ROPER ST. FRANCIS HEALTHCARE

RSFH Laboratory Services

LABORATORY QUALITY PROGRAM OVERVIEW

ORIENTATION FOR LABORATORY TEAMMATES

RSFH LABORATORY CLIA/QA COORDINATORS

10/21/21.RO

LABORATORY QUALITY OVERVIEW- ACCREDITATION

What is CLIA? The Beginnings…

- **"Pap Mills" scandal in mid-'80s - Essentially "fake" laboratories masquerading as real laboratories**
  - Laboratories offered low cost pap smears screened by unqualified personnel
- **CLIA '88 established government oversight of clinical laboratories (Accreditation)**
  - CLIA – Clinical Laboratory Improvement Amendments
  - Designed to weed out poor laboratory testing services
- **Oversight by Center for Medicare and Medicaid Services (CMS)**

  The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

Modified from Wexner Medical Center presentation

LABORATORY QUALITY OVERVIEW- ACCREDITATION
More About CLIA - Oversight

Three federal agencies are responsible for CLIA:

- **Food and Drug Administration (FDA),**
- **Center for Medicare and Medicaid Services (CMS), and**
- **Centers for Disease Control and Prevention (CDC).**

Each agency has a unique role in assuring quality laboratory testing.

LABORATORY QUALITY OVERVIEW - ACCREDITATION
More About CLIA – FDA Role

FDA

- Categorizes tests based on complexity
- Reviews requests for Waiver by Application
- Develops rules/guidance for CLIA complexity categorization

LABORATORY QUALITY OVERVIEW - ACCREDITATION
More About CLIA – CMS Role

CMS

- Issues laboratory certificates
- Collects user fees
- Conducts inspections and enforces regulatory compliance
- Approves private accreditation organizations for performing inspections, and approves state exemptions
- Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs
- Publishes CLIA rules and regulations

LABORATORY QUALITY OVERVIEW - ACCREDITATION
More About CLIA – CDC Role

CDC

- Provides analysis, research, and technical assistance
- Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducts laboratory quality improvement studies
- Monitors proficiency testing practices
- Develops and distributes professional information and educational resources
- Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

LABORATORY QUALITY OVERVIEW - ACCREDITATION
CLIA Basics – Testing Complexity Categories

Waived
- Simple, accurate tests without routine oversight
- Lab must follow manufacturer instructions.

Moderate
- Automated
- Lab must meet quality standards & be surveyed/inspected.

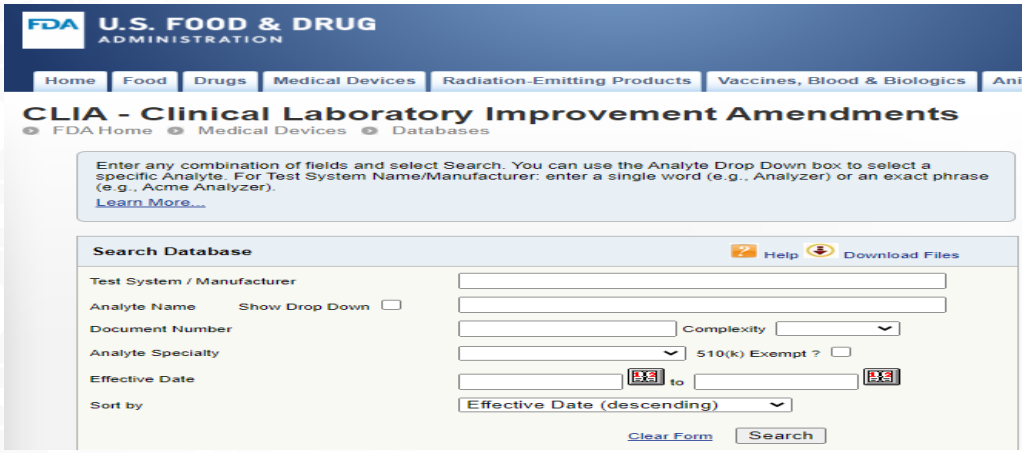
PPM
- Subcategory of moderate
- Only instrument is microscope
- Must meet quality standards and testing personnel requirements
- No routine oversight

High
- Manual testing
- Require more training, technique & result interpretation
- Most stringent standards
- Surveyed/inspected

From Wexner Medical Center presentation

LABORATORY QUALITY OVERVIEW - ACCREDITATION
CLIA Basics - Testing Complexity Determinations

