SOUTH COUNTY HEALTH LABORATORY

I. SCOPE OF SERVICES

A. TYPES OF SERVICES

The Laboratory Department provides:

- Clinical and anatomic laboratory services to patients and employees primarily referred by hospital and community medical providers of Washington County, extending throughout Rhode Island, southern Massachusetts and nearby parts of Connecticut.
- Quality test results in an effective time frame to support treatment.
- An appropriate and comprehensive test menu to meet the needs of the population served.
- Clinical laboratory and anatomical pathology specimen processing and specimen/tissue storage.
- Appropriate and efficient transfusion services in collaboration with Rhode Island Blood Center and/or New York Blood Center.
- Appropriate selection of reference laboratory services.
- Appropriate waived, non-waived, and point-of-care testing (POCT).
- Consultation for laboratory test interpretation and utilization.
- Continuing education and guidance to students, physicians and hospital staff.
- Laboratory statistics to medical staff, administration, and inter-departmental committees.

Specific services provided include:

Service	Description
Anatomic pathology and Cytopathology	Biopsy, PAP test, fine-needle aspirate, endoscopic ultrasound, frozen section analysis, pathology consultations, histology processing/staining, immunohistochemical staining, surgical pathology
Blood Bank & Serology	Transfusion services, Serology testing
Clinical Laboratory Testing	Analytical testing in the following specialties: Hematology, Urinalysis, Coagulation, Chemistry, Immunochemistry, Toxicology
Microbiology Testing	Bacteriology, mycology and molecular testing.
Point-of-Care testing (POCT)	At numerous units and clinics within the hospital- POCT includes waived testing, moderate complex texting and provider-performed testing.
Hospital-based Inpatient Phlebotomy	Adult patients of all acuity levels, including those requiring the intensive care involved in emergency services, cardiac and oncology services. Newborn patients that are not NICU level of care.
Outpatient and Home Care Phlebotomy	Operate outpatient phlebotomy stations throughout Rhode Island. Serve as a referral laboratory to physician offices within the hospital system and other community providers including nursing and group homes for patients of all ages and stages of life.
Pathologist Consultations	On-site, telephone or electronic consultations as needed for questions regarding the ordering of appropriate laboratory tests and interpretation of laboratory data for both anatomic and clinical pathology. Applies to questions that arise from laboratory staff and/or hospital medical staff. While most questions can be answered by the laboratory director or associate pathologists. Occasionally the laboratory director or associate will seek external consultations from outside sources, which may include other pathologists from University Pathologists, LLC and reference laboratories (i.e. Rhode Island Blood Center, LabCorp, etc.).

Reference Laboratory Services	The department contracts with several reference laboratories to provide laboratory testing which is not performed in-house. The Medical Director/Pathologist-in-Chief, Laboratory Director, medical staff and hospital administration work together to assess and select appropriate reference laboratories.

The Lab Test Menu is linked to the Lab website. The list includes tests performed in-house, and the most commonly ordered reference lab tests. The list is not comprehensive of all tests that are available- providers may contact the laboratory at 401-788-1418 to request information regarding tests that they need to order but are unable to find or do not appear on the list.

The Laboratory Department further:

- Maintains appropriate accreditation
- Responds to information needs of the organization and the community
- Participates on appropriate committees to facilitate communication of service needs, appropriate utilization management, and performance improvement efforts
- Supports, conducts and participates in clinical research appropriate to furthering knowledge of pediatric disease and treatment

The services provided occur in various settings appropriate to the defined need, with limited laboratory testing provided at satellite locations. The laboratory performs testing based on requests from persons authorized by law to write laboratory test orders (i.e., physicians, physician assistants, and advanced registered nurse practitioners).

B. Billable Test Volume

- **Clinical Laboratory-** approximately 725,000 billable clinical laboratory tests performed per year, of which about 10% are sent to reference laboratories.
- **Anatomic Pathology-** approximately 7,000 surgical pathology cases and 2,000 cytology cases are signed out annually.

C. Complexity of Patient Care Needs

The department is expected provide all diagnostic and therapeutic evaluations needed by the medical staff (includes tests performed on site and at reference laboratories).

- Most needs are identified in the following ways:
  - Medical staff indicate a need to adopt new test procedures or additional testing considered standard-of-care via written requests or consultation with the Chief Pathologist
  - Pathologists and laboratory staff indicate need for updated methodologies, to increase specificity and sensitivity, or to improve turnaround times.

D. Timeliness of Services

The department is expected to be available for Hospital laboratory services at all times, on all days, to assure continuity of care for inpatients and emergency services.
Staff are expected adhere to defined turnaround times in both the clinical laboratory and anatomic pathology.

E. Availability of Services

- **South County Health Main Laboratory-** 100 Kenyon Avenue, Wakefield, RI

The Main Lab operates twenty-four hours per day, seven days per week for all inpatient and emergency room services, STAT outpatient newborn bilirubin testing, and other STAT outpatient testing as deemed necessary by the patients' providers.

- **South County Health Outpatient and Home Care Laboratory Services-**

The department operates multiple outpatient lab locations throughout Rhode Island with operating hours to suit the patient population and volume of each location.
Locations and hours of operation are documented in Policy #83 and kept up-to-date on the Laboratory Services website, in the event of an unexpected closure/change in hours.
Home Care phlebotomy services are routinely provided to patients who meet criteria for Homebound as defined by CMS.

F. Staffing to Meet Departmental Needs

Lab leaders review daily workload requirements and staff to meet needs.
The department staffs all lab areas based on time of day, day of week and season of the year, and has defined minimum staffing levels accordingly.
The laboratory staff consists of:

- Approximately 60 full-time equivalents (FTEs) in support of the inpatient, outpatient and referral needs of the organization and the community.
- Staffing plans for the individual laboratory sections, developed to ensure quality of laboratory testing and predictable turn-around-times
- A clinical pathologist available by phone at all times (Ext 1341 during day or 1418 off hours).
- An organizational laboratory structure that includes laboratory leadership as follows:
    - Chief Pathologist/Lab Medical Director
    - Director, Laboratory
    - Team Leaders/Technical Specialists
    - LIS and POCT Coordinators
    - Lead Technologists and Lead Phlebotomists

- The clinical staff includes:
    - Pathologists
    - Director, Laboratory
    - Team Leaders/Technical Specialists
    - LIS and POCT Coordinators
    - Medical Lab Scientists/Technologists
    - Medical Lab Technicians

- Lab Assistants/Phlebotomists
- Histotechnologists
- Cytotechnologists

The laboratory first responds to staffing shortages by utilizing "on call" and per diem staff, flexing up part time staff, and offering overtime and bonus pay on a volunteer basis. If the laboratory is unable to reach minimum staffing in the testing departments utilizing voluntary methods, the assignment list portion(s) of Policy #146- MT/MLT Schedule Guidelines take effect, to ensure minimum staffing levels are reached in a fair and standardized manner.

G. Quality Objectives and Metrics

Medical Director/Pathologist-in-Chief, Laboratory Director, Team Leaders/Technical Specialists and Coordinators monitor document performance of processes within their area(s) of responsibility. Each lab section establishes measurable operation-level improvement indicators consistent with the quality policy. Below are a few examples:

Element of Policy	Quality Objective	Metrics
Service Excellence	Timely result reporting	1. Stat turnaround times for emergency department (ED). 2. STAT result reporting outliers 3. Specimen Acceptability rates
	Meet and exceed customer satisfaction.	1. Press Ganey Patient Satisfaction Surveys 2. Monitoring and resolution of complaints. 3. Outpatient Call-backs
	Cost effectiveness	1. Blood Product Wastage 2. Repeat collections 3. Outpatient Lab volume monitoring
Accurate and Timely Result Reporting	Maintain or improve scores in Proficiency Testing	Proficiency test result monitoring and tracking
	Perform all defined quality control measures.	1. Blood Culture Contamination Rates 2. Blood Culture Fill Volumes 3. Corrected Results reports 4. Specimen Acceptability monitoring 5. Computer calculation checks 6. Corrected Reports. 7. Data Transmission 8. Amended Reports – Anatomic Pathology 9. Surgical Pathology/Cytology Specimen Labeling

