Quality Assurance Program For Hospital Based Point of Care Testing

JOHNS HOPKINS
MEDICINE

Presented by: Jeanne Mumford, MT(ASCP)
Pathology Supervisor, QA Manager

Objectives

At the end of the session, participants will be able to:

- Develop a QA program for the testing performed
- Monitor the performance of point of care tests
- Assure appropriate training of clinical staff
- Utilize various tools to monitor and assess quality

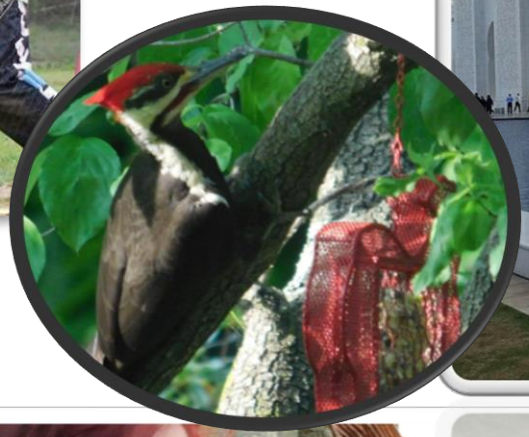
JOHNS HOPKINS MEDICINE

Disclosures

- Nonfinancial: Board of Directors- COLA Resources, Inc; President, KEYPOCC Keystone Point of Care Coordinators
- Financial – Honorarium/Author: AAFP POL Insight 2015A
- Financial – Honorarium/Speaker: AACC; KEYPOCC; Whitehat Communications
- Financial – Advisory Committee: BioFire; ASM

cap ACCREDITED

JOHNS HOPKINS MEDICINE



JOHNS HOPKINS
MEDICINE

Point of Care Coordinators

JOHNS HOPKINS MEDICINE

JHCP Hagerstown
JHCP Westminster
Johns Hopkins White Marsh
JHCP Water's Edge
JHCP Green Spring Station
Johns Hopkins Green Spring Station
JHCP White Marsh
JHCP Frederick
JHCP Wyman Park
The Johns Hopkins Hospital
East Baltimore Medical Center
JHCP Canton Crossing
Baltimore
JHCP Greater Dundalk
JHCP Bayview Internal Medicine
Howard County General Hospital
Johns Hopkins Bayview Medical Center
JHCP Germantown
JHCP Howard County
JHCP Fulton
JHCP Glen Burnie
JHCP Montgomery
Suburban Hospital
JHCP Odenton
JHCP North Bethesda
JHCP Laurel
Johns Hopkins Odenton
JHCP Rockledge
Sibley Memorial Hospital
JHCP Bowie
Johns Hopkins Bethesda
Washington D.C.
JHCP Annapolis
JHCP I Street
JHCP Downtown Bethesda
JHCP Sibley Memorial Hospital
JHCP Ballston
Not shown on map
All Children's Hospital St. Petersburg, Florida
JHCP Charles County
Hospitals
Health Care & Surgery Centers
Johns Hopkins Community Physicians

List of Current POCT

Interfaced Devices:

- ✓ ACT-LR, ACT Plus
- ✓ Creatinine
- ✓ INR
- ✓ Hgb
- ✓ Urinalysis
- ✓ HBA1c
- ✓ Glucose, whole blood
- ✓ O2 Saturation
- ✓ Blood Gases

- ✓ pH
- ✓ Strep A
- ✓ Rapid HIV 1/2 Antibody
- ✓ Rapid HCV
- ✓ Urine Drug Screen
- ✓ PPM
- ✓ Tear Osmolality
- ✓ Fecal Occult Blood
- ✓ Specific Gravity
- ✓ Urine HCG

Importance of POCT

- Inpatient and Outpatient Testing
- Potential for faster patient treatment
- Enhance achievement of national quality benchmarks
- Connectivity available on most platforms

