SYLLABUS

VIROLOGY

STUDY GUIDE

for

MEDICAL TECHNOLOGISTS

Effective January 2020 for exams from March 2021

CONTENTS

1. Introduction

1.1 Examination Information

The examination will consist of 2 theory papers written on the same day. Candidates should expect a mixture of essays and short questions. No reference material under study may be taken into the examination.

Both papers will be broadly based and will cover the entire field under study. Details relating to specific times and quantities involved in methods will not be asked. Candidates will however be expected to know the principles on which the tests are based and how to identify positives verses negative results (interpretation of results) obtained.

In order to pass the examination the candidate must achieve 50 % in each paper.

1.2 Purpose of the module

This course focuses on clinically important viruses associated with human disease with emphasis on the laboratory isolation of the virus from relevant specimens, the identification of the virus using morphological, microscopic, biochemical, serological and molecular characteristics. The importance of maintenance, safety, ethics and quality control.

1.3 Technician Training

To the Supervisor

Please ensure that your laboratory is registered with the Health Professionals Council of South Africa at a Virology training laboratory.

To the Student

Please ensure that your laboratory is registered as a Virology training laboratory with Health Professionals Council of South Africa.

1.4 COURSE OUTCOME:

At the end of this course the student will be able to:

- Name the different types of specimens that are received in the virology laboratory.
- Describe how the different specimens are obtained from the patient.
- Discuss the importance of correct sampling and transport in the quality of the final result.
- Apply the correct terminology to the classification of the viruses.
- Differentiate between different viral genera and species associated with human disease.
- Discuss the replication cycle of both RNA and DNA viruses.
- Select the appropriate method/s to isolate viruses from various specimens.
- Outline the methods used to process the specimens.
- Explain the principles of the methods used in the processing of specimens.
- Choose the correct tests to identify the viral pathogens.
- Rationalise the choice of culture media and tests selected for the isolation and identification of virus.
- Assess the different types of Molecular testing for viral identification.
- Give examples of treatment used in the various diseases.
- Explain the principles of the methods and tests used in the isolation and identification of viruses.
- Interpret the results of identification tests.
- Discuss the impact of various diseases in populations around the world.
- Discuss the prophylaxes available for the prevention of various diseases.
- Explain laboratory safety including the basis of the Occupational Health and Safety Act and the responsibilities of safety and first aid representatives.
- Describe the procedures for the storage, handling and disposal of hazardous chemicals and laboratory waste.
- Describe quality control and practical application thereof according to relevant SOP's.
- Discuss ethical rules relating to reporting of results and confidentiality.
- Explain the preparation and use of disinfectants including cleaning of glassware and sterilisation techniques.
- Describe the operation and maintenance of standard laboratory equipment

- Calculations for making up laboratory solutions.

2. Statutory regulations governing Medical Technology

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Introduction:

This article serves to provide information regarding the statutory regulations governing the training, scope of practice and career paths of Medical Laboratory Personnel. It also provides an overview of the rules regarding confidentiality and continuous professional development.

1. Regulations governing Medical Technology personnel

Medical Technologists, Medical Technicians, Laboratory Assistants and Medical Scientists make up the core of the technical laboratory personnel in a medical laboratory.

The scope of practice (procedures that may or may not be performed within the category of registration) is regulated by the Health Professions Council of South Africa (HPCSA). This means that the profession operates within strict guidelines to ensure that the welfare of the patient is placed above all else.

1.1 About the HPCSA

The HPCSA is a statutory (legal) body established in terms of the Health Professions Act (Act No. 56 of 1974). There are 12 Professional Boards operating under it. The Professional Boards control the professions within their field.

The Main Objectives of Council and Professional Boards are to: Promote the health of the South African population Determine and uphold the standards of education and training Keep the Registers of each profession Determine and maintain standards of professional practice and conduct Advise the Minister of Health on matters pertaining to the Act

1.2 Professional Ethics:

Ethics can be defined as a set of standards of conduct and moral judgment and as a code of morals of a particular profession.

In medical Technology we are concerned with the code of morals of individuals as professionals.

Code of ethics for Medical Technologists (applicable to all medical laboratory personnel):

1. Being fully aware of my responsibility in the practice of Medical Technology, I commit to performing my duties with accuracy, thoughtfulness and care.

2. Realizing that the knowledge obtained concerning patients in the course of my work must be treated as confidential.

3. I will conduct myself at all times with integrity (honour) and uphold the dignity of my profession.

4. I pledge myself to practice Medical Technology strictly according to the principles, standards, traditions and regulations of the HPCSA and South African law.

5. I will always be aware that I have been entrusted with patient care through the practice of my Medical Technology duties.

6. It is my responsibility to strive constantly to increase my technical knowledge of Medical Technology and exchange knowledge with other competent practitioners of Medical Technology.

7. I pledge accuracy and reliability in the performance of tests and to seek competent professional assistance when in doubt of my own judgment or competence in a particular test or investigation.

8. As a further consideration for registration, I pledge myself to avoid dishonest, unethical or illegal compensation for such services as I shall render to the patient I'm serving.

