National Health Insurance Authority

SPECIMEN COLLECTION CENTER INSPECTION CHECKLIST

Specimen Collection Center: _____

Inspector(s): _____

Inspection Date: _____

Definition: Specimen Collection Center - A place where specimens are taken or collected from the human body for examination to obtain information for diagnosis, prevention, or treatment.

OVERALL SCORE: _____%

Revised: May 2023

STANDARD NUMBER	STANDARDS	COMPLIANCE STATUS		
		Y	N	NA
RESPONSIBILITIES OF MANAGEMENT STANDARDS (ROM)				
ROM.1	The Specimen Collection Center Medical Director/Laboratory Director/designee is present for the inspection.			
ROM.2	The Specimen Collection Center has a certificate to prove compliance with The Bahamas building code regulation **(business license, healthcare facilities certificate).**			
ROM.3	All personnel providing Specimen Collection Center services are appropriately registered and licensed as required by local laws.			
ROM.4.1	Authorized Personnel Only/Employees Only signage in places where appropriate.			
ROM.4.2	There is a list of all procedures/tests that are carried out by the center that is available for the client or the Inspector, when requested.			
ROM.5	The Specimen Collection Center's infrastructure includes a functional telephone system (Land line, cell phone or Fax machine)			
ROM.5.1	Interim measures are implemented when telephone system is damaged, nonfunctional or in need of repair. **Evidence that emergency/alternative phone contact(s) are made available to clinicians, beneficiaries & staff**.			
ROM.6	The Specimen Collection Center's infrastructure has designated specimen collection area(s). (Centers must be in an enclosed space, no tents, or outdoor cubicles).			
ROM.7	The center infrastructure has designated waiting area(s).			
ROM.7.1	No Smoking sign(s) are posted in waiting area or in an area where it is visible. No smoking includes vapes/vaporizers & e-cigarettes.			
ROM.8	The Specimen Collection Center has emergency power (generator) and UPS during power outage to provide for required refrigeration and equipment. **(All major equipment should be on an Uninterruptible Power Supply (UPS).**			
STAFFING (STAFF)				
STAFF.1	The Specimen Collection Center is under the direction of a competent Laboratory Director/Designee with medical, scientific and clinical background. She/he must be registered and licensed by the Health Professions Council of the Bahamas and must have a minimum of two (2) years technical experience in a clinical laboratory. (Health Professions Act 1998)			
STAFF.2	The name and credentials of the Laboratory Director shall be posted in a clear & visible location.			
STAFF.2.1	The names & credentials of all professional staff shall be available for review by the Inspector(s).			
STAFF.3	The Specimen Collection Center 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.			
QUALITY CONTROL PROCESSES (QCP)				
QCP.1	**The Specimen Collection Center 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 (Specimen Collection Center overview, mission, vision, objectives & scope).			
	Facilities and safety (security, working environment, waste disposal)			
	Purchasing and inventory (reagents & supplies management, stock management).			
	Process management (specimen collection & transport, specimen/sample receiving, specimen/sample handling, preparation, and storage, validation, verification, quality control, reporting, sample retention & disposal)			
	Customer satisfaction & complaints management			
	Incident reporting and management			
	Information management (information security, confidentiality).			

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BENEFICIARY SAFETY CRITERIA (BSC)				
BSC.1	The Specimen Collection Center 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.**			
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 in active laboratory areas.			
	Daily monitoring of room temperature, freezer, refrigerator is required. 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 Specimen Collection Center to avoid clutter and rodent/insect infestation.			
IPC.4	Supplies used in the care of beneficiaries are stored directly on the floor. S**hould not be kept 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 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 Specimen Collection Center has a process of managing expired reagents and supplies.** Expired reagents or supplies found on site**.**			
	Evidence of a defined process for destruction of expired reagents or supplies. E.g., process outlines how expired items are managed. Process to cover, if applicable, how they are stored & labeled (stored separately and labeled "expired" or "not for use" or "for destruction") or discarded in the sharp container.			
IPC.7	**The Specimen Collection Center 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.			