- Determined by FDA
- Per analyte AND per instrument
- Determination based on user complexity and instrument function



LABORATORY QUALITY OVERVIEW - ACCREDITATION

CLIA Basics - Types of Certification

Certificate of Waiver

- Perform on waived testing

Certificate of PPM

- Perform only PPM or waived testing

Certificate of Compliance

- Surveyed by CMS / SCDHEC
- Waived, Moderate and/or High complexity Testing

Certificate of Accreditation

- Inspected by deemed authority
- TJC, CAP, COLA, etc
- Waived, Moderate and/or High

Modified from Wexner Medical Center presentation

LABORATORY QUALITY OVERVIEW – ACCREDITATION
Laboratory Accreditation Surveys/Inspections Required by CMS/CLIA

RSFH Laboratory surveys/inspections are every TWO years.

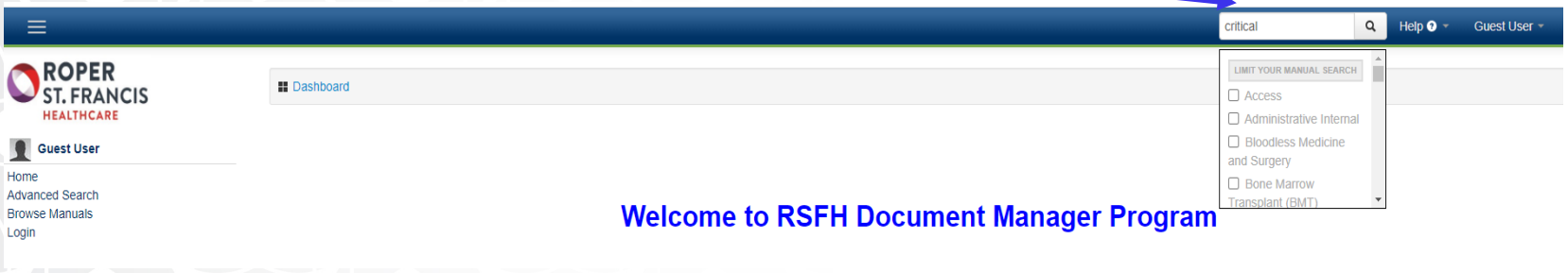
- **RSFH Hospital Laboratories** – Waived and Nonwaived Testing Surveyed by The Joint Commission
- **RSF Physicians Partners Laboratory (Leeds)** – Waived and Nonwaived Testing Currently Surveyed by COLA
- **RSF Physicians Partners Office Laboratories** – Nonwaived Testing Surveyed by SCDHEC
- **RSF Express Cares Laboratories** – Nonwaived Testing Surveyed by SCDHEC

LABORATORY QUALITY OVERVIEW - POLICIES AND PROCEDURES

RSF Document Manager

Laboratory Services General System-wide Policies and Procedures are located online via RSF Document Manager (Selection on the CareLine red bar).

As Guest User, you can type a keyword in the blue bar to search for a specific policy.



Department-specific technical policies are located at each testing laboratory site.

LABORATORY QUALITY OVERVIEW - POLICIES AND PROCEDURES

Laboratory General System Manuals via RSF Document Manager

Reminder—Laboratory Services General System-wide Policies and Procedures are located online via RSF Document Manager (Selection on the CareLine red bar).

Or as Guest User, you can use Browse Manuals to find Laboratory Services system-wide manuals.

LABORATORY QUALITY OVERVIEW - POLICIES AND PROCEDURES

Laboratory General Manual Quality Management Policies

Laboratory General Manual Section 3 – Quality Management Policies online via RSF Document Manager

SECTION 3 – QUALITY MANAGEMENT PLAN	
LG-S3-11	Proficiency Testing – Survey Program
LG-S3-12	Quality Management Plan
LG-S3-13	Quality Assurance and Patient/Visitor Occurrence Reports
LG-S3-14	Quality Control Program
LG-S3-20	Laboratory Method Implementation: New, Change, or Deletion
LG-S3-20A	• Appendix A = Laboratory Method Implementation Checklist
LG-S3-32	Individualized Quality Control Plan (IQCP) - General
LG-S3-32A	• Appendix A = IQCP Section Examples
LG-S3-46	Unacceptable Proficiency Testing Investigation
LG-S3-54	Medical Device Reporting for Laboratory
LG-S3-55	Laboratory Quality Management Committee
LG-S3-56	Laboratory-Wide External Audit System
LG-S3-59	Contracted Services Performance Measures

Department-specific quality control and technical policies are located at each testing laboratory site.

LABORATORY QUALITY OVERVIEW – PERSONNEL PREPARATION
Education, Orientation, and Training for Laboratory Personnel

Education is the process of receiving instruction resulting in the acquisition of knowledge.

- New laboratory employees must have basic education requirements as specified in job descriptions prior to hiring.

Orientation as defined by TJC, is "a process used to provide initial training and information while assessing the competence of clinical staff relative to job responsibilities and the organization's mission and goals." Orientation may also be an introductory program and/or activities intended to guide a person in adjusting to new surroundings, employment, policies/procedures, or essential job functions.

- New laboratory employees complete RSFH system introductory orientation as well as RSFH laboratory orientation.

Training differs from education because training focuses on gaining specific – often manually performed – technical skills.

- New laboratory employees complete specific training checklists for his/her job responsibilities.

Orientation and Training Summary - Once hired, new laboratory employees start the orientation and training to the specific job.

LABORATORY QUALITY OVERVIEW – PERSONNEL PREPARATION

Competency for Laboratory Personnel

Competency includes the attribute of ability. Ability means being able to do something. Competency incorporates knowledge, technical skills, and ability which are all required to deliver safe and high quality patient care and to correctly perform technical tasks.

Competency Assessment is the process by which the laboratory validates, via a defined, standardized process, that an individual can perform a task consistent with the education and training provided.

Competency Assessment Frequency – For laboratory testing personnel, evaluating and documenting competency is required at least semiannually during the first year of employment. Thereafter, competency assessments must be performed at least annually.

- New laboratory *testing* personnel competency is assessed initially (after training and before performing patient testing), at six months, and at twelve months. Thereafter, competency assessment are performed annually.
- Refer to Laboratory General policy *Employee Competency Evaluation Plan* for additional details related to competency assessments.

Competency Assessment Summary - Once trained, laboratory employees are assessed on the ability to competently understand and correctly apply the knowledge and technical skills to a laboratory task.

LABORATORY QUALITY OVERVIEW - COMPETENCY REQUIREMENTS

Laboratory Testing Personnel Competency for Nonwaived Testing

For nonwaived testing, all six elements listed below must be assessed as per policy (unless the element is not applicable to the test system).

The six elements of competency assessment include, but are not limited to:

1. Direct observation of the employee performing routine patient test performance such as patient preparation, specimen handling, specimen processing, and testing;
2. Monitoring the employee's recording and reporting of patient test results (including critical results, as applicable);
3. Review of the employee's intermediate patient test results or worksheets, proficiency testing results, quality control records, and preventive maintenance records;
4. Direct observation of employee performing instrument maintenance and instrument function checks;
5. Assessment of test performance by requiring employee to analyze a previously analyzed specimen, an internal blind sample, or an external proficiency testing sample (after result submission if previously tested); and
6. Assessment of the employee's problem-solving skills (e.g., case studies or written tests).

LABORATORY QUALITY OVERVIEW - COMPETENCY REQUIREMENTS

Laboratory Testing Personnel Competency for Waived Testing

For waived testing, each laboratory may select at least two elements to assess for each test system.

- The two elements must be from #1, #3, #5, or #6 in the list of elements above.
- For each waived test system on the appropriate checklist(s) for the designated employee, the observer or gatherer initials and dates a minimum of two elements as noted above. Observer or gatherer initials and date of performance is the minimum acceptable information required, however, best practice is to attach documentation of performance.

The most common elements documented for waived testing competency are:

- **Element #3 – Perform and document QC for review, and**
- **Element #6 – Complete NetLearning or Written Test.**

LABORATORY QUALITY OVERVIEW - PROFICIENCY TESTING (PT) REQUIREMENTS
What is Proficiency Testing?

"**Proficiency testing**, or PT, is the testing of unknown samples sent to a laboratory by an HHS-approved PT program.

Most sets of PT samples are sent to participating laboratories on a scheduled basis (usually three times per year).

After testing, the laboratory reports its sample results back to their PT program.

The program grades the results using the CLIA grading criteria and sends the laboratory their scores.

CMS and accreditation organizations routinely monitor their laboratories' performance."

From CLIA Proficiency Testing and PT Referral booklet, September 2017

LABORATORY QUALITY OVERVIEW - PROFICIENCY TESTING (PT) REQUIREMENTS
PT for Nonwaived Testing - Regulated vs Nonregulated Analytes

Is PT required for all non-waived testing?