JOHNS HOPKINS MEDICINE

Ongoing Monitoring

- Mock inspections and intracycle monitors
  - Follow regulatory body checklist
- Enroll in a CLIA approved Proficiency Testing Program
- Perform semi-annual patient correlations
- Patient Safety Net (PSN) which allows for staff to submit lab issues and other patient safety concerns
- Safety Officers program
  - Safety officers are engaged in the unit practices. Safety Officers include nurses, medical assistants, unit managers, providers

Ongoing Monitoring

- Schedule internal audits or inspections to each unit
  - Inspect all storage areas where POC supplies are kept
  - Look for open and expiration dates on all POC containers and/or test kit/devices
- Observe testing and sample collection techniques
- Review all Quality control and patient documents
- Inspect devices/instruments
  - Look for QC liquid on device surfaces
  - Ensure that back up batteries are charging
  - Ensure that docking stations are properly plugged in and charging devices

Ongoing Monitoring

- Host a monthly meeting with the major lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
  - Review cancellation reports
    - Trends in cancel reasons
    - Education
    - Supplies
    - Courier schedules
    - New Test Codes
    - New Specimen Collection Devices

Developing a QA Program

- ✓Waived
- ✓Moderate Complexity
- ✓Provider Performed Microscopy
- ✓High Complexity

JOHNS HOPKINS MEDICINE

CLIA Expectations - Waived

- Waived laboratories must meet only the following requirements under CLIA:
  - Enroll in the CLIA program;
  - Pay applicable certificate fees biennially; and
  - Follow manufacturers' test instructions
  - Allow announced or unannounced CLIA inspections
- The Manufacturer’s recommendations, suggestions or requirements MUST be followed.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html

CLIA Expectations - Waived

- Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary)
- Instructions on how to perform test
- Define QC frequency
- Units of measure for reporting results
- Expiration dates for controls and reagents
- Storage conditions and stability or testing materials
- QC documentation
- Reviewed every 2 years

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html

CLIA Expectations - Waived

Conducting Surveys of Waived Tests

- Waived tests are not subject to routine CLIA survey
- A survey of waived tests may be conducted to:
  - Collect information on waived tests;
  - Determine if a laboratory is testing outside their certificate
  - Investigate an alleged complaint
  - Determine if the performance of such tests poses a situation of immediate jeopardy

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html

PATIENT TESTING IS IMPORTANT.

Get the right results.

http://wwwn.cdc.gov/clia/Resources/WaivedTests/

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office

CS242576-A

Ready Set Test

- CLIA requires that waived tests must be simple and have a low risk for an incorrect result. However, this does not mean waived tests are completely error-proof.
- This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf

Ambulatory QA Plan

Details from an Ambulatory Laboratory QA Plan

Staff Training and Competency Ambulatory

- New Hire competency during orientation
- Annual competency checklists and/or computer based training (CBT)
- Quiz
- Must encompass 2 of the 6 key CLIA elements
- *Key is engaging testing personnel

JOHNS HOPKINS MEDICINE

Vendor support/ training Ambulatory

- Utilizing Vendor Reps for support in training
- Vendor reps are brought into sites to perform on site training with our competency checklist
- Vendor reps have a great report with sites and reach out several times a year for support

Proficiency Testing Ambulatory

- Example of failed proficiency leading to investigation of POC device
  - Corrective action plan – repeat sample, vendor representative training with competency checklist, correlation samples, Technical service rep download data and evaluate
  - As a result of failed QA specimens, we isolated one Afinion, the device that we use to measure HBA1c, needed to be replaced
- HBA1c, Hgb, Strep A, pH, fecal occult blood, glucose

JOHNS HOPKINS MEDICINE

Quality Control Testing Ambulatory

- Documenting internal and external controls
- Follow manufacturers instructions in package inserts
- State and Federal guidelines
- External QC materials often made by company that does not make test kits

JOHNS HOPKINS MEDICINE

Example of EMR documentation

POCT hCG, Urine, Qualitative

	Range	3wk ago
POC HCG, Urine	Negative	**Positive**
POC QC Performed?		**Yes**

Resulting Agency

- Internal QC documented with each POC test entered into patient chart
- Example is from manual test entry where interface is not in place

