

Medical Scientist - Intern Training Programme – Virology **National Institute for Communicable Diseases**

Compiled by Nishi Prabdhial-Sing, Monica Birkhead, Nicola Page, Florette Treurnicht, Beverley Singh, Gillian Hunt, Etienne Muller, Shelina Moonsamy, Sheilagh Smit, Jacqueline Weyer.

Date: April 2020

1. Introduction

1.1 Background to the National Institute for Communicable Diseases

The National Institute for Communicable Diseases (NICD) provides laboratory based surveillance and diagnostic testing for diseases of public health importance to South Africa and the Southern African region. The NICD also sends outbreak response teams to sites confronted with infectious disease epidemics. The NICD houses national and regional referral laboratories. The NICD comprises ten centers, each of which focuses on different diseases, including HIV, Tuberculosis, malaria, diarrhoeal diseases and meningitis. The NICD serves as an expert authority, providing advice to Department of Health and medical practitioners. The NICD is a resource to all universities and technical colleges in South Africa, with multiple training programs in place and a strong complement of university-affiliated staff. The NICD is a division within the National Health Laboratory Service (NHLS), the national laboratory diagnostic network.

The Virology aspect of training encapsulates teaching and training across various centres within the NICD: Centre for Vaccines and Immunology (CVI), Centre for Enteric Diseases (CED), Centre for Emerging Zoonotic and Parasitic Diseases (CEZPD), Centre for HIV and STI (CHIVSTI), Centre for Respiratory Diseases and Meningitis (CRDM).

At orientation:

- (1) An overall explanation of the program will be provided to the intern
- (2) Expectation of the program will be discussed as per training program
- (3) Training dates
- (4) Discuss- logbook, self-assessment, written tests/exams, evaluations, affiliations to professional societies
- (5) An interim program will be discussed (an in-depth training program and timelines will be discussed in more detail for the respective laboratories)
- (6) An evaluation report to be completed after rotation in each laboratory (Appendix 1).
- (7) A list of supervisors and contact details is provided (Appendix 2)

1.2 Optional Host Centres with specific competencies

1.2.1	Centre for Vaccines and Immunology
1.2.2	Centre for HIV and STI
1,2.3	Centre for Respiratory Disease and Meningitis
1.2.4	Centre for Enteric Diseases

1.2.1 Centre for Vaccines and Immunology

The Centre for Vaccines and Immunology provides laboratory support to South African and Southern African departments of health for surveillance of vaccine preventable diseases including acute flaccid paralysis (polio), measles, rubella, hepatitis A, hepatitis B, hepatitis C, enterovirus and tetanus. Specialized molecular diagnostic services are offered.

For the understanding of virological techniques and skill, the Centre divides its teaching and training program in three essential parts:

1.2.1.1 Laboratory technique: cell culture

The following sterile techniques are performed in cell culture and intern scientists will be trained on:

- Maintenance of cell lines
- Trypsinisation of continuous cell lines
- Cell counts and viability
- Bacterial control testing
- Preservation of cell lines
- Thawing/Resuscitation of cell lines
- Prevention of contamination of cell lines

1.2.1.2. Laboratory technique: Poliovirus serology and isolation, measles serology

Intern scientists usually visit the laboratory for a week. This makes it impractical for performance of lab techniques; however, they are allowed to observe procedures performed at the time of training. Intern scientists must read and acknowledge the following lab specific SOPs in order to achieve a better understanding of lab procedures – specific acknowledgment forms to be completed for reference purposes.

Procedures to be discussed:

Polio Serology:

1. Principle of the polio antibody neutralization test
2. Interpretation of results

Polio Virus Isolation:

1. Sample receipt and processing
2. Virus isolation procedure
3. Interpretation of virus isolation results
4. Principle of virus neutralization assays and interpretation of results

Measles Serology:

1. Detection of measles-specific IgM antibodies
2. Immunity testing (IgG)

1.2.2.3. Laboratory technique: Molecular Virology

Introduction to PCR and real-time PCR; introduction to sequencing,
Understanding quantitative tests, alternative viral load assays,
Measles genotyping, nested conventional PCR and Gel electrophoresis
HCV genotyping by Sequencing and Line Probe assay (LiPA)
TrakCare training