Proficiency testing is required for regulated analytes.

"PT is required for only the limited number of tests found in Subpart I, Proficiency Testing Programs for Non-Waived Testing, of the CLIA regulations. If your laboratory performs any of the tests found in Subpart I, you must enroll in a CMS-approved PT program and perform PT on each of the tests. We refer to the tests listed in Subpart I as 'regulated' analytes."

From CLIA Proficiency Testing and PT Referral booklet, September 2017 and 42 CFR 493, Subpart H.

Per CLIA, the laboratory must evaluate the accuracy and reliability of non-regulated analytes at least every six months so RSFH laboratories use proficiency testing to meet this requirement in most instances.

Per CLIA and at RSFH, the laboratory must evaluate the accuracy and reliability of both nonregulated and regulated analytes for which proficiency testing samples are not available. This must be documented at least every six months.

LABORATORY QUALITY OVERVIEW - PROFICIENCY TESTING (PT) REQUIREMENTS
PT for Nonwaived Testing - Regulated vs Nonregulated Analytes

RSFH Proficiency Testing Requirements:

1. At RSFH, laboratory testing personnel must complete the NetLearning module *Proficiency Testing Requirements for Laboratory Testing Personnel*.
2. Laboratory testing personnel who perform proficiency testing must sign the Attestation Statement page included with each shipment.
3. Laboratory testing personnel who perform proficiency testing must sign the *RSF Laboratory Services Proficiency Testing Acknowledgment* form.

LABORATORY QUALITY OVERVIEW - PROFICIENCY TESTING (PT) REQUIREMENTS
PT for Waived Testing

For waived testing, the laboratory is not required to perform proficiency testing unless mandated by its accreditation agency.

- The Joint Commission (TJC) nor CLIA requires proficiency testing for waived tests.
- At RSFH, if proficiency testing is performed for waived tests, laboratory personnel follow all applicable policies for nonwaived proficiency testing.

LABORATORY QUALITY OVERVIEW - INCIDENT REPORTING

If it's not documented, it did not happen!

Document any incident affecting the quality of patient results.

- **Laboratory QA Forms for internal documentation**
- **Marsh ClearSight Online Risk Management System for Manager Corrective Actions**

QA Form

ROPER ST. FRANCIS HEALTHCARE LABORATORY SERVICES
LABORATORY QUALITY ASSURANCE REPORT

Applicability: This form applies to Roper Hospital, St. Francis Hospital, Mount Pleasant Hospital, and any departments owned or operated by these hospitals.

QM CODE:
F/N UNIT:
LAB/EMP:
OBS:

Attach printed label or complete:

PATIENT NAME: _____ LOCATION: _____
MEDICAL RECORD #: _____ PHYSICIAN: _____
ACCESSION #: _____

	INVOLVED AT TIME OF INCIDENT	REPORTING INCIDENT
DEPARTMENT/LOCATION		
DATE/TIME/SHIFT		
EMPLOYEE (print name)		

DETAILED ACCOUNT OF INCIDENT	ACTION TAKEN
• Improperly labeled specimen received in Laboratory. Mark labeling error below: 1. ___ Unlabeled Specimen 2. ___ Mislabeled Specimen 3. ___ Mislabeled Specimen and Request 4. ___ Inadequate Labeled Specimen • Describe details or any other incident below:	Action for Labeling Errors: 1. ___ Recollect (cancel and re-order) 2. ___ Relabel (MUST complete separate form to authorize) • Notified: _____ Date/Time: _____ • Describe any other action below:

COMMENT: _____

EMPLOYEE INVOLVED: _____ (Signature) DATE: _____
EMPLOYEE REPORTING: _____ (Signature) DATE: _____
SUPERVISOR: _____ (Signature) DATE: _____
COPY TO: _____ DATE: _____

Marsh ClearSight

ONLINE INCIDENT REPORTING

Patient Fall Documents

Welcome to the Incident Reporting Page. Click on the link below to start entering an incident report. If you need assistance with your report please call the CALM department.

The ClearSight System is where teammates report all **patient safety events, near miss events, unsafe conditions, complaints & grievances, security & general safety, and teammate injuries.**

ClearSight Launch Site

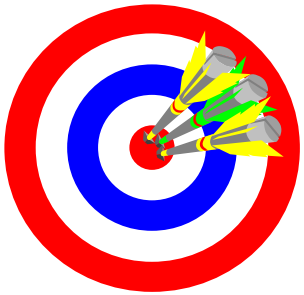
Nurse Peer Review Reports of any nursing peer review referral.

