



**CMS 02 MBS**

**GUIDELINE FOR SUBMISSION AND ASSESSMENT OF PORTFOLIO OF EVIDENCE:  
MEDICAL BIOLOGICAL SCIENCE**

**MEDICAL AND DENTAL PROFESSIONS BOARD: MEDICAL SCIENCE**

This document serves as the *prescribed template*, which has to be compiled as a *structured and concise Portfolio of Evidence in a standardized format*. The Portfolio of Evidence is the equivalent of a Medical and Dental Professions Board-approved competency-based examination for intern medical scientists after completion of internship training. Internship determines the overall competency by assessing the discipline-specific learning outcomes. Successful submission and assessment of the Portfolio of Evidence allows the intern candidate to apply for registration with the HPCSA as a professional medical scientist.

This guideline is a user-friendly template, which contains all the required components as prescribed by the National Curriculum (CMS 01 MBS). You will use this template to compile your evidence-based Portfolio of Evidence, which is a competency-based assessment. It is design to serve as a template to either allow you to (a) complete a document or to (b) insert a document. It contains a Table of Contents, a cover page, all the mandatory forms and a list with all the discipline-specific outcomes. The components and sub-components of each discipline-specific outcome is defined as a (a) teaching and learning activity, (b) an assignment, (c) specified assessment and (d) required evidence. With completion of the Portfolio of Evidence, you will use the list to allocate page numbers to the specific evidence and completed tables.

By using this structured guideline, the candidate can evaluate progress, while the assessment panel can apply this as an easy navigation tool to confirm appropriateness of evidence

This guideline is a summary of The National Curriculum for Medical Biological Science (*CMS 01 MBS*) and must be read with the following documents:

- *The National Curriculum for Medical Biological Science – CMS 01 MBS*
- *Policy regarding the training of intern medical scientists - CMS A*
- *Template for the development of a facility-based intern training program (CMS 03)*
- *Guideline on Assessment and Moderation of Portfolio of Evidence: Intern Medical Scientists – CMS H*

Submission of required forms

- All forms required for submission are included in the three policies and guidelines (*see above*) of the Committee for Medical Science and available from HPCSA website (<https://www.hpcsa.co.za>)
- Forms 23, 24, 26 and 36 are available on the HPCSA website (<https://www.hpcsa.co.za>)

#### Instructions for use

- The assessment panel will use the checklist to direct themselves to the evidence of each learning outcome
- Page numbers will be allocated to the entire Portfolio of Evidence
- The intern candidate will compile evidence under each heading and sub-heading and summarize all evidence in a prescribed table
- Scan this document in as two separate and independent PDF documents:
  - Part 1: Guidelines for the submission and assessment of the Portfolio of Evidence.
  - Part 2: Administrative requirements

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**DETAILS OF THE INTERN MEDICAL SCIENTIST AND TRAINING FACILITY**

**PORTFOLIO OF EVIDENCE: MEDICAL BIOLOGICAL SCIENCE**

Name and Surname of Intern Candidate	
HPCSA Intern Registration Number	
Registration Date	
Contact Details: Telephone Number Email	
Professional Category	
Period of Internship	
Date of letter of Intent to Submit Portfolio of Assessment (CMS A-02)	
Date of Submission of Portfolio of Evidence	
Training Facility Name of Head of Training Facility	
Training Department Name of Head of Training Departmental	
Name of Supervisor Professional Category HPCSA Registration Number Registration date	



**CMS 02-01 MBS**

**INTERN DUTY CERTIFICATE: MEDICAL BIOLOGICAL SCIENCE  
COMPLETION OF 2-YEAR INTERNSHIP TRAINING AT AN HPCSA ACCREDITED TRAINING  
FACILITY**

**MEDICAL AND DENTAL PROFESSIONS BOARD: MEDICAL SCIENCE**

1. COURSE OUTCOMES <i>At the end of the training program the candidate should have gained knowledge, expertise, skill and a certain degree of experience in the following areas:</i>	PERIOD		Completion by the <u>Head of Training Department</u> or official deputy confirming that the internship period had been completed <b>satisfactorily</b> and in an <b>approved diagnostic/clinical setting</b>		
	FROM	TO	PRINTED NAME	SIGNATURE	DATE
1.1 Application of professional conduct and ethical rules in the practice of clinical diagnostics					
1.2 Application of good laboratory practice (GLP) and laboratory safety in a diagnostic environment					
1.3 Quality management in a diagnostic environment					
1.4 Application of scientific principles and discipline-specific knowledge					
1.5 Performance of laboratory methods and interpretation of patients results in a diagnostic environment – competency training					
1.6 Research principles and scientific reporting					
<b>2. LEAVE TAKEN:</b>			Total number of weeks		
2.1 Vacation leave			Total number of weeks		
2.2 Maternity leave			Total number of weeks		
2.3 Sick leave / Other leave (specify)			Total number of weeks		

**This signature is compulsory and validates internship training**

\_\_\_\_\_

Name and signature of Head of Training Facility

Date \_\_\_\_\_

Official stamp

**No alterations to this document will be accepted**



**THE PORTFOLIO OF EVIDENCE: MEDICAL BIOLOGICAL SCIENCE**  
**MEDICAL AND DENTAL PROFESSIONS BOARD: MEDICAL SCIENCE**

	To be completed by intern  <i>Page number</i>	Compliance (assessor) ✓ for Yes X for No
<b>A. Mandatory documents</b>		
A1. Copy of Identity Document		
A2. Copy of HPCSA intern certificate		
A3. Copy of Exemption of Research project based on Prior Learning (if applicable)		
A4. Copy of Exemption of various components of training program based on migration to another professional grouping		
A5. Copy of HPCSA-approved facility-based internship-training program		
A6. Facility-based rotation roster – <i>Table 1</i>		
A7. Completed rotation roster – <i>Table 2</i>		

### **3. DISCIPLINE-SPECIFIC LEARNING OUTCOMES**

#### **3.1 Professional Conduct and Ethical Rules**

3.1.1	<p><b>Understand and apply Professional Conduct and Ethical Rules.</b></p> <p><i>Teaching and learning activities:</i> Lectures and interactive discussions.  <i>Assignment:</i> Apply the knowledge from the sessions on Booklets 1 to 12 and 16 to 17 to the case examples given.  <i>Assessment:</i> Summative assessment of case studies.</p> <p><b>Evidence:</b>            (a) Complete Table 3            (b) Case studies with assessment to cover all 14 booklets.</p>		
3.1.2	<p><b>Understand and apply the General guidelines for health researchers and biotechnology research in South Africa dealing with patients and patient samples, Booklets 13, 14 and 15</b></p> <p><i>Teaching and learning activities:</i> Lectures and interactive discussions.  <i>Assignment:</i> Apply the knowledge from the sessions on Booklets 13 to 15 to the case examples given.  <i>Assessment:</i> Summative assessment of case studies.</p> <p><b>Evidence:</b>            (a) Complete Table 3            (b) Case studies with assessment to cover all 3 booklets.</p>		
3.1.3	<p><b>Understand and apply Occupational Health and Safety Act.</b></p> <p><i>Teaching and learning activities:</i> Lectures and interactive discussions.  <i>Assignment:</i> Apply the knowledge from the sessions to the case examples given  <i>Assessment:</i> Summative assessment of case studies.</p> <p><b>Evidence:</b>            (a) Complete Table 4            (b) Case studies with assessment.</p>		
3.1.4	<p><b>Understand and apply Acts and Guidelines relevant to professional category.</b></p> <p><i>Teaching and learning activities:</i> Lectures and interactive discussions.  <i>Assignment:</i> Apply the knowledge from the sessions to the case examples given.</p>		



