National Health Insurance Authority

LABORATORY FACILITY INSPECTION CHECKLIST

Facility Name: _____

Inspector(s): _____

Inspection Date: _____

OVERALL SCORE: _____%

Revised June 2023

STANDARD NUMBER	STANDARDS	COMPLIANCE STATUS		
		Y	N	NA
RESPONSIBILITIES OF MANAGEMENT STANDARDS (ROM)				
ROM.1	The facility Medical Director/Laboratory Director/designee is present for the inspection.			
ROM.2	The facility has a certificate to prove compliance with The Bahamas building code regulation **(business license, healthcare facilities license).**			
ROM.3	The facility infrastructure includes an emergency vehicle access (ramp) that is not obstructed to transport wheelchair and stretcher bound beneficiaries, if applicable.			
ROM.4	All personnel providing laboratory services are appropriately registered and licensed as required by local laws.			
ROM.5	There is "Authorized Personnel Only" signage in places where necessary.			
ROM.6	There is a list of all procedures/tests that are carried out by the facility that is available for the inspector or client when requested.			
ROM.7	There is a registration system in place for beneficiaries. System can be electronic or manual (paper).			
ROM.8	The facility's infrastructure includes a functional telephone system			
ROM.8.1	Interim measures are implemented when telephone system is damaged, non-functional or in need of repair. **Evidence that emergency/alternative phone contact(s) are made available to beneficiaries & staff**			
ROM.9	The facility's infrastructure has designated waiting area(s).			
ROM.9.1	No Smoking sign(s) are posted in waiting area or in an area where it is visible. No smoking includes vapes/vaporizers & e-cigarettes that is used for vaping.			
ROM.10	The facility has a system in place to accommodate ambulatory beneficiaries to meet their needs. **For example, wheelchair(s) are readily available.**			
ROM.11	The facility has emergency power (generator) and UPS during a power outage to provide for required refrigeration and equipment. **(All major equipment should be on a UPS).**			
STAFFING (STAFF)				
STAFF.1	The facility is under the direction of a competent Laboratory Director/Designee with medical/scientific and clinical laboratory technical background who is registered and licensed by the Health Professions Council or Bahamas Medical Council. The Laboratory Director/Designee must have a minimum of five (5) years technical experience in a clinical laboratory.			
STAFF.2	The names & credentials of all professional staff shall be available for the Inspectors to review.			
STAFF.3	The facility has an orientation program for new staff. Orientation process includes information technology requirements for professional and clerical staff and NHIA program benefits for staff who deal with beneficiaries.			

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		Y	N	NA
QUALITY CONTROL PROCESSES (QCP)				
QCP.1	The facility has a documented quality manual of policies and procedures and other documents that is accessible to and used by staff. The manual includes the following: Introduction to quality manual (facility overview, mission, vision, objectives & scope)			
	Quality policy (facility commitment to continual improvement, establishment of quality indicators)			
	Governance structure (organization chart, role of management, internal communication, staff responsibilities/roles, meeting frequency, etc.)			
	Facilities and safety (security, working environment, waste disposal)			
	Equipment management (selection, installation & acceptance, inventory, validation, verification, preventative maintenance & repair, decommissioning)			
	Purchasing and inventory (reagents & supplies management, equipment procurement, stock management, referral lab/subcontracting)			
	Process management (specimen collection & transport, specimen/sample receiving, specimen/sample handling, preparation, and storage, validation, verification, quality control, reporting, sample retention & disposal)			
	Quality assessments (internal audits, quality indicators, proficiency testing, external audits (benchmarking)			
	Staffing (recruitment, personnel file, training, competency, continuous education, orientation, performance appraisal)			
	Customer satisfaction & complaints management			
	Incident reporting and management			
	Documentation management (review and approval of policies and other documents, documents and records control, retention of records and disposal)			
	Information management (information security, confidentiality).			
QCP.2	The facility establishes acceptable parameters for quality control for each test method, and quality control data is available and used to monitor and ensure the stability of test systems.			
QCP.3	The facility establishes a program of externally graded interlaboratory comparison testing, or proficiency testing, for all tests available.			
QCP.4	The facility performs initial validation/verification for new instruments & analytic systems to ensure that the method(s) will produce accurate and reliable results. Appropriately signed validation/verification records shall be available.			
QCP.5	The facility performs calibration, calibration verification, and function checks of instruments and analytic systems used for testing based on established standards.			
QCP.6	A qualified individual is responsible for the oversight and supervision of the point-of-care testing program. Oversight and supervision of the POCT program shall be by a licensed and experienced Medical Technologist.			