9. I pledge myself to report the results of my findings free from all personal opinion to the attending physician. I shall not make or offer a diagnosis or interpretation except as the result of the report may of itself so indicated, or unless I am asked to by the physician taking care of the patient.

10. I will strive for increased efficiency and quality through organization.

11. I will be willing to accept responsibility for my own work and results

12. I will assume a professional manner, attire and conduct on a daily basis.

1.3 Performance of Professional Acts

Medical Technologists, technicians and Laboratory Assistants shall confine themselves to practicing in the specific discipline of medical technology in which they were educated, trained and registered.

Although Medical Technologists may conduct private practice if they have two years of postgraduate experience and prior written approval from the Board, Medical Technicians and Laboratory Assistants shall not conduct private practice.

Further to this, medical technicians shall only perform professional acts under the supervision of a medical practitioner or medical technologist registered in the relevant discipline.

According to the ethical rules published as Government Notice No R 717 of 4 August 2007, Medical scientists shall be involved with the development, evaluation and practice of scientific procedures which involve human or human biological material

provided that such acts lead to or impact the treatment diagnosis and genetic counseling of humans.

Medical Technologists, medical technicians, laboratory assistants and their respective students/interns are registered with the Medical Technology Board of the HPCSA.

Medical Scientists and their interns are registered with the Medical and Dental Professions Board of the HPCSA.

2. Medical Technologist

2.1 Education and training requirements for Medical Technologists

The National Diploma in Biomedical Technology is obtained through three years of full time study at a University of Technology UoT (Accredited Higher Education Institution previously called Technikons).

During the last semester of study, the student technologist is given opportunity to spend 6 months in an approved (registered) training laboratory to integrate their academic theoretical education with the workings of a medical laboratory (experiential learning). This work integrated learning provides invaluable experience to the student on the scope of each medical technology discipline (chemical pathology, haematology, microbiology, histology and cytology). Blood transfusion, virology, cytogenetics and immunology are other disciplines in medical technology but are not routinely covered during experiential learning.

Although you are awarded your National Diploma after 3 years of UoT full time study, you may only register and practice as a medical technologist after 12 months of internship and passing the Medical Technologist National Board Exam administered by the Society of Medical Laboratory Technologists of South Africa (SMLTSA).

Internship may be done in any of the disciplines listed above. Chemical pathology, haematology and microbiology may be combined in equal duration (4 months each) in the 12 month internship period and is called clinical pathology. At this point in your training, you are registered as an intern technologist (no longer a student

technologist) and you will follow a syllabus that specifies the scope of tests that you must be trained on.

Important criteria that must be adhered to during internship: Internship is completed in an approved (registered) training laboratory (laboratory which has been accredited by the Professional Board for the training of intern medical technologists and/or student technicians). The intern technologist registration must be done after the National Diploma has been completed and before internship commences.

- No more than one months leave or 12 days of annual leave may be taken during internship. If this happens the internship period must be extended to compensate.

- The supervising technologist (trainer) must be registered for at least 2 years and practicing in the same category in which the intern is being trained. Their CPD (discussed in detail in criteria 4 below) must be up to date.

- The intern must qualify as a medical technologist within three years of registration as an intern technologist.

3. Medical Technology Training Laboratories

A laboratory that wishes to train intern medical technologists and/or student technicians in a particular discipline must apply to the education committee of the Medical Technology Board of the HPCSA for training lab accreditation status.

The application is evaluated on the scope of tests performed on site compared to the relevant syllabus, the qualifications of the supervising personnel, availability of training resources such a space, training program alignment, reference material etc.

If the application is accepted, a site audit is conducted to evaluate the implementation of the proposed training program, the laboratories quality system and laboratory and personnel capacity to facilitate learning.

A laboratory accredited to train technologists may train technicians however a laboratory accredited for the training of technicians may only train technicians.

A laboratory accredited for the training of clinpath technologists could also train technicians in the categories chemical pathology, haematology and microbiology.
A laboratory approved for training may not employ more than five intern technologists and or student technicians and or qualified medical technicians in respect of every medical technologist registered in the specific discipline/category.
The board may during their audit decide to limit the number of interns/students that the lab can employ based on capacity to train.
Approved training laboratories are subject to annual audits by the Professional Board

Apply the rules of confidentiality and ethical practice as prescribed by, HPCSA and the Patient Bill of Rights.

"Health care provider or practitioner" is a term used to describe a person providing health services in terms of any law (doctors, nurses, technologists, technicians, pharmacists etc.). They are registered with a statutory council such as HPCSA or Nursing Council.
"Health care worker" refers to people in the medical field who render a service but are not required by law to register with a Statutory Health council e.g. admin staff and drivers in a hospital or laboratory.

"Health care personnel" is a term that refers to both health care providers and health care practitioners.

Both the statutory council and organization will define the access and distribution of confidential information by health care personnel.

Confidential information means all information, technology, know-how and trade secrets concerning or relating to the business or affairs of the company that are confidential and personal to the company.