	<p><i>Assessment:</i> Summative assessment of case studies.</p> <p><b><i>Evidence:</i></b>  (a) Complete Table 5.  (b) Case studies with assessment</p>		
<b>3.2 Good Laboratory Practice (GLP) and Laboratory Safety</b>			
3.2.1	<p><b>Define and practice the correct use of Personal Protective Equipment (PPE).</b></p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b><i>Evidence:</i></b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		
3.2.2	<p><b>Define and practice the safe handling, storage and disposal of biological samples.</b></p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b><i>Evidence:</i></b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		
3.2.3	<p><b>Define and practice the safe handling, storage and disposal of chemicals (including, but not limited to radioactive material, where applicable).</b></p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b><i>Evidence:</i></b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		

3.2.4	<p><b>Identify and practice the managing of chemical and biological spills</b> (including radioactive materials where applicable).</p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b>Evidence:</b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		
3.2.5	<p><b>Identify fire hazards and partake in safety drills.</b></p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b>Evidence:</b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		
3.2.6	<p><b>Identify and locate physical and ergonomic hazards.</b></p> <p><i>Teaching and learning activities:</i> Facility based induction-training program.  <i>Assignment:</i> Apply the knowledge from the session(s) to complete the questionnaire  <i>Assessment:</i> Summative assessment of questionnaire.</p> <p><b>Evidence:</b>  (a) Complete Table 6  (b) Assessed questionnaire</p>		
<b>3.3 Quality Management</b>			
3.3.1	<p><b>Partake in various components of laboratory management and administration in the diagnostic environment.</b></p> <p><i>Teaching and learning activities:</i></p> <p>(a) Procurement of reagents / consumables  (b) Management of stock levels.</p>		

	<p>(c) Monitoring of Internal Quality Indicators: Sample volumes, turn-around time, sample rejection rates and success rate of each test method to produce a clinical relevant patient report.</p> <p>(d) Document control and implementation of logbooks.</p> <p>(e) Identification of non-conformances, resolution thereof, root cause analysis and trend analysis.</p> <p>(f) Costing of a procedure / test method.</p> <p>(g) Acknowledge yourself with Disciplinary procedure in the diagnostic setting</p> <p><i>Assignment:</i> Part take in the activities</p> <p><i>Assessment:</i> Summative assessment of documentation of the protocols / procedures performed.</p> <p><b>Evidence:</b>  (a) Complete Table 7  (b) Documentation with assessment on each activity</p>		
3.3.2	<p><b>Participate in laboratory accreditation and audits.</b></p> <p><i>Teaching and learning activities:</i> Physical accreditation and audits</p> <p><i>Assignment:</i> Part take in an accreditation visit and audits</p> <p><i>Assessment:</i> Root cause analysis and resolution of non-conformances raised.</p> <p><b>Evidence:</b>  (a) Complete Table 8  (b) Resolution of non-conformances, completed root cause analysis and resolutions</p>		
3.3.3	<p><b>Participate in Internal and external quality assurance programs.</b></p> <p><i>Teaching and learning activities:</i> Active participation in EQA programs.</p> <p><i>Assignment:</i> Discussion of evaluation reports, performing root cause analysis, resolution of non-conformances and possible trend analysis.</p> <p><i>Assessment:</i> Summative assessment</p> <p><b>Evidence:</b>  (a) Complete Table 9  (b) Assessed assignment (root cause analysis, resolution of non-conformances and trend analysis.</p>		

3.3.4	<p>Perform validation/verification of diagnostic test methods / platforms / kits.</p> <p><i>Teaching and learning activities:</i> Active participation in the verification / validation of a test method / platform / kit. (lot-to-lot / shipment-to-shipment / batch-to-batch) verification is included under Internal Quality Control).</p> <p><i>Assignment:</i> Write a validation / verification report.</p> <p><i>Assessment:</i> Formal team discussion and summative assessment</p> <p><b>Evidence:</b>  (a) Complete Table 10  (b) Assessed verification / validation report.</p>		
3.3.5	<p><b>List and apply Standard Operation Procedures (SOP's) and guidelines.</b></p> <p><i>Teaching and learning activities:</i> Understand and apply SOP's and guidelines.</p> <p><i>Assignment:</i> List, reading, revision and implementation of SOP's and guidelines.</p> <p><i>Assessment:</i> Acknowledgement of reading and summative assessment of revisions.</p> <p><b>Evidence:</b>  (a) Complete Table 11  (b) Assessed revisions</p>		
3.3.6	<p><b>Participate in the safe operation, maintenance, troubleshooting and service of laboratory equipment.</b></p> <p><i>Teaching and learning activities:</i> Training in the safe operation, maintenance and servicing of laboratory equipment.</p> <p><i>Assignment:</i> Adherence to maintenance schedule and management of book of life.</p> <p><i>Assessment:</i> Summative assessment of maintenance and servicing.</p> <p><b>Evidence:</b>  (a) Complete Table 12  (b) Certificate of training and record of maintenance and servicing.</p>		
3.3.7	<p><b>Successful completion of a Vertical Assessment (SANAS F95-07) of each test method.</b></p> <p><i>Teaching and learning activities:</i> Completion of a Vertical Assessment.</p> <p><i>Assignment:</i> Undergo a Vertical Assessment.</p> <p><i>Assessment:</i> Determine root cause analysis and resolutions of non-conformances.</p> <p><b>Evidence:</b></p>		

	<p>(a) Complete Table 13.  (b) Completed Vertical Assessment form  (c) Completed resolution of non-conformance(s) / root cause analyses</p>		
<b>3.4 Scientific and Discipline-Specific Knowledge</b>			
3.4.1	<p><b>List of appropriate textbooks and literature or accredited online resources</b></p> <p><i>Teaching and learning activities:</i> Interactive lectures.  <i>Assignment:</i> Written tests  <i>Assessment:</i> Formal assessment to cover all academic training (at least once annually).</p> <p><b>Evidence:</b>  (a) Complete Table 14  (b) Assessed written tests and questionnaire.</p>		
3.4.2	<p><b>List Journal clubs attended and presented.</b></p> <p><i>Teaching and learning activities:</i> Attendance and participation.  <i>Assignment:</i> Attend, prepare and present journals  <i>Assessment:</i> Attendance register / CPD certificate</p> <p><b>Evidence:</b>  (a) Complete Table 15  (b) Program of Journal Club  (c) Attendance register / CPD certificate</p>		
3.4.3	<p><b>List all lectures / seminars / workshops / conferences / courses attended and presented.</b></p> <p><i>Teaching and learning activities:</i> Attendance and participation.  <i>Assignment:</i> Attend, participation and present  <i>Assessment:</i> Attendance register, certificate of attendance and/or approved abstract.</p> <p><b>Evidence:</b>  (a) Complete Table 16  (b) Attendance register, certificate of attendance and/or approved abstract.</p>		

