MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA(MLSCN)

CHECKLIST FOR MEDICAL LABORATORY PRE-APPROVAL.

INSPECTION SCORING

This laboratory inspection checklist contains 105 items worth 208 points. Each item has been awarded a point value of either 1, 2, 3 or 5 points-based upon relative importance and/or complexity. Responses to all questions must be either "yes", "partial" or "no".

- Items marked "yes" receive the corresponding point value (either 1, 2, 3 or 5 points). All elements of a question must be present in order to indicate "yes" for a given item and thus award the corresponding points.
- Items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching item.
- Items marked "partial" receive 1 point.
- Items marked "no" receive no point.

When marking "partial" or "no", notes should be captured in the comments field to assist the laboratory in addressing these areas. For example, if the question reads "Are environmental checks/temperature logs complete, accurate and regularly reviewed?" and the inspector's finding is that the logs are complete but are not reviewed by the supervisor, the item will be marked "partial" and should include an explanation noting the absence of supervisor's review in the comment field.

INSPECTION SCORE SHEET:

Section	***Total points***	***Inspection score***
General Information	1	
Section 1: Documents and Records (22 items)	42	
Section 2: Personnel (11 items)	29	
Section 3: Process Control, Internal/External Quality Assessment (13 items)	30	
Section 4: Equipment (18 items)	33	
Section 5: Facilities and Safety (36 items)	64	
Section 6: Purchasing and inventory (5 items)	9	
TOTAL SCORE	**208**	

GENERAL INFORMATION 1 Point								
Date of Assessment								
Name(s) and Affiliation(s) of Assessor(s)								
Laboratory Name								
Laboratory Address								
Laboratory Telephone		**Fax**		**Email**				
Head of Laboratory		**Telephone** (Head of Lab)		**Personal?**				
				Work?				
Laboratory Level (check those that apply)				**Laboratory Affiliation** (check those that apply)				
	National		Regional/Provincial		Public		Academic	
	Zonal		District		Private		NGO/Religious Institution	
Laboratory Staffing Summary								

Profession	**Number of Full Time Equivalents (FTEs)**	**Adequate for facility operations?**
Med. Lab. Scientists		Yes No Insufficient Data
Med. Lab. Technicians		Yes No Insufficient Data
Med. Lab. Assistants		Yes No Insufficient Data
Data Clerk		Yes No Insufficient Data
Phlebotomists		Yes No Insufficient Data
Cleaners		Yes No Insufficient Data
Is the cleaner(s) dedicated for only laboratory? Yes No		Has the cleaner(s) been trained in safe waste handling? Yes No
Drivers		Yes No Insufficient Data
Is the driver(s) dedicated for only laboratory? Yes No		Has the driver(s) been trained in biosafety? Yes No
Other		Yes No Insufficient Data

If the laboratory has IT specialists, accountants or non-laboratory-trained management staff this can be indicated when describing the organizational structure on the following page.

MANDATORY REQUIREMENTS

MEASUREMENT OF LABORATORY
MLSCN STD:
Minimum required standard space for a main laboratory should be 10" x 10" and could exceed 5m x 6m or 16.4ft x 19.7ft based on available space which will exclude other adjoining functional spaces like

1. MLS Office
2. Media room
3. Washup
4. Sample collection
5. Convenience
6. Reception, 5m x 6m or 16.4ft x 19.7ft

Proprietor's Office	Actual measurement:	RECOMMENDATION
Scientist's Office	Actual measurement:	
Reception/waiting Area	Actual measurement:	
Main lab or Labs	Actual measurement:	

PERSONNEL

NAME	RA/RF NUMBER	AREA OF SPECIALTY	RECOMMENDATION

MINIMUM PERSONNEL REQUIRED:
The medical laboratory shall be managed by a licensed Medical Laboratory Scientist certified by the Medical Laboratory Science Council of Nigeria.

In areas where Medical Laboratory Scientists are not available a MLSCN certified Medical Laboratory Technician with three (3) years training on clinical laboratory sciences quality control and laboratory management, may manage a primary category clinical laboratory with supervision by a licensed Medical Laboratory Scientist.

The clinical laboratory shall employ qualified and adequately trained personnel for the level of service. Work assignment shall be consistent with the qualification of the concerned personnel.

A clinical laboratory shall have sufficient number of registered medical scientists, proportional to the work load and shall be available at all times during hours of laboratory operation. For
Hospital based clinical laboratory, there shall be at least one registered medical scientist per call duty to cover the laboratory operation.