1.2.2.4. Epidemiology

Introduction to epidemiology

Understanding Notifiable Medical Conditions

Understanding epidemic curves, line list, reports sent to National Department of Health, World Health Organization

Database entry, management, analyses, interpretation of results

Specialized Facilities and equipment in Centre for Vaccines and Immunology

- Thermal Cycler
- 7500 Real Time PCR System
- Horizontal Gel Electrophoresis Apparatus
- Flash Gel Dock
- UV Transilluminator
- Nanodrop Spectrophotometer
- Life Technologies 3500XL Genetic Analyser

1.2.2 Centre for HIV and Sexually Transmitted Infections

The Centre for HIV & Sexually Transmitted Infections (STI) is a resource of knowledge and expertise in HIV and other regionally relevant STIs to the South African Government, to SADC countries and to the African continent at large, in order to assist with the planning of policies and programmes related to the control and effective management of HIV/STIs. The Centre also aims to be a place of academic excellence in terms of both research and teaching/training. The Centre has a strong record of accomplishment in the research disciplines of HIV virology, HIV immunology, HIV/STI epidemiology, HIV/STI diagnostics and HIV-STI interactions, as well as in successful supervision of PhD and MSc students.

1.2.2.1 Support for HIV vaccine trials- HIV Serology and Molecular Virology

The Centre provides results from validated end-point humoral antibody and molecular HIV assays for the HIV Vaccine Trial Network (HVTN).

Laboratory Techniques:

Manual ELISA HIV antibody (Ab) and Antigen (Ag)/Ab

Automated ELISA- Ag/Ab

HIV Incidence Assay

HIV Rapid tests

HIV Western Blot 1 and 2

Validation of serologic assays

HIV-1 DNA PCR training (Fully automated Qualitative PCR)

HIV-1 Viral load training (Fully automated Quantitative QS PCR)

1.2.2.2 HIV drug resistance surveillance

HIV drug resistance testing- genotypic

Sample handling.

Extraction of total nucleic acid (TNA) from plasma and dried blood spots.

PCR for HIV-1 *pol* gene.

Sequencing of the PCR products.

Sequence analysis using ReCall.

Interpretation of HIV-1 drug resistance report from the Stanford database.

Bioinformatics for HIV drug resistance:

Align and edit sequences using Mega 7.
Calculate genetic distances between patient viruses.
Generate neighbour-joining tree using Mega.
Interpretation of phylogenetic trees and contamination identification

1.2.2.3 Molecular diagnosis and typing of HSV (STI Section)

Intern Medical Scientists rotating at the STI Section will receive training in molecular procedures for the diagnosis and typing of herpes simplex virus (HSV)

1.2.2.3.1 HSV diagnosis and typing

Processing of ulcer-derived swabs

Automated DNA extraction

In-house real-time multiplex PCR for ulcer-causing organisms

Confirmatory HSV-1/2 typing real-time PCR (commercial Sacace HSV-1/2 typing assay)

Equipment for Centre for HIV and STI

- MagNa Pure Extraction System, or NUcliSens easyMAG 27500 Real Time PCR System
- PCR thermocyclers
- ARCHITECT i1000SR CMIA system
- COBAS® Ampliprep/ COBAS® TaqMan®
- Horizontal Gel Electrophoresis Apparatus
- Flash Gel Dock
- UV Transilluminator
- Nanodrop Spectrophotometer
- Life Technologies 3130XL Genetic Analyser
- 2 ultra-deep sequencing platforms, a 454 Junior and MiSeq
- microplate washer

1.2.3. Centre for Respiratory Diseases and Meningitis

Background

The Centre for Respiratory Diseases and Meningitis (CRDM) is a resource for surveillance, diagnostics, expertise and research in the field of communicable respiratory diseases and meningitis for South Africa and the African continent. The Centre generates data and provides expertise related to respiratory diseases and meningitis of public health importance to the South African national Department of Health, healthcare providers and regional and international collaborators, to assist with the planning of public health policies, programmes and response to respiratory disease and meningitis outbreaks. The Centre is also a source of capacity building and formal training within South Africa and the African region. CRDM includes bacteriology and virology laboratories, and a team of epidemiologists and surveillance field staff.