Privacy / HIPAA: of any potential wrongful access, use or disclosure of patient health information.

LABORATORY QUALITY OVERVIEW - LABORATORY METRICS
Quality Management (QM) Scorecard Metrics Overview

Laboratory QM Scorecard Examples for Quality Metrics

- AM TAT
- ED TAT
- LABELING ISSUES
- BLOOD CULTURE CONTAMINATION RATES
- DEPARTMENT SPECIFIC METRICS - examples
  - Pathology Metrics
  - Blood Bank Type and Screen TAT
  - Critical Call Compliance
  - Specific Test TATs



Current QM Metrics are posted on laboratory bulletin boards.

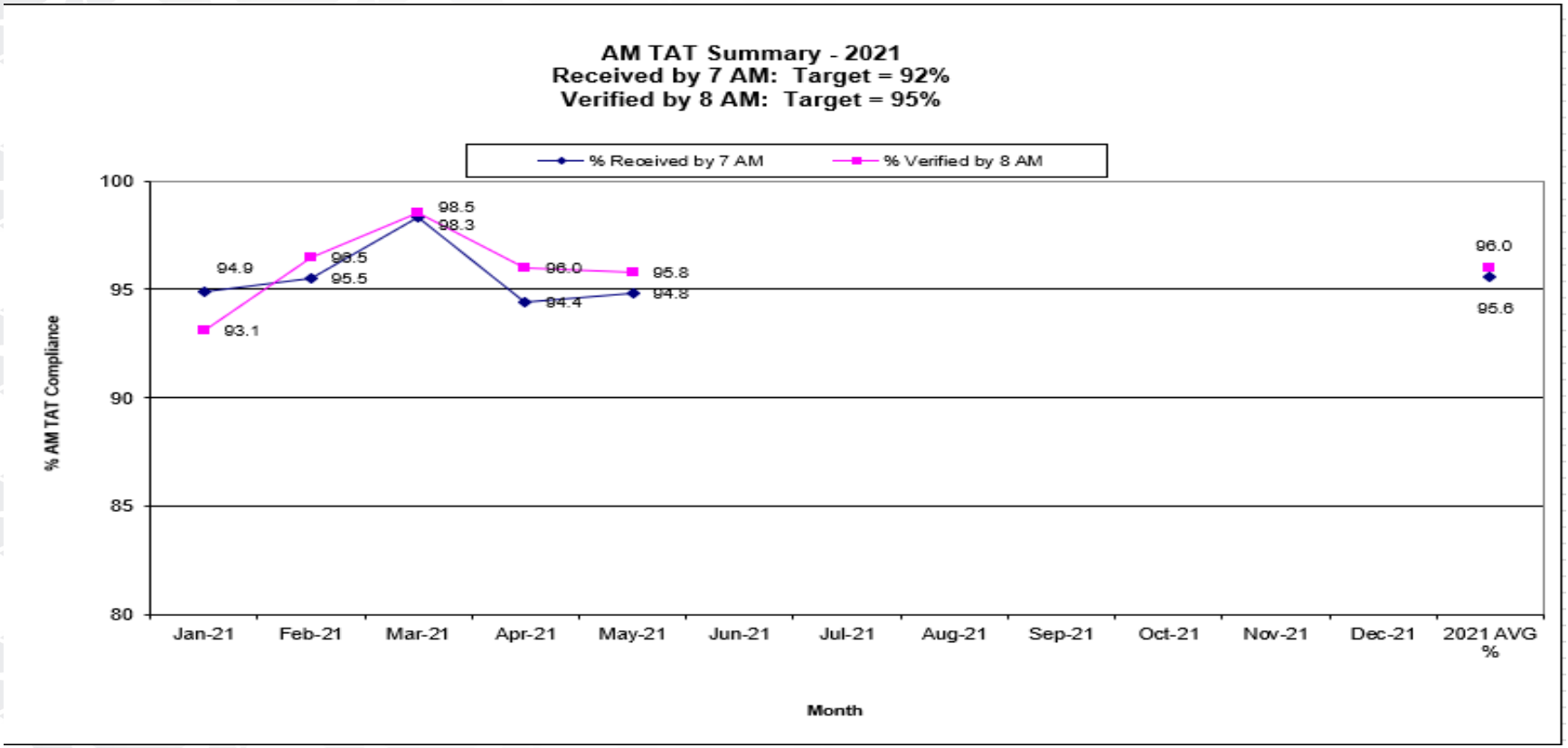
LABORATORY QUALITY OVERVIEW - LABORATORY METRICS

