

Internal Lab Inspections: Are You Inspection Ready?



JOHNS HOPKINS

M E D I C I N E

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HEALTH SYSTEM

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Disclosures

- Nonfinancial - Member of Board of Directors, COLA Resources, Inc, receives no financial compensation
- Financial – Honorarium – Author for AAFP POL Insight 2015A: Quality Assurance Program for Physician Office Laboratories
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Johns Hopkins Medicine



List of Current POCT

- ACT-LR, ACT Plus
- Specific Gravity
- Creatinine
- INR
- Hgb
- Urine HCG
- Urinalysis
- HBA1c
- Glucose, whole blood
- O2 Saturation
- pH
- Strep A
- Rapid HIV 1/2 Antibody
- Rapid HCV
- Urine Drug Screen
- PPM (Fern, KOH, Sperm-Qual, Postcoital mucus, Urine Sediment)
- Tear Osmolality
- Fecal Occult Blood

Objectives

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

- Develop internal inspections as part of a QA program
- Address challenges that point of care coordinators face
- Develop and implement corrective action plans
- Implement strategies to stay Inspection Ready

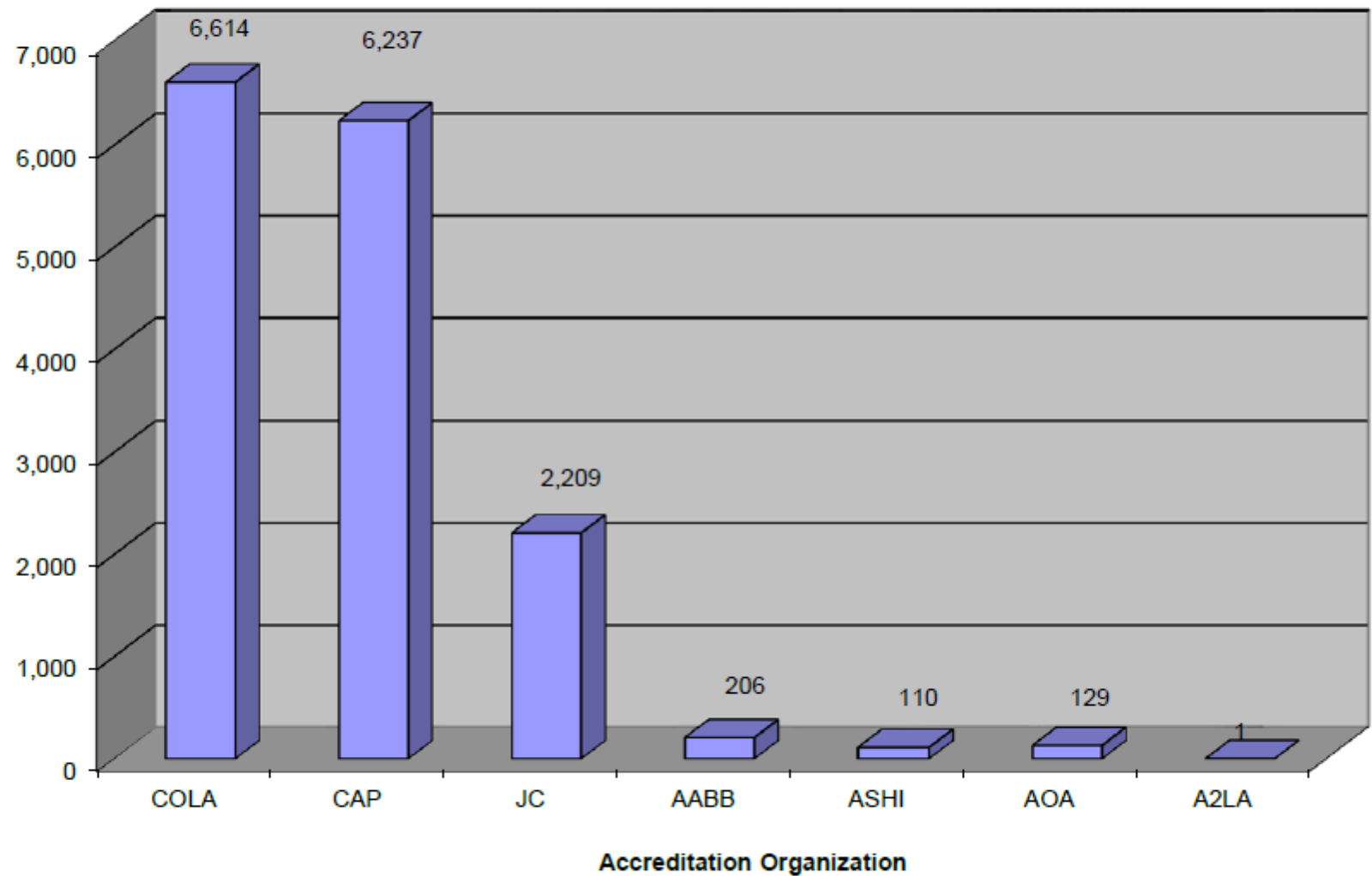
Laboratory Accreditation

- Outside agency: COLA, CAP, CLIA, AABB, The Joint Commission, FDA
- Most outside agencies perform their own version of lab inspections
- CLIA program utilizes State agencies to conduct surveys

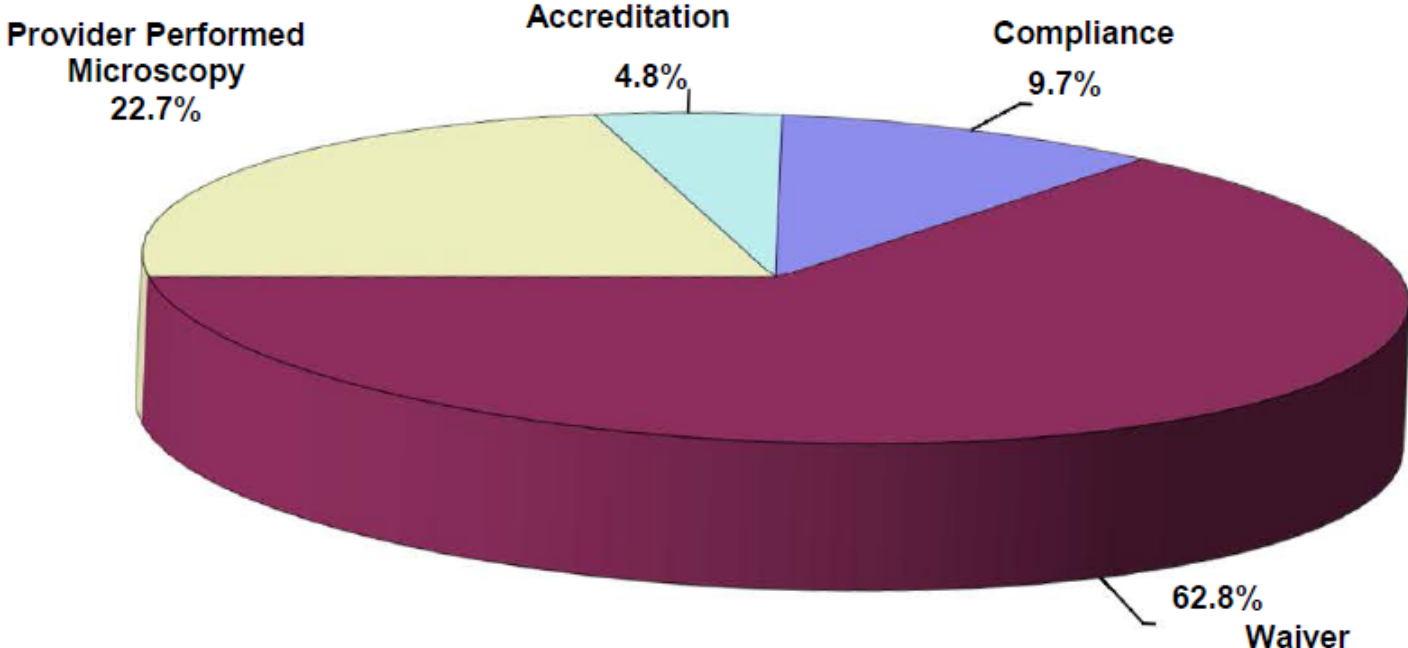
Laboratory Types

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

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



Source: CMS CLIA database Jan 2016

CLIA UPDATE – January 2016
Division of Laboratory Services
Centers for Medicare and Medicaid Services
Top 10 DEFICIENCIES in the Nation – CMS Surveys

Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency	# POLs with deficiency	% POLs with deficiency
Analytic Systems (D5413) STANDARD	493.1252(b)	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented.	927	5.3%	594	5.3%
General Lab Systems (D5217) STANDARD	493.1236(c)(1)	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.	808	4.7%	578	5.2%
Analytic Systems (D5403) STANDARD	493.1251(b)	The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.	768	4.4%	491	4.4%
Analytic Systems (D5791) STANDARD	493.1289(a)	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.	758	4.4%	314	2.8%
Post Analytic Systems (D5805) STANDARD	493.1291(c)	The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number, the name and address of the laboratory location where the test was performed, and other requirements specified in 493.1291(c).	728	4.2%	483	4.3%



CLIA '88 Overview

Clinical Laboratory Improvement Amendments of 1988

Survey 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

CLIA Inspection

- 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
- Corrective Actions are required for deficiencies

Common Deficiencies

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

Common Pitfalls of Lab Inspections. Kendall, Jason. 2012A POL Insight.

Surviving a Laboratory Inspection

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

CLIA Inspection Survival Tips. Barry Craig, MLT(ASCP). 2010C POL Insight.



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.

CLIA Inspection Survival Tips. Barry Craig, MLT(ASCP). 2010C POL Insight.

Self-conducted inspections/audits 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



Checklist Basics

- Establish a checklist that covers all tests performed and all documentation required for these tests
- Review existing checklists such as College of American Pathology (CAP), CLIA, COLA, TJC
- Allow for updates each year to accommodate growth and internal changes

Sample CAP Question

Cap question:

GEN.20377

Are laboratory record sand materials retained for an appropriate time?

Ambulatory 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

Sample Joint Commission Standard



Waived Testing

WT.01.01.01

Policies and procedures for waived tests are established, current, approved, and readily available.



Rationale:

HCO Score	Tier	SC	DOC	Risk	MOS	Elements of Performance
Satisfactory Compliance	4	A				1. The director named on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate approves a consistent approach for when waived test results can be used for diagnosis and treatment and when follow-up testing is required. (See also LD.04.01.01, EP 1)

Checklist at a Glance



Indicator	Score	Comment	CAP Details	CAP Date Completed
Maintenance and Calibration of Centrifuges and Microscopes	1			

Indicator	Score	Comment	CAP Details	CAP Date Completed
Eyewash checked and documented weekly	1			

Inspection Score: 31/31 = 100.0

Indicator	Score	Comment	CAP Details	CAP Date Completed
Lab Permits up to date and displayed in all testing areas	1			

Indicator	Score	Comment	CAP Details	CAP Date Completed
Accu Check Glucometer quality control log maintained	1			