1.2.3.1 Laboratory Techniques:

Respiratory Virus propagation techniques in cell cultures

Immunofluorescence

Influenza and other respiratory virus isolation

Hemagglutination inhibition assays to determine sensitivity of circulating influenza viruses to vaccine-induced antibodies or to evaluate exposure to novel or zoonotic influenza A viruses and other respiratory pathogens and lastly this assay can be used to evaluate the immune responses induced in vaccine recipients.

Conventional live virus based microneutralization assays.

Pseudovirion-based microneutralization assays for BSL3 pathogens performed under BSL2 conditions

Conventional PCR and sequencing of respiratory virus gene fragments

Allelic discrimination real time RT-PCR assay to identify influenza B lineages and to identify known drug resistant mutation in the M and NA genes of influenza

Phenotypic assay to determine sensitivity of influenza virus neuraminidases to antiviral drugs
Multiplex real time RT-PCR for human respiratory viruses including influenza viruses
Virus discovery for unknown causes of respiratory disease
Genome sequencing using both Sanger and next generation sequencing methods

Specialized Facilities and equipment in Centre for Respiratory Diseases and Meningitis

- Thermal Cyclers
- 7500 Real Time PCR Systems and Roche 480
- ViiA7 real time PCR machine with block and centrifuge for TLDA cards
- Horizontal Gel Electrophoresis Apparatus
- Western blot apparatus with semi-dry transblot
- UV Transilluminator
- Nanodrop Spectrophotometer
- Bio-Rad Bio Plex 200
- Multi-label plate reader with stacker
- Glomax Luminometer
- GeneGnome imaging system for luminescence
- Bio-Rad Gel documentation system
- Magnapure 96 RNA extraction system
- Nanophotometer

1.2.4 Centre for Enteric Diseases

The Centre for Enteric Diseases (CED) is concerned with activities related to surveillance of pathogens associated with diarrhoea and enteric fevers, and investigation/response to enteric disease outbreaks (including foodborne and waterborne disease outbreaks). CED is tasked with developing strategies and providing information to combat diarrhoeal diseases in South Africa. CED monitors trends in diarrhoeal pathogen incidence and identifies areas for the introduction of additional interventions.

The bacterial division of the CED collects data on patients presenting throughout South Africa with both invasive and non-invasive disease caused by Salmonella species (including Salmonella Typhi), Shigella species, Vibrio cholerae, Listeria monocytogenes and diarrhoeagenic Escherichia coli. In order to make these data representative and reflective of disease burden in each province in the country, we actively motivate all diagnostic laboratories throughout the country to voluntarily submit limited demographic details and isolates to us centrally. In exchange, we offer serogrouping and serotyping results, regular feedback (quarterly reports by province sent to every laboratory participating) and aggregated numbers are published in the NICD Bulletin.

In addition to serogrouping and serotyping, E-tests are used to determine the minimum inhibitory concentration (MIC) of each isolate to antimicrobial agents, according to CLSI guidelines. The bacterial division also performs genotypic characterization of isolates, which includes various PCR tests and whole-genome sequencing (WGS) analysis. PCR tests are used to assist with diagnosis of particular pathogens and elucidate the presence of particular virulence (toxin) genes, such as those found in toxigenic E. coli and toxigenic V. cholerae. The molecular epidemiology of some bacterial pathogens is continually being elucidated, specifically that of outbreak or epidemic-prone pathogens such as Salmonella Typhi, L. monocytogenes and V. cholerae O1. The molecular epidemiology of bacterial pathogens is investigated via WGS. Analysis of WGS data is used to assess the genetic relatedness of isolates, for investigation of clusters and outbreaks. Core-genome multi-locus sequence typing (cgMLST) and single nucleotide polymorphism (SNP) analysis, are the two most commonly used tools to assess the genetic relatedness of isolates. These WGS data are interpreted together with epidemiological data to assist with investigation of outbreaks and identification of the source of outbreaks.

The introduction of the rotavirus vaccine into the national expanded program of immunization (EPI) in August 2009 was a positive step in combating diarrhoeal disease burden in children < 5 years in South Africa. The viral division of the CED has been tasked with monitoring the impact of the rotavirus vaccine and surveillance is planned to continue into 2015. Projects investigating rotavirus vaccine safety, optimal vaccine use, and improved vaccine efficacy are also being undertaken and will generate practical regional data for African countries considering introducing the rotavirus vaccine.