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BENEFICIARY SAFETY CRITERIA (BSC)				
BSC.1	The facility improves accuracy of beneficiary identification. **Three (3) unique identifiers are used, example, full name, date of birth and NIB or passport or driver's license number. Staff must proactively ask the beneficiary to state at least two (2) identifiers (their full name and date of birth) rather than providing the identifying information. Two (2) identifiers are required before taking blood and other specimens for testing.**			
BSC.2	**A documented process exists to improve the effectiveness of verbal/telephone communication by ensuring:** Verbal/telephone communications are documented immediately by the individual receiving order(s) and should be followed by a written/electronic request within 24 hours.			
BSC.3	A documented process exists that clearly defines how critical results of diagnostic tests are communicated to providers and how the information is documented. **(E.g., define what critical results may represent urgent or emergent life-threatening values, critical results shall be reported/communicated immediately, information documented shall include the critical result, the lab personnel that called, the person notified, the date and time called and if there were any difficulties in contacting the Clinician). Critical values need to be accessible.**			
INFECTION PREVENTION AND CONTROL (IPC)				
IPC.1	There is evidence of at least one sink with running water for hand washing that is connected to the internal drainage system per testing room.			
IPC.2	**There is evidence that reagents and supplies are stored safely to ensure proper cold chain management.** Food or staff personal items stored in fridge.			
	Food or drink found in active laboratory areas.			
	Daily monitoring of room temperature, freezer, refrigerator is conducted. Can use digital or manual thermometer that has been calibrated and verified.			
	Maintain temperature log to demonstrate temperature recording.			
	Documentation of corrective action plan when temperatures are out of range or refrigerator is not operational.			
	Evidence of contingency plan when fridge/freezer is not operational.			
IPC.3	Reagents and supplies are removed from cardboard boxes and boxes removed from the facility to avoid clutter and rodent/insect infestation.			
IPC.4	Supplies used in the care of beneficiaries are stored directly on the floor. **E.g., on a raised platform). They should be stored according to the manufacturer's instructions.**			
IPC.5	Shelves used for storage of clean/sterile medical supplies and devices are at least 25 cm (10 inches) off the floor and 45 cm (18 inches) from the ceiling and sprinkler head. **Example, you can measure 18 inches from the ceiling and place colored (red, blue) tape to mark the point where items are not be stored above that marker.**			
IPC.6	The facility has a process of managing expired reagents and supplies. Expired reagents or supplies found on site.			
	A process for destruction of expired reagents or supplies exists. **Example, the process outlines how expired items are managed. Process to cover, if applicable, how they are stored & label (stored separately and labeled "expired" or "not for use" or "for destruction") or discarded in the sharp container.**			

