

Applicability

This guideline shall apply to Bridgeport Hospital Laboratory- Bridgeport Campus and Milford Campus

Scope of Service

The Bridgeport Hospital Laboratories are a full service, twenty-four hour per day, seven day per week operation with locations at the Bridgeport and Milford Campuses of Bridgeport Hospital. The Laboratories perform over 5.5 million tests per year under the direction of the Chairperson of the Department of Pathology, Laboratory Medical Director and the Administrative Director of Laboratory Services. Each section of the Laboratory is overseen by the Laboratory Medical Director, Technical Supervisor and manager. The Laboratory offers clinical services in the following areas: Hematology, Chemistry, Molecular Microbiology (cultural Microbiology is performed at YH), Immunology, Blood Bank, Point of Care Testing and Surgical Pathology. The hospital operates several outpatient service centers in the community; a complete listing of all Outreach draw stations with locations and hours of operation can be found on the Yale New Haven Health System web site @ [Blood Draw Stations at Yale New Haven Health \(ynhhs.org\)](http://ynhhs.org). The Laboratory follows standards to ensure compliance with all applicable National, Federal, State (or Provincial) and local laws and regulations defined by multiple regulatory organizations including, but not limited to CMS, the College of American Pathologists (CAP), the Joint Commission, the Federal Drug Administration (FDA) and the State of Connecticut Department of Public Health.

Goals and Objectives

The Laboratory's goal is to offer timely and accurate Laboratory test information to care-givers for our patients.

Patient rights and organizational ethics

The Laboratory participates with other disciplines in ensuring patients' access to care and that patient rights are guaranteed.

The Department actively participates with other disciplines and the Patient Relations Department in resolving patient and family issues.

The Laboratory, along with other disciplines, allows patients and families to express their spiritual beliefs and cultural practices and inputs these practices into their interventions.

The Laboratory actively participates with the Investigational Review Board to ensure appropriate

use and monitoring of investigational studies for patients.

Assessment of patients

The Laboratory is involved in the assessment of patients through the collection and analysis of data obtained by providing Laboratory testing services on specimens obtained from patients. The data is then utilized to provide information to the patients' caregivers. Testing services are provided in the Laboratory by credentialed staff members. At the Point of Care, selected testing is performed by other hospital staff members through a multidisciplinary, collaborative effort. Technical oversight is provided by the Laboratory at the Bridgeport Campus. Point of Care testing at the Milford Campus is under the direction of the Department of Nursing.

Care of patients

The Laboratory provides accurate and timely information to physicians and nursing staff concerning all clinical testing results. Critical values have been defined for selected results and an immediate notification process has been established.

Patient and family education

The Laboratory does not provide direct patient or family education.

Continuum of care

The Laboratory provides care to the patients at various times throughout the continuum. From the One Stop Testing Center and Ambulatory sites, through hospital stays on an inpatient or outpatient basis, to a post discharge basis, Laboratory services are provided.

Organizational function

Improving organization performance

The Laboratory participates in Improving Organizational Performances through many vehicles which include but are not limited to the following:

1. The Chairman of the Department of Pathology and Laboratory Medicine and the Administrative Director are active and participating members of the Hospital Quality Council along with other hospital leaders ensure that a collaborative approach to patient care measurements are monitored, communicated and improved.
2. Laboratory participates in many CQI Teams with other disciplines to investigate ways of improving patient care standards and Nursing practices. The hospital systemically achieves performance improvement by identifying performance opportunities, collecting data and assessing it, recommending change and by measuring the change effectiveness.

3. The Laboratory utilizes performance improvement monitoring tools to receive information on the effectiveness, efficiency and timeliness of care. An example of these tools is the Patient Satisfaction Survey.
4. The Laboratory, along with other disciplines, uses performance improvement findings (where appropriate) to change processes that benefit the patient.
5. The Laboratory reports the results of its Quality Measures regularly to the Committee of Regulatory, Safety & Quality and Bridgeport Hospital's board of directors. The Department Chair also reports QM results to the Medical Executive Committee.
6. Employees are encouraged to report safety and quality concerns to lab management. Personnel may report their concerns to the CAP (or other regulatory organizations) directly if their concern is not addressed by laboratory management without facing punitive action or harassment in response to the complaint or concern made to CAP/regulatory agency.

Leadership

As a member of the Senior Management Staff, the Chairman of the Department of Pathology and Laboratory Medicine participates in the strategic planning for the hospital.

The Laboratory Leadership participates with other hospital leaders in ensuring communication of the organization's mission, goals, objectives and strategic plans across the organization. They participate in hospital management meetings whereby the hospital's mission and vision are communicated and in turn communicate the information through their individual staff meetings. Through this mechanism they define for their staff the mission and values that underlie the day to day activities carried out throughout the hospital.

The Laboratory Leadership participates with other hospital leaders in planning and developing new hospital programs consistent with the hospital's mission, developing operating budgets and monitoring compliance, establishing annual capital budgets, monitoring and establishing resource allocation and policies, and monitoring ongoing evaluation of the plans, implementation and success.