While rotavirus cases are being reduced by the introduction of efficacious vaccines, the remaining 70% of diarrhoeal cases need to be investigated. Stools collected through the rotavirus sentinel surveillance program are examined via an integrated diagnostics platform within the divisions of the CED. Surveillance for enteric viruses, other than rotavirus, has previously only been conducted on an *ad hoc* basis and the contribution of mixed pathogen infections has never been studied in the South African population. Expansion of the current diarrhoeal surveillance program to include more sentinel sites and offer a wider range of screening options will increase the quality and representativeness of the data generated.

1.2.4.1 Laboratory Techniques:

Manual ELISA (Rotavirus detection)

Rapid tests (Rotavirus detection)

Automated/manual extraction of viral nucleic acids (RNA/DNA) from stool

Extraction of nucleic acids from other clinical specimens

RT-PCR detection and genotyping of rotavirus strains

Real time RT-PCR detection of enteric viruses

Detection of *Listeria monocytogenes* by real-time PCR

Typing of enteric viruses (only for interns hosted in CED)

Evaluation of detection methods/kits for enteric pathogens (only for interns hosted in CED)

1.2.5 Centre for Emerging Zoonotic and Parasitic Diseases

The CEZPD aims to establish itself as a national and international Centre of excellence for emerging and parasitic diseases. CEZPD aim to function as a resource for knowledge and expertise to the South African government, the SADC countries and the African continent, in order to assist in the planning of relevant policies and programmes and to harness innovation in science and technology to support surveillance, detection and outbreak response systems. In observing this goal, the CEZPD supports South Africa's commitment to the International Health Regulations.

1.2.5.1 Laboratory Techniques:

The following techniques will be discussed and demonstrated only (when possible) due to biosafety issues related to laboratory handling of haemorrhagic fever virus, rabies virus and arboviruses. The CEZPD operates multiple biosafety level 3 laboratories and the only biosafety level 4 laboratory in South Africa. In addition, the Centre operates several biosafety level two laboratories.

Interns will be required to attend lectures, demonstrations and participate in presentations and assignments.

Interns will be exposed to the following:

- Introduction to and analyses of molecular detection protocols for diagnosis of viral haemorrhagic fevers, rabies and arboviral infection including the use of real time, conventional and isothermal amplification protocols.
- Protocols for the detection of complete, IgG and IgM antibodies for diagnosis of viral haemorrhagic fevers, rabies and arboviral infection (including ELISA, indirect immunofluorescence analysis, haemagglutination inhibition assays and virus neutralization assays).
- Protocols for isolation of live virus from clinical specimens using cell culture and/or suckling mice for diagnosis of viral haemorrhagic fevers, rabies and arboviral infection.
- Presentation of principles and techniques of EM, including practical processing of specimens for viral diagnostics (identification) and research applications: fixation, formvar coating of grids, negative staining, embedding in resin for sectioning with glass knives on the ultramicrotome, staining of

sections, viewing and imaging on the transmission electron microscope. Ultrastructural review of pathogens, pathogenesis and hosts.

1.2.5.2 Epidemiology:

Interns will be exposed to the following:

- Epidemiology of viral haemorrhagic fevers, arboviral infections and human rabies
- Aspects of outbreak management of these diseases

Specialized facilities and equipment in the Centre for Emerging Parasitic and Zoonotic Diseases

The CEZPD operates multiple biosafety level 3 laboratories and the only biosafety level 4 laboratory in South Africa. These facilities are geared for bacteriological, virological and animal work. In addition, the Centre operates several biosafety level 2 laboratories including PCR facilities and general molecular laboratories.

- Equipment for molecular biology applications includes:
 - Lightcycler® v1.5 real time PCR machine (Roche)
 - Lightcycler® 480 real time PCR machine (Roche)
 - Smartcycler II real time PCR machine (Cepheid)
 - GeneAmp 2720 automated thermocyclers (Applied Biosystems)
 - Real time turbidimeter for loop mediated isothermal amplification (LAMP) (Teramecs)
 - Agarose gel electrophoreses equipment
 - Ultraviolet transilluminator with gel documentation system
 - PAGE gel electrophoresis equipment
 - Western blot equipment (i.e. semi dry and wet blotting equipment)
 - Incubators, water baths, centrifuges, laminar flow cabinets, biosafety cabinets etc.

