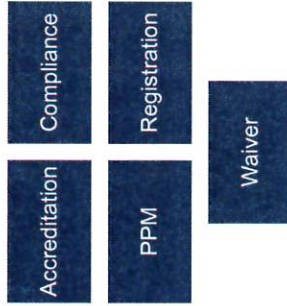


Point of Care Leading the Way

Jo D Fontenot, MS, MT(ASCP)
Division Manager
Urinary Division
ARUP Laboratories

8/2/2017

CLIA Certifications



Joint Commission Standards

Waived and Non-Waived Standards

Hospital Standards Defined

Responsible Staff

Policies/Procedures

Document Control

QC including IQCP/Test Records

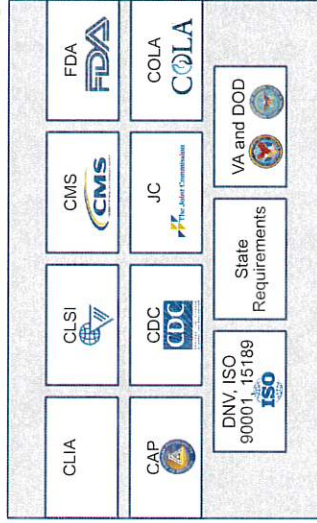
Reference Intervals on Chart

Source: Joint Commission Standards 2014

Overview



Structural Sources and Regulatory Agencies that have Deemed Status for Point of Care Testing



CLIA Testing

- Waived Testing
 - Minimum Standard
 - Certificate of Waiver
 - Manufacturer's Guidelines
 - JC, CAP, VA - Require More Stringent Compliance Standards
- Non-Waived Testing
 - Quality Control
 - Quality Assessment
 - Proficiency Testing
 - Procedure Manual
 - Inspection
 - Personnel Requirements
 - "Off-Label Use"

CAP

- ✓ QM
- ✓ QC
- ✓ Proficiency Testing
- ✓ Reagents
- ✓ Procedure Manuals
- ✓ Document Control
- ✓ Training Competency
- ✓ QC for Non-Waived Tests
- ✓ IQCP
- ✓ Instrument/Method Comparison
- ✓ AMR Validation



CAP

- For laboratory accreditation: All analytes must be included in on-site inspection and comply with CAP Standards.
- Point of Care Checklist is used in conjunction with the All Common and Laboratory General Checklists.
- Point of Care does not include satellite laboratories with dedicated testing space for CAP; These are covered under the Limited Service Checklist.
- POC checklist covers tests classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests).
- If registered under the same CLIA number as the central laboratory, the program must be included in the on-site inspection. If they are under separate CLIA numbers, they must have a separate Lab General and Team Leader checklists completed for each Point of Care program for each CLIA number.

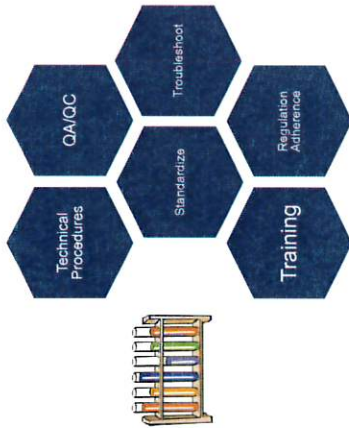
Source: CAP Point of Care Checklist 8/17/2016

CAP New/Revised



Source: CAP Point of Care Checklist 8/17/2016

Laboratory's Role



Training and Competency Assessment:

What is required?

Joint Commission Standards

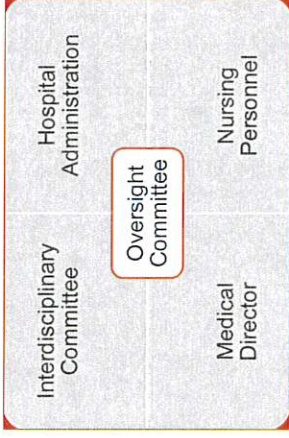
- Competency Assessment at orientation, at least annually, must consist of 2 of the following:
 - Testing of unknown specimen
 - Observation of test performance
 - Evaluation of QC performance
 - Written test

Source: Joint Commission Standards 2014

ISO 15189

- Quality Management System
- Pre-Analytical
- Analytical
- Post-Analytical

Oversight of Point of Care Programs



Non-Laboratory Professionals:

Training, Competency, Communication, and Compliance



- Large Number of Personnel to be Trained
- Time Limitations of Personnel
- Ongoing Training Requirements and Types of Competency Assessment
- Lack of Appreciation or Understanding of Testing Limitations
- Different Education and Experience Levels of Personnel

Challenges

Training and Competency Assessment:

What is required?