<b>3.5 Practical Competency Training</b>			
3.5.1	<p><i>Overall teaching and learning activity:</i> Apply the most appropriate test method from your test repertoire to a request from a Request Form to provide an integrated patient report.</p> <ul style="list-style-type: none"> <li>• List the entire scope of testing (repertoire) of the training department. It is required that the intern candidate will be proficient in the full scope of test methods at the end of internship-training - <i>Table 17</i></li> <li>• Tabulate the summary of the total number of repetitive testing with competency levels (levels 1, 2, 3 and 4) – <i>Table 18. Table 18.1 or 18.2 or 18.3 or 18.4 or 18.5 etc.</i>.</li> <li>• Tabulate a list of unique sample numbers of each sample used in a specific test method – <i>Table 19. Table 19.1 or 19.2 or 19.3 or 19.4 or 19.5 etc.</i>.</li> </ul>		
3.5.2	<p><i>Assignment 1:</i> Describe the general principles, limitations, benefits (specificity, sensitivity / positive predictive value / negative predictive value / verification data / validation data / reproducibility) of every test method in your test repertoire. <i>Assessment:</i> Summative assessments</p> <p><b>Evidence:</b> (a) Complete Table 20 (b) Assessed written report</p>		
3.5.3	<p><i>Assignment 2:</i> Define the aetiology / pathology of every disease listed in your test repertoire <i>Assessment:</i> Summative assessments</p> <p><b>Evidence:</b> (a) Complete Table 21 (b) Assessed written report</p>		
3.5.4	<p><i>Assignment 3:</i> Perform the test method based on Standard Operation Procedure <i>Assessment:</i> Direct Witness Activity (SANAS F15-11)</p> <p><b>Evidence:</b> <i>Provide evidence of at least five (5) complete test reports, as described in assignment 3 (b) to (h) will be provided as evidence for each test method</i></p> <p>(a) Complete Table 22 (b) Completed Direct witness form</p>		

	<p>(c) Request Form which accompanied the sample to the laboratory</p> <p>(d) Pre-analytic worksheet</p> <p>(e) Post analytical – this activity will provide evidence on how you evaluate data:</p> <ul style="list-style-type: none"> <li>• Qualitative analysis – provide raw data printed in color and use colored pencils to indicate the various aspects used in the interpretation of data</li> <li>• Quantitative analysis – provide raw data obtained / interfaced from instrumentation</li> </ul> <p>(f) Patient report / template by intern candidate</p> <p>(g) Final report by relevant health professional</p> <p>(h) Recommend reflex or other follow up testing</p>		
3.5.5	<p><b>Assignment 4:</b> Troubleshoot any failed test procedure / equipment / operator procedure</p> <p><b>Assessment:</b> Summative assessment</p> <p><b>Evidence:</b></p> <p>(a) Complete Table 23</p> <p>(b) Completed trouble-shooting form with resolution</p>		
<b>3.6 Principles of Research</b>			
3.6.1	<p><b>Assignment 1:</b> Develop a protocol for your research study.</p> <p><b>Assessment:</b> Summative assessment by supervisor</p> <p><b>Evidence:</b> Assessed protocol</p>		
3.6.2	<p><b>Assignment 2:</b> Apply for ethical approval to perform your research project by using Health Science Research Ethical Committee application documents.</p> <p><b>Assessment:</b> Summative assessment.</p> <p><b>Evidence:</b> Approval letter of ethical clearance from Training Department</p>		
3.6.3	<p><b>Assignment 3:</b> Avoid plagiarism in the development of your protocol and scientific report.</p> <p><b>Assessment:</b> Apply the tool used, for example Turnitin.</p> <p><b>Evidence:</b> Provide Turnitin report (or similar)</p>		
3.6.4	<p><b>Assignment 4:</b> Compile a budget and apply for funding of disposables, reagents and other to perform your project.</p> <p><b>Assessment:</b> Summative assessment by supervisor.</p> <p><b>Evidence:</b> Budget and funding application</p>		

3.6.5	<p><b>Assignment 5:</b> Select and apply biostatistics and / or databases (if applicable), in the interpretation of your results / research.</p> <p><b>Assessment:</b> Summative assessment by supervisor</p> <p><b>Evidence:</b> Use and interpretation in scientific report (if applicable)</p>		
3.6.6	<p><b>Assignment 6:</b> Compile a scientific report to be prepared in the following format:</p> <ul style="list-style-type: none"> <li>• Abstract (250-300 words), Introduction, Methods, Results, Discussion, Conclusion, References.</li> </ul> <p><b>Assessment:</b> Summative assessment</p> <p><b>Evidence:</b> Assessed Scientific report</p>		
3.6.7	<p><b>Assignment 7:</b> Present your research findings as a scientific report by using a Power Point presentation.</p> <p><b>Assessment:</b> Formal assessment team by training department – Table 24</p> <p><b>Evidence:</b> Assess Power Point presentation</p>		

**Final exit assessment by the Training Department**

**4. Final approval by the supervisor of the intern candidate:**

- I \_\_\_\_\_ hereby confirm that the candidate:
- has acquired the necessary skills, academic knowledge and practical competencies outlined in the syllabus (discipline-specific learning outcomes as prescribed in The National Curriculum – CMS 01 MBS), and
  - recommends this Portfolio of Evidence for summative assessment by the Head of the Training program.

Signature of Supervisor \_\_\_\_\_

Date \_\_\_\_\_

**5. Final approval by the head of the training program of the intern candidate:**

- I \_\_\_\_\_ hereby confirm that by *summative assessment*, the candidate:
- performed satisfactory over the entire internship training and by scrutinizing the completed Portfolio of Evidence has successfully complied with the overall course outcomes outlined in the syllabus (as prescribed in The National Curriculum – CMS 01 MBS), and
  - provides consent for formal assessment of this Portfolio of Evidence by the Board.

Signature of Head of Training Program \_\_\_\_\_

Date \_\_\_\_\_



- Documentation for all forms of assessment done during the training period needs to be included. It is important to note that proof of skills or competency should be in the form of tests/assignments/case reports or similar. Proof of on-the-bench training only i.e. technical competency is not sufficient.
- Summarize all evidence in the relevant tables. These have to be signed and dated by the candidate and verified by the supervisor. Final endorsement by head of training program with signature, date and official stamp.

# **Evidence of all components**

## **A. Mandatory documents**

A1. Please insert a copy of your Identity document

A2. Please insert a copy of your HPCSA Intern Certificate

A3. Please insert a copy of HPCSA approval letter on exemption of Research project based on prior learning (if applicable)

A4. Please insert a copy of HPCSA approval letter of exemption of various components of internship-training program based on migration to another professional grouping (if applicable).

A5. Please insert a copy of your HPCSA-approved facility-based internship training program

**A6. Table 1.**

**Summarize the rotation roster based on your facility-based training program over entire 24-month internship training period**

<b>Period</b>	<b>Component</b>	<b>Trainer</b>	<b>Supervisor</b>	<b>Comments</b>



**A7. Table 2. Rotation Roster – complete this roster after every successful rotation as indicated in Table 1.**

Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				
Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				
Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				
Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				

Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				
Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				
Name of Laboratory / Bench	From	To	Total Period	Supervisor signature
Short description of activities				

### **3. Discipline-Specific Learning Outcome**

## **3.1 Professional Conduct and Ethical Rules**

### 3.1. Professional Conduct and Ethical Rules

**Table 3. Professional conduct and Ethical rules**

**Method of Instruction: Lectures and interactive discussions**

Booklet	Subject	Case study number	Method of Assessment Summative assessment of case studies Mark	Date	Signature of Intern Candidate	Signature of Trainer
1	General ethical guidelines for health care professions					
2	Ethical and professional rules of the Health Professions Council of South Africa as promulgated in Government Gazette R717/2006					
3	National Patients' Rights Charter					
4	Seeking patients' informed consent: The ethical consideration					
5	Confidentiality: Protecting and providing information					
6	Guideline for the management of patients with IV infections or AIDS					
7	Guidelines withholding and withdrawing treatment					
8	Guidelines on Reproductive Health Management					
9	Guideline on Patient Records					
10	Guidelines for the practice of Telemedicine					
11	Guidelines on over servicing, perverse incentives and related matters					
12	Guidelines for the management of health care waste					
13	General ethical guidelines for health researchers					
14	Ethical guidelines for Biotechnology Research in South Africa					
15	Research, development and the use of chemical, biological and nuclear weapons					
16	Ethical guidelines on Social Media					
17	Ethical guidelines on Palliative care					

**Insert evidence:**

**3.1.1 Professional Conduct and Ethical Rules – Booklets 1 to 17**

Evidence: Case studies with summative assessment to cover all 17 Booklets.