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INFECTION PREVENTION AND CONTROL (IPC) – Cont'd				
IPC.8	**Reduce the risk of Specimen Collection Center 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. **Example, 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. **(Health Professional Act 1998, Part X General Medical Laboratory 47:2).**			
SP.2	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 beneficiary.			
SP.3	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.4	Urine specimen containers labeled with patient's name, DOB, & collection date			
SP.5	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.6	Written instructions exist for the collection, handling, preservation, storage, transportation, retention, and disposal of specimens. **E.g., policy(ies) exists that define the process for each area listed above.**			
SPECIMEN COLLECTION CENTER ENVIRONMENT (ENVN)				
ENVN.1	Work areas illuminated. **E.g., adequate lighting provided.**			
ENVN.2	Aisles and passageways are clear and free from obstruction.			
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 Specimen Collection Center 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 Specimen Collection Center 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) unobstructed (nothing blocking extinguisher).			
	Fire extinguisher inspection up to date. Checked once a year.			
	Adequate # of smoke detectors are installed throughout the Specimen Collection Center.			
	Smoke detectors are checked at least once a year. **E.g., check batteries and change, as necessary.**			
EQUP.2	**The Specimen Collection Center has a process for responding to spills of hazardous materials emergencies.**			
	Portable or stationary eyewash unit within 10 seconds of hazard.			
	Stationary Eyewash unit inspection up to date, if applicable. **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, noses and mouth splashes.**			
EQUP.3	**The Specimen Collection Center ensures that the appropriate equipment/supplies are available for specimen taking.**			
	Holder/adapter with evacuated collection system.			
	Tourniquet.			
	70% isopropyl alcohol wipes.			
	Povidone-iodine if taking blood cultures.			
	Cotton and/or gauze, band aids for application on site.			
	Syringes (maybe used in place of evacuated collection system).			
	Needles.			
	Blood tubes			
EQUP.4	**Staff are educated/orientated on fire and non-fire (smoke) safety practices and how to appropriately respond to a hazardous spill.**			
	The Specimen Collection Center 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 shall be done at least annually.**			
	Maintain a "sign in" sheet to document who was present during fire training.			
PERSONAL PROTECTIVE EQUIPMENT (PPE)				
PPE.1	**Gloves, masks, eye protection and other protective equipment are available and used correctly when required.**			
	Personnel are wearing appropriate eye and face protection, when applicable.			
	Appropriate eye and face protection are available in the Center.			
	Personnel are wearing appropriate gloves.			
	Appropriate gloves are available in the Center.			
PPE.2	**The Specimen Collection Center ensures appropriate clothing is worn by all staff.**			
	Shoes are appropriate for the Center. **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 center.			

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REQUIRED INFORMATION AND POSTING/SIGNAGE (SIGN)				
SIGN.1	**All refrigerators and freezers located in the Specimen Collection Center 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 Specimen Collection Center.**			
	Biohazard signs are posted in the areas handling infectious materials.			
ELECTRICAL HAZARDS (HAZD)				
HAZD.1	**Electrical safety hazard measures are implemented.**			
	Flexible cords in good condition.			
	Cords are on surfaces where flammable liquids may pool.			
	Cover plates on outlets & 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 Specimen Collection Center 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.**			
	Cleaning supplies/chemicals are stored separately.			
	Supplies are stored in a separate or designated area.			
STOR.3	**Safe storage of hazardous waste is implemented.**			
	Waste containers are sealed during transfers.			
	Waste containers labeled with the contents, "Hazardous Waste."			
INFORMATION MANAGEMENT SYSTEM (IMS)				
IMS.1	The Specimen Collection Center maintains records of all requisitions for tests undertaken at the Specimen Collection Center as well as samples received externally. **Kept for 7 years.**			
IMS.2	**The Specimen Collection Center maintains confidentiality, privacy and security of records, data, and information to protect against loss, theft, damage, and destruction & 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 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.3	Downtime policies/procedures exists to ensure data integrity and timely reporting of results. **E.g., policies define the activities for the collection process. Downtime records are available for all equipment used in the collection process, e.g., analyzers, computers, etc. Should another Collection Center/Lab be used during downtime, the Collection Center/Laboratory should either be accredited or an NHI approved Specimen Collection Center/Laboratory.**			
	Downtime policies/procedures are available for all equipment (analyzers, computers, etc.).			
	Another Specimen Collection Center/Laboratory used during downtime. **If applicable, Center should either be accredited or an NHI approved Specimen Collection Center/ Lab.**			

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-606.16

Checklist Tracking Sheet

	Title	**Institution**	**Date**
Written by	Laboratory Consultant	National Health Insurance Authority (NHIA)	2022
Reviewed by	Leadership Team	NHIA	
Consultation Undertaken	BAMT Quality and Regulatory Committee	Bahamas Association of Medical Technologist (BAMT)	2022
Approved by			

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Next Review Date: