collaboration
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