For example:

**Case 1 - General ethical guidelines for health care professions**

***Insert evidence***

***Case 2 - Ethical and professional rules of the Health Professions Council of South Africa as promulgated in Government Gazette R717/2006***

**Insert evidence:**

**3.1.2 General guidelines for health researchers and Biotechnology research in South Africa dealing with patients and patient samples - Booklets 13,14 and 15).**

Evidence: Case studies

**Case study number - General ethical guidelines for health researchers**



**Insert evidence**

**Case study number - Ethical guidelines for Biotechnology Research in South Africa**

**Insert evidence**

**Case study number - Research, development and the use of chemical, biological and nuclear weapons**

### 3.1.3 Occupational Health and Safety Act

Table 4. Occupational Health and Safety Act

Method of Instruction: Lectures and interactive discussions

	Subject	Case study number	Method of Assessment Summative assessment of case studies Mark	Date	Signature of intern candidate	Signature of trainer
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

**Insert evidence:**

### **3.1.3 Occupational Health and Safety Act**

Evidence: Case studies with summative assessment

#### **Case study 1**

**Insert evidence**

**Case study 2**

### 3.1.4 Acts and Guidelines relevant to professional category

Table 5. Acts and Guidelines relevant to professional category

Method of Instruction: Lectures and interactive discussions

	Subject	Case study number	Method of Assessment Summative Mark	Date	Signature of intern candidate	Signature of trainer
1						
2						
3						
4						
4						

**Insert evidence:**

### **3.1.4 Acts and Guidelines relevant to professional category**

Evidence: Case studies with summative assessment

#### **Case study 1**

## Case study 2



## **3.2 Good Laboratory Practice (GLP) and Laboratory Safety**

## 3.2 GOOD LABORATORY PRACTICE (GLP) AND LABORATORY SAFETY

Table 6. Good Laboratory Practice (GLP) and Laboratory Safety

Method of Instruction: Lectures and Questionnaires

Method of assessment: Summative Assessment

Subject	Questionnaire number	Assessment Mark	Date	Signature of intern candidate	Signature of trainer
3.2.1 Define and practice the correct use of personal protective equipment (PPE).	1				
3.2.2 Define and practice the safe handling, storage and disposal of biological specimens.	2				
3.2.3 Define and practice the safe handling, storage and disposal of chemicals (including radioactive materials, where applicable).	3				
3.2.4 Identify and practice the managing of chemical and biological spills (including radioactive materials where applicable).	4				
3.2.5 Identify fire hazards and partake in safety drills.	5				
3.2.6 Identify and locate the physical and ergonomic hazards.	6				

**Insert evidence:**

### **3.2.1 Personal protective equipment (PPE)**

Evidence: Assessed questionnaire number

## **Insert evidence:**

### **3.2.2 Safe handling, storage, and disposal of biological samples**

Evidence: Assessed questionnaire number

**Insert evidence:**

**3.2.3 Define and practice the safe handling, storage and disposal of chemicals (including radioactive materials, where applicable).**

Evidence: Assessed questionnaire number

## **Insert evidence:**

### **3.2.4 Identify and practice the management of chemical and biological spills (including radioactive materials where applicable)**

Evidence: Assessed questionnaire number

## **Insert evidence:**

### **3.2.5 Identify Fire hazards and partake in safety drills**

Evidence: Assessed questionnaire number

**Insert evidence:**

**3.2.6 Identify and locate physical and ergonomic hazards**

Evidence: Assessed questionnaire number



## **3.3 Quality Management**

### 3.3.1 QUALITY MANAGEMENT

Table 7. Laboratory Management and Administration

Method of Instruction: Partake in activities

Method of assessment: Summative Assessment of documents protocols

Subject	Document / Protocol	Assessment Mark	Date	Signature of intern candidate	Signature of trainer
a) Procurement of reagents / consumables					
b) Management of stock levels					
c) Monitoring of internal quality indicators: sample volumes, turnaround time, sample rejection rates and success rates					
d) Document control and implementation of logbooks.					
e) Identification of non-conformances, resolution thereof, root cause analysis and trend analysis					
f) Costing of procedure / test method					
g) Acknowledge yourself with Disciplinary procedure in the diagnostic setting					

**Insert evidence:**

**3.3.1 Laboratory management and administration**

Evidence: Documentation with assessment of each activity

**(a) Procurement of reagents / consumables.**

**Insert evidence:**

**3.3.2 Laboratory management and administration**

Evidence: Documentation with assessment of each activity

**(b) Management of stock levels.**

**Insert evidence:**

**3.3.2 Laboratory management and administration**

Evidence: Documentation with assessment of each activity

**c) Monitoring of internal quality indicators: sample volumes, turnaround time, sample rejection rates and success rates of each test method to produce a clinical relevant patient report.**

**Insert evidence:**

**3.3.2 Laboratory management and administration**

Evidence: Documentation with assessment of each activity

**(d) Document control and implementation of logbooks.**

**Insert evidence:**

**3.3.2 Laboratory management and administration**

Evidence: Documentation with assessment of each activity

**(e) Identification of non-conformances, resolution thereof, root cause analysis and trend analysis.**

**Insert evidence:**

**3.3.2 Laboratory management and administration**

**Evidence: Documentation with assessment of each activity**

**(f) Costing of a procedure / test method**



**Insert evidence:**

**3.3.2 Laboratory management and administration**

**Evidence: Documentation with assessment of each activity**

**(g) Acknowledge yourself with Disciplinary procedure in the diagnostic setting**

### 3.3.2 Laboratory Accreditation and Audits

Table 8. Laboratory accreditation and audits

Method of Instruction: Partake in activities

Method of assessment: Summative Assessment of resolution of non conformances and root cause analysis

Type of Audit / Accreditation	Number of non-conformances	Type of participation	Resolution of non-conformances and root cause analysis Case number	Date	Signature of intern candidate	Signature of trainer
			1			
			2			
			3			
			4			

**Insert evidence:**

**3.3.2 Laboratory accreditation and audits**

**Laboratory accreditation and audits**

**Case 1**

Evidence: Resolution of non-conformances, completed root cause analysis and resolutions

**Insert evidence:**

**3.3.2 Laboratory accreditation and audits**

**Case 2**

**Laboratory accreditation**

Evidence: Resolution of non-conformances, completed root cause analysis and resolutions

**Insert evidence:**

**3.3.2 Laboratory accreditation and audits**

**Case 3**

**Laboratory audits**

Evidence: Resolution of non-conformances, completed root cause analysis and resolutions

**Insert evidence:**

**3.3.2 Laboratory accreditation and audits**

**Case 4**

**Laboratory accreditation**

Evidence: Resolution of non-conformances, completed root cause analysis and resolutions



### 3.3.3 Internal and External Quality Assurance programs

**Table 9. Internal and External Quality Assurance programs**

**Method of Instruction:** Discussion of evaluation reports, resolution of non-conformances, performing root cause analysis and possible trend analysis.

**Method of assessment:** Summative Assessment of resolution of non-conformances and root cause analysis

Program	Number of challenges	Outcome in percentage	Resolution of non-conformances, performing root cause analysis and possible trend analysis. Case number	Date	Assessment Mark	Signature of intern candidate	Signature of trainer



**Insert evidence:**

**3.3.3 Internal and External Quality Assurance programs**

Case number

Evidence: Assessed assignment (root cause analysis, resolution of non-conformances and trend analysis).