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IPC.7	**The facility ensures effective environmental cleaning and disinfection practices to maintain environmental cleanliness.** Environment to be cleaned at least daily.			
	Ceiling tiles are intact, none missing or stained.			
	Fans are clean and dust free.			
	Air condition filters/vents are cleaned at least twice a year.			
	Trash should be removed daily or as needed.			
	Disinfectants are on hand for sanitizing benchtops.			
IPC.8	**Reduce the risk of facility associated infections.** Implement hand hygiene guidelines to reduce the risk of infections Centers for Disease Control and Prevention (CDC) guideline posted near washing stations/sinks. **See reference list at the back with link containing free handwashing posters.**			
	Soap, disinfectant, hand towels are available and located in areas where hand washing is required.			
	Staff can demonstrate and/or speak to proper hand hygiene techniques outline on CDC website. **E.g., how long should you wash your hand? Wash hand for at least 20 seconds. Can count to 20 or sing happy birthday song from beginning to end twice.**			
SPECIMEN PROCESSING (SP)				
SP.1	There is a process established and implemented for collecting, handling, preserving, transporting, storing, retaining and disposal of specimens.			
SP.1.1	All venipuncture specimens are labeled by personnel performing Phlebotomy procedure with the beneficiary's name, DOB, date, and time of collection and the personnel's initials before leaving the patient.			
SP.1.2	All capillary tubes are placed in a test tube, which is then labeled with the beneficiary's name, DOB, date of collection and the personnel's initials before leaving the beneficiary.			
SP.1.3	Urine specimen containers labeled with patient's name, DOB, & specimen collection date			
SP.1.4	All miscellaneous specimens collected are labelled with the beneficiary's name, DOB, date of collection and type of specimen with additional labeling, if required.			
SP.1.5	Written instructions exist for the collection, handling, preservation, storage, transportation, retention, and disposal of specimens. **E.g., policy that define the process for each area listed above.**			
LABORATORY ENVIRONMENT (ENVN)				
ENVN.1	Work areas illuminated. **E.g., adequate lighting provided.**			
ENVN.2	Aisles and passageways are clear and unobstructed.			
ENVN.3	**Safe exit when fire and non-fire (smoke) emergencies occur by ensuring: -** Exit/emergency illuminated signs/lights working.			
	Exit/emergency paths free from obstruction			
	Exit/emergency door(s) free from obstruction			
	Exit/emergency door(s) are unlocked from the inside			
ENVN.4	**The facility reduces the risk of infections by ensuring proper waste disposal and safe handling of needles.** Waste container(s) are closed unless actively adding or removing waste.			
	Waste container(s) are marked with words "Hazardous Waste."			
	Sharps waste (needles, syringes, etc.) are immediately discarded into proper sharp container.			
	Sharps containers closed & secured for disposal once three-quarters full (¾).			

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EMERGENCY EQUIPMENT AND PLANNING (EQUP)				
EQUP.1	**The facility has a process for fire and non-fire (smoke) emergencies. Fire extinguisher safety measures implemented.** Class ABC or BC fire extinguisher(s) available. **Records should be available.**			
	Fire extinguisher(s) mounted or visible.			
	Fire extinguisher(s) are free from obstruction (nothing blocking extinguisher).			
	Fire extinguisher inspection up to date. Checked once a year.			
	Adequate # of smoke detectors are installed throughout the facility.			
	Smoke detectors are checked at least once a year. **E.g., check batteries and change, as necessary.**			
EQUP.2	**The facility has a process for responding to spills of hazardous materials emergencies.** Eyewash unit and safety shower within 10 seconds of hazard.			
	Eyewash unit and safety shower inspection up to date. Checked weekly and results recorded on inspection card. An inspection card shall be available upon request.			
	In the absence of an eyewash unit/station, a procedure exists that defines how a mishap in which blood and blood products splashes are handled. E.g., procedure outlines the process for eyes, nose, and mouth splashes.			
EQUP.3	**The facility establishes and implements a program for inspecting, testing, and maintaining laboratory equipment and documenting results.** Maintain an equipment inventory list of all equipment used for the delivery of care to beneficiaries. Inventory equipment list includes date of purchase, brand, serial number, date of last service, location, date of arrival, date of entering into service, condition when received and vendor's contact.			
	Evidence that equipment/devices were checked twice a year or according to manufacturer's requirements. Affix PM sticker indicating month and year maintenance was done and signature of person completing same.			
EQUP.4	**Staff are educated/orientated on fire and non-fire (smoke) safety practices and how to appropriately respond to a hazardous spill.** The facility involves staff in regular exercises to evaluate fire safety process. **E. g. conduct fire drills or simulate drill process, determine frequency of drills/simulation. Online fire training course can be completed. Fire training is to be done at least annually.**			
	Maintain a "sign in" sheet to document who was present during fire drill/simulation.			
PERSONAL PROTECTIVE EQUIPMENT (PPE)				
PPE.1	**Gloves, masks, eye protection and other protective equipment are available and used correctly when required. Evidence of staff training is.** Appropriate eye & face protection available for all hazards in the laboratory.			
	Personnel are wearing appropriate gloves. **Specific to specialty labs or hospital labs that use harsh chemicals or autoclaves requiring gloves for these purposes.**			
	Appropriate gloves are available for all hazards in the laboratory.			
PPE.2	**The facility ensures appropriate clothing is worn by all staff.** Shoes are appropriate for the lab. **E.g., closed-toe, closed-heel shoes with non- slip soles. Shoes must cover the entire foot. Shoes with holes shall not be worn.**			
	Clothing (lab coats, gowns, scrubs) is appropriate to the hazards posed in the lab.			