4. What are the rules of confidentiality as prescribed by the Health Professions council of South Africa (HPCSA)?

Health care practitioners should:

a) Recognize that the patient has the right to expect that health care practitioners will not disclose any personal and confidential information they acquire in the course of their professional duties, unless the patient agrees to such disclosure, or unless health care practitioners have good and overriding reason for doing so (for example, if disclosure is not made, there is a likelihood of serious harm to an identifiable third party, or there is a public health emergency, or any overriding and ethically justified legal requirement).

b) Not breach confidentiality without sound reason and without the knowledge of their patients. (Reference: HPCSA, Guidelines for good practice in the health care professions – Booklet 1 – General ethical guidelines for the health care professions – May 2008)

What are the patients right to confidentiality?

The National Health Act (Act No.61 of 2003) states that all patients have a right to confidentiality and this is consistent with the right to privacy in the South African Constitution Act (Act No. 108 of 1996)

Rule 13 of the Ethical Rules of the HPCSA states that a practitioner may divulge information regarding a patient only if this is done:

a) In terms of a Statutory (legal) provision,

b) At the instruction of a court,

c) In the public interest

d) With the express consent of the patient

e) With the written consent of a parent or guardian of a minor under the age of 12 years,

f) In the case of a deceased patient with the written consent of the next of kin or the executor of the deceased estate.

Disclosures in the public interest would include but not be limited to situations where the patient or other persons would be prone to harm as a result of risk related contact.

Patients have the right to expect that information about them be held in confidence by health care practitioners.

The National Act requires that health care providers and health care establishments are responsible for personal information about their patients and must make sure that such information is effectively protected against improper disclosure at all times.

(Reference: HPCSA, Guidelines for good practice in the health care professions. Booklet 11 Second Edition – Confidentiality: Protecting and providing information – 30th May 2007

4.1 What are the ethical rights in practice with regards to HIV?

The South African constitution (Act 108 of 1996) and the law recognize the importance of maintaining the confidentiality of the HIV status of a patient.

The test results of HIV positive patients should be treated with the highest possible level of confidentiality.

Confidentiality regarding a patient's HIV status extends to other health care practitioners. Other health care professionals may not be informed of a patients HIV status without that patient's consent unless the disclosure is clinically indicated.

The decision to divulge information relating to the HIV status of a patient must always be done in consultation with the patient.

The report of HIV test results by a laboratory, as in the case with all laboratory test results should be considered confidential information. It is therefore essential that health care institutions, pathologists and health care practitioners formulate a clear policy as to how such laboratory results will be communicated and how confidentiality of the results will be maintained.

(Reference: HPCSA, Guidelines for good practice in the health care professions – Booklet 12 – Ethical Guidelines for good practice with regards to HIV – 30th May 2007)

The promotion of **Access to Information Act** states that a health care practitioner shall provide any person over the age of 16 years with direct access to his or her own records on request and provide them with a copy or abstract of such records.

Some laboratories have amended the application of this section allowing the patient to receive full benefit of the test result interpretation from their referring doctor. Patient results may only be given to the referring doctor. This rule is documented on the requisition form that the patient signs in which they consent for the collection of specimens for laboratory testing. Only on the request of the referring doctor may the test results be made available to a patient.

Adhere to the Continuous Professional Development (CPD) guidelines as specified for the profession.

4.2 What is CPD?

Section 26 of The Health Professions Act, 1974 (Act No 56 of 1974) prescribes that all registered practitioners with council undergo continuous education and training in order to retain their registration. Commitment to update and develop knowledge, skill and attitude is an ethical requirement for competent practice.

Continuous Professional Development (CPD) is a means for maintaining and updating professional competence to ensure that the public interest will always be promoted and protected as well as ensuring the best service to the community.

4.3 Who needs to participate in CPD?

All persons registered with the HPCSA are required to participate in CPD in order to retain their council registration.

4.4 What are Continuous Education units (CEUs)?

Each activity has a certain amount of points allocated to it, called CEUs.
Units are accumulated by attending CPD registered activities.
Certificates of attendance and the amount of CEUs earned will be issued after each activity.

4.5 How many CEUs do I have to accumulate?

a) The HPCSA requires that all qualified and registered Medical Technologists and Scientists accumulate 30 CEUs per year or 60 CEUs over 2 years

b) Medical Technicians are to accumulate 15 CEUs per year or 30 CEUs over 2 years.

c) All registered Laboratory assistants must accumulate 10 CEUs per year or 20 CEUs over 2 years.

d) A total of 5 CEUs must be earned in the category of Ethics, Human Rights and /or Medical Law.

a) Each CEU is valid for 24 months.

It is advised that practitioners accumulate an average of:

- 2.5 CEUs – for Technologists and Scientists
- 1.5 CEUs – for Medical and Phlebotomy Technicians and
- 1.0 CEUs – for Lab Assistants

per month to facilitate the process in order to meet the regulatory requirements.