**Insert evidence:**

**3.3.3 Internal and External Quality Assurance programs**

Case number

Evidence: Assessed assignment (root cause analysis, resolution of non-conformances and trend analysis).

**Insert evidence:**

**3.3.3 Internal and External Quality Assurance programs**

Case number

Evidence: Assessed assignment (root cause analysis, resolution of non-conformances and trend analysis).

**Insert evidence:**

**3.3.3 Internal and External Quality Assurance programs**

Case number

Evidence: Assessed assignment (root cause analysis, resolution of non-conformances and trend analysis).

**3.3.4 Validation / verification of diagnostic test methods/platforms/kits**

**Table 10. Validation / verification of diagnostic test methods / platforms / kits**

**Method of Instruction: Active participation and writing of validation / verification report.**

**Method of assessment: Formal team discussion and assessment of report.**

<b>Test method / Platform / Kit</b>	<b>Report number</b>	<b>Assessment of report Mark</b>	<b>Date</b>	<b>Signature of intern candidate</b>	<b>Signature of trainer</b>

**Insert evidence:**

**3.3.4 Validation / verification of diagnostic test methods/platforms/kits**

Report number

Evidence: Assessed verification / validation report.

**Insert evidence:**

**3.3.4 Validation / verification of diagnostic test methods/platforms/kits**

Report number

Evidence: Assessed verification / validation report.

### 3.3.5 SOP's and Guidelines

Table 11. Laboratory SOPs and Guidelines

Method of Instruction: Understand, apply and revision of SOP's and guidelines

Method of assessment: Acknowledgement of reading and assessment of revisions.

Read, acknowledge, understand, apply and revisions of SOP's and guidelines	Revisions Case number	Assessment of revisions Mark	Date	Signature of intern candidate	Signature of trainer



**Insert evidence:**

**3.3.5 SOP's and Guidelines**

Case number

Evidence: Assessed revisions.

**Insert evidence:**

**3.3.5 SOP's and Guidelines**

Case number

Evidence: Assessed revisions.

### 3.3.6 SAFE OPERATION, MAINTENANCE, TROUBLE-SHOOTING AND SERVICING OF LABORATORY EQUIPMENT

Table 12. Safe operation, maintenance and servicing of laboratory equipment

**Method of Instruction:** Training in the safe operation, maintenance, trouble-shooting and servicing of laboratory equipment.

**Method of assessment:** Summative assessment of adherence to maintenance schedule and maintenance of Book of Life.

Safe operation / maintenance / troubleshooting / service of Equipment	Adherence to schedule and maintenance of Book of Life Assessment Mark	Date	Signature of intern candidate	Signature of trainer
1.				
2.				
3.				
4.				
5.				
6.				

**Insert evidence:**

**3.3.6 Operation, maintenance, and servicing of Laboratory Equipment**

Evidence: Certificate of training and record of maintenance and servicing and trouble-shooting – Book of Life.

**INSTRUMENT and number**

**Insert evidence:**

**3.3.6 Operation, maintenance, and servicing of Laboratory Equipment**

Evidence: Certificate of training and record of maintenance and servicing and trouble-shooting – Book of Life.

**INSTRUMENT and number**

**Insert evidence:**

**3.3.6 Operation, maintenance and servicing of Laboratory Equipment**

Evidence: Certificate of training and record of maintenance and servicing and trouble-shooting – Book of Life.

**INSTRUMENT and number**

**Insert evidence:**

**3.3.6 Operation, maintenance and servicing of Laboratory Equipment**

Evidence: Certificate of training and record of maintenance and servicing and trouble-shooting – Book of Life.

**INSTRUMENT and number**

### 3.3.7 SUCCESSFUL COMPLETION OF A VERTICAL ASSESSMENT (SANAS F95-07)

Table 13. Completion of a Vertical assessment

Method of Instruction: Undergo a Vertical Assessment (SANAS F95-07).

Method of assessment: Summative assessment of Assessment form, resolution of non-conformance and root cause analysis.

Vertical Assessment		Resolution of non-conformances / root-cause analysis	Assessment Mark	Date	Signature of intern candidate	Signature of trainer
Test Method	Disease					



**Insert evidence:**

**3.3.7 Vertical assessment ISO 15189 for Medical Laboratories (F95-07)**

**Test method and Disease**

Evidence: (a) Completed Vertical Assessment form  
(b) Completed non-conformances (if applicable)

**Insert evidence:**

**3.3.7 Vertical assessment ISO 15189 for Medical Laboratories (F95-07)**

**Test method and Disease**

Evidence: (a) Completed Vertical Assessment form  
(b) Completed non-conformances (if applicable)

**Insert evidence:**

**3.3.7 Vertical assessment ISO 15189 for Medical Laboratories (F95-07)**

**Test method and Disease**

Evidence: (a) Completed Vertical Assessment form  
(b) Completed non-conformances (if applicable)

## **3.4 SCIENTIFIC AND DISCIPLINE-SPECIFIC KNOWLEDGE**



**Insert evidence:**

**3.4.1 List of appropriate textbooks, literature and credible online resources endorsed by the training facility**

Completion of Table 14 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: *(b) Assessed* written tests and questionnaire - Test 1

**Insert evidence:**

3.4.1 List of appropriate textbooks and literature

Completion of Table 14 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: (b) Assessed written tests and questionnaire - Test 2

### 3.4.2 LIST OF JOURNAL CLUBS ATTENDED / PRESENTED

Table 15. List of journal clubs attended and presented

Method of Instruction: Attend, prepare and present.

Method of assessment: Attendance register / CPD certificate.

Date	Subject	Presented	Attended	Signature of intern candidate	Signature of Trainer/presenter



**Insert evidence:**

**3.4.2 List of Journal Clubs attended / presented**

Completion of Table 15 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: (a) Program of Journal Club

(b) Attendance register / CPD certificate / Power point presentation

**Insert evidence:**

**3.4.2 List of Journal Clubs attended and presented**

Completion of Table 15 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: (a) Attendance register / CPD certificate

**Insert evidence:**

**3.4.2 List of Journal Clubs attended / presented**

Completion of Table 15 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: (a) Attendance register / CPD certificate

**Insert evidence:**

**3.4.2 List of Journal Clubs attended / presented**

Completion of Table 15 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: (a) Attendance register / CPD certificate

### 3.4.3 LIST OF LECTURES / SEMINARS / WORKSHOPS / CONFERENCES / COURSES ATTENDED AND PRESENTED

Table 16. List of lectures / seminars / workshops / conferences / courses attended and presented

Method of Instruction: Attend, prepare and present.

Method of assessment: Attendance register / certificate of attendance / approved abstract.

Date	Lectures / Seminars / Workshops / Conferences / Courses	Presented	Attended	Signature of intern candidate	Signature of trainer/presenter

**Insert evidence:**

**3.4.3 List of lectures / seminars / workshops / conferences / courses attended and presented**

Completion of Table 16 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Attendance register, certificate of attendance and/or approved abstract.

**Insert evidence:**

**3.4.3 List of lectures / seminars / workshops / conferences / courses attended and presented**

Completion of Table 16 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Attendance register, certificate of attendance and/or approved abstract.

**Insert evidence:**

**3.4.3 List of lectures / seminars / workshops / conferences / courses attended and presented**

Completion of Table 16 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Attendance register, certificate of attendance and/or approved abstract.



**Insert evidence:**

**3.4.3 List of lectures / seminars / workshops / conferences / courses attended and presented**

Completion of Table 16 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Attendance register, certificate of attendance and/or approved abstract.