1. DOCUMENTS AND RECORDS

		POINTS	YES	NO	PARTIAL	JUSTIFI-CATION	SCORE
1	Is there a Quality Manual?	3					
2.	Is there a Safety Manual?	3					
3.	Are there SOPs?	3					
4.	Availability of Laboratory Request/Report forms?	2					
5.	Client's information / Bio-data Register?	2					
6.	Is there a Referral Register?	2					
7.	Are there Bench Books?	2					
8.	Master Report/Result Register?	2					
9.	Dispatch Register	2					
10.	Proper archiving records?	2					
11.	Are Records legible?	2					
12.	Are laboratory results easily retrievable?	2					
13.	Is record retention period stated?	2					
14.	Is there evidence of review and approval of the quality manual by authorized personnel	1					
15	Is there evidence to show that the quality manual was communicated to and understood by the laboratory personnel	1					
16	Does the laboratory have a system in place to control all documents and information from internal and external sources?	2					
17	Is there a list of all documents used in the quality management system indicating their editions and distribution?	2					
18.	Is there an audit plan/schedule that ensures all activities of the QMS are audited?	1					
19.	Is there documented assessment of potential risks for all processes	1					

20.	Is there documented actions taken to reduce or eliminated identified potential risks	1					
21.	Are testing personnel identified on the result report or other records (manual or electronic?)	2					
22.	When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing?	2					
		42 POINTS					

Additional Information:

2. PERSONNEL

		POINTS	YES	NO	PARTIAL	JUSTIFICATION	SCORE
1	Is the Head of the Laboratory a Medical Laboratory Scientist?	5					
2.	Is His/her license current?	3					
3.	Is there Support staff (i.e. MLT and MLA)?	3					
4.	Does the Support Staff have current work permit?	2					
5.	Is there a Receptionist?	2					
6.	Is there a Cleaner?	2					
7.	Is Competency testing for staff done?	3					
8.	Does the Staff Participate in Continued Professional Development (CPD)?	2					
9.	Are personnel files available?	2					
10.	Does the laboratory have a duty roster that covers normal and after hours?	2					

11	Is there a system for training that covers the following?	3					
	a. The quality management system						
	b. Assigned work processes, procedures and tasks?						
	c. The applicable laboratory information system?						
	d. Health and safety, including the prevention or containment of the effects of adverse incidents?						
	e. Laboratory Ethics?						
	f. Confidentiality of patient information?						
	g. Is there supervision for persons undergoing training?						
	h. Continuous medical education						
	i. Review of effectiveness of the training program						
		29 POINTS					

Proprietors to make available staff nominal rolls stating their individual functions

3. PROCESS CONTROL, INTERNAL AND EXTERNAL QUALITY ASSESSMENT

1.	Is internal quality control (IQC) performed and documented prior to release of results?	2					
2.	Are test results validated, interpreted and released by appropriately authorized and qualified personnel?	2					

3.	Does the laboratory participate in a proficiency testing or inter-laboratory comparison?	3					
4.	Does the laboratory participate in External Quality Assurance of Council and reports documented?	3					
5.	Are policies and SOPs easily accessible/available to all staff and written in a language commonly understood by respective staff?	2					
6.	Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities?	2					
7.	Are policies and procedures dated to reflect when it was put into effect, its location, when it was reviewed and when it was discontinued?	2					
8	Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system?	3					
9	Is internal quality control performed, documented, and verified for all tests/procedures before releasing patients' results?	3					
10	Are the following environmental conditions checked and recorded daily? a. Room temperature b. Freezers c. Refrigerator d. Incubators e. Water bath	2					
11.	Does the laboratory participate in interlaboratory comparison program or alternative assessment systems for all tests?	2					
12.	Does the laboratory identify and undertake continual quality improvement projects?	2					

13.	Are quality indicators (TAT, rejected specimens, stock-out, etc.) selected and tracked?	2					
		30 POINTS					

4. EQUIPMENT

		POINTS	YES	NO	PARTIAL	JUSTIFICATION	SCORE
1.	Is there enough equipment to run, at least 50% of tests listed on the Request form?	5					
2.	Is the equipment functional?	3					
3.	Is regular equipment service information readily available (e.g. last date of service)	2					
4.	Are newly introduced equipment validated and record of this kept?	2					
5.	Is non-functional equipment removed from the laboratory storage area?	2					
6.	Is routine preventive maintenance performed on all equipment and recorded?	2					
7.	Are there back-up procedures for equipment failure?	2					
8.	Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked?	2					
9.	Are equipment operated by trained, competent and authorized personnel?	2					
10.	Are specific verification/validation protocols in place for each equipment and examination procedure?	1					
11.	Have the verification/validation	1					

	results/reports been reviewed and approved by an authorized person?						
12.	Is current equipment inventory data available for all equipment in the laboratory?	2					
13.	Is relevant equipment service information readily available in the laboratory	2					
14.	Is routine calibration of laboratory ancillary equipment (including pipettes, centrifuges, balances, and thermometers) scheduled, at minimum following manufacturer recommendations and verified?	1					
15.	Is the calibration traceable (e.g. use of reference materials and equipment like certified thermometers, tachometer?	1					
16.	Is there evidence of review of calibration certificates/results by the laboratory before acceptance back into use?	1					
17.	Is certified reference materials, examination and calibration by another procedure, use of mutual consent standards or methods used for in house calibrations?	1					
18	Are the manufacturer's operator manuals readily available to testing staff and available in the language understood by staff?	1					
		33 POINTS					