	Retain qualified and competent staff	1. Turnover report monitoring 2. Employee Surveys 3. Annual competency evaluations and continuing education
Quality Patient Care	Accurately identify all patients and samples	1. Lab-collected Patient Identification and Specimen Labeling errors 2. Blood Bank requisitions-audit for completion
	Report critical values in a timely manner	1. Critical Value Reporting 2. Critical Value Documentation 3. Frozen Section TAT
	Reduce Nosocomial Infections	1. MRSA/CDIFF surveillance audits. 2. CAUTI monitoring 3. Flu and Covid activity monitoring
Safety	Ensure Employee Safety and Regulatory Safety Requirements are met.	1. Occupational Injury reports and monitoring 2. Environmental Audits 3. Safety Rounds 4. Staffing Levels
	Safety Event Reporting System-S.A.F.E. and QA Variance Reports	1. Monitor and investigate events entered in S.A.F.E. and QA Variance forms 2. Identify and investigate non-conforming events using RCA when appropriate/necessary.

H. ROLES AND RESPONSIBILITIES

Overall responsibilities for ensuring compliance with the QMS, are described below:

Position	Responsibility
Chief Nursing/Operating Officer	Responsible for nursing and operations at the senior executive level.
Director of Allied Health Services	Responsible for executive sponsorship of laboratory management and laboratory quality providing oversight and alignment within the System.
Laboratory Medical Director/Chief Pathologist	Responsible for the clinical aspects of laboratory testing, which includes approval of the new tests, test procedures, reference ranges, report format, clinical interpretation, and consultation. Responsible for the approval of overall QMS activities.
Director, Laboratory	Responsible for the business management and strategic direction of the laboratory in support of overall quality management. Ensures that QMS is established, implemented, monitored, documented and quality is continuously improving. Responsible for periodic reviews by organizational committees and Senior Management for effectiveness and continuing suitability. Provides guidance for staff to develop and document appropriate operational procedures and monitoring metrics, aligned with the QMS. Responsible for activities involved in daily laboratory operation such as testing, reporting, and logistics.
Team Leaders/Technical Specialists	Responsible for planning and controlling QMS processes within their area of responsibility, including the implementation of Quality Management objectives and the provision of resources needed to implement and improve these processes. Team Leaders/Technical Specialists are responsible for corrective action related to quality variances. Maintain control of lab costs within budget. Evaluate quality control and quality assurance statistics and maintains policies and procedures
Lead Technologists and Lead Phlebotomists	Responsible for supervising the activities of the QMS on the frontline and creating an environment of trust and accountability. Ensure performance of standard biological, microbiological, and chemical tests to assure their delivery in an accurate and timely fashion using proper safety precautions. Participate in root cause analyses for the management of quality variances and safety events.

Staff	Responsible for the quality of individual work and the development and implementation of the policy and procedures applicable to the processes performed. Identifying and reporting of quality variances.

I. ETHICAL CONDUCT

1. **The hospital system has a Corporate Compliance Program, which requires all dealings be conducted in a lawful and ethical manner.**

2. **Through adherence to Professional Conduct and Responsibility standards, all staff members conduct themselves in a professional and ethical manner, to protect and promote organization-wide integrity**

J. LEADERSHIP COMMITMENT

Laboratory leaders provide evidence of commitment to the development and implementation of the quality management system and continually improve its effectiveness utilizing the following activities:

- Establish the quality management system and review annually.
- Communicate the policy to employees during laboratory training/orientation and annual competency.
- Leaders ensure that employees at all levels understand, implement and maintain the quality management system. Document through training procedures, competency assessment and the employee performance review. The internal audit and the leadership review processes demonstrate compliance.
- Testing personnel understand and implement section policies and procedures. Leaders document through training/competency and maintain documentation in the employee file.
- Communicate information related to the quality management system through daily huddles, emails, text application messages, Lab Leadership meetings, Lab Staff meetings, document read & signs, stay interviews, text application messages and via email.

K. QUALITY SYSTEM SUMMARY

1. **The laboratory defines policies for each applicable standard.**
Laboratory policies will be maintained in a document control system approved by the Medical Director. Members of the Lab Leadership Team develop and maintain documented procedures that further describe how the specific policy objectives and goals are implemented within the department.