JOHNS HOPKINS MEDICINE

Example of Paper Logs

Johns Hopkins Community Physicians
SITE_____

QuickVue One Step hCG Urine Pregnancy Test Control Log
External Controls are done with Each New Lot # and Each New Shipment

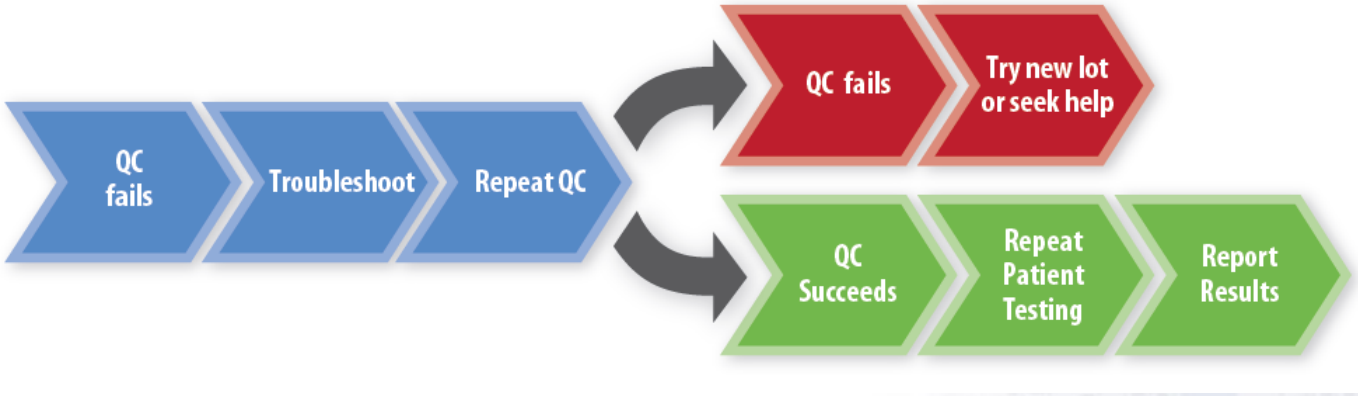
Date	Kit Lot Number	Kit Expiration Date	POSITIVE CONTROL: (POS) Lot #:_____ Exp Date:_____	NEGATIVE CONTROL: (NEG) Lot #:_____ Exp Date:_____	SIGNATURE	Problems? (Y/N) if Yes document below*

DATE	PROBLEM	ACTIONS

Actions include but are not limited to: re-testing the specimen with a new kit; using a kit from a new box; using a new lot number; informing manager

JOHNS HOPKINS MEDICINE

QC Troubleshooting



http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf

JOHNS HOPKINS MEDICINE

Example of Paper Logs

Johns Hopkins Community Physicians
SITE_____

QuickVue One Step hCG Urine Pregnancy Test Control Log
External Controls are done with Each New Lot # and Each New Shipment

Date	Kit Lot Number	Kit Expiration Date	POSITIVE CONTROL: (POS) Lot #:_____ Exp Date:_____	NEGATIVE CONTROL: (NEG) Lot #:_____ Exp Date:_____	SIGNATURE	Problems? (Y/N) if Yes document below*

DATE	PROBLEM	ACTIONS

Actions include but are not limited to: re-testing the specimen with a new kit; using a kit from a new box; using a new lot number; informing manager

JOHNS HOPKINS MEDICINE

Semiannual Lab Inspections Ambulatory

Checklist based on CAP and COLA guidelines to include:

- Point of care areas
- Phlebotomy areas
- Specimen collection containers
- Centrifuges and microscopes
- QC logs for every POCT
- Tracking logs
- Refrigerator logs
- Eyewash logs
- Testing supplies in date and marked opened
- Availability of procedures (printed or intranet)
- Competency Checklists/Computer Based Training Modules
- Lab environment
- Record retention

