

# HEALTH PROFESSIONS COUNCIL OF ZAMBIA

## COMPLIANCE MONITORING ASSESSMENT TOOL FOR LABORATORY

Facility Name \_\_\_\_\_ Catch pop \_\_\_\_\_

Physical Address \_\_\_\_\_ District \_\_\_\_\_

Postal Address \_\_\_\_\_ Phone No \_\_\_\_\_ Imprest \_\_\_\_\_

HPCZ No. \_\_\_\_\_ Class \_\_\_\_\_ Date \_\_\_\_\_ Nationality: \_\_\_\_\_

Inspectors 1. \_\_\_\_\_ 2. \_\_\_\_\_ 3. \_\_\_\_\_

### 1. Introduction

### 2. Objectives

### 3. Scope of service

Categories	Service				
Radiological services	X-ray unit	Ultrasound	MRI	Endoscopy	
	Dental X-ray	Mammogram	CT Scan	Barium studies	
Simple Lab Tests	RDT-Malaria	Urinalysis	Pregnancy	HIV antibody	
	RPR	Blood sugar	Heamoque	Hepatitis BSag	
	Other serological tests (Specify).....				
Standard Lab services	Grouping & cross	Malaria	CD4 testing	Full Blood Count	
	Microscopy Culture & sensitivity	TB- Microscopic	Semen Analysis	Clinical	
		Sickling test	CSF Examination	Blood Transfusion	
	Peripheral smear	ESR	HIV DNA PCR		
Advanced Laboratory services	Advanced Chemistry	HB	HIV Viral load		
	Hormonal profiling- fertility diagnosis	Bone marrow aspirate	HIV drug resistance testing	Paternity Studies (DNA testing)	
	Thyroid studies	Histopathology	Forensic studies		

### 4. Human Resource

#### a) Staffing Level

S/N	Name	Profession	HPCZ/ GNC #	Position	F/Time	P/Time	NRC	Nationality
1								
2								
3								
4								
5								

**b) Staffing Level**

Profession	Full Time		Part Time		Profession	Full Time		Part Time	
	Need	Available	Need	Available		Need	Available	Need	Available
Biomed Scientist					Receptionist/Cashier				
Biomed Technologist					Data Clerks				
Biomed Technician					Cleaners – Indoor				
Reg. Nurse					Cleaners – Outdoor				
Enrolled Nurse					Watchman				
Phlebotomist									

**5. Standard 1: Legal Establishment, Leadership and Governance**

Assessment Area	Assessment Criteria (scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)					Score		
						2	1	0
Facility	Valid Annual License from HPCZ available and displayed							
Staff files	<b>Sample 4 Files and check the following:</b>				<b>Y</b>	<b>N</b>	<b>Comment</b>	
	Appointment Letter/ Contract							
	Photocopy of Professional and Academic Qualification							
	Photocopy of NRC/Passport							
	Valid work permit ( <i>Applicable to non-citizens</i> )							
	Valid Practicing Licence							
	Job Descriptions on file & distributed to staff							
	Evidence of staff performance Appraisal available							
	Disciplinary/Awards records where applicable							
Staff levels	Practitioners are -----for the scope of service		Qualified		Adequate			
Training	Records of CPD/Workshops		CPD/Training Plan					
Leave	Leave schedule (Booking log)		Records of Leave taken against accrual					
Dress Code	Official Id's won appropriately		Staff adhered to work place dress code					
Disciplinary	Discipline code available		Records of disciplinary cases and actions					
	HPCZ Code of ethics available		GNC Code of ethics available					
Governance	Evidence of business registration		Evidence of Tax Registration					
	Updated ZRA Annual returns		Updated PACRA Annual returns					
	Valid fire certification		Valid Business Permit					
	Waste management Contract		Evidence of updated NAPSA returns					
Strategy management	Latest strategic plan available		Vision statement documented/displayed					
	Latest action plan available		Mission statement documented/displayed					
	Review of progress on plans		Scope of service documented/displayed					
	Approved Organogram displayed		Evidence of management meeting					
<b>Achieved Score / Total Applicable Score</b>								<b>18</b>