2. Training programme in molecular biology

2.1 Description of Training programme

Each intern medical scientist will complete a 2-year training program. The training program will comprise a minimum of 21 months in the host Centre. Core competencies are expected to be met by each intern. Each host Centre will additionally train in Centre specific competencies. There will be 2- 3 months of rotations as part of the established 3-month NICD annual rotation programme, when all laboratories at the NICD are visited for up to 2 weeks each.

2.2 Summary of training programme

A	21-22 months	Host centre at NICD	Any of the listed centres at NICD
B	2-3 months*	Rotation	Rotation programme through various NICD centres

*For the rotation through other NICD centres – a minimum of 4 other centres will be visited.

Rotation choice depends on workload and logistical considerations.

Choice will be determined by consultation between NICD staff and relevant laboratories.

2.3 Overall Outcomes of the internship:

2.3.1 To be able to recognise and apply professional conduct and ethical principles.

2.3.2 To be able to perform the administration and management of a laboratory in terms of maintaining the quality process, Good Laboratory Practice, laboratory safety and the quality management system)

2.3.3 To be able to apply basic scientific principles and academic knowledge.

2.3.4 To be able to perform laboratory methods in accordance with standard operating procedures and the interpretation of results relevant to a laboratory diagnostic environment.

2.3.5 To be able to define and apply research principles, compile a scientific report and present the findings. (Use of database/s and apply bioinformatics).

2.4 Outline of training programme during twenty-one-month program

The following general principles will be covered in the 21-month rotation.

- **Good Laboratory Practice:** Regular training is conducted for all staff. Laboratory divisions conducting patient testing have SANAS accreditation for ISO 15189. This will include exposure to laboratory management, quality assurance activities of the department, role of standard operating procedures and adherence to these, documentation such as quality manual, safety manual etc. This will involve an orientation program and ongoing bench exposure.
- **Safety Training** – regular training provided for all staff. The safety representative in the laboratory will be responsible for the training.
- **General Laboratory techniques:** centrifugation, pipetting, sample preparation, chain of custody, laboratory information system, sample storage.

The 21-month rotation will ensure that the intern emerges with expert knowledge in virology, be able to troubleshoot as well as use initiative to instigate new work in a particular area. During this time, they will be expected to spend at least 50% of their time on routine work done by the laboratory. Research projects they are doing, including the possibility of a Masters project, should fit within the remaining 50% of time.

Each Centre will offer at least two modules to the intern scientist during the 21-month period. Intern scientists will be expected during this time to become proficient in running the routine assays carried out by their unit. They will become expert in the molecular assays including troubleshooting when there are problems, instrument maintenance and quality control measures. They will be expected to attend the academic teaching available in the unit e.g. tutorials, journal clubs etc. They will also attend the bi-monthly NICD research meeting. Interns may be given an opportunity to present at university research days and/or national conferences, where possible.

The intern scientist will be expected to compile a portfolio suitable for assessment as determined by the HPCSA. This will include an information on all assays witnessed and performed as well as one or more projects. The project(s) may include at least one of the following

- Instrument validation
- Test validation
- Test optimisation
- Research question

With appropriate university or ethics approvals, if necessary.

2.5 Outline of training included in the 2-3 month modules

During the 2-3 month rotations, the intern will be exposed to the theory and techniques spanning the tests offered by the laboratory. The aim is to give an overview of tests available, equipment and expertise available, an introduction to the pathology tested in the various units, and to stimulate the interest of the intern. The intern will be expected to understand the principles involved in the techniques. They will NOT however be expected to have performed all the techniques mentioned, nor to be able to run the tests without supervision. Rather the aim is to learn which tests are available and for which patients they would be applicable.