5. FACILITIES AND SAFETY

		POINTS	YES	NO	PARTIAL	JUSTIFICATION	SCORE

1	Is the size of the laboratory adequate?	2					
2.	Is the layout of the laboratory such that work plan are positioned for optimal work flow (spacing)?	2					
3.	Is the reception / client area separated from testing area?	1					
4.	Are testing areas clearly demarcated?	1					
5.	Is each workstation maintained free of congestion?	2					
6.	Are all supplies needed for work present and easily accessible?	1					
7.	Are all chairs/stools at the work stations appropriate for bench height and testing operations being performed?	1					
8.	Are the needed reference materials (e.g. critical values and required action, population reference ranges, frequently called numbers etc.) posted for easy accessibility?	1					
9.	Is the physical work environment appropriate for testing i.e. (a) Free of clutter? (b) Adequately ventilated? (C) Have adequate lighting (d) Climate for optimum equipment function (i.e. Air conditioner, not fan)? (e) Are wires and cables properly located and protected from traffic? (f) Is there a functioning back – up power supply (generator) (g) Is critical equipment supported by uninterrupted power source? (h) Is equipment placed appropriately, i.e. away from water hazards, out of traffic areas etc.? (i) Is there a steady water supply, including deionized water or distilled water (if needed) ? (j) Is clerical work completed outside the testing area? (k) Is a major safety signage posted and enforced? (l) Are functional fire extinguishers available? (m) Are there posted guidelines in case of	1 1 1 1 1 1 1 1 1 1 1 2 1					

	fire outbreak, needle prick, spills or breakages?						
10	Is the laboratory properly restricted from unauthorized access?	2					
11	Is the laboratory – dedicated cold and room temperature storage free from staff food items?	1					
12.	Are patient's samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?	1					
13.	Is the work area clean, free of leakages and spills	1					
14.	Are disinfection procedures conducted and documented?	1					
15.	Is sufficient waste disposal available?	1					
16.	Is waste separated into infectious and non-infectious?	1					
17.	Is infectious waste autoclaved, incinerated, or buried?	1					
18.	Are hazardous chemicals properly labeled?	1					
19.	Are hazardous chemicals properly stored?	1					
20.	Are hazardous chemicals properly utilized?	1					
21	Are hazardous chemicals properly disposed?	1					
22.	Are "sharps" handled and properly disposed of in appropriately utilized sharp containers?	2					
23.	Are all electrical cords, plugs, and receptacles appropriately used and in good condition?	1					
24.	Are there appropriate fire extinguishers and are they properly located?	1					
25.	Are the fire extinguishers in good working condition and inspected routinely?	1					

26.	Is an operational fire alarm system in place in the laboratory with periodic fire drills	2					
27.	Are the following standard safety equipment available: (a) Bio-safety Cabinet? (b) Covers on Centrifuges? © Hand – washing station? (d) Eye-wash station / bottles? (e) Spill Kit(s) (f) First aid Kit(s)	1 1 1 1 1 1					
28.	Is personal protective equipment (PPE) available, readily accessible at the work station?	1					
29.	Are the PPE appropriately and consistently used?	1					
30.	Are laboratory personnel appropriately vaccinated?	1					
31.	Are occupational injuries/illness documented in safety / occurrence log?	1					
32.	Are cleaners, drivers/couriers working with the laboratory trained in Bio-safety practices relevant to their jobs?	1					
33.	Is there documented evidence that the laboratory has evaluated the adequacy of the size and overall layout of the laboratory and organized the space so that workstations are positioned for optimal workflow?	2					
34.	Where a Biosafety cabinet is required to perform work, is it certified and appropriate?	2					
35.	Is sufficient waste disposal available and adequate? Is waste separated into infectious and non-infectious waste, with infectious waste autoclaved/incinerate?	2					
36.	Is fire safety included as part of the laboratory's overall safety program?	2					

		64 POINTS	

6. **PURCHASING AND INVENTORY**

		POINTS	**YES**	**NO**	**PARTIAL**	**JUSTIFICATION**	**SCORE**
1.	Is there a system for accurately forecasting needs for supplies and reagents?	2					
2.	Does the laboratory monitor the performance of the suppliers to ensure that the stated criteria are met?	2					
3.	Are storage areas set up and monitored appropriately?	2					
	a. Is adequate cold storage available?						
	b. Are storage areas monitored as per prescribed storage conditions?						
	c. Is the ambient temperature monitored routinely?						
	d. Is storage in direct sunlight avoided?						
	e. Is the storage area adequately ventilated?						
	f. Is the storage area clean and free of dust and pests?						
	g. Are storage areas access-controlled?						
4.	Are all reagents/test kits use (and in stock) currently within the manufacturer-assigned expiration or within stability?	2					
5.	Are procedures in place to process “urgent” specimens and verbal requests?	1					
		9 POINTS					