## **3.5 COMPETENCY TRAINING**

### 3.5.1 LIST THE ENTIRE SCOPE OF TESTING OF THE TRAINING DEPARTMENT.

It is required that the intern candidate will be proficient in the full scope of test methods

Table 17. List of entire Scope of Testing (Test Repertoire) – *completed example to assist in completion*

<b>A.</b>	<b>TEST METHOD:</b>	<b>REAL TIME PCR GENOTYPING</b>
	(a)	Genetic disorder: <i>BRCA</i> genotyping
	(b)	Genetic disorder: Porphyria variegata genotyping
	(c)	Genetic disorder: Hereditary Haemochromatosis genotyping
<b>B.</b>	<b>TEST METHOD:</b>	<b>QUANTITATIVE FLUORESCENT PCR</b>
	(a)	Genetic disorder: Aneuploidy QF-PCR
	(b)	Genetic disorder: MLPA
	(c)	Genetic disorder: Cystic Fibrosis
<b>C.</b>	<b>TEST METHOD:</b>	<b>NEXT GENERATION SEQUENCING</b>
	(a)	Genetic disorder: <i>BRCA1 and BRCA 2</i> genes
<b>D.</b>	<b>TEST METHOD:</b>	<b>DNA ISOLATION</b>
<b>E.</b>	<b>TEST METHOD:</b>	<b>FLUORESCENT IN SITU HYBRIDIZATION</b>
	(a)	Genetic disorder: Dual color, Dual fusion probe (t(8;21) - AML
	(b)	Genetic disorder: Break apart probe ( <i>CBFB</i> ) - AML
	(c)	Genetic disorder: Deletion and enumeration probe (del5, del7, del20q) – AML / MDS

<b>F. TEST METHOD: CELL CULTURING AND KARYOTYPING</b>
(a) Genetic disorder: Constitutional genetics
(b) Genetic disorder: Hematology oncology
(c) Genetic disorder: Prenatal analysis
(c) Genetic disorder: DEB sensitivity in Fanconi anemia

**Table 18. Total number of samples per test method and disease with competency levels – example to assist in completion**

TEST METHOD	<sup>1</sup> COMPETENCY LEVEL			
	1	2	3	Grand Total
<b>RT PCR genotyping</b>				
BRACA genotyping	4	7	163	
Porphyria variegates	1	2	14	
Hereditary Haemochromatosis	3	2	32	
<b>TOTAL</b>	<b>8</b>	<b>11</b>	<b>209</b>	
<b>Quantitative Fluorescent PCR</b>				
Aneuploidy QF PCR	6	13	74	
MLPA	2	4	22	
Cystic Fibrosis	7	4	34	
<b>TOTAL</b>	<b>15</b>	<b>21</b>	<b>130</b>	
<b>NGS (only variant analysis)</b>				
<i>BRCA 1 and BRCA 2</i>	9	15	11	
<b>TOTAL</b>	<b>9</b>	<b>15</b>	<b>11</b>	
<b>DNA isolation</b>				
	6	3	351	
<b>TOTAL</b>	<b>6</b>	<b>3</b>	<b>351</b>	
<b>FISH</b>				
All probes	4	1	4	

TOTAL	4	1	4	9
<b>Cell culturing and karyotyping</b>				
Constitutional genetics (birth defects) Peripheral blood	10	8	41	
Hematology oncology (acquired) Bone marrow aspirate	3	3		
Prenatal birth defect Amniotic fluid	3	2	2	
DEB sensitivity in FA Peripheral blood	2	1	2	
TOTAL	18	14	45	77

<sup>1</sup>1 = Observed, <sup>1</sup>2 = Under direct supervision, <sup>1</sup>3 = Independent performance, still under supervision,  
<sup>1</sup>4 = Independent performance, experienced, still under supervision.

**Table 19. List of all the samples per test method and competency levels example for easy completions**  
**Test Method: Aneuploidy QF-PCR - *example to assist in completion***

Internal number	Date	<sup>1</sup> Competency Level				Signature of intern candidate	Signature of trainer
		1	2	3	4		
2200123	01/02/22	x					
2200224	02/02/2	x					
2200357			x				
			x				
			x				
			x				
				x			
				x			
				x			
					x		
					x		
					x		

<sup>1</sup>1 = Observed, <sup>1</sup>2 = Under direct supervision, <sup>1</sup>3 = Independent performance, still under supervision,  
<sup>1</sup>4 = Independent performance, experienced, still under supervision.

**3.5.2 ASSIGNMENT 1: Understand the general principles and limitations (specificity, positive / negative predictive value, verification data, validation data, reproducibility) of a test method to apply to a specific disease / request as listed in your test repertoire.**

**Table 20. Understand the principles and limitations (specificity, positive/negative predictive value, verification data) of a test method to apply to a specific disease / request as per entire Scope of Testing – Table 17**

The test method	Assessment Mark	Date	Signature of intern candidate	Signature of trainer

*Each report has to describe the applicability of a test method in order to choose the most applicable test method per disease. Maximum length of half a page*



**Insert evidence:**

**3.5.2 Understand the principles and limitations (specificity, positive/negative predictive value, verification data) of a test method to apply to a specific disease / request**

Completion of Table 20 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Assessed written report all diseases in your Scope of Testing

*Each report has to describe the applicability of a test method in order to choose the most applicable test method per disease. Maximum length of half a page*

**Insert evidence:**

**3.5.2 Understand the principles and limitations (specificity, positive/negative predictive value, verification data) of a test method to apply to a specific disease / request**

Completion of Table 20 with signatures of intern and supervisor and head of training program (official stamp)

Evidence: Assessed written report all diseases in your Scope of Testing

*Each report has to describe the applicability of a test method in order to choose the most applicable test method per disease. Maximum length of half a page*

**3.5.3 ASSIGNMENT 2: Define the aetiology of the disease to enable the application of the most appropriate test method to provide a possible diagnosis / treatment**

**Table 21. The aetiology of every disease as per entire Scope of Testing – Table 17**

The disease/disease groups	Assessment Mark	Date	Signature of intern candidate	Signature of trainer

*Each report has to describe the pathology of each disease in order to choose the most applicable test method. Maximum length of half a page*

**Insert evidence:**

**3.5.3 Assignment 2: Define the aetiology of the disease to enable the application of the most appropriate test method to provide a possible diagnosis / treatment**

Completion of Table 21 with signatures of intern and supervisor and head of training program (official stamp).

*Each report has to describe the pathology of each disease in order to choose the most applicable test method. Maximum length of half a page*

**Insert evidence:**

**3.5.3 Assignment 2: Define the aetiology of the disease to enable the application of the most appropriate test method to provide a possible diagnosis / treatment**

Completion of Table 21 with signatures of intern and supervisor and head of training program (official stamp).

*Each report has to describe the pathology of each disease in order to choose the most applicable test method. Maximum length of half a page*

3.5.4 ASSIGNMENT 3: Perform the test method based on Standard operation procedure

Table 22. List all Direct Witness Activity forms – SANAS F15-11

Set number (each set contain documents (a) to (h))	The test method	Disease	Date	Signature of intern candidate	Signature of trainer
1					
2					
3					
4					
5					
6					
7					
8					
9					

*This list must include all test methods in combination with all diseases as listed in the Scope of Testing – Table 17.*

## Insert evidence:

### 3.5.4 Assignment 3: Perform the test method based on Standard Operating Procedure

Completion of Table 22 with signatures of intern and supervisor and head of training program (official stamp)

#### Set 1

Evidence: Evidence shall be provided as a set of documents for:  
Each and every test method and disease listed in the Scope of Testing - Table 17.  
Five (5) test will be provided – one (1) negative report and four (4) positive reports

- a) Completed Direct witness form
- b) Written report from assignment 1 - Why did you select this specific test method from you Scope of Testing?
- c) Written report from assignment 2 - Describe the aetiology of the disease in order to enable you to select the most appropriate test method.
- d) Request Form (fully completed).
- e) Pre-analytic worksheet (if applicable)
- f) Post analytical - this activity will provide evidence on how you evaluate data:
  - Qualitative analysis – provide raw data printed in color and use colored pencils to indicate the various aspects used in the interpretation of data) or
  - Quantitative analysis – provide raw data obtained/interfaced from instrumentation.
- g) Patient report / template by intern candidate - recommend reflex or other follow up testing in the report
- h) Final report by relevant health professional

## Insert evidence:

### 3.5.4 Assignment 3: Perform the test method based on Standard Operating Procedure

Completion of Table 22 with signatures of intern and supervisor and head of training program (official stamp)

#### Set 2

Evidence: Evidence shall be provided as a set of documents for:  
Each and every test method and disease listed in the Scope of Testing - Table 17.  
Five (5) tests will be provided – one (1) negative report and four (4) positive reports

- a) Completed Direct witness form
- b) Written report from assignment 1 - Why did you select this specific test method from you Scope of Testing?
- c) Written report from assignment 2 - Describe the aetiology of the disease in order to enable you to select the most appropriate test method.
- d) Request Form (fully completed).
- e) Pre-analytic worksheet (if applicable)
- f) Post analytical - this activity will provide evidence on how you evaluate data:
  - Qualitative analysis – provide raw data printed in color and use colored pencils to indicate the various aspects used in the interpretation of data) or
  - Quantitative analysis – provide raw data obtained/interfaced from instrumentation.
- g) Patient report / template by intern candidate - recommend reflex or other follow up testing in the report
- h) Final report by relevant health professional



## Insert evidence:

### 3.5.4 Assignment 3: Perform the test method based on Standard Operating Procedure

Completion of Table 22 with signatures of intern and supervisor and head of training program (official stamp)

#### Set 3

Evidence: Evidence shall be provided as a set of documents for:  
Each and every test method and disease listed in the Scope of Testing - Table 17.  
Five (5) set will be provided – one (1) negative report and four (4) positive reports

- i) Completed Direct witness form
- j) Written report from assignment 1 - Why did you select this specific test method from you Scope of Testing?
- k) Written report from assignment 2 - Describe the aetiology of the disease in order to enable you to select the most appropriate test method.
- l) Request Form (fully completed).
- m) Pre-analytic worksheet (if applicable)
- n) Post analytical - this activity will provide evidence on how you evaluate data:
  - Qualitative analysis – provide raw data printed in color and use colored pencils to indicate the various aspects used in the interpretation of data) or
  - Quantitative analysis – provide raw data obtained/interfaced from instrumentation.
- o) Patient report / template by intern candidate - recommend reflex or other follow up testing in the report
- p) Final report by relevant health professional



**Insert evidence:**

**3.5.5 Assignment 4: Trouble-shoot any failed test procedure**

Evidence: Completed trouble-shooting form and resolution as per Table 23.

**Insert evidence:**

**3.5.5 Assignment 4: Trouble-shoot any failed test procedure**

Evidence: Completed trouble-shooting form and resolution as per Table 23.

**Insert evidence:**

**3.5.5 Assignment 4: Trouble-shoot any failed test procedure**

Evidence: Completed trouble-shooting form and resolution as per Table 23.

**Insert evidence:**

**3.5.5 Assignment 4: Trouble-shoot any failed test procedure**

**Evidence: Completed trouble-shooting form and resolution as per Table 23.**

**Insert evidence:**

**3.5.5 Assignment 4: Trouble-shoot any failed test procedure**

**Evidence: Completed trouble-shooting form and resolution as per Table 23.**

## **3.6 PRINCIPLES OF RESEARCH**



**Insert evidence**

**3.6.1 Develop a protocol for your research study.**  
***Assessed Protocol***

## **Insert evidence**

**3.6.2 Apply for ethical approval to perform your research project by using Health Science Research Ethical Committee application documents.**

### **Note:**

- **You have to complete the facility's Health Science Research Ethical Committee application forms.**
- **However, reviewing of the application may be performed by your training department.**
- **The approval letter of ethical clearance may be provided by your Training Department**

**Evidence: Approval letter of ethical clearance from Training Department.**

**Insert Evidence**

**3.6.3 Avoid plagiarism in the development of your protocol and scientific report.**

**Evidence: Provide Turnitin program result**

**Insert Evidence**

**3.6.4 Compile a budget and apply for funding of disposables, reagents and other to perform your project**

**Evidence: Budget and funding application**

**Insert evidence**

**3.6.5 Select and apply biostatistics and / or databases (if applicable), in the interpretation of your results / research.**

**Evidence: Use and interpretation in scientific report (if applicable).**

## **Insert Evidence**

**3.6.6 Compile a scientific report in the following format:**

**Abstract (250-300 words), Introduction, Methods, Results, Discussion, Conclusion, References. Scientific report**

Evidence: Assessed Scientific report.

**Insert Evidence**

**3.6.7 Present your research findings as a scientific report by using a Power Point presentation.**

**Evidence: Power Point presentation**

### 3.6.8 Peer-review assessment

Name of intern candidate:

Title of research project:

Date of presentation:

**Table 24. Formal assessment of research project by Training Department**

Criteria	Allocated weight	Mark per peer-review assessor			
		<i>Name and HPCSA number of assessor</i>			
Literature	15				
Aim	10				
Methodology	15				
Results and Discussion	15				
Conclusion	10				
Presentation	20				
Power Point	15				
Total	100	<i>Total per assessor</i>			
		<i>Signature of assessor</i>			
<i>Average score</i>			%		



# PART 2

## ADMINISTRATIVE DUTIES

The Intern candidate has to complete the following Administrative duties, and scan this in as a separate document entitled “Administrative Duties”

- (a) Complete the details of the intern medical scientist and training facility
- (b) Please insert a copy of intent to submit Portfolio of Evidence (CMS A-03)
- (c) Please insert a copy of your qualifications notarized by Notary Public
- (d) Please insert a copy of Proof of payment of Assessment fee



**CMS 02 MBS**

**DETAILS OF THE INTERN MEDICAL SCIENTIST AND TRAINING FACILITY**

**PORTFOLIO OF EVIDENCE: MEDICAL BIOLOGICAL SCIENCE**

Name and Surname of Intern Candidate	
HPCSA Intern Registration Number	
Registration Date	
Contact Details: Telephone Number Email	
Professional Category	
Period of Internship:	
Date of letter of Intent to Submit Portfolio of Assessment ( <b>CMS A-02</b> )	
Date of Submission of Portfolio of Evidence	
Training Facility Name of Head of Training Facility	
Training Department Name of Head of Training Departmental	
Name of Supervisor Professional Category HPCSA Registration Number Registration date	

(a) Please insert a copy of intent to submit Portfolio of Evidence (*CMS A-03*)

**(b)** Please insert a copy of your qualifications notarized by Notary Public

c) Please insert a copy of Proof of payment of Assessment fee

## 4. ADMINISTRATIVE REQUIREMENTS (FOR OFFICIAL USE)

**Parts 4 A and B** have to be completed by the Education and Training Division **before** sending to the assessment team

A copy of Administrative Requirements of each Portfolio of Evidence shall be (i) kept by the Education and Training Division, (ii) updated **per hand** as per stepwise process and (iii) available at all times to the members of the Committee for Medical Science or delegates.