AM Turnaround Time (AM TAT)

For Phlebotomy – Monitor % specified 5am collections delivered to lab by 7am

For Core Lab Testing – Monitor % specified 5am collections verified/completed by 8am

Example from RHL May 2021 data:



LABORATORY QUALITY OVERVIEW - LABORATORY METRICS
ED Turnaround Time (ED TAT)

Top 10 Core Lab Tests from ED:

CBC, CBC w/AUTODIFF, CMP, BMP, PT/INR, PTT, D-Dimer, UA Macro w/Rflx Microscopic, Troponin T, and Lactic Acid

Parameter Monitoring (modified as of July 1, 2020):

ED TAT for "8 of top 10 tests" received to completed within 30 mins.

ED TAT for "8 of top 10 tests" ordered to completed within 45 mins.

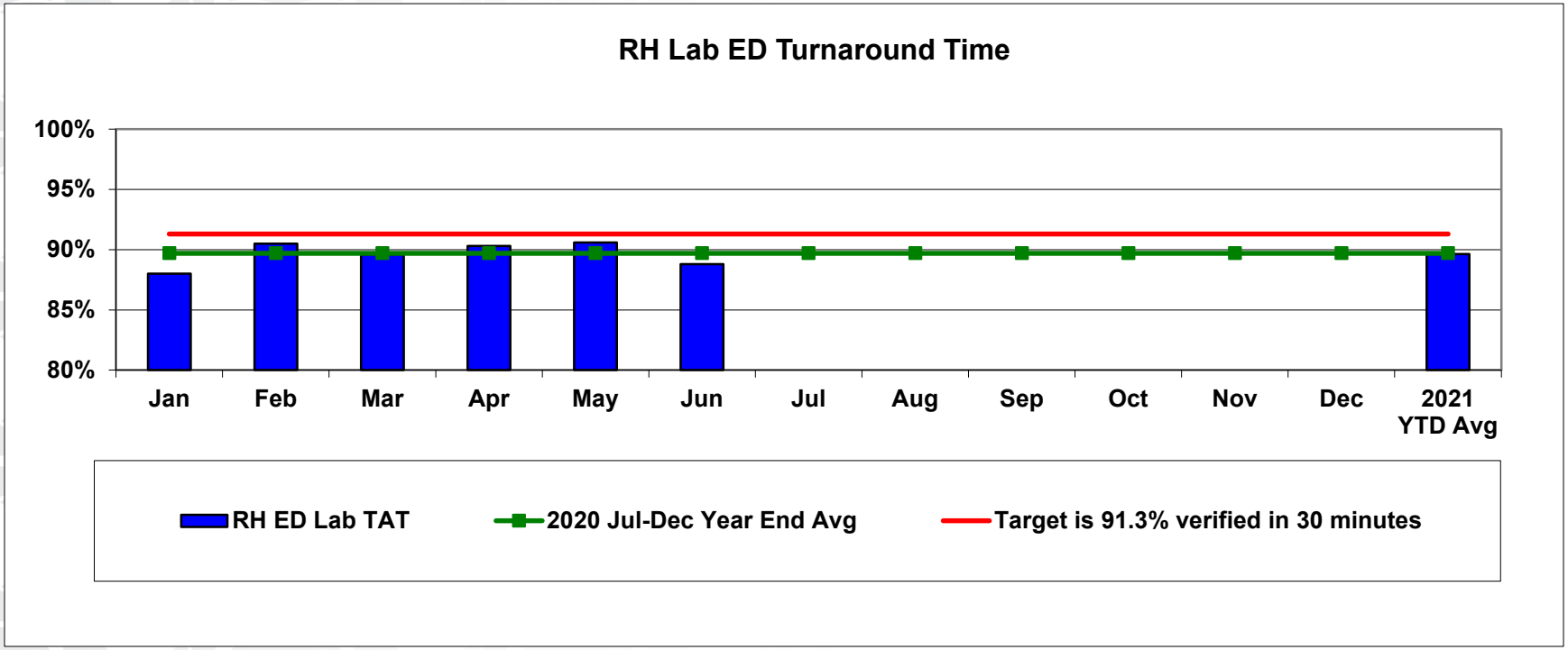
ED TAT for Troponin T received to completed within 30 mins (as of 11/1/2021).