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REQUIRED INFORMATION AND POSTING/SIGNAGE (SIGN)				
SIGN.1	**All refrigerators, freezers and ice machines located in the facility are clearly labeled for their intended purpose.**			
	Chemical (reagents) refrigerators labeled "No food."			
	Food refrigerators labeled "Food only – no chemicals/reagents."			
SIGN.2	**General information signage to assist staff in emergencies and to identify potential hazards are posted throughout the facility.**			
	Biohazard signs are posted in the lab areas handling infectious materials.			
	Biosafety cabinets shall be appropriately labelled according to the usage, e.g., "Flammable."			
SIGN.3	**Equipment shall be uniquely labelled and identifiable using any of the following: -** Manufacturer's name, serial number, or other unique identifier.			
	When there are two of the same equipment, the serial number can be used as a unique identifier.			
ELECTRICAL HAZARDS (HAZD)				
HAZD.1	**Electrical safety hazard measures are implemented.** Flexible cords in good condition.			
	Cords are not on surfaces where flammable liquids may pool.			
	Cover plates in place for outlets and switches to prevent accidental contact with electrical wires.			
	Extension cords used. No extension cords should be used.			
HAZD.2	**Electrical Panel safety measures are implemented.** Electrical panel(s) are obstructed/blocked.			
	Electrical panel(s) are labeled and have functional latches & power switches (on/off).			
	Staff knows where electrical panels are located.			
CHEMICAL/HAZARDOUS STORAGE (STOR)				
STOR.1	**The facility is designed with adequate shelving to store chemicals safely.** Heavy items on lower shelves.			
	Storage at least 18 inches below ceiling.			
STOR.2	**Safe chemical storage measures are implemented.** Chemicals stored by compatibility and hazard class.			
	Chemical containers clearly labeled with contents.			
	Safety data sheets (SDS) accessible. SDS comes with chemical shipment & must be retained by laboratory.			
STOR.3	**Safe storage of hazardous waste is implemented.** Waste containers are sealed during transfers.			
	Waste containers labeled with the contents, "Hazardous Waste."			