4.6 How do I participate?

Points may be accumulated by attending activities hosted by the company you work for or other organisations provided the activity has been accredited for CPD points by an Accredited Service provider or CPD Accreditor such as SMLTSA. Examples of activities and the levels under which they are categorised are listed below. Medmall articles are easily accessible through the internet to accumulate CEUs All required points may be accumulated in one level. It is compulsory to acquire five of the points in Ethics. All activities accredited for CPD points must contribute to uplifting/enhancing the competence of the practitioner in a particular HPCSA registered Profession. If a CPD activity has been accredited by an Accreditor for a specific Professional Board, all health care professionals may attend that activity if it is relevant to their specific scope of practice (cross accreditation).

- No CPD points may be earned for training of undergraduates (interns and students) or postgraduates if this is part of your job description.

- If you are registered in two professions from two Professional Boards (e.g. Psychology and Medical Technology), you are required to obtain 30 CEUs per profession. The 5 ethics CEUs are credited to both professions.
- If you are registered in more than one category (e.g. Technician and Technologist), the higher CEU requirement is required i.e. 30 CEUs per year, 5 of which must be for ethics.
- Interns and students are not required to accumulate CEUs but are encouraged to participate as this will support the learning process.

Level One Activity

These activities do not have measurable outcomes i.e. no form of assessment is administered.

Examples of Level one activities:

Presentations, Case study discussions, formally organised special purpose lectures, conferences.

1 CEU per hour to a maximum of 8 CEUs per day.

Presenters may be allocated double CEUs (e.g. if activity was 1 hour in duration, attendee gets 1 CEU and presenter 2 CEUs). Please note that if the presenter repeats the lecture (presentation), to another group of attendees, the points cannot be re-earned.

Level Two Activity

These activities have measurable outcomes i.e. a form of assessment is administered (case study analysis, written test etc.)

Examples of Level Two activities:

a. Principle author of a peer reviewed publication or chapter in a book: 15 CEUs. Co-author: 5 CEUs

b. Principle presenter/author of a poster/paper at a congress/symposium: 10 CEUs. Co-presenter/co-author: 5 CEUs

c. Interactive skills workshop with an evaluation of the outcome: 5 CEUs. Please note that this is not a lecture or presentation. It involves a group of subject matter experts who come together to evaluate a particular methodology or procedure and culminates in a product or process for implementation.

d. All learning material (which could include DVD, CD, internet or e-mail activities) with multiple choice questions for evaluation with a pass rate of 70%: 3 per questionnaire.

e. Workshops, lectures, seminars on ethics (not including general presentations with a so called component of ethics): 2 per hour

f. Journal clubs: Participative discussion that occurs not less than 6 times per year in which clinical and laboratory findings, aetiology, method specificity and sensitivity etc. is discussed: 3 CEUs per meeting.

Level Three Activity

This level comprises structured learning in an accredited training institution, assessed by an accredited assessor and has measurable outcomes.

The postgraduate degree and diploma must be recognised as additional qualifications by the relevant Board.

At the end of each year of study, 30 CEUs may be claimed upon submitting an academic report on progress. An additional 30 CEUs may be claimed on successful completion of the qualification.

4.7 How do I record evidence of accumulating CEUs?

Practitioners are personally responsible for accumulating the required CEUs, keeping records of attendance and submission of CEUs to HPCSA as required.

Portfolios of proof of progress should be kept in your personnel file at the site of work. Each portfolio should consist of the following:

- CPD individual activity record sheet
- Original certificate/copies of attendance in the case of Level 1 and/or 2 activities attended.
- Certified certificates of qualifications in the case of Level 3 activities completed.
- Medmall certificate representing the electronic activities completed
- Documents prior to the current cycle must be kept for a minimum of two years.

4.8 Will the HPCSA check that I have accumulated my CEUs?

The HPCSA conduct audits every 2 months. Should a practitioner be randomly selected in the audit, he/she will be expected to submit the portfolio within 21 day of receiving the audit call.

A paper copy of the Practitioners CPD Activity Record may be submitted to:

The CPD Officer
HPCSA
P.O Box 205
Pretoria
0001

Alternately, an electronic copy of the Practitioners CPD Activity record may be submitted to: cpd@hpcsa.co.za

4.9 What happens if I do not have enough CEUs?

a) The council will request reasons for non-compliance.

b) Should your reasons be accepted, you will have 6 months to comply and submit your portfolio to the HPCSA CPD committee.

c) In the event that your reasons for non-compliance are not accepted, your case will be handed to a Preliminary Enquiry committee where your past records will be reviewed.

d) If past record proves to be satisfactory, you will have 6 months to comply and submit your portfolio to the HPCSA CPD committee.

e) If past records are unsatisfactory, the council may require you to:

Work under supervision

- Be suspended from practice for a time period determined by the HPCSA's Medical Technology Board.
- Follow a program of continuing education and training recommended by the board (i.e. rewrite the board examination, etc.)

4.10 What will happen when I will not be able to accumulate CEUs?

Practitioners may request from the SMLTSA a deferment from accruing CEUs for up to 3 years. The application should be strongly motivated with appropriate evidence/documentation. All applications will be reviewed on an ad hoc basis.

Deferment may be granted in the following cases:

- Non-practicing
- Have has long term illness
- Practitioners who are employed outside of South Africa and not practicing his/her profession.
- Practitioners who are practicing outside South Africa in a country where formal continuing professional development does not take place.
- Practitioners who are registered for an additional qualification but is of the view that she/he will not meet the outcome within two years and thus will not be able to claim CEUs.

Reference:

1. Education and training requirements in Medical Technology in South Africa, Professional Board for Medical Technology

2. Policy regarding intern Medical Technologists and Training Medical technologist, Form 160-MT

3. Regulation relating to Intern Medical Technologists and Registration of intern Medical Technologist,2002

4. www.hpcsa.co.za

Study themes

The outcomes of each unit are listed in the table below:

UNIT: 3.1	**THEME:** Viruses and the clinical diagnostic laboratory
OUTCOMES: ***At the end of the unit the student will be able to:***	• Compare the sizes of viruses • Describe arrangements and compositions of viruses • Learn family names and nucleic acid composition • Be familiar with viral replication • Be familiar with routes of transmission and mechanisms for pathogenesis • Describe approaches for diagnosing viral disease • Assess the significance of viral laboratory investigation in a definitive diagnosis
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.2	**THEME:** Laboratory Safety
OUTCOMES: ***At the end of the unit the student will be***	• Itemise and discuss safety precautions that should be taken to minimise infection or injury when carrying out the following – • Cell culture and virus isolation: ▪ specimen receipt and processing

able to:	▪ centrifugation ▪ homogenising ▪ disposing of infected tissue ▪ culture of cells, which may be ▪ infectious e.g. primary monkey kidney ▪ disposal of unused cell or tissue e.g. products of conception • Serology: ▪ specimen receipt, processing, shipping and disposal of all sample types including highly contagious samples e.g. Viral haemorrhagic fever (VHF) specimens ▪ Manual techniques involving pipetting and centrifugation of potentially infected materials e.g. sera. CSF, reagents and controls ▪ labelling and disposal of infectious and chemical waste ▪ storage of specimens • Molecular: • Assess the safety precautions taken for Molecular work with regard to: ▪ specimen receipt, processing, shipping and disposal of all sample types including highly contagious samples e.g. Viral haemorrhagic fever (VHF) specimens ▪ disposal of amplicons, extraction waste and molecular reagents ▪ Manual techniques involving pipetting and centrifugation of potentially infected materials e.g. blood products, CSF, repiratory, stools, urines, tissues, amniotic fluid, eye fluids ect and reagents and controls ▪ labelling and disposal of infectious and chemical waste ▪ storage of specimens • Detail and an official plan of action in the event of: ▪ minor injury, cut or needle stick ▪ cleaning up of infectious and chemical waste ▪ Cleaning up a lab contaminated with wild type or control amplicons. ▪ screening of laboratory staff for immunity including storage of baseline sera and vaccines available to staff ▪ protection of pregnant staff ▪ fire and bomb scares and gas leaks

	• Discuss the decontamination and/or the disposal of the following: ▪ working surfaces including benches, BSC and hoods ▪ syringe needles ▪ scalpels ▪ mortar and pestle ▪ infected cell lines ▪ leaking specimens ▪ pipettes ▪ tips ▪ disposable Pasteur pipettes ▪ broken glass • List agents that may be incriminated in a laboratory accident. ▪ infectious viral agents ▪ contaminated cell line with bacteria or Chlamydia ▪ chemicals organic, inorganic and flammable • State how chemical or molecular, serological, cell culture reagents may be stored and disposed of. • Discuss the role of biological safety cabinets in prevention of laboratory accidents insure correct hood is used ▪ list precautions ▪ insure correct functioning ▪ be aware of consequences of a malfunctioning Biosafety cabinet • Be familiar with personal protective equipment ▪ goggles, earmuffs and face shields ▪ white coats and gloves ▪ bench shields • Be conversant with computer safety and laboratory ethics e.g. ▪ keeping patient records ▪ keeping laboratory results of patients confidential ▪ maintaining discretion amongst peers and colleagues.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment

KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.3	**THEME:** Equipment
OUTCOMES: ***At the end of the unit the student will be able to:***	• Describe the following pieces of equipment and explain how they are used in a virology lab: Autoclaves, balances (including single pan and top pan analytical balances), Biosafety cabinet class 2 and clean air bench, rotating racks, standard and UV fluorescence lights, centrifuges and microfuges, incubators (including CO2 incubators), membrane filter systems for sterilisation of liquids, -20 and -70 C freezers, tissue grinders, Teflon coated slides, shell vials, microscopes (including light, inverted and fluorescent microscopes), pH meters, photometers, pipettes and pipette aids, water baths ,water purification systems, ELISA plate washer and reader, tissue grinders,-20 and -70ºC freezers, refrigerators, rotating racks and vortexes, PCR machines, gel electrophoresis apparatus & UV GEL DOC system for photographing gels. • Discuss the maintenance of the equipment • Describe briefly how the equipment should be tested or checked to ensure that it is operating efficiently and accurately • Trace the flow of air though a Biosafety cabinet and describe the features of this piece of equipment. • List features necessary for desktop centrifuges and/or microfuges for use in the routine virology lab. • List the advantages of the inverted microscope in virology.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.4	**THEME:** Cell cultures
OUTCOMES: ***At the end of the unit the student will be able to:***	• Characterise the major categories of cell cultures used in clinical virology, providing origin of cells, ploidy, and potential for successive generations. Give one example of a cell type or line that is included in each category. • Name the basic constituents used in cell culture medium, and discuss their action and reasons for inclusion in the medium. • Name the various cell types used for diagnostic virology. • Discuss the types, quality and treatment of the glass and plastic ware used in the cell culture laboratory. • Discuss the manipulation of a continuous cell line. • Describe the procedure for cryopreservation of a cell culture. • Describe the procedure for cell culture from frozen ampoules. • Fully describe the procedure used to initiate a primary cell culture of monkey or rabbit kidney, human amnion, or similar cells. • Discuss the possible ways in which contaminations could be introduced into cell cultures, and name the common contaminants. • Discuss the precautions taken and aseptic techniques used to prevent contamination of these, and other cell cultures. • Explain how the quality of cell cultures is monitored.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.5	**THEME:** Virus isolation in traditional cell cultures
OUTCOMES: ***At the end of***	• Identify the preferred clinical specimens for viral isolation in various disease syndromes and for isolation of common human

the unit the student will be able to:	viral pathogens. • Provide instructions for the collection of the various types of clinical samples for virus isolation including urine, peripheral blood, throat swab, rectal swab, stool, CSF, sputum and lesion or vesicle samples. • Describe proper containers for specimen collection and transport, and indicate whether viral transport medium should be used. • Give directions for short- and long-term storage and for transport of clinical samples for virus isolation studies to both in-house laboratories and off-site reference facilities. • Describe viral transport media, listing components and their purpose. • List the basic steps in the processing of clinical samples of inoculation into cell cultures and explain the purpose of each step. • Define cytopathic effects (CPE) with examples of how CPE might appear. • Explain how traditional cell cultures are examined for evidence of viral CPE. • Explain the procedure and underline biological features that are important in haemadsorption, interference challenge and haemagglutination. • Provide examples of viruses that can be definitely identified by immunofluorescence and neutralisation techniques. • Describe viral neutralisation testing including test principle, viral titration and back titration. • Describe the shell vial system, including proper inoculation, incubation and staining. • Give specific information comparing isolation of CMV in shell vials and traditional cell cultures. • Give examples of other viruses, other than CMV, that can be identified in shell vials. • Describe virus isolation in cell cultures grown in micro well plates and indicate how the system is used for virus isolation. • Describe human lymphocyte suspension cultures and list viruses that require this kind of system for their isolation.
TEACHING ACTIVITIES:	Lecture, questions and tutorials

LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.6	**THEME:** Viral antigen detection
OUTCOMES: ***At the end of the unit the student will be able to:***	• List and discuss the advantages and disadvantages of viral disease diagnosis through viral antigen detection. • Describe proper specimen collection and antigen smear preparation for immunofluorescence testing. • Give an overview of the steps required in direct and indirect immunofluorescence methods. • Compare virus isolation in culture with detection of viral antigen by immunofluorescence for Herpes simplex virus, RSV and other respiratory viruses. • Describe enzyme immunoassay for antigen detection and profile the advantages and disadvantages of antigen detection enzyme immunoassay in detecting rotavirus, hepatitis B, RSV, influenza A and HSV antigens. • Describe latex agglutination methods for viral antigen detection and discuss clinical application of this technique. • Describe the Cytomegalovirus antigenemia assay, and explain how it is used in viral antigen detection.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.7	**THEME:** Viral Immunology

OUTCOMES: ***At the end of the unit the student will be able to:***	• List the different parts of the immune system. • List the immune responses to viral infections. • Give the definition of a vaccine. • Compare attenuated vaccines and inactivated vaccines. • List general factors that affect *in vitro* immunoserological assays. • For the following serological principles give an overview of the procedural steps (including a diagram for those principle that are widely used in clinical virology) and describe the appearance of positive and negative results: direct haemagglutination, passive haemagglutination, viral haemagglutination, haemagglutination inhibition, direct immunofluorescence and indirect immunofluorescence, complement fixation, enzyme immunoassay (competitive and non-competitive), immunoblotting and virus neutralisation. • Define and provide formulas for calculation of sensitivity, specificity and predictive values and when provided with data, calculate these values.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.8	**THEME:** Serology diagnosis of viral infections

OUTCOMES:
 	