**6. Standard 2: Minimum Infrastructure Requirement**

Assessment Area (Room)	Assessment Criteria (scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)				Score	
	Specification	Y	N	Comment if No	2 or 1 or 0	
Reception	All rooms in the building meeting Public Health Act Cap 295 of the Laws of Zambia(Floor area not less than 8.4 m <sup>2</sup> , Horizontal dimensions not less 2.1m, Height not less than 2.6m)					
Phlebotomy rooms						
Toilets						
Testing rooms						
Store room						
Rest room						
<b>Achieved Score / Total Applicable Score</b>						<b>12</b>

## 7. Standard 3: Sanitary Facilities

Assessment Area	Assessment Criteria (scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)								Score 2/1/0			
	Male Sanitary	Toilet	Clean state		Running water		Lighting		Hand washing signage			
Good state of infrastructure				Adequate Natural ventilation								
Female Sanitary	Toilet	Clean state		Running water		Lighting		Hand washing signage				
		Good state of infrastructure				Natural ventilation		Sanitary bin				
Staff sanitary	Toilet	Clean state		Running water		Lighting		Hand washing signage				
		Good state of infrastructure				Natural ventilation		Sanitary bin				
<b>Achieved Score / Total Applicable Score</b>											<b>6</b>	

## 8. Standard 4: Environment, Health & Safety

Assessment Area	Assessment Criteria (Scoring Criteria: Met =2, Partially Met = 1 and Not Met = 0)								Score				
												<b>2</b>	<b>1</b>
Human Resource	Infection Prevention Committee or Designated person overseeing IPC activities												
Parking space	Adequate parking space		Ambulances		Clients/visitors		Designated staff						
State of infrastructure	All rooms in good state of repair with the following well maintained?												
	Walls		Fixtures		Windows		Doors		Floors		Roof		
Ventilation	Adequate natural ventilation				Artificial ventilation (Air conditioner/fan)								
Lighting	Adequate natural lighting				Artificial lighting								
Surrounding	Clean environment			Outdoor sanitary bin			No littering of rubbish						
	Ground maintenance			Drainage system									
Waste Disposal	Incinerator or waste contract			Rubbish pit if incinerator not available			Rubbish pit Secured						
	Segregation of waste Adhered to			Adequate pedal bins			Sharp boxes						
				Adequate bin liners			Waste storage section						
Occupation Health & Safety	OHS Guidelines/SOP			Wheelchairs available			Personal protective equip						
	Signage in all rooms			Provision for disabled's			Staff vaccination Program						
Fire Safety	Fire extinguishers			Extinguisher servicing			Bucket of sand						
	Available fire exit marks			Evidence of fire drills			Fire assembly point						
Power supply	Electricity Available			Backup power supply									
Security	Perimeter Fence			Security Guards									
<b>Achieved Score / Total Applicable Score</b>											<b>22</b>		

## 9. Standard 5: Patient focus and Feedback

Assessment Area	Assessment Criteria (Scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)								Score				
												<b>2</b>	<b>1</b>
Patient Focus	Appropriate Sign posts			Safe water for drinking provided									
	Adequate waiting area			Waiting area appropriately furnished									
	Adequate IEC materials			HPCZ Approved patient charter									
Patient feedback	System for collecting patient feedback (suggestion boxes/complaint register)												
	System for collecting feedback from referral facility (referral form with feedback)												
Confidentiality & Consentin g	Adequate screens available			Facility has written consent form									
	Availability of the following guidelines from HPCZ;												
	Guidelines on Patient Consent			Guidelines on Patient Confidentiality									
	Guidelines on Patient's record			Guidelines on Pervasive Incentives									
<b>Achieved Score / Total Applicable Score</b>											<b>6</b>		

## 10. Standard 6: Generation, Storage and management of Records

Assessment Area	Assessment Criteria (scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)				Score		
					2	1	0
Ventilation	Adequate natural ventilation		Artificial ventilation (Aircon/fan)				
Lighting	Adequate natural lighting		Adequate artificial lighting				
Paper base data	Adequate shelves/cabinets		Records lockable and secure				
	Adequate Section for archiving		Active & inactive files separated				
Generation and Storage Practices	Health facility maintains patients records for minimum of 5 years before disposal						
	Facility captures sufficient patient contact information						
	Age		Patient ID No.		Emergency Contact person		
	Sex		Patients phone No.		Phone for contact person		
	Patients Name		Address				
Managing Health Information	SOP for Data management		Monthly report to next level done				
	Assigned responsibility for HMIS		Appropriate data equipment				
	Specimen Register						
<b>Achieved Score / Total Applicable Score</b>							<b>10</b>

## 11. Standard 7: Laboratory Services

### a. Staffing

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)						Score 2/1/0
Licences	Valid practicing license for medical Lab Personnel available and displayed						
Staff levels	Qualified appointed Lab Manager to manage the Lab						
	Adequate staff	Lab Scientist		Lab Tech		Lab Assistants	

### b. Infrastructure

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)							Score 2/1/0
Number of rooms	All rooms in the medical ward meeting PHA Cap 295 (Floor area not less than 8.4 m <sup>2</sup> , Horizontal dimensions not less 2.1m and Height not less than 2.6m			Phlebotomy		Office		
				Testing room 1		Store room		
				Testing room 2		Rest room		
				Testing room 3		Toilet		
State of building	The Lab is in good state of repair with the following well maintained?							
	Doors	Windows	Fixtures	Floors	Roof	Walls		
	No evidence of linkages in the Celine							
Layout	Size & layout organized with workstations positioned for optimal workflow.							
	Patient care and testing areas of the lab distinctly separate from one another.							
Ventilation	Adequate natural ventilation			Artificial ventilation (Aircon/fan)				
Lighting	Adequate artificial lighting			Artificial lighting				

### c. Standard Operating Procedures

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)				Score 2/1/0	
Available SOPs	Quality Manual		Specimen collection		Specimen processing	
	Safe waste disposal		Results transmission		Inventory management	
	HIV Antibody Test		Fasting Blood Sugar		Grouping/cross match	
	Malaria RDT		Random Blood Sugar		Histopathology	
	Malaria microscopy		Clinical chemistry		PCR's	
	RPR (Syphilis testing)		Hematology		Pregnancy testing	
	TB Testing		CD4 Count		Urinalysis	
	Hepatitis B Testing		Sickling testing		Stool Analysis SOPs	
Ready	All Staff have read		Some have read		None has read	
Up to date	All SOPs		Some SOPs		None	

#### d. Laboratory Equipment and supplies

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)						Score 2/1/0
Equipment	Adequate Benches		Culture incubators		Centrifuge		
	Chemistry Analyzer		Counting chambers		CD4 Analyzer		
	Hematology analyzer		Bunsen/spirit burner		Adequate Fridges		
	Microscope		Mechanical balance		Fridge Thermometer		
	Microscope cabinet		Working refrigerator		Room Thermometer		
	Timer		Standard Pipette				
Protective equipment	Lab coats		Face mask/shield		Goggles		
	Exam gloves						
Equipment maintenance	Equipment register			Equipment service schedule			
	Competent equipment service personnel/Company			Equipment installed per operator's manuals & uniquely labeled			
	non-functioning equipment isolated			Lab equipment inventory up to date			
	Is equipment routinely serviced per schedule by qualified and competent			Manufacturer's operator manuals available to testing/servicing staff			
	Is there onsite validation of new equipment			Is equipment (pipettes, electronic balances, analyzers) calibrated			

#### e. Laboratory Supplies

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)						Score 2/1/0
Test strips	Malaria RDT		Gravindex		HIV Screening		HB test kits
	Syphilis (RPR)		Hepatitis B		HIV Confirmation		
Reagents	Hematology		Sickling test		Grouping/X-Match		Culture media
	Chemistry		CD4		PCR		Histopathology
Specimen Containers	Universal bottle		Plain bottle		Heparin bottle		Culture swabs
	EDTA bottle		Blood culture		Microscope slides		Culture plates
Other supplies	Syringes/Needle		Paper/hand towel		Disinfectants/JIK		Stains- Malaria
	Liquid Soap		Pipettes tips		Methylated spirit		Stains- TB

