Quality Assurance Program
For Hospital Based Point of Care Testing

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
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
Point of Care Coordinators
**List of Current POCT**

<table>
<thead>
<tr>
<th>Interfaced Devices:</th>
<th>✓ pH</th>
<th>✓ Urine HCG</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ ACT-LR, ACT Plus</td>
<td>✓ Strep A</td>
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<tr>
<td>✓ Creatinine</td>
<td>✓ Rapid HIV 1/2 Antibody</td>
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<tr>
<td>✓ INR</td>
<td>✓ Rapid HCV</td>
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<tr>
<td>✓ Hgb</td>
<td>✓ Urine Drug Screen</td>
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<tr>
<td>✓ Urinalysis</td>
<td>✓ PPM</td>
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<tr>
<td>✓ HBA1c</td>
<td>✓ Tear Osmolality</td>
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<tr>
<td>✓ Glucose, whole blood</td>
<td>✓ Fecal Occult Blood</td>
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<tr>
<td>✓ O2</td>
<td>✓ Specific Gravity</td>
<td></td>
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<tr>
<td>Saturation</td>
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<tr>
<td>✓ Blood Gases</td>
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</table>
Importance of POCT

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

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

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

READY?
SET?
TEST!

PATIENT TESTING IS IMPORTANT.
Get the right results.

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

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
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
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
Example of EMR documentation

### POCT hCG, Urine, Qualitative

<table>
<thead>
<tr>
<th></th>
<th>Range</th>
<th>3wk ago</th>
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<tbody>
<tr>
<td>POC HCG, Urine</td>
<td>Negative</td>
<td>Positive</td>
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<tr>
<td>POC QC Performed?</td>
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<td>Yes</td>
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- Internal QC documented with each POC test entered into patient chart
- Example is from manual test entry where interface is not in place
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Kit Lot Number</th>
<th>Kit Expiration Date</th>
<th>POSITIVE CONTROL: (POS) Lot #:</th>
<th>NEGATIVE CONTROL: (NEG) Lot #:</th>
<th>SIGNATURE</th>
<th>Problems? (Y/N) if Yes document below</th>
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</table>

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
QC Troubleshooting

## Example of Paper Logs

### 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) | NEGATIVE CONTROL (NEG) | SIGNATURE | Problems? (Y/N) if "Yes", list below*
|------|----------------|---------------------|------------------------|------------------------|-----------|-------------------------------------
|      |                |                     | Lot #: ________________ | Lot #: ________________ |           |                                     |
|      |                |                     | Exp Date: _____________ | Exp Date: _____________ |           |                                     |

### Notes

- 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.
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
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
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
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
Quality Control Review Hospital

- Monthly review
- Some manual via paper logs
- Some electronic via interface
- Opportunity to identify system trends
PROVIDER-PERFORMED MICROSCOPY PROCEDURES
A Focus on Quality Practices

http://www.cdc.gov/clia/Resources/PPMP
PPM – Provider Performed Microscopy

CLIA Sec. 493.1365 Standard; PPM testing personnel responsibilities.

- Online competency assessment modules completed semi-annually
- 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
QA Projects
Identifying QA Opportunities
Ambulatory Sites

• Tracked Data
• Trends from Safety Reports or Data
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
Questions

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