College of American Pathology

- POC.06875 and 06910: Is there a documented program to ensure that each person performing (waived and non waived) POC maintains satisfactory level of competence?
 - Direct observation
 - Monitor recording and reporting of results
 - Review of intermediate results or worksheets
 - Direct observation of performance of instrument maintenance and function checks
 - Assessment of performance through proficiency testing
 - Evaluation of problem solving skills

Source: Point of Care Testing Checklist 8/17/2016

Training and Competency Assessment:

What is required?

College of American Pathology

- POC.06850: Is there evidence that testing personnel have adequate specific training to ensure competence? (Phase I)
- POC.06800: Is there a current list of POC personnel that delineates that specific tests that each individual is authorized to perform? (Phase II)

Source: Point of Care Testing Checklist 8/17/2016

Training and Competency:

Orientation, Modules, and Emphasis

- Training Objectives
- Checklist
- Review of Procedure
- Observation of Performance
- Initial Competencies
 - Unknown Samples
 - Record Success of Results
 - Document
- Potential Pitfalls
- Emphasize:
 - Pre-Analytical Variables
 - Analytical Limitations
 - Post-Analytical Reporting
- Goal: Consistent performance by staff members to ensure high quality testing.

Source: CLSI Document GP21-A2: Training and Competency Assessment, Approved Guideline

Compliance and Training the Trainer

Compliance

- Challenge to ensure new employees are trained prior to testing
- Audit training
 - Limiting access to system until training is accomplished
 - Lock out capabilities
 - Issuing barcodes
 - Programming in the system

Training the Trainer

- Nursing education involved
 - Incorporate into nursing program
 - May obtain better compliance
 - Requires patience and communication
 - Nursing education committees
 - Participate in skills day



On Line Programs and Intranet



- Intranet
 - Procedures online
 - Online programs available
 - Interactive
 - PowerPoint presentations
 - Videos on performance of procedures
 - Online Programs
 - Point of Care webpage

Involve the Vendors

Provide Trainers	Incorporate
Specify Expectations	Continuing Education
Schedule Sessions	E-Connectivity and Training

Auditing for Compliance

Monitor	Online Resources
Audits	Retraining Program in Place
Corrective Action for Errors	Documentation

Introduce a New Point of Care Test



Determine Patient Population to be Tested	Detail Requirements	Consider Potential Interferences
Available Systems/FDA Cleared/Intended Use	Create a Short List to Evaluate	Base Quality Specifications on Biological Variation
Pre-Analytical Sources of Variation	Analytical Sources of Variation	Changes in Patient Data Must Exceed All Sources of Variation

Outcome Studies

Evaluate Changes in Patient Outcomes	Observe
Prospective Study	Limit Variables
Consistent Intervention	Quantify Studies

Glucometers



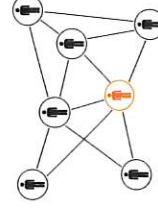
- Critical Patients
- Tight Glycemic Control
- Patient Safety

STRIP SAFELY
Accurate Diabetes Testing Matters

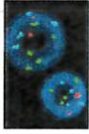


Connectivity and Potential Pitfalls

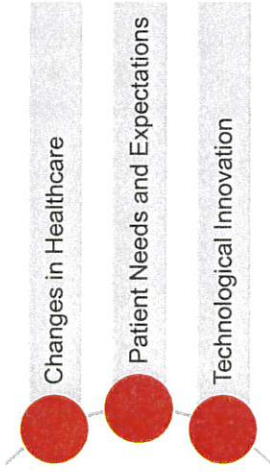
- Post-Analytical Errors
 - Clerical Errors
 - Inappropriate Reporting
 - Compliance
 - Reduce Labor Costs
- Patient Bar-Coding System
- Employee Bar-Coding System
- Ensure Network's Server Capabilities
- Coordination with Vendors, IT, and Hospital



Technological Trends and Future Considerations



Driving Forces for Point of Care Testing



Questions?



Every Specimen Represents a Life



Useful Web Sites

- www.pointofcare.net
- www.cap.org/html/checklist.html#cklist_poc.html
- www.cms.hhs.gov/CLIA/
- www.phppo.cdc.gov/clia/
- www.accessdata.fda.gov/scripts
- www.jointcommission.org/AccreditationProgram/LaboratoryServices
- www.nach.org (Information NACB Laboratory Medicine Practice guidelines)
- www.colia.org

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