The Laboratory Leadership ensures staffing resources are available to appropriately meet the patients served. The Department participates with Human Resources in the recruitment of appropriate staff; with the Education and Development Department to educate staff; and through a Clinical Ladder Program, encourages staff to pursue job related advancement.

Management of the environment

Through a joint effort between Facilities Management, Clinical Engineering, Risk Management

and the Laboratory, a plan to maintain equipment is in place. The Laboratory, along with other staff, participates in the hospital Risk Management Program and document findings in the SAFER platform.

The Laboratory ensures that the hospital and laboratory are safe and secure environments for patients, staff and other individuals. Laboratory staff participates in the Employee Safety Committee as part of the hospital's overall plan for safety; the Laboratory employees receive yearly orientation on fire, PPE, electrical safety, safety, infection control, back safety and hazardous materials and waste. The Laboratory along with other hospital departments participates actively in the Hospital's Emergency Preparedness Plan. Staff is oriented to their response to internal or external disasters and drills are conducted to test preparedness. Through a program conducted by Facilities Management, Laboratory staff is educated on the utility systems management plan.

Evaluation of the area's environment is the responsibility of the Director or designee. Formal environmental rounds are conducted semi-annually and reported to the Quality Improvement Department. Corrective action is taken immediately upon identification of issues whenever possible. Evidence of corrective action is documented on the work/repair order.

Management of human resources

The Laboratory Department, along with other disciplines, participates in the hospital wide orientation program and in the department's individual department-specific programs.

The Laboratory, in conjunction with Human Resources, develops job descriptions, which define, in writing, performance expectations. Through a performance measurement system, job expectations are measured annually. The Human Resources Department will conduct a background investigation for all potential employees as well as background investigation clearance including references. The primary source verification is conducted by a third party and is reviewed for acceptability upon receipt by the Laboratory. That organization verifies education, previous employment, conviction history, and licensure. Education is verified for both domestic and international schools. The laboratory testing personnel are required to provide their diploma and/or transcript for their personnel file. The Laboratory hires ASCP certified or equivalent or certification eligible technologists and technicians.

Laboratory Leadership ensures the competency of all staff that provides care. Through orientation, performance evaluations, proficiency testing and ongoing in-services and credentialing, the Laboratory Department ensures competent care. The Laboratory Staff participate in CAP's proficiency testing program.

The Laboratory Leadership ensures staffing resources are available to appropriately meet the care needs of patient and allow for staff to participate in hospital performance improvement activities. A formal on call schedule is maintained as indicated. In the event of the need for additional staff, a telephone tree is maintained by each area.

Management Information

The Laboratory Department ensures that confidentiality of patient information is ensured at all times. Each member of the department receives an orientation to confidentiality and signs a written statement regarding their understanding of the policy.

Through individual security passwords, the Laboratory Department assures appropriate access to the Clinical Information Systems. Through defined policies and procedures, the level of access is determined and confidentiality is maintained. Members of the Laboratory have been initiated to HIPAA compliance training.

Clinical Laboratory information is currently available on patient care units through the use of computer terminals and EPIC system. Many Physician offices have access by means of a portal to Laboratory results.

Knowledge based information is available for the Laboratory and other disciplines through the hospital library, internet, teleconferences, lectures, rounds, ASCP and CAP webinars and other resource material.

Surveillance prevention and infection control

The Laboratory Department in conjunction with the Industrial Medicine Center ensures that all staff members meet current health status requirements to be in compliance with hospital policy, applicable laws and regulations.

Support services

The Laboratory is supported by:

- Information Services Department
- Biomedical Engineering
- Facilities Services
- Patient Care Area Staff
- Medical Staff
- Finance
- Administration
- Industrial Medicine
- Infection Control

Technology

Laboratory technology includes:

- Chemistry/ Immunology analyzers - routine and immunochemistry
- Blood cell analyzers
- Coagulation analyzers
- Molecular Microbiology- PCR technology
- Blood Bank cell washers and automated gel analyzers
- Blood Bank unit refrigerators and freezers
- Histopathology stainers,
- Histology tissue processors and microtomes
- Chemical fume and biological safety hoods
- Computer hardware
- Urinalysis Instrumentation

Turn Around Time (TAT)

Expected turn-around times for laboratory test results performed on-site.

*Note tests that are sent-out to reference laboratory’s may have extended TAT’s.

Bridgeport Campus Laboratory:

The following Laboratory sections perform their respective testing menus on a daily (seven days/week) basis with the following exceptions:

Blood Bank:	Antibody Titers	Days/Eves
Chemistry:	None	
Hematology:	Urine – Hemosiderin	Mon.-Fri.
Immunology:	ANCA	Tues,Fri
MRSA surveillance (by PCR)		2 hours
SARS-CoV-2 (by PCR)*/Flu A, B/RSV		same day
Stat gram stains (CSF only)		1 hour
Stool for Clostridium difficile PCR		same day

*SARS-CoV-2 tests that are sent to reference lab may have TAT’s up to 3 days

Blood smears (Malaria, Babesia)	same day
Blood for Malaria EIA	same day
Virology:	
Respiratory viral PCR testing	24 hou

Pathology: All tests Mon-Fri, Pathologist on call 24 hours/7 days

There are a number of tests which require special patient preparation and /or specimen handling. Information concerning these tests must be obtained from the Laboratory Section involved. The following tests must be scheduled with the Laboratory.

