Internal Lab Inspections:
How we Stay ‘CLIA Ready’
at our Physician Office Laboratories

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DESCRIPTION:
Semiannual self-conducted lab inspections are a great way to stay “CLIA Ready.” This session will go over useful criteria and how they relate to the current CLIA regulations, and how to prepare and understand the materials that will be reviewed. We will explore some challenges that are faced by laboratorians working with medical office assistants, nurses and providers in a laboratory setting and vice versa. There will also be a review of some of the corrective action plans that are expected when a site “fails” an inspection and how to follow up on those corrective action plans.

OBJECTIVES:
At the end of the session, participants will be able to:
- Develop internal inspections as part of a QA program
- Address challenges that laboratorians face
- Develop and implement corrective action plans
- Implement strategies to stay “CLIA Ready”
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Background

Laboratory Quality Assurance (QA) Specialist

• Laboratory Quality Assurance Specialist for Johns Hopkins Community Physicians (JHCP)
  – Oversight of 36 physician office waived laboratories
  – Technical consultant for JHCP @ Kent Island, moderately complex laboratory
• Provide ongoing training and competency as well as staff support
  – New hire orientation include POCT

Organizational Successes

• Successfully passed CLIA inspections at Moderately Complex site; successfully passed CLIA Waived inspection
• National achievements
  – 97% “Meaningful Use” of an Electronic Health Record (EHR)
  – Level 3 recognition at all sites for the Patient Centered Medical Home (PCMH) program; this is the highest level set by the National Council for Quality Assurance (NCQA)
  – Incentive range cervical cancer screening, lead testing, and SSI Adult & Child measures with Value-Based Purchasing
• JHCP has used an electronic medical record (EMR) for over 7 years. In April 2013, Hopkins began implementation of an universal EMR.
Laboratory Accreditation

- Outside agency: COLA, CAP, etc. or CLIA
- Most outside agencies perform their own version of lab inspections
- CLIA program utilizes State agencies to conduct surveys

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

Common Deficiencies
- Not having the appropriate federal or state license
- Personnel qualifications
- Proficiency testing program
- Manufacturer requirements
- Temperature monitoring & requirements

CLIA EXPECTATIONS

- Inspector will review policies and procedures
- Observe workflow and documentation
- Review all laboratory documents, EMR and LIS systems and patient records
- Conduct exit interview to outline any deficiencies and give overall grade

Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)
At JHCP, 1 out of 35 sites is Moderately Complex, therefore only 1 site has scheduled CLIA inspections once every 2 years. All 35 sites are inspected internally twice a year.

SURVIVING A CLIA INSPECTION

“For some, notification of an impending inspection ranks close to finding out that you have a terminal illness.”

5 Stages of Emotion

- 1st: Denial – It can’t be time for my inspection, it hasn’t been two years
- 2nd: Anger – CLIA has nothing better to do than torture me!
- 3rd: Bargaining – God, just let me get through this and I will never forget to run controls again!
- 4th: Depression – I’m going to fail, get fired and have to flip burgers for a living
- 5th: Acceptance – Well, they will be here in two weeks… I better get ready.

Self-conducted inspections are low cost options to improve the quality of the tests offered in the lab

CHECKLIST AT A GLANCE
General Overview of Checklist for CLIA Compliance
• General Administrative & Personnel
• Facility and Safety
• Patient Test Management
• Proficiency Testing
• Instrument maintenance
• Procedure manual
• Quality Control

Checklist Based on CLIA and COLA
• 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

Sample CAP Question
Cap question: GEN.20377
Are laboratory record sand materials retained for an appropriate time?
JHCP Indicator:
Lab records from last 2 years are present and available

Sample COLA Question
COLA question: ORG 1 E
Does your laboratory have the appropriate CLIA certificate and/or state license required based on the complexity of testing performed and is the certificate and license current?
JHCP Indicator:
Lab permits up to date and displayed in all testing areas

JHCP Checklist at a Glance
Suggestions

- Sign off on every laboratory document every 6 months
- Inspect exam rooms and storage areas where specimen collection containers are kept

Workflow

- Inspection reports sent to practice administrators
- Practice administrators may add corrective action comments or dispute score
- Final, graded inspection report back to practice administrator

What Can Internal Audits Tell Us?

- Training and Knowledge deficits
- Procedure updates
- Maintenance pitfalls
- Patient Safety
- Staff Safety
- Best Practices
- Corrective Action Plan Successes/Failures

Overall Indicator Percentage Score
100% Compliance
Lab Inspections Oct-Dec 2011

Accu Check Gluometer Log Score
Sites not keeping logs up to date were revisited or required to send logs via email for review.
Sites not documenting troubleshooting for out of range QC were subject to peer review.
**Microscope Maintenance**

- Sites were identified in inspection to be missing basic microscope maintenance materials and procedures.

**Electronic Medical Record: Think ‘Outside’ the Checklist**

- In April, Johns Hopkins implemented a universal electronic medical record.
- Fall inspection rounds will include indicator for specific lab ordering observation.
- Grading overall knowledge of EMR and lab orders:
  - Identify opportunities for improvement.
  - Increase knowledge and training at site level.

**Medical Office Assistants**

- Often not trained to perform POC tests in school.
- Training not concentrated in chemistry or laboratory methodologies.
- Balancing patient workload with regulatory requirements.

**Documentation Shortcuts**

- "Why can’t I use an arrow or tick marks on my QC logs?"
- Staff using the following to complete QC logs:
  - Check marks
  - Arrows
  - Tick marks

**Laboratory Director**

- Learning how to share responsibilities with our Office Medical Director who are the Laboratory Directors.
- Communicating in a busy environment.
- Corrective Action Plans and follow up.
- Proficiency testing results.
- QC documentation.
CORRECTIVE ACTION PLANS

Where to Start?

- When CLIA requires corrective action plans (CAP), they outline the specific need in the inspection report including the regulation reference number
- CLIA will require a written action plan
- Therefore, written plans are suggested for all internal inspections

“Communication is fundamental to achieving the desired improvements.”
Point of Care Testing. James H Nichols, PhD, DABCC, FACB. Clinics in Laboratory Medicine. 2007

Corrective Action Plans are created to correct significant clerical and analytical errors and unusual or unexpected results
- They can be:
  - Brief statements a few sentences long
  - Multiple pages with references
    » A good CAP puts all the pieces together
    » Cause
    » Correction
    » Follow Up

Summary

- A comprehensive self-conducted inspection process includes:
  - Developing a Quality Assurance Program to support the inspection process
  - Ongoing monitoring
  - Corrective action plans
  - Compliance with federal and local regulations
- All of which are strategies to keep you CLIA Ready!

QUESTIONS