Hospital QA Plan

Details from a Hospital POC QA Plan
Moderate Complex

Provider Performed Microscopy

JOHNS HOPKINS MEDICINE

Site Visits
Hospital

- Some units are visited twice per week
- Moderate complex testing
- Waived testing once per month
- Opportunities for improvement easily identified and addressed with frequent site/unit visits

Patient Correlations Hospital

- Same analyte with different methodologies
- Same analyte at different sites
- Same analyte with different instruments
- At least once every six months
- Opportunities to identify meters that don’t correlate

JOHNS HOPKINS MEDICINE

Patient Tracer Hospital

- Periodic
- Randomly selected patient care areas
- Trace from test result on the POC meter to the patient record (EMR)
- Opportunity to identify clerical or systematic errors

JOHNS HOPKINS MEDICINE

Environmental Rounds Hospital

- Conducted by Health, Safety and Environment Department
- Twice a year
- Unannounced
- Opportunity to identify compliance issues for Institution, local, state or federal regulations
- Corrective action plans are submitted to DHMH

Mock CAP Surveys Hospital

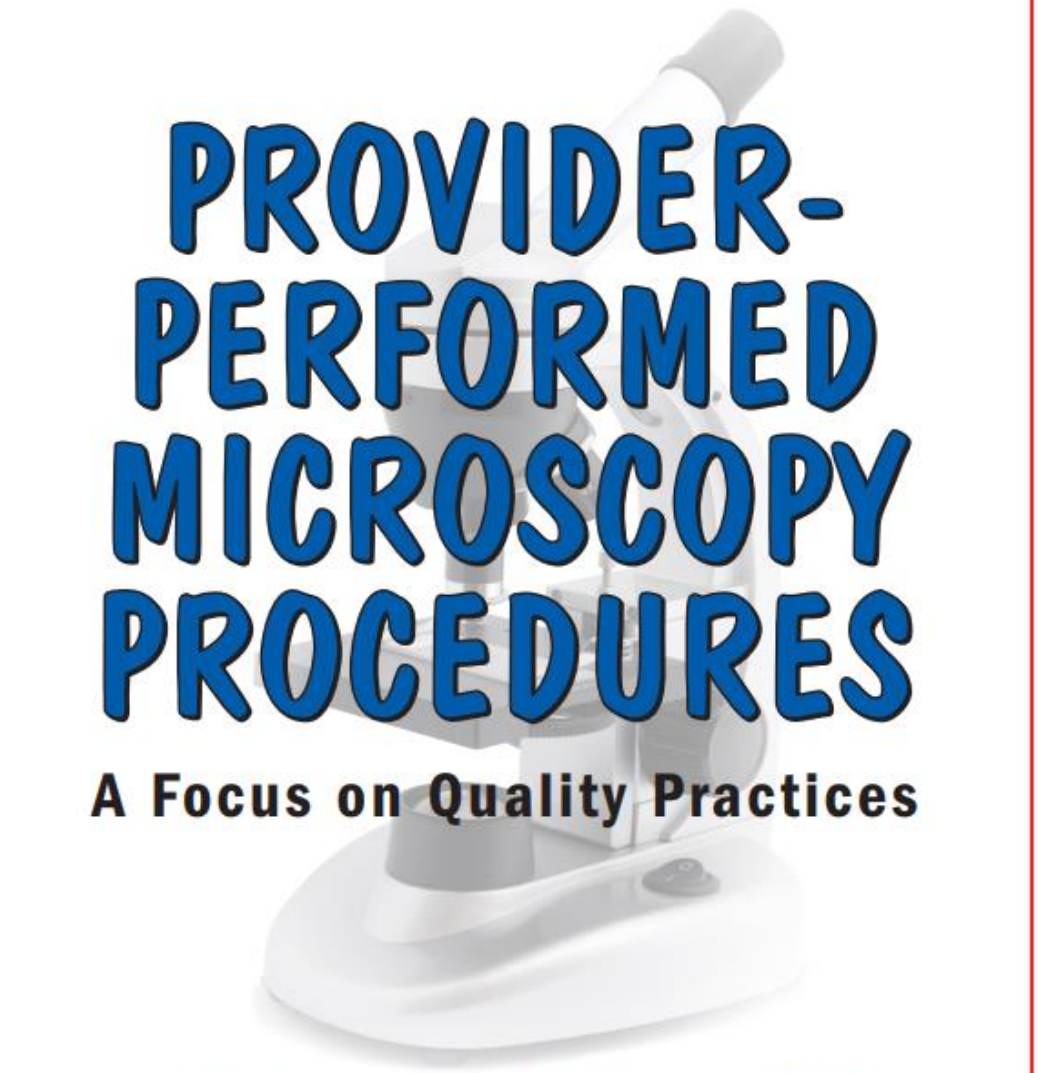
- College of American Pathologists, CAP Standards
- Continuous Quality Improvement (CQI) Office recruits system wide staff volunteers to conduct Mock Surveys
- Corrective Action Plans are submitted to CQI for documentation purposes
- Opportunity to identify and correct issues before CAP inspection