Workflow - Ambulatory

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



Suggestions - Ambulatory

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



Analyzing Internal Inspection Reports

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



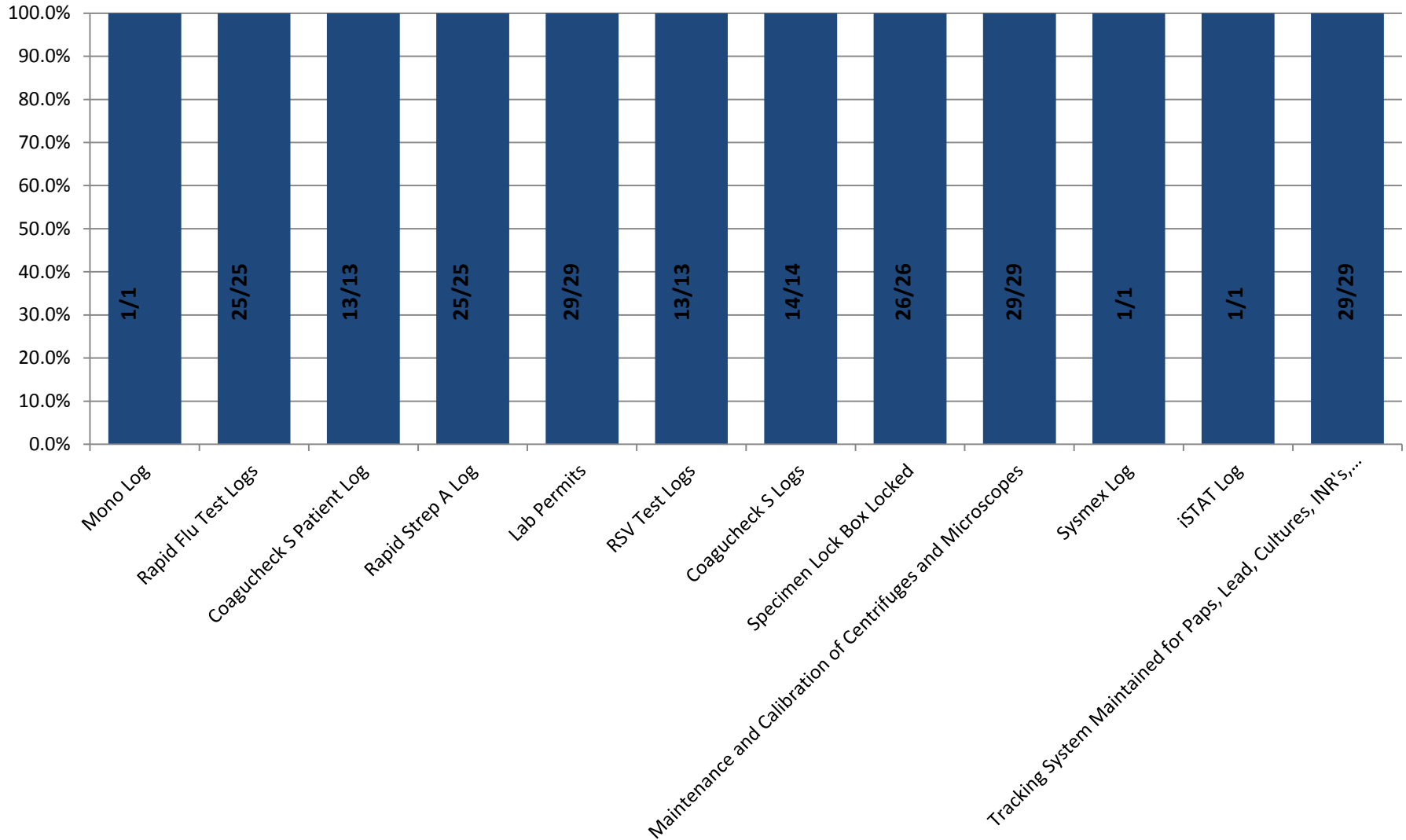
Inspection Reports

The following findings are from
Ambulatory sites

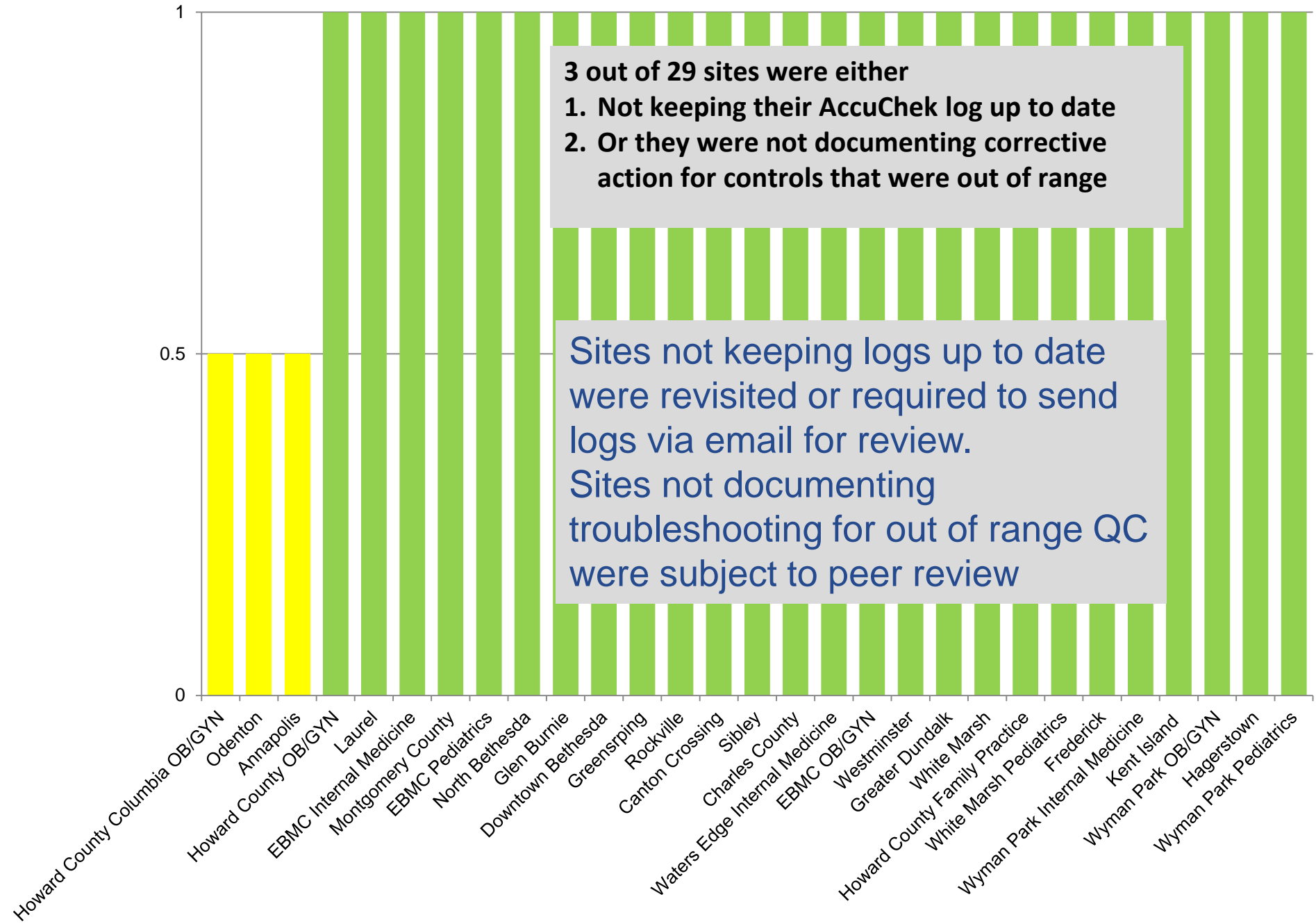
Overall Indicator Percentage Score

100% Compliance

Lab Inspections Oct-Dec 2011



Accu Check Gluometer Log Score



Microscope Maintenance



Microscope dust cover

Sites were identified in inspections to be missing basic microscope maintenance materials



Lens Cleaner



Lens Cleaning Wipes

Electronic Medical Record: Think 'Outside' the Checklist

- In April 2013, Johns Hopkins started the implementation of an universal electronic medical record
- Fall inspection rounds in 2013 included 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

Inspection Reports

The following findings are from
Hospital units

Hospital Unit Findings

Date	Coordinator	Problems Noted	Items Performed	Suggestions for next visit
2/22/2007	LAP	<ul style="list-style-type: none"> -LQC not dated - no daily reports for Feb. filled 	<ul style="list-style-type: none"> -dated QC -filed faxed daily reports -filed overlay reports in binders -noted that CLIA certificate is posted and current -found competency records for 7/05 and 2006 in file cabinet -removed outdated procedure 	<ul style="list-style-type: none"> -make new folder for competency records - review survey results for attestation signatures -make cheat sheet for printing reports -take QC and reagents
3/6/2007	LRS	<ul style="list-style-type: none"> - No deficiencies were found 		<ul style="list-style-type: none"> - Will continue to monitor
4/12/07	LAP	<ul style="list-style-type: none"> Lot # A7JPR010 cuvettes start date was not recorded 	<ul style="list-style-type: none"> -started a new binder labeled for 2007 survey data - e-mailed Margie from office reminder about recording lot #'s for cuvettes -verified that competency records exist for Hemochron for 2004 - 2007 	<ul style="list-style-type: none"> Continue to monitor

Review of Greenspring Cardiology Clinic

Review by: K.Dyer, MT(ASCP), DLM

- I. CAP Surveys:
 - a. Worksheets and final reports kept in same binder
 - b. 2004 Surveys - no director review on final summary reports
 - c. 2005 Surveys - summary results for XL-A received. Copy in clinic does not yet have the signature of the director indicating review.
- II. Coumadin Clinic Documents Book
 - a. QC results are written on calendar, and then recorded on QC log sheet at a later time. This increases the potential for transcription errors.
 - b. Old Coaguchek S procedure found in front pocket of book
 - c. Hemochron procedure in book with last update of 3/15/04
 - d. Other pages found in this book:
 - Temperature logs for Jan-April 2005
 - Training/competency forms for Margie from 2004
 - Loose pages for a Hemochron JR procedure
 - e. QC logs for May, June, and July paper clipped together and tucked in the front of the book
 - f. QC records from 2000 through 2004

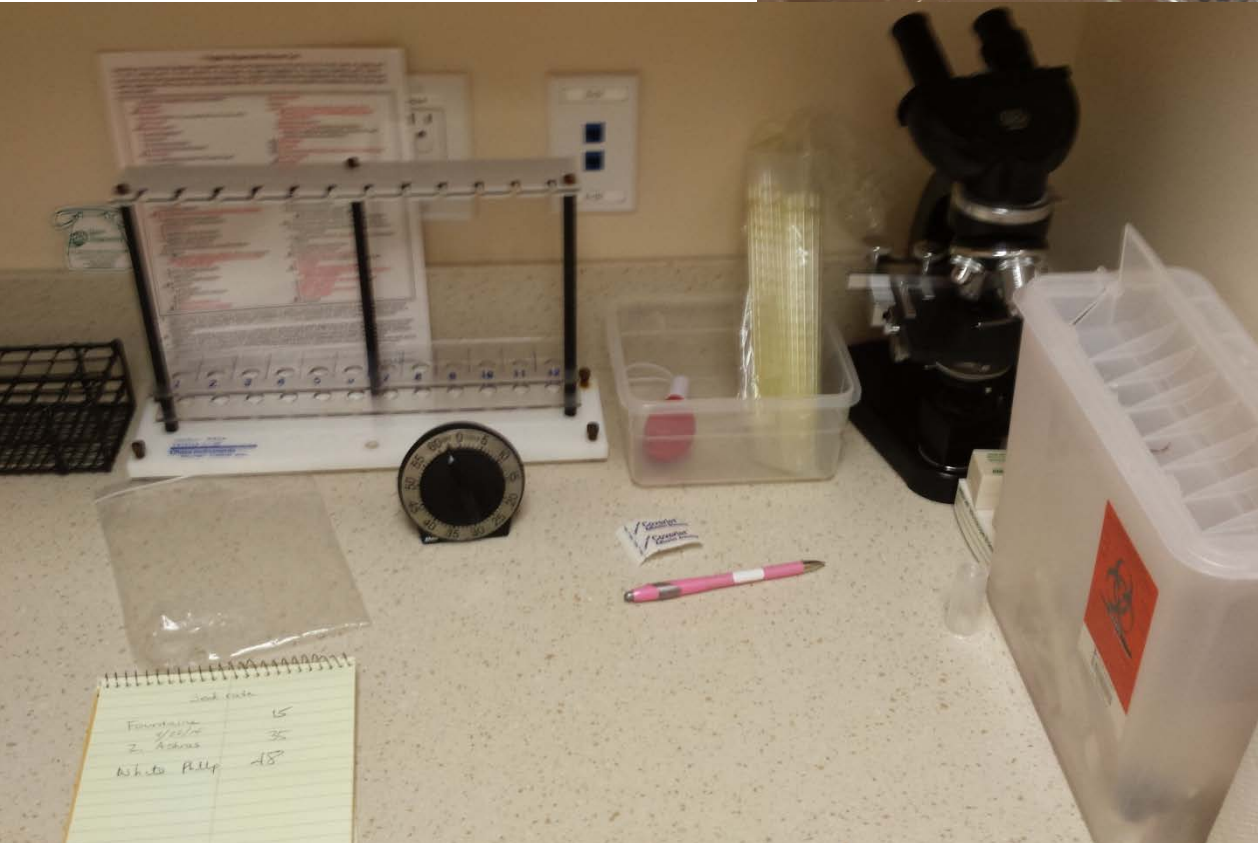
Recommendations:

1. Standardization of forms used in Whitemarsh, Greenspring and JHOC Coumadin clinics so that each clinic uses the same patient, QC and temperature log sheets.
2. Updated copy of the Hemochron procedure needed.
3. Reorganization of records and forms for ease of retrieval- additional file cabinet may need to be ordered.
 - a. Utilize file folders for old QC records, discontinued procedures and other old records
 - b. Operator competency records should be placed in their own file.
 - c. Keep CAP survey worksheets and final summary reports in separate notebooks.
 - d. All notebooks and file folders properly labeled as to contents.
4. Johns Hopkins POCT Office to work with Margie on re-organization of GS Coumadin Clinic files and records.
5. Copy of the Coumadin Clinic procedure needs to be on file in the GS Coumadin Clinic.
6. Develop system whereby GS notifies the POCT office of the need for reagents prior to using the last box of cartridges.

Group Activity: Case Studies

- Divide into groups
- Work through each case study and identify what is wrong in each picture
- Answer the questions for each set of slides
- Review findings

Before We Get Started



Before We Get Started



Before We Get Started

Label Here

Johns
Hopkins
Medicine
E-Req



Ordering Site Information:	Physician Information:
<p>Department ID: JH-661 Department Name: Women's Services at Odenton Address: 1132 Annapolis Road, Suite 100 City, State Zip: Odenton, MD 21113-1672 Phone: [Redacted] Fax: [Redacted]</p>	<p>Ordering Provider: [Redacted] RN Not Doc NPI: 123 [Redacted]</p> <p>Encounter Provider: [Redacted] PA-C</p> <p>↓</p>

Before We Get Started



Month/Year: Aug 2011 Days 1-15

The inspection date was October 2011. This log was in the temperature binder.

Temperature Log for Vaccines (Fahrenheit)

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. Store the vaccine under proper conditions as quickly as possible. 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. 3. Call the immunization program at your local health department for further assistance: (____) _____. 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																
Room Temp.																
Exact Time																
°F Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
• 49°																
48°																
47°																
46°																
45°																
44°																
43°																
42°																
41°																
40°																
39°																
38°																
37°																
36°																
35°																
34°																
33°																
• 32°																

Too warm

Refrigerator temperature

Aim for 40°

Too cold

Take immediate action if temperature is in shaded section*

Take immediate action if temperature is in shaded section*

Before We Get Started

Quality Control Log CoaguChek® XS System

Facility: Odenton
 CoaguChek® XS Meter Serial Number: UP0453824
 Reviewed By: JMB
 Date: 10/10/12

	Liquid Controls Lot Number	Exp. Date	Range
Control 1	21206600	10/2012	1.0 - 1.4
Control 2	21206608	10/2012	2.5 - 3.7

Test Strip Code	Test Strip Lot Num.	Strip Exp. Date	Date	Time	Operator ID	Control 1 Result	Control 2 Result	Corrective Action if Unacceptable
425	21214611	9/2013	10/10/12	8:08A	JMB	1.7	2.9	Ran second test from same bottle
425	21214611	9/2013	10/10/12	8:09A	JMB	1.2	—	
425	21214611	9/2013	10/10/12	8:19A	JMB	1.2	3.0	Gray cap not seated tight on bottle when opened