	Name	Date
<b>A. Verification of processes with selected Evaluation panel members based on Intent to submit Portfolio of Evidence – <u>Education and Training Department</u></b>		
a) Was intent to submit Portfolio of Evidence ( <b>CMS A-03</b> ) send 12 weeks prior to submission?		
b) Was qualifications notarized by Notary Public included		
c) Proof of payment of Assessment fee		
d) Was assessment team informed about assessment in time?		
Information provided to the assessment team should include: <ul style="list-style-type: none"> <li>• Link to Portfolio of Evidence</li> <li>• Deadline for the report</li> <li>• Request formal acceptance</li> </ul>		
Test link accessibility and process		
Acknowledgement of assessment by Evaluation team		
Confirm the number of Portfolios of Evidence to be assessed		
Submission date of Portfolio of Evidence ( <b>CMS 02 MBS</b> )		
<b>e) Verification of completeness of Portfolio of Evidence before sending to Evaluation panel members - “Ready for assessment” - <u>Education and Training Department</u></b>		
Application for the National Board assessment of Competence included ( <b>CMS A-03</b> ).		

Confirmation of signatures by supervisor, heads of training department and facility a) Supervisor: Section 6 of Portfolio of Evidence b) Head of Training Department: Section 7 of Portfolio of Evidence <b>and</b> complete of Intern Duty Certificate ( <b>CMS 02-01</b> ) c) Head of Training Facility: Intern Duty Certificate ( <b>CMS 02-01</b> ) signature and official stamp		
Is the details of the Intern Medical Scientist completed in full on the Cover Page?		
Is the Table on Contents available with headings as well as page numbers and linked to contents?		
Is the pages of Portfolio of Evidence numbered?		
Is the accredited facility-based training program included?  If not request program.		
Is the Intern Duty Certificate ( <b>CMS 02-01 MBS</b> ) correctly completed with the official stamp of the training Facility?		
Is The Minimum requirement: Portfolio of Evidence fully completed?		
Is the Rotation roster included ( <i>including dates, duties, location and supervisor for entire internship period</i> ) – <b>Table 1?</b>		
Curriculum vitae of intern candidate included.		
Copy of Identity document included.		
Qualification(s)		
HPCSA intern certificate included.		
Fees for assessment (proof available)?		
Is the entire Portfolio of Evidence completed with dates, signatures and page numbers of evidence		
Are the Portfolio of Evidence “Assessment Ready”		
Send PoE link to assessor and request formal acknowledgement		
Send PoE link to moderator and request formal acknowledgement		
Formal acknowledgement of receiving link from assessor		
Formal acknowledgement of receiving link from moderator		

Report from assessor received		
Send report from assessor to moderator and request formal acknowledgement		
Formal acknowledgement from moderator of receiving assessor report		
Report from moderator received		
<b>f) Successful candidate</b>		
<b><u>Education and Training Department</u></b>		
a) Submit Declaration of Competence: National Board Competency-based Assessment ( <b>CMS A-04</b> ) to intern candidate and supervisor as "Approved for registration"		
b) and;		
Request intern to send original copies of the following to <b><u>Registration Division:</u></b>		
a) Application for registration as Medical Biological Scientist ( <b>Form 24 MS - Application for registration Medical Biological Scientist</b> ) - Original		
b) Declaration of completion of internship ( <b>Form 36 MS - Application for registration: Certificate for Medical Biological Scientist Intern training</b> ) - Original		
c) Proof of payment of registration fee as Medical Biological Scientist		
Receive from intern by <b><u>Registration Division:</u></b>		
a) Completed Application for registration as Medical Biological Scientist ( <b>Form 24 MS - Application for registration Medical Biological Scientist</b> ) - Original		
b) Completed Declaration of completion of internship ( <b>Form 36 MS - Application for registration: Certificate for Medical Biological Scientist Intern training</b> ) - Original		
c) Proof of payment of registration fee as Medical Biological Scientist		
<b><u>Registration Division:</u></b>		
a) Register the candidate and provide hard copy of registration certificate to intern candidate		
b) Open the <b>allocated HPCSA post number</b> of the successful candidate as <i>vacant</i> on list and;		
c) Amend relevant Annual report to the Committee for Medical Science ( <b>CMS C</b> ) with vacant post number.		
<b><u>Education and Training Department</u></b>		



Provide feedback on assessment to the <u><b>Committee for Medical Science</b></u>		
<u><b>Registration Division</b></u> Provide feedback on registration of successful candidates to the <u><b>Committee for Medical Science</b></u>		
<b>g) Unsuccessful candidate</b> <b>Conditional approval – Minor revisions</b>		
<u><b>Education and Training Department</b></u>  a) Submit Declaration of Competence: National Board Competency-based Assessment ( <b>CMS A-04</b> ) to intern candidate and supervisor as “ <b>Conditional approval – Minor revisions</b> ” <ul style="list-style-type: none"> <li>• Request submission of proof of evidence-based assignments (missing evidence)</li> <li>• Reassessment will be conducted by moderator</li> <li>• Re-assessment fee not applicable</li> <li>• Provide a due date for resubmission</li> </ul> b) Ensure follow up of missing evidence after deadline		
<b>h) Unsuccessful candidate</b> <b>Not approved – Major revisions</b>		
<u><b>Education and Training Department</b></u>  c) Submit Declaration of Competence: National Board Competency-based Assessment ( <b>CMS A-04</b> ) to intern candidate and supervisor as “ <b>Not approved – Major revisions</b> ” <ul style="list-style-type: none"> <li>• Request resubmission and reassessment of an updated revised Portfolio of Evidence</li> <li>• Reassessment will be conducted by evaluators</li> <li>• Re-assessment fee payable</li> <li>• Usually, a due date for resubmission cannot be determine in these cases and the submission dates of the three assessment cycles will be applicable.</li> </ul>		
Advise Assessment panel if date is available		
Provide feedback on assessment to <u><b>Committee for Medical Science</b></u>		

i) Unsuccessful candidate: Re-submission and re-assessment		
<b><u>Education and Training Department</u></b>		
Receive re-submission of evidence		
Contact assessment team and forward link for re-assessment		
Confirm		
Assessment		
Reports to <b><u>Education and Training Department</u></b>		
a) If successful, proceed with section <b>C. Successful candidate (above)</b>		
j) Successful candidate submit		
<b><u>Education and Training Department</u></b> - Submit Declaration of Competence: National Board Competency-based Assessment ( <b>CMS A-04</b> ) to intern candidate and supervisor		
and;		
<b><u>Request intern to send original copies of the following to Registration Division:</u></b>		
a) Application for registration as Medical Biological Scientist ( <b>Form 24 MS - Application for registration Medical Biological Scientist</b> ) - Original		
b) Declaration of completion of internship ( <b>Form 36 MS - Application for registration: Certificate for Medical Biological Scientist Intern training</b> )		
c) Proof of payment of registration fee as Medical Biological Scientist		
d) and;		
Receive from intern by <b><u>Registration Division</u></b>		
a) Application for registration as Medical Biological Scientist ( <b>Form 24 MS - Application for registration Medical Biological Scientist</b> ) - Original		
b) Declaration of completion of internship ( <b>Form 36 MS - Application for registration: Certificate for Medical Biological Scientist Intern training</b> )		
e) Proof of payment of registration fee as Medical Biological Scientist		

<p><b><u>Registration Division</u></b></p> <p>a) Register the candidate and provide hard copy of certificate and  b) Open the post number as vacant (<i>amend the relevant Annual Report</i>)</p>		
<p><b><u>Education and Training Department</u></b></p> <p>Provide feedback on assessment to the <b><u>Committee for Medical Science</u></b></p>		
<p><b><u>Registration Division</u></b></p> <p>Provide feedback on registration of successful candidates to the <b><u>Committee for Medical Science</u></b></p>		