ED TAT for Lactate received to completed within 5 minutes.

2021 targets based upon site-specific July – December 2020 ED TAT data.

LABORATORY QUALITY OVERVIEW - LABORATORY METRICS
ED Turnaround Time (ED TAT)

Example from RHL June 2021 data for received to completed within 30 minutes:

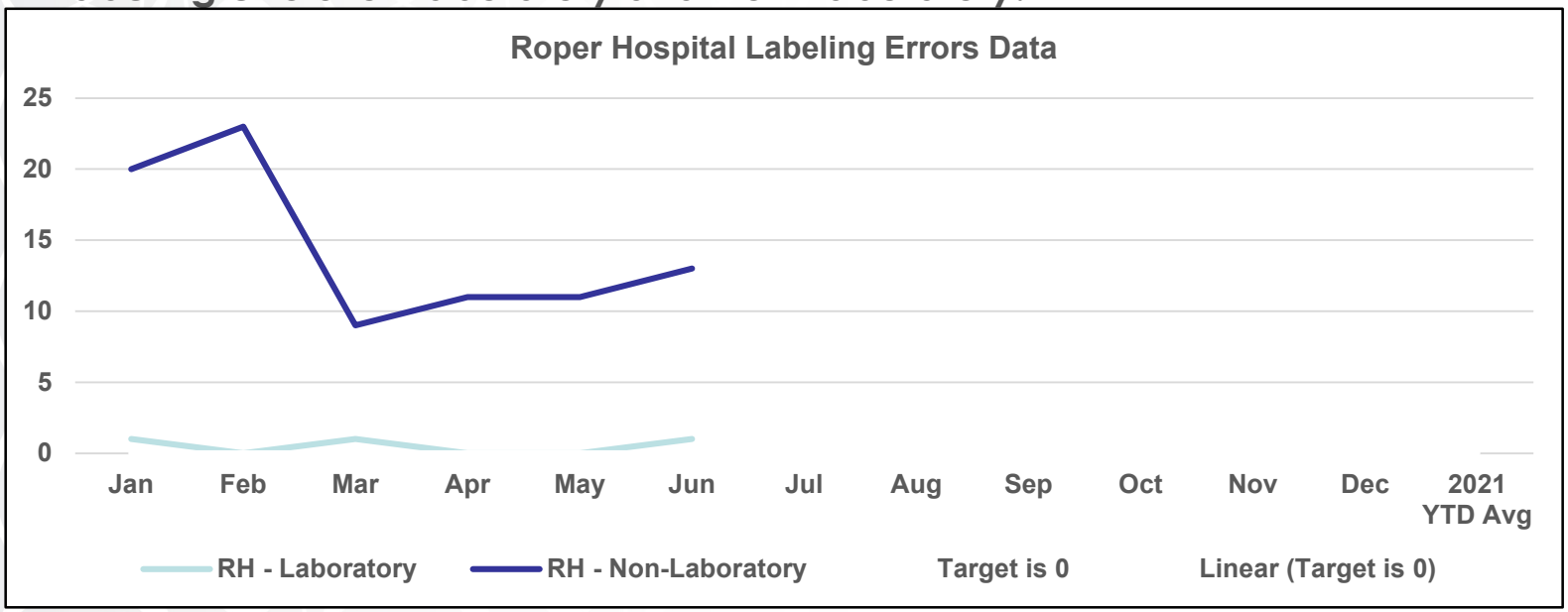


LABORATORY QUALITY OVERVIEW - LABORATORY METRICS

Patient Identification Labeling Errors

Monitor documented patient identification labeling errors, i.e., unlabeled and mislabeled specimens due to no or wrong patient identification affixed to specimen.

Example from RHL June 2021 data for documented patient identification labeling errors for Laboratory and Non-Laboratory:

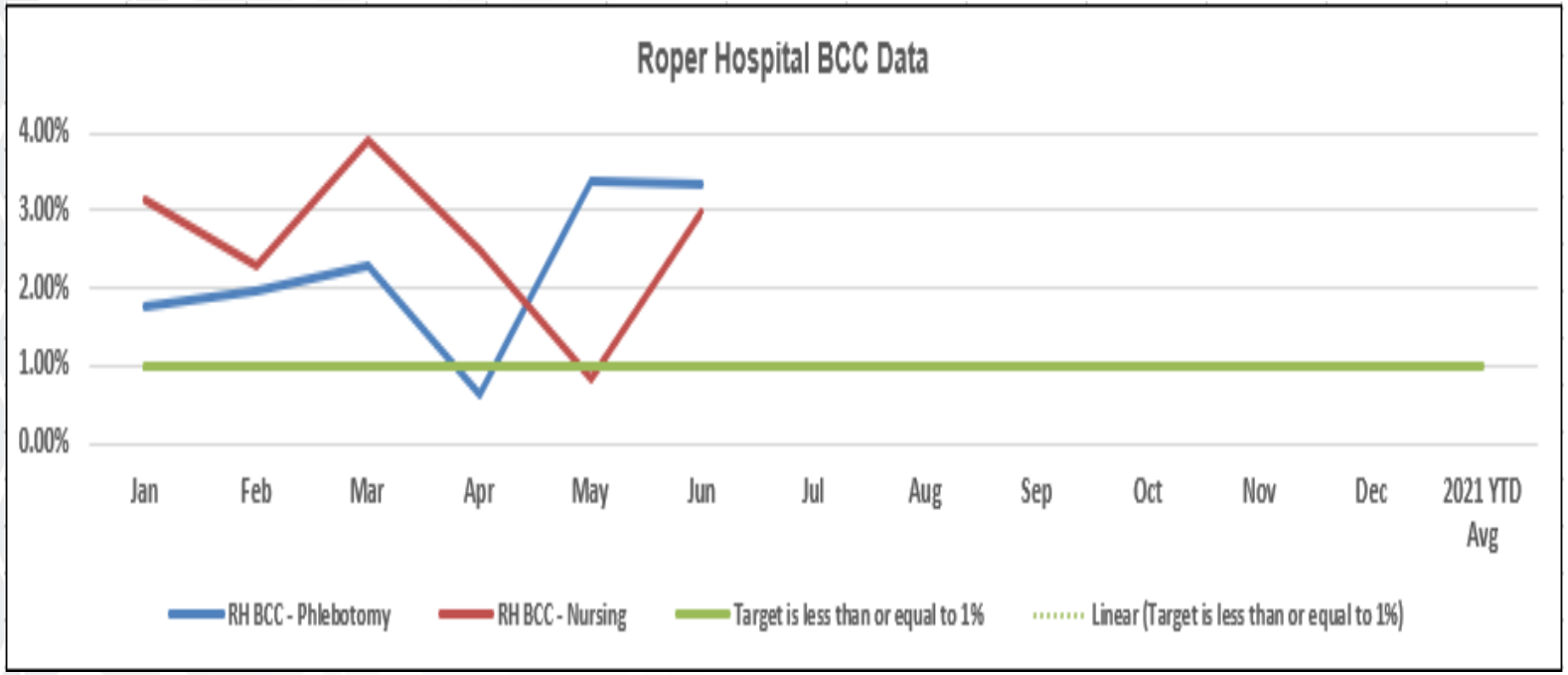


LABORATORY QUALITY OVERVIEW - LABORATORY METRICS

Blood Culture Contamination Rates

Monitor blood culture collections with growth of contaminants due to collection techniques needing improvement.

Example from RHL June 2021 data for blood culture contamination rates for Phlebotomy and Nursing:



LABORATORY QUALITY OVERVIEW - SUMMARY

If you have questions about anything related to the RSFH Laboratory Quality Management Program, ask:

- **Your Laboratory Supervisor,**
- **Your Laboratory Manager, or**
- **Your Laboratory CLIA/QA Coordinators – Loretta Redwood or Sally Newman.**

LABORATORY QUALITY OVERVIEW - REFERENCES

CLIA Brochures available from the CMS website: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures

CLIA Overview for Laboratory Directors, presentation by Sandra VanVranken, MS, MT(ASCP)SH, Director, Laboratory Compliance, The Ohio State University Wexner Medical Center.

CMS website on CLIA: https://www.cms.gov/regulations-and-guidance/legislation/clia?redirect=/clia/

FDA CLIA Complexity website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

Ready, Set, Test Booklet – available on the CDC website: https://www.cdc.gov/labquality/images/waived-tests/RST-Booklet_Dec-2019.pdf

The Joint Commission. Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. E-dition, Last Accessed October 6, 2021.