#### f. Laboratory Practices

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)						Score 2/1/0
Laboratory audit (Practices)	Evidence of adherence to SOPs for all tests						
	Evidence of running/documenting appropriate controls before running tests						
	All results are signed by qualified lab personnel			Counter verified by supervisor			
	Testing staff appropriately records all results in the register						
	Date tested	Time tested	Test Results	method	Signature		
	Lab personnel ensures		Readable handwriting		Name/Initials		
Storage practices of Lab reagents & supplies	Functional Air conditioner (stores)			Essential laboratory supplies list			
	Adequate shelves for reagents			Adequate pellets for reagents storage			
	Bin (stock control) cards available			All bin cards up to date			
	Inventory is organized on "FEFO-First Expired First Out" or "FIFO-First In First Out"						
	Clearly marked section for expired laboratory reagents/supplies						
	Allied products (diagnostic reagents & flammable substance) stored properly/separate						
	No expired laboratory supplies/reagents found displayed on the fridge or shelf for use						
Receiving and ordering	Supplies traced to delivery notes			Supplies traced to supply vouchers			
	Supplies traced to GRNs			Appropriate ordering system used			

### g. Quality Control

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)				Score 2/1/0
Quality Control & Assurance	Availability of QA/QC SOPs			Evidence of external QC	
	Evidence of internal QC			Calibration of lab machines up to date	
	No expired reagents/supplies used			Are test turnaround times established	
Testing Room Temperature	Room 1	Functional thermometer		Updated room temperature charts	
	Room 2	Functional thermometer		Updated room temperature charts	
	Room 3	Functional thermometer		Updated room temperature charts	
Fridge Temperature	Fridge 1	Functional thermometer		Updated fridge temperature charts	
	Fridge 2	Functional thermometer		Updated fridge temperature charts	
	Fridge 3	Functional thermometer		Updated fridge temperature charts	
Corrective Action	System for resolution of incidences			Procedure for resolution of complaints	
	Corrective Action forms available			Are complaint record form available	
	Incidences are investigate/resolved			Complaints are investigate/resolved	

### h. Other Laboratory Safety Measures

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)				Score 2/1/0
Sanitation	Running water		Hand washing signage		Signage in all rooms
Waste management	Lab testing area restricted			Bin liners - Red	
	Recommended Pedal bin			Bin liners - Black	
	Bins for waste segregation			Sharps box	
Fire Safety	Functional Fire extinguisher			Fire extinguisher servicing up to date	
Power supply	Electricity Available			Backup power supply	
Achieved Score / Total Applicable Score					54

### 12. Summary of scores for all Standard

Standard No.	Standard Description	Achieved Score	Applicable standards Scores	Total available Scores
Standard 1	Legal Establishment, Leadership and Governance			20
Standard 2	Minimum Infrastructure requirements			12
Standard 3	Sanitary Facilities			6
Standard 4	Environment, Health & Safety			38
Standard 5	Patient focus and Feedback			6
Standard 6	Generation, Storage and management of Records			10
Standard 7	Laboratory Services			56
Total scores				148

$$Total\ Score = \frac{Total\ Score}{Expected\ Score} = \frac{\quad}{\quad} \times 100 = \quad\%$$

### 13. Risk Grading

Score	Risk Level Identified	Colour Code	Tick (/)	Comment
100%	No risk of harm identified	Green		
75 – 100%	Relative risk of harm Identified	Yellow		
50 – 75 %	Moderate risk of harm identified	Orange		
< 50 %	High risk of harm identified	Red		

**14. Summary of Major Inspection Findings and Recommendations**

S/N	Major Findings	Recommendations
1		
2		
3		
4		
5		

**15. Conclusion**

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**16. Inspection Team**

S/N	Name	Station	Station	Signature
1				
2				
3				

**17. Signature of Facility Representative**

S/N	Name	Positon	Signature
1			
2			

**18. Facility Official Stamp (where available)**

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