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INFORMATION MANAGEMENT SYSTEM (IMS)				
IMS.1	The facility maintains records and reports of all tests undertaken at the facility. The facility also maintains records and reports of tests carried out by another facility on behalf of the facility.			
IMS.2	All records and reports of tests performed, including reports received from another laboratory shall be kept for a period of at least 7 years.			
IMS.3	**Policies/procedures exists that define those authorized to access data and information and those who are authorized to enter patient results and change results.**			
	Data/information access restricted to "authorized" personnel only. **For CLIA-waived tests, results can be entered by authorized non-testing personnel trained in this procedure. For CLIA non-waived tests, results should be entered by trained and competent testing personnel.**			
	Those authorized to enter results and change results are identified.			
IMS.4	**The facility maintains confidentiality, privacy and security of records, data, and information to protect against loss, theft, damage, and destruction and facilitates easy retrieval. Policies/procedures should be available to guide these processes, including retention of documents. Process covers paper and/or electronic records.**			
	Paper records are kept secured where only authorized agents can access them.			
	Electronic records shall have a backup system.			
	With electronic medical records, computer screens are minimized as appropriate.			
	Beneficiary records, data, information are destroyed in a manner that does not compromise confidentiality. **E.g., utilizing a shredder machine.**			
IMS.5	Downtime policies/procedures exists to ensure data integrity and timely reporting of results. **E.g., policies define the activities for all phases of testing (pre-analytic, analytic and post analytic). Downtime records should be available for all equipment, e.g., analyzers, computers, etc. Should another laboratory be used during downtimes, the laboratory should either be accredited or an NHI approved laboratory.**			
	Downtime policies/procedures defined for Pre-analytic testing.			
	Downtime policies/procedures defined for Analytic testing.			
	Downtime policies/procedures defined for Post-analytic testing.			
	Downtime records is available for all equipment (analyzers, computers, etc.).			
	Another Laboratory used during downtime. **If applicable, Laboratory should either be accredited or an NHI approved Laboratory.**			
IMS.6	A process exists for proper authorization and release of information (**e.g., reports and/or images**)			
IMS.7	The facility develops & maintains policies/procedures to provide uniform knowledge on their clinical & non-clinical functions/processes.			
RESULT REPORTING (RPT)				
RPT.1	**The facility establishes procedure(s) to ensure that results are not misinterpreted. Result reporting is critical to the diagnosis and treatment of the beneficiary. It is important that lab results are not misinterpreted. Clear, legible results are to be released and there is an indication of any interfering substances that may cause a deviation in reported results.**			
	Results are legible and easily understood.			
	The presence of sample interference is mentioned in the report, e.g., lipemia, hemolysis, etc.			
RPT.2	**The facility ensures that all results are traceable. When there is a revision or amendment to a result, the original record of the result is accessible.**			
	The date, time and personnel amending the report is captured.			
	The reason for the change is clearly stated.			
	Results that are verbally communicated are to be documented.			
	Manually amended results (e.g., in workbooks/log) are neatly crossed-out, initialed and dated with the correct result clearly stated. There is to be no use of white-out and no coverups.			
	The Clinician is informed when there is a correction or revision of results.			

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RPT.3	**The facility ensures that the Fecal Immunochemical Test (FIT) is the only test that is offered to NHI Beneficiaries for Colon Cancer Screening.**			
	FIT sample kit expired.			
	Test card used for the "FIT" is present.			
	Package insert is labeled "FIT."			
	One test per stool sample is performed once per year or biennially (every 2 years).			
	Staff can describe the steps for performing test: -			
	Stool sample collection tube/test card is labeled with beneficiary's name, date of birth & date of collection.			
	Stick is scraped on the stool, or the surface of the stool is brushed. Ensure all of the groves on the end of the stick is covered with stool.			
	Stick is placed in the collection tube or the space on the test card is touch with the brush.			
	Sample is placed in a biohazard zip-lock bag, if applicable.			
	A copy of the test card submitted to the Inspector.			

Reference List

1) **Joint Commission International Accreditation Standards for Laboratories – 4th Edition.**
   https://www.jointcommissioninternational.org/-/media/jci/jci-documents/accreditation/laboratory/jci_standards_for_laboratories_standards-onlypdf.pdf

2) **International Organization for Standardization.**
   ISO 15189:2012. Medical laboratories - Requirements for quality and competence in medical laboratories.
   https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:en

3) **Pan American Health Organization/World Health Organization & US Centers for Disease Control and Prevention/Department and Human Services Joint Initiative for Laboratory Quality Management Systems – Step-Wise Improvement Process (LQMS-SIP) Checklist.**
   https://www.cmedlabsfoundation.com/wp-content/uploads/2020/11/Guidance-Stepwise-Final-04-10-2012.pdf

4) **Hospitals and Health Care Facilities (General) Regulations, 2000**
   http://laws.bahamas.gov.bs/cms/images/LEGISLATION/SUBORDINATE/2000/2000-0098/HospitalsandHealthCareFacilitiesGeneralRegulations_1.pdf

5) **CLIA 2013 Laboratory Record Retention Requirements 493.1105 Standard**
   https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-J/section-493.1105

6) **CLIA 2013 Laboratory Record Retention Requirements 606.160(d) Standard**
   https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606/subpart-I/section-606.160

Checklist Tracking Sheet

	Title	**Institution**	**Date**
Written by	Healthcare Quality Specialist	National Health Insurance Authority (NHIA)	December 2021
Reviewed by	Leadership Team	NHIA	February 28, 2022
Consultation Undertaken	BAMT Quality and Regulatory Committee	Bahamas Association of Medical Technologist (BAMT)	April 14, 2022
Approved by			

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