2. **Technical procedures are maintained in each section's manuals.**
   Technical procedures specify the equipment and resources needed to produce quality results in accordance with the applicable standards and policies. Section policies and procedures are maintained in the document control system and are approved by the Team Leaders/Technical Specialists and Medical Director.

3. **All employees are responsible for the quality system.**
   Individual policies and procedures further define specific employee responsibilities. The quality system includes a formal system of planned activities. The quality manual is maintained current, to reflect changes to the system.
4. **Lab Leadership members assess and monitor quality on an ongoing basis.**
   Processes are observed and monitored to assess whether the quality management system is implemented as planned, is effective and is consistently in use in all laboratory sections and sites. This information is shared with staff on a regular basis.
5. **As need is identified, the department takes corrective action and makes changes to improve.**
   When leaders identify trends in errors and/or opportunities to improve, they modify processes and procedures with the goal of preventing errors and improving for the future.
   Non-conforming events are identified and investigated in accordance with hospital policy for root cause analysis.

II. QUALITY ASSURANCE, ASSESSMENT AND IMPROVEMENT

A. GENERAL LABORATORY

Essential components in the quality assurance, assessment and improvement process include:

- Identify aspects of service to be monitored and evaluated
- Identify indicators
- Establish criteria
- Collect data
- Analyze data and identify problems (if any)
- Develop a plan for corrective action and future prevention
- Document actions taken
- Monitor and evaluate effectiveness of actions taken

1. **On-site Inspections**
   - Accrediting agencies provide standards of compliance in all aspects of safety, quality control and proficiency.
   - College of American Pathologists (CAP), The Joint Commission (TJC), American Association for Blood Banks (AABB), Rhode Island Department of Health (RIDOH) and Health Care Financing Administration (HCFA)

2. **Proficiency Survey and Q-Track results and intradepartmental monitors** are reviewed individually.

- Medical Director/Pathologist-in-Chief, Laboratory Director, and Team Leaders/Technical Specialists to identify trends and opportunities to improve

3. **Quality Assurance Variance Reports**
   - Refer to Policy #95- Quality Assurance Variance Reports
   - Reviewed by the Lab leadership to identify trends and opportunities to improve, and to document follow-up with staff members as appropriate.

4. **Safety Event Reporting System- Events and Feedback**
   - Refer to Policy #113- Handling and Resolution of Complaints
   - Members of Lab leadership review and investigate reports, and follow up as needed with staff members and/or to develop process improvement plans and policy/procedure updates.

B. CLINICAL LABORATORY

1. **Internal Quality Control Activities-**

   - Each section of the clinical laboratory maintains section-specific quality assurance programs, which include a written policy and documentation thereof.

Process	Category	Metric
Core	Pre-analytic	-Patient and specimen identification -Specimen integrity
	Analytic	-Materials -Equipment -Quality Control -Calibration
	Post-analytic	-Manual result entry review -Turnaround Time Monitoring -Calculation checks
Support		-Procedures -Training and Competency

2. **External Proficiency Program**

   - CAP Proficiency Survey Programs- received two to three times per year depending on the survey. Results are compared to national peer-groups.
   - For full list of enrolled proficiency surveys, see reference guide- CAP Proficiency and Q-tracks Monitors

3. **Q-track Quality Monitors**

- For full list of enrolled Q-tracks, see attached reference guide- CAP Proficiency and Q-tracks Monitors

C. Anatomic Pathology (Surgical and Autopsy Pathology)

1. Internal Quality Control Activities-

- Anatomic pathology maintains a section-specific quality assurance program, which includes a written policy and documentation thereof.

Process	Category	Metric
Core	Pre-analytic	-Patient and specimen identification -Specimen integrity
	Analytic	-Intra-departmental Case Review- Prospective review prior to issuance of final reports (Consultation) -Intraoperative Consultations
	Post-analytic	-Extra-Departmental Case Review -Retrospective audit of completed cases after issuance of final reports (Peer review) -Turnaround Time Monitoring- frozen sections and surgical pathology cases -Synoptic report review -Annual audit of receptor studies for breast cancer cases -Tissue/Transfusion Review Committee
Support		-Procedures -Training and Competency

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