3 Assessment

Assessment will be performed according to rules and regulations stipulated by the HPCSA. Requirements for internal assessment of the candidate will be the following:

3.1: Ongoing assessment

Ongoing assessment will consist of an evaluation report of the intern scientist by the unit head after a year of internship and finally before portfolio submission. The report will be based on the interim portfolio being collated by the intern (see below) as well as an evaluation of his/her general laboratory demeanour including:

- Attention to good laboratory practice
- Participation in academic activities
- Laboratory expertise acquired

The evaluation will be discussed in full with the scientist during an interview and relevant feedback given. Opportunities for improvement will be discussed and noted.

3.2: Final Portfolio

For registration in the discipline of Immunology, the portfolio will consist of:

- Logbook of tests performed
- Logbook of tests witnessed but not performed
- Printout of any oral presentations e.g. PowerPoints
- Copy of any journal articles presented with short explanation of for which forum it was presented e.g. “presented at immunology journal club, 27 January 2019” and signed by a senior staff member or the journal presenter.
- At least one of the following
 - **1. Project demonstrating capability in the scientific method and computer literacy. This may have the form of a research paper i.e. including introduction, methods, results, discussion, conclusion and references or in the form of an instrument or test validation and written up as a report.** These must comply with ethical guidelines and ethics approval must be included, if required, by the study. Dissemination of the results via conference presentation or publication is desirable.
 - **2. A case study related for which a molecular diagnostic test has been used, including patient history, clinical investigations, laboratory investigations, discussion and references.** These must comply with ethical guidelines and ethics approval must be included, if required, by the study. Dissemination of the results via conference presentation or publication is desirable.
- Evaluation reports/ attendance certificate from head of relevant units at the end of each rotation.

Understand confidentiality – read and acknowledge SOP GPQ0061

Read and understand the NHLS code of conduct - sign acknowledgement, SOP POLH0009

Quality management – attend and participate in laboratory meetings, internal and/or external quality meeting – sign register. Read reference below.

Understanding troubleshooting and report on at least two experiences during training with evidence.

Laboratory case reports – at least 2 short reports explaining and interpreting results

4 Competencies

The following are the specific competencies expected from all intern medical scientists on completion of internship in virology:

4.1. Technical Competencies

- Understanding of the principles associated with a range of techniques employed in the various virology specialities.
- knowledge of the standards of practice expected from these techniques used in virology
- Experience of performing techniques in virological diagnosis/surveillance, by understanding and following of SOPs.
- the ability to solve problems that might arise during the routine application of techniques (troubleshooting) used in virology
- understanding of the principles of quality control and quality assurance
- Experience of the use of quality control and quality assurance techniques including restorative action when performance deteriorates.
- a critical ability to review the results and determine the significance of quality control and assessment information for relevant analytical procedures in virology
- An understanding of the hazards (environmental, biological, chemical, radioisotopic) associated with the practice of virology and the appropriate controlling legislation and appropriate procedures of risk assessment.

4.2. Scientific Competencies

- Understanding the science of virology and the broader aspects of medicine and clinical practice.
- Experience of searching for knowledge, critical appraisal of information and integration into the knowledge base of virology.
- ability to apply knowledge to problems associated with the routine provision, and development, of the service
- ability to identify the clinical decision which the test/intervention will inform
- ability to make judgements on the effectiveness of procedures performed in virology
- application of the knowledge base to the virology specialty and to the range of procedures/investigations available in virology
- a critical understanding of the application of investigative protocols/ diagnostic tests/surveillance testing used in virology
- understand the principles of the techniques and methods employed in virology
- able to advise on appropriate choice of investigation and sample preparation
- must be familiar with information on technical developments and emerging technologies in virology
- a critical understanding of classification criteria for viruses
- An understanding of sensitivity, specificity, positive and negative predictive values of an assay and how these are affected by prevalence of a disease.

The following are the generic competencies expected from all intern medical scientists on completion of internship:

4.3 Research and Development Competencies

- ability to read and critically appraise the literature ability to develop the aims and objectives associated with a project
- Ability to develop an experimental protocol to meet the aims and objectives in a way that provides reliable and robust data.
- ability to perform the required experimental work ability to produce and present the results (including statistical analysis)
- ability to critically appraise results in the light of existing knowledge and the hypothesis developed and to formulate further research questions
- ability to present data and provide a critical appraisal to an audience of peers – both spoken and written
- developed research skills and expertise sufficient to support supervised and collaborative research initiative in haematology

- an awareness of the current extent of knowledge in virology and an ability to employ appropriate information tools to search for, consolidate and critically examine information
- participation in local research meetings and supervised and collaborative research initiatives, leading to in-house reports (e.g. validation reports), publications or a research Master's degree
- Self-endeavour (e.g. literature awareness) under the tutelage of an appropriate virology specialist.