Bone marrow	Chromosome analysis
Fine Needle Aspirations	Lactose tolerance
Muscle biopsy/electron microscopy	Renal biopsy/Electron microscopy

Milford Campus Laboratory:

The following Laboratory sections perform their respective testing menus on a daily (seven days/week) basis with the following exceptions:

Core Lab and Blood Bank: none

*SARS-CoV-2 tests that are sent to reference lab may have TAT's up to 3 days

Anatomic Pathology/Special Tissue Processing: Pathologist available on-call 24 hours/7 days

There are a number of tests which require special patient preparation and /or specimen handling. Information concerning these tests must be obtained from the respective laboratory section involved. Frozen section/intraoperative consultation, bone marrow biopsy, cytology (fine needle aspiration), chromosome analysis, renal biopsy with immunofluorescence and/or electron microscopy, and muscle biopsy with/without electron microscopy to be scheduled with the Laboratory to coordinate Pathologist and Anatomic Pathology personnel availability in advance. For emergent/unforeseen special tissue processing needs, the on-call Pathologist will be available.

Turnaround times at both campuses may be monitored by the LIS system.

Lab Staffing Matrix

The staffing matrix represents the least number of people needed to handle routine volume with no esoteric testing.

Laboratory Staffing Matrix

Bridgeport Campus

Section	Days/Shifts	Monday-Friday	Weekend/Holiday	Personnel
	S-S 24/7			
Central Processing	shift 1	4	2	Central Processors
	shift 2	3	1*	
	shift 3	1*	1*	
Blood Bank	shift 1	1	1*	MLS/MLT
	shift 2	2	1*	
	shift 3	1*	1*	
Chemistry	shift 1	5	3	MLS/MLT
	shift 2	2	1	
	shift 3	1	1	
Hematology	shift 1	4	2	MLS/MLT
	shift 2	2	1	
	shift 3	1	1	
Microbiology	shift 1	4	2	MLS/MLT
	shift 2	2	1	
	shift 3	1	1	
Anatomic Pathology	shift 1	2	0.25*	PA
		5	2	Histotech
		1	0	Transcriptionist
		1	0	Secretary
	Shift 2	1.5	0	Histotech
	Shift 3	1.5	0	Histotech
One Stop Testing	shift 1	2	0	Ambulatory Support Tech.
Management (Both Campuses)		6**		

A Pathologist is on-call at all times and can be reached through the clerical section in the Laboratory by calling 203-384-3488

* on-call schedule

**call if needed

Milford Campus

Core Lab & Blood Bank	shift 1	3	2	MLS/MLT
	Shift 2	2	2*	
	Shift 3	1*	1*	
Anatomic Pathology	Shift 1	0.25*	0*	Histotech/Lab Associate
One Stop Testing	shift 1	1	0	Ambulatory Support Tech.

A Pathologist is on-call at all times and can be reached through the clerical section in the Laboratory by calling 203-301-1256

* on-call schedule

**call if needed

History:

01/2019 Added local laws to Scope of service paragraph

02/2019 Removed Cytology at BH

08/2019 Added new header and incorporated MC into policy by Laura Buhlmann

10/2019 Added Applicable National and Provincial laws and regulations

8/2020 Updated number of tests performed at both campuses and number of draw stations operated, removed LEAN and six sigma models for quality improvement to not limit quality processes used by laboratory and hospital. Added Employees are encouraged to report safety and quality concerns to lab management. Personnel may report their concerns to the CAP (or other regulatory organizations) directly if their concern is not addressed by laboratory management without facing punitive action or harassment in response to the complaint or concern made to CAP/regulatory agency under improving organization performance. Removed only from sentence: The Laboratory hires ASCP certified or equivalent or certification eligible technologists and technicians by L. Buhlmann

1/2021 updated number of draw stations by L. Buhlmann

5/2021 clarified terminology and added laboratory interpretation table by Teodorico Lee.

10/21 changed draw station number from 18 to 19 by L. Buhlmann

12/2022 Rev: Combined Staffing matrix policy and Turn around time exception policy into the lab scope of service policy by L. Buhlmann

3/2023 Rev: Updated to single Laboratory Medical Director, updated BH pathologist on call from “every weekend” to “24 hours/7 days” by C. Minerowicz.

3/2023 Merged BH department Services policy into Scope of Service policy. Omitted listing of all drawstations and hours and provided link to draw station locations by L. Buhlmann.

8/2023 Revised: Removed Ova & Parasites, HSV/VZV, all of Immunology section except ANCA from BH. Added *Note tests that are sent-out to reference laboratory's may have extended TAT's by L. Buhlmann.

11/2023 Revised: Changed 19 Outpatient service centers to multiple outpatient service centers, removed NAAT testing for GC/CT by L. Buhlmann.

Revised 4/2025-Removed Microbiology from BH by L. Buhlmann