

# HEALTH PROFESSIONS COUNCIL OF ZAMBIA

## COMPLIANCE MONITORING ASSESSMENT TOOL FOR SAMPLE COLLECTION CENTRE

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	Services							
Simple Lab Tests	RDT-Malaria		Urinalysis		Pregnancy		HIV antibody	
	RPR		Blood sugar		Heamoque		Hepatitis B Sag	
	Other serological tests (Specify).....							
	Specimen collection							
Other Lab test	malaria microscopy		CD4 testing		Chemistry		Full Blood Count	Grouping
	TB- Microscopic		ESR		Sickling test		Microscopy Culture & sensitivity	

### 4. Human Resource

#### a) Staffing Level

S/N	Name	Profession	HPCZ/ GNC #	Position	F/Time	P/Time	NRC	Nationality
1								
2								
3								
4								
5								
6								
7								

## 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							
	Disciplinarily/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						
Phlebotomy rooms						
Toilets						
<b>Achieved Score / Total Applicable Score</b>						<b>6</b>

## 7. Standard 3: Environment, Health & Safety

Assessment Area	Assessment Criteria (Scoring Criteria: Met =2, Partially Met = 1 and Not Met = 0)				Score		
					2	1	0
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				
	Schedule of maintenance works			Records-maintenance works done			
	Records of reported plumbing work			Records of plumbing works done			
<b>Achieved Score / Total Applicable Score</b>							<b>24</b>

## 8. Standard 4: Sanitary Facilities

Assessment Area	Assessment Criteria (scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)				Score 2/1/0		
					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>

## 9. Standard 5: Patient focus and Feedback

Assessment Area	Assessment Criteria (Scoring criteria : Met =2, Partially Met = 1 and Not Met = 0)				Score		
					2	1	0
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 & Consent	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				
Electronic data	System password protected		Access is restricted				
	System for back up of records		user rights clearly defined				
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 (HMIS)	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>12</b>

## 11. Standard 7: Specimen Collection 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	Adequate staff	Lab Scientist		Lab Tech		Lab Assistants	
		Phlebotomy Nurse		Cleaners		Security Guard	

### 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 specimen collection centre meeting PHA Cap 295 (Floor area not less than 8.4 m2, Horizontal dimensions not less 2.1m and Height not less than 2.6m)		Reception				
			Phlebotomy Room				
			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 Ceiling						
Layout	Size & layout organized with workstations positioned for optimal workflow.						
	Patient waiting and specimen collection areas 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		
	Specimen Transport		Specimen Storage		Specimen Rejection		
	Confidentiality and conduct undertaking		Resolution of complaints procedure		Identification of referral labs		
	Document Control		Phlebotomy Procedure		Safety Manual		
	PEP Procedure		Infection Prevention				
	Personnel policies						
	Orientation		Training		Competence		
Read	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		Centrifuge		Specimen Fridge		
	Standard Pipettes		Storage cabinets		Screens		
	Fridge Thermometer		Room Thermometer		Adequate Fridges		
	Tables		Collection Chairs		Timer		
	Couch		Foot Step		Chairs		
	Cooler boxes						
Protective equipment	Non-Latex Gloves		Goggles		Face mask/shield		
	Latex 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 staff			
	Is equipment (pipettes, electronic balances) calibrated						

#### e. Laboratory Supplies

Assessment Area	Assessment Criteria (scoring criteria : Score =2, Partially Score = 1 and Not Score = 0)						Score 2/1/0
Specimen Containers	Vacutainer tubes						
	Plain with Clot Activator-red		Sodium Fluoride-Grey		Lithium Heparin-Green		
	EDTA-Purple		SST II- Yellow				
	Other containers						
	Blood culture		Stool containers		Microscope slides		
	Culture swabs with media		Dry swabs without media		Universal containers		
Other supplies	Syringes/Needle		Paper/hand towel		Disinfectants/JIK		
	Vacutainers needles		Vacutainer holders		Slide holder		
	Liquid Soap		Pipettes tips		Methylated spirit		
	Alcohol Swabs		Gauze		Lancets		
	Toniquets		Alcohol Hand rub				
Stationery	Sample registers		Result registers		Consent forms		
	Lab request forms		Specimen Rejection Form		Specimen rejection register		
	Complaints log		Corrective action log		Adverse event log		
					Complaints form		
					Sterile urine containers		
					Stains- Malaria		
					Capillary Tubes		
					Cotton wool		
					Ziplock bags		
					Communication log		
					Transportation checklist		

### 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 procedures conducted				
	All samples collected by qualified lab personnel				
	All samples appropriately recorded all in the registers				
	Date collected		Time collected/received		Test requested
	Patient Name		Tests Requested		Name/Initials
	Patient ID Number		Method of collection		Signature
	Lab personnel ensures			Readable handwriting	
Storage practices of Lab reagents & supplies	Functional Air conditioner (stores)		Essential laboratory supplies list		
	Adequate shelves/cabinets 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 equipment 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		
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		
	Collective 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	Collection room separate		Bin liners - Red		Staff have access to PEP Adherence to waste management SOP
	Recommended Pedal bin		Bin liners - Black		
	2 Pedal Bins		Sharps box		
Fire Safety	Functional Fire extinguisher		Fire extinguisher servicing up to date		
Power supply	Electricity Available		Backup power supply		
<b>Achieved Score / Total Applicable Score</b>					<b>56</b>

## 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		18	18
Standard 2	Minimum Infrastructure requirements		6	6
Standard 3	Environment, Health & Safety		22	22
Standard 4	Sanitary Facilities		6	6
Standard 5	Specimen Collection Services		56	56
Standard 6	Patient focus and Feedback		6	6
Standard 7	Generation, Storage and management of Records		12	12
Total scores			<b>126</b>	<b>126</b>

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

## 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

--

**16. Inspection Team**

S/N	Name	Station	Station	Signature
1				
2				
3				

**17. Signature of Facility Representative0**

S/N	Name	Positon	Signature
1			
2			

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