4.4 Communication Competencies

- ability to assess a situation and act accordingly when representing the specialty
- ability to respond to enquiries regarding the service provided when dealing with clinical colleagues
- ability to communicate with patients, carers and relatives, the public and other healthcare professionals as appropriate
- ability to communicate the outcome of problem solving and research and development activities
- evidence of presentation of scientific material at meetings and in the literature
- must be able to communicate effectively with professional colleagues within the discipline and in the wider scientific and clinical community
- must be able to present findings effectively in a variety of written and spoken media must be able to educate and train professional colleagues within and without the department
- must understand the requirements and responsibilities associated with the supervision of junior colleagues
- must be able to use modern communication devices
- must understand basic management techniques and be aware of topical management issues

4.5 Problem Solving Competencies

- ability to assess a situation which may pose a problem
- ability to determine the nature and severity of the problem
- ability call upon the required knowledge and experience to deal with the problem
- initiate resolution of the problem
- demonstrate personal initiative
- must be able to interpret internal quality control and external quality assurance data
- must be able to recognise when a test or procedure is not within adequate performance limits
- must be able to recognise the consequences of inadequate performance of individual tests or procedures
- must be able to identify potential causes of problems and to investigate these appropriately
- must be able to identify and appropriate solution to the problem and propose an effective and timely solution, including any requirement for clinical follow-up

4.6 Management Competencies

- Understanding of the legal and ethical boundaries of scientific research.
- Ability to recognise the limits of personal practice and when to seek advice.
- Ability to manage personal workload and prioritize tasks appropriately.
- Understanding of the principles of clinical governance including importance of confidentiality, informed consent and data security clinical audit, accreditation requirements relevant to the virology specialty.
- The ability to contribute effectively to work undertaken as part of a multi-disciplinary team
- Ability to supervise others as appropriate to area of practice.
- Understanding of the role of appraisal in staff management and development.
- Understanding of the need for career-long self-directed learning and the importance of continuing professional development.
- Understanding of the need for, and ability to establish and maintain a safe practice environment.
- understanding of the structure and organization of the department

4.7 Ethics and Values Competencies

- Apply and maintain appropriate professional ethics, values attitudes and behaviour.
- use science and technology effectively and critically, showing responsibility towards the environment and health of others
- understand and apply ethics in both human and animal research (refer below for reading material)
- understand and comply with the laws of copyright protection, confidentiality and ownership of intellectual property
- take responsibility within own limits of competence and recognise the need for lifelong learning with an awareness of personal and knowledge limitations
- Demonstrate an ability to work as a team and to show respect for colleagues and other health care professionals and the ability to foster a positive collaborative relationship with others.
- recognise the ethical and legal aspects in the field including record keeping and documentation (refer to NHLS compliance SOP GPL2773)
- flexibility to adapt to uncertainty and change

Bibliography

Acts

Occupational Health and Safety Act, <https://www.gov.za/documents/occupational-health-and-safety-act>
Compensation for Occupational Injuries and Diseases Act, <https://www.saica.co.za/Technical/LegalandGovernance/Legislation/COIDA/tabid/3039/language/en-US/Default.aspx>

National Health Act, <http://section27.org.za/wp-content/uploads/2019/07/Stevenson-National-Health-Act-Guide-2019-1.pdf>

Labour Relations Act especially the aspects regarding HIV/AIDS and the Human Tissue Act. <http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r%3Fdownload%3D138:regulations-relating-to-categories-of-hospitals-r185-2012>

HPCSA Regulations

REGULATIONS DEFINING THE SCOPE OF THE PROFESSION OF MEDICAL SCIENCE

http://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/regulations/mdb/regulations/regulations_gnr_579_2009.pdf

REGULATIONS RELATING TO THE QUALIFICATIONS FOR REGISTRATION OF MEDICAL SCIENTISTS

http://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/regulations/mdb/regulations/regulations_gnr_581_2009.pdf

REGULATIONS RELATING TO THE REGISTRATION OF INTERNS IN MEDICAL SCIENCE

http://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/regulations/mdb/regulations/regulations_gnr_578_2009.pdf

REGULATIONS RELATING TO THE REGISTRATION OF STUDENTS IN MEDICAL SCIENCE,

http://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/regulations/mdb/regulations/regulations_gnr_580_2009.pdf

REGULATIONS RELATING TO THE REGISTRATION OF CERTAIN CATEGORIES OF MEDICAL SCIENTISTS

http://www.hpcs.co.za/Uploads/editor/UserFiles/downloads/legislations/regulations/mdb/regulations/regulations_gnr_52_97.pdf

Registration

<http://www.hpcs.co.za/> (registration forms may change, please use the most recent update)

Ethics and medico-legal aspects

HPCSA Guidelines on Ethical Rules (version available from the HPCSA website – Booklets 1 to 11)

https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

The general guidelines for health researchers and Biotechnology research in South African dealing with patients and patient samples (version available from the HPCSA website – Booklets 13 and 14).

https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

NHLS SOP GPL2773, Minimizing transcription errors, compliance checks....

NHLS SOP POLH0009, NHLS code of conduct

NHLS SOP CHE0599, GLP in a molecular laboratory

NHLS SOP IMM0201, GLP for immunology

NHLS SOP GPQ0061, Confidentiality in the NHLS

Safety and Quality Management

NHLS Safety Manual, NHLS POLS0001

Occupational Health safety Programme, NHLS POLS0002

Health and Safety Policies, NHLS POLS0003

Safety Procedures, NHLS POLS0004

Potential Work Hazards, NHLS POLS0005

NHLS safety manual – hazardous biological agents, NHLS POLS0006

Safety and Waste Management forms, NHLS POLS0009

NHLS safety health and environment (SHE) policy, NHLS POLS0010

Part 2 - ISO 15189:2012 “Medical laboratories - Requirements for quality and competence”

<https://www.westgard.com/iso-15189-2012-requirements-1.htm>

Appendix 1

Evaluation Report – Intern Scientist

Name of intern scientist:.....

HPCSA no.....

Name of supervisor.....

HPCSA no.....

Position.....

Date:.....

The intern scientist has been under supervision by the supervisor from..... until..... in thelaboratory.

The supervisor has found the intern scientist’s performance in the following categories to be:

	<u>1 good</u>	<u>2 satisfactory</u>	<u>3 needs further training</u>
Processing routine samples:			
Working under pressure			
Working as part of a team			
Punctuality			
Enthusiasm			
Understanding scientific principles of diagnostic tests			
Understanding clinical impact of diagnostic test results			
Following the principles of good quality assurance			
Conducting research projects			
Presenting data to a scientific forum			
Troubleshooting laboratory assays			

Is the supervisor aware of any patient/doctor/customer complaints that resulted from the actions of the intern scientist? If so please provide details.

.....

Is the supervisor aware of any laboratory results of poor quality issued by the intern scientist?

.....

Are there specific areas in which the intern scientist excelled?

.....

Areas for improvement?

.....

Does the supervisor have any reservations about the intern scientist registering as a biological scientist with the HPCSA upon completion of the necessary requirements?

.....(yes/no)

Signature..... (intern scientist)

Date.....

Signature.....(supervisor)

Date.....

Appendix 2:

Supervisor(s):			
Centre for Vaccines and Immunology (CVI)	Dr. Melinda Suchard	melindas@nicd.ac.za	011-3866387
Centre for Vaccines and Immunology (CVI)	Dr. Nishi Prabdial-Sing	niship@nicd.ac.za	011-3866347
Centre for HIV & Sexually Transmitted Infections (CHIVSTI)	Prof Adrian Puren	adrianp@nicd.ac.za	011-3866328
Centre for Respiratory Diseases and Meningitis (CRDM)	Dr. Mignon du Plessis	mignond@nicd.ac.za	011-5550387
Centre for Enteric Diseases (CED)	Dr. Anthony Smith	anthonys@nicd.ac.za	011-5550348