JOHNS HOPKINS MEDICINE

Quality Control Review Hospital

- Monthly review
- Some manual via paper logs
- Some electronic via interface
- Opportunity to identify system trends

JOHNS HOPKINS MEDICINE



PROVIDER-PERFORMED MICROSCOPY PROCEDURES

A Focus on Quality Practices

http://wwwn.cdc.gov/clia/Resources/PPMP

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems

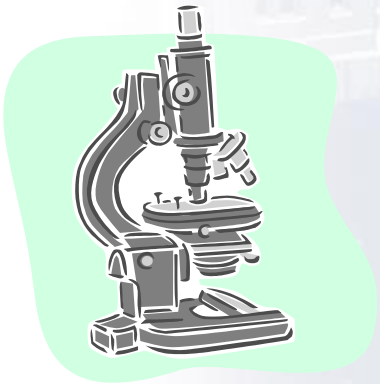
CDC

CS258020-A

PPM – Provider Performed Microscopy

CLIA Sec. 493.1365 Standard; PPM testing personnel responsibilities.

- Online competency assessment modules completed semi-annually http://medtraining.org/
- Utilized by providers who bill for PPM tests



PPM – Provider Performed Microscopy

- Providers, including mid-level providers complete modules
- Twice a year, once every 6 months
- MTS – reports for completion
- Ability to assign modules for only those tests performed

JOHNS HOPKINS MEDICINE

QA Projects

JOHNS HOPKINS MEDICINE

http://wwwn.cdc.gov/mpep/labquality.aspx

Identifying QA Opportunities Ambulatory Sites

- Tracked Data
- Trends from Safety Reports or Data

JOHNS HOPKINS MEDICINE

QA Opportunities
Ambulatory Sites

- Use corrective action plans for all deficits identified
- Monitor all events (i.e., PT that is 80% and passed)
- Monitor the process post-corrective action
- Follow up on all changes made

Future Growth
Hospital Program

- Standardized interface platform for Point of Care tests across 5 Hospitals
  - Will allow for quality indicators across the enterprise
- Standardized electronic medical record
  - Primary care and specialty care access
- Standardized laboratory information system
  - Harmonized test panels
- Standardized testing platforms
  - Chemistry and Hematology lines

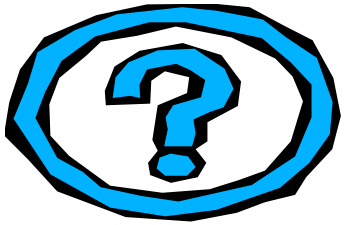
Summary

- A comprehensive Quality assurance program includes:
  - Continuous Quality Improvement
  - Staff training and ongoing competency assessment
  - Monitoring program specific to the test(s) performed
  - Ongoing quality assurance assessments with appropriate corrective plans and interventions

JOHNS HOPKINS MEDICINE

Questions

Jeanne Mumford, MT(ASCP)
Pathology Manager, Point of Care Testing
jmumfor3@jhmi.edu
Johns Hopkins Hospital



JOHNS HOPKINS MEDICINE