At the end of the unit the student will be able to:
	• List and discuss the advantages and disadvantages of viral disease diagnosis through viral antigen and antibody detection.
	• Give an overview of the steps required in µ Capture, Sandwich and Competitive ELISA's.
	  ○ Discuss the mechanical factors affecting ELISA assays.
	  ○ Discuss the reasons for having controls and calibrators.
	• Give an overview of an Immunochromatographic & latex

	agglutination tests. • Compare virus isolation in culture with detection of viral antigen by immunofluorescence for Herpes simplex virus, RSV and other respiratory viruses. • Describe enzyme immunoassay for antigen detection and profile the advantages and disadvantages of antigen detection enzyme immunoassay in detecting rotavirus, hepatitis B, RSV, influenza A and HSV antigens. • Describe the Cytomegalovirus antigenemia assay, and explain how it is used in viral antigen detection. • Interpretation of results for chronic and acute infections resulting from HBV, HCV, EBV, HSV, Hep A, CMV, Measles and Rubella. • Explain the basis of viral diagnosis through serology and determine the circumstances in which serology rather than virus isolation or viral antigen detection is the test of choice. • Detail how non-specific inhibitors and agglutinins are removed from the patient's serum prior to testing in the rubella haemagglutination inhibition (HAI) assay; • Using Rubella virus infection as an example and assuming that assays detect primarily IgG, provide answers to the following for serological diagnosis of acquired and congenital infections and for determination of immune status: o How many sera samples should be tested? o When should these samples be tested? o Should the test be in a quantitative or qualitative format? o How are the results of testing interpreted? • Tabulate the haemagglutination viruses, the type of red blood cells they agglutinate and the conditions required for haemagglutination such as pH and temperature; • Illustrate with a labelled diagram the morphology of HIV • Briefly discuss the properties, characteristics and classification of HIV • Outline the precautions taken in your laboratory to minimise HIV infection. • Describe and perform the screening and confirmatory tests done in your laboratory for HIV and explain their significance in the

	diagnosis of HIV/AIDS • Describe test modifications and pre-treatments used to make assay specific for IgM, and explain how IgG and Rheumatoid factor may interfere in IgM specific assays. • Give examples of clinical situations in which IgM specific assays may be of use and discuss the problems, both technical and biological, that must be considered in interpreting the results of IgM specific assays. • Be able to diagram at least 3 methodologies used routinely in viral antibody detection. • List at least 5 viruses whose diagnosis at present relies on the serological approach. • Describe the proper collection and storage of blood samples that will be tested for viral antibodies. • When presented with sample results of quantitative serological test, be able to differentiate significant from non-significant differences in titre
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT: 3.9	**THEME:** Molecular diagnostic techniques
OUTCOMES: ***At the end of the unit the student will be able to:***	• Describe the principle of a PCR. • Explain controls necessary for a PCR. • Discuss the three steps of a PCR. • Design a PCR program. • List the key reagent within a PCR and discuss the role/function of each reagent. • Calculate primer dilution volumes (see Calculations UNIT 4).

	• Explain factors that can affect a PCR. • Describe the workflow dynamics in a PCR laboratory. • Discuss and differentiate between Traditional PCR, NASBA, Reverse-transcriptase PCR, Multiplex and Real Time PCR. • Assess the different applications of PCR • Discuss the prevention of contamination in a PCR laboratory. • Describe the safety aspects of working with specimens, reagents and equipment in the PCR laboratory. • The student must be able to perform the electrophoresis of PCR products and analyse & interpret the gel results. • Explain the procedures necessary to discard PCR products. • Describe the principle of agarose gel electrophoresis. • Explain factors that affect the rate of migration of nucleic acids within an agarose gel. • Explain the function of Ethidium Bromide within an agarose gel and the hazards of using Ethidium Bromide. • Trouble shooting of false negative and positive results with reference to amplification, extraction, detection, reagents, equipment and human errors.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.10	**THEME:** DNA Viruses
OUTCOMES: ***At the end of the unit the student will be able to:***	• ***Adenoviridae****:*Adenovirus • ***Hepadnaviridae***:Hepatitis B virus • ***Herpesviridae:*** Cytomegalovirus; Epstein-Barr virus; Herpes simplex virus type 1 and 2; Varicella-zoster virus • ***Papovaviridae****:* Papillomavirus; Polyomavirus • ***Parvoviridae****:* Human parvovirus B19

	• ***Poxviridae**:* Variola; Molluscum Contangiosum • Give the classification by family. • Define the different disease syndromes and vectors to which each virus is commonly associated. • Identify the approaches (virus isolation, viral antigen detection, serodiagnosis, molecular tests) that are useful in laboratory diagnosis of infection. • Indicate whether viral antigen detection methods are available and useful clinically, and list and describe specific methodologies used for this purpose. • Indicate which types of clinical samples should be collected and submitted for diagnosis. • Distinguish the various modes of transmission, pathogenesis, epidemiology, treatment, prevention and presentation of DNA viruses • Discuss Emerging and re-emerging viruses
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.11	**THEME:** RNA Viruses
OUTCOMES: ***At the end of the unit the student will be able to:***	• ***Arenaviridae:*** Lassa fever virus; Lymphocytic choriomeningitis • ***Bunyaviridae:*** California encephalitis virus • ***Orthomyxoviridae:*** Influenza A, B, and C • ***Paramyxoviridae:*** Measles; Mumps; Parainfluenza 1,2,3, and 4; Respiratory syncytial virus; Human Metapneumovirus (hMPV) • ***Picornaviridae:*** Enterovirus; Coxsackie A and B; Echovirus; Poliovirus; Hepatitis A; Rhinovirus; **Reoviridae:** Rotavirus • ***Retroviridae*:** HIV type 1 • ***Rhabdoviridae:*** Rabies

	• ***Togaviridae**:* Eastern and western equine encephalitis; Rubella • Unclassified: Hepatitis C virus (flavivirus) • **Other RNA viruses** • Astroviruses • ***Caliciviridae*:** Norwalk • *Coronaviridae* • ***Filoviridae*:** Marburg and Ebola • Hepatitis D • Hepatitis E • Give the classification by family. • Define the different syndromes and vectors to which each virus is commonly associated. • Identify the approaches (virus isolation, viral antigen detection, sero diagnosis, molecular testing of infection). • Indicate whether viral antigen detection methods are available and useful clinically, and list and describe specific methodologies used for this purpose. • Indicate which types of clinical samples should be collected and submitted for diagnosis. • Distinguish the various modes of transmission, pathogenesis, epidemiology, treatment, prevention and presentation of DNA viruses • Discuss Emerging and re-emerging viruses.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.12	**THEME:** Quality Control
OUTCOMES: ***At the end of***	• Outline and discuss Good Laboratory practice with respect to: Organization, personnel, facilities, equipment.

the unit the student will be able to:	• Give a brief outline of the South African National Accreditation Systems (SANAS) ISO/15189 for medical laboratories. • Understand and discuss the quality management system – as described per Local Laboratory Manual – with reference to the following sub-headings: ▪ Organization and management ▪ Document control ▪ Identification of non-conformances ▪ Corrective action ▪ The audit process ▪ Laboratory Equipment – monitoring and calibration ▪ Reagents – monitoring storage and dates of expiry ▪ Standard Operating Procedures ▪ Quality Assurance vs. Quality Control ▪ Ethical Guidelines relating to confidentiality
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

Unit: 3.13	**THEME:** Accreditation
OUTCOMES: ***At the end of the unit the student will be able to:***	• Outline the principle of the accreditation process in the laboratory referring to the South African National Accreditation Systems (SANAS) ISO/15189 for medical laboratories. • Describe the document control system. • Describe the requirements for equipment management under the following headings. ▪ Standard operating procedures ▪ Record keeping ▪ Calibration

	▪ Monitoring ▪ Services • Discuss the accommodation and environmental conditions necessary for accreditation. • Discuss the difference between a vertical audit and a horizontal audit • Explain the non-conformance process. • Discuss the process of issuing a non-conformance up to the point of completion.
TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training
ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	National Diploma in Biomedical Technology

UNIT 4.	**THEME:** Laboratory related mathematics

OUTCOMES:
At the end of the unit the student will be able to:
	• Basic calculations using formulas in making laboratory solutions
	$C_1V_1=C_2V_2$
	#moles = mass/molar mass
	Conc. = #moles/volume
	• Basic calculations using formulas in primer dilutions
	Conc of primer = 33 x OD (ug/ml)
	MW of DNA = 325 daltons x number of base pairs (ug/ umol)
	Conc primer in umol/ ul = conc (ug/ml) / MW (ug/ umol)

TEACHING ACTIVITIES:	Lecture, questions and tutorials
LEARNING ACTIVITIES:	Practical training

ASSESSMENTS	Written assessment
KNOWLEDGE BASE:	Grade 12

5. Reference materials

- Medical Virology, 3rd Edition
    - David O. White and Fank J Fenner
- A practical Guide to Clinical Virology
    - G. Haukenes, L.R. Haaheim and J.R. Pattison
- Diagnostic procedures for Virsal, Rickettsial and Chlamydial Infections, 7th Edition
    - Edwin H. Lennette, and Nathalie J Schmidt
- Principles and practice of Clinical Virology, 2nd Edition
    - A.J. Zuckerman, J.E. Banatvala and J.R. Patteson
- Culture of animal cells, 2nd Edition
    - R.I. Freshney

6. Nomenclature / Acronyms

SOP: Standard operating Procedure

CPE: Cytopathic effect

BSC: Biosafety cabinet

UV: ultra violet

CO_2: Carbon dioxide

ELISA: Enzyme Linked Immunosorbant Assay

CSF: cerebrospinal fluid

CMV: Cytomegalovirus

HSV: Herpes Simplex Virus

RSV: Respiratory Syncytial Virus

HBV: Hepatitis B Virus

HCV: Hepatitis C Virus

EBV: Epsteinbarr Virus

Hep A: Hepatitis A Virus

PCR: Polymerase chain reaction

hMPV: Human Metapneumovirus

SANAS: South African National Accreditation Systems

Conc.: concentration

OD: optical density

MW: molecular weight

HIV: Human Immunodeficiency Virus

AIDS: Acquired Immune Deficiency Syndrome

HAI: Haemagglutination inhibition