New Same Controls

Group Activity: Case Studies

- Divide into groups
- Work through each case study and identify what is wrong in each picture
- Answer the questions for each set of slides
- Review findings

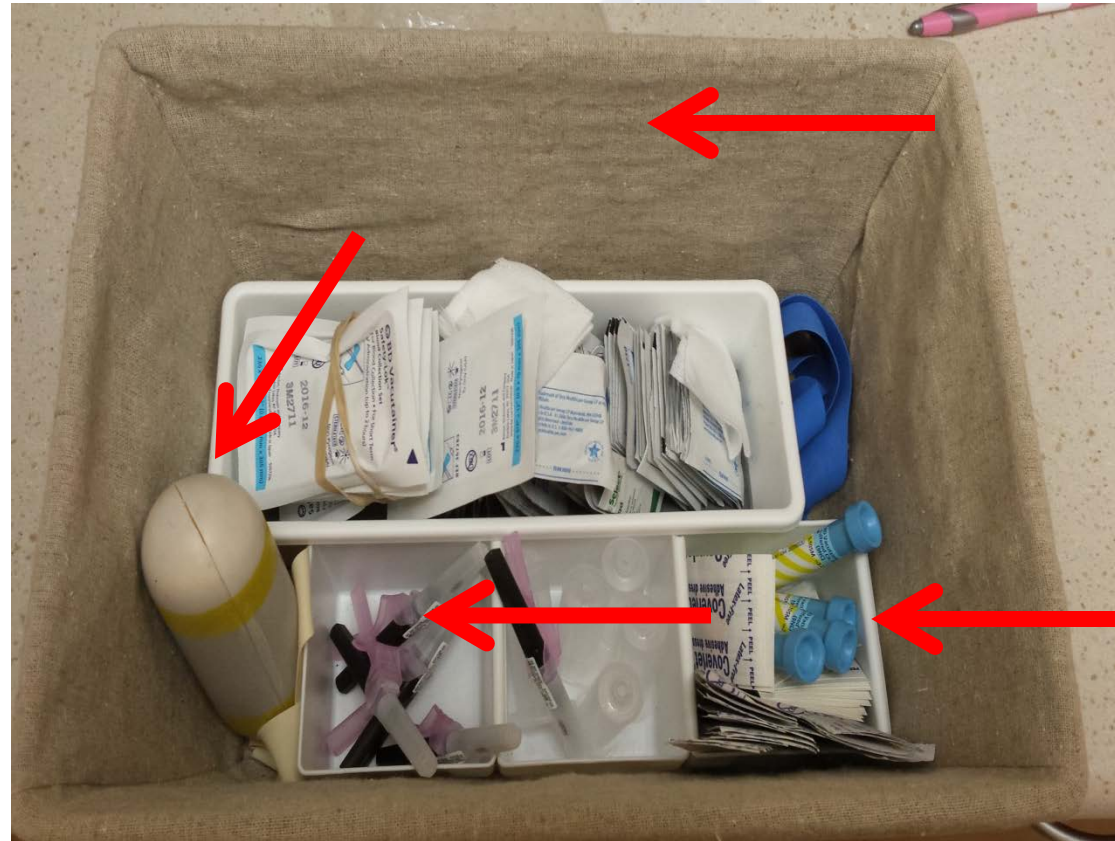
Case Study #1

What is wrong in this picture?

Are any of these things preventable? (Procedure, training, self checks)

Corrective Action Plan

Put yourself in the shoes of your inspector, how would you react if you found this during an inspection?



Case Study #2

What is wrong in this picture?

Are any of these things preventable? (Procedure, training, self checks)

Corrective Action Plan

Put yourself in the shoes of your inspector, how would you react if you found this during an inspection?



Case Study #3

What is wrong in this picture?

Are any of these things preventable? (Procedure, training, self checks)

Corrective Action Plan

Put yourself in the shoes of your inspector, how would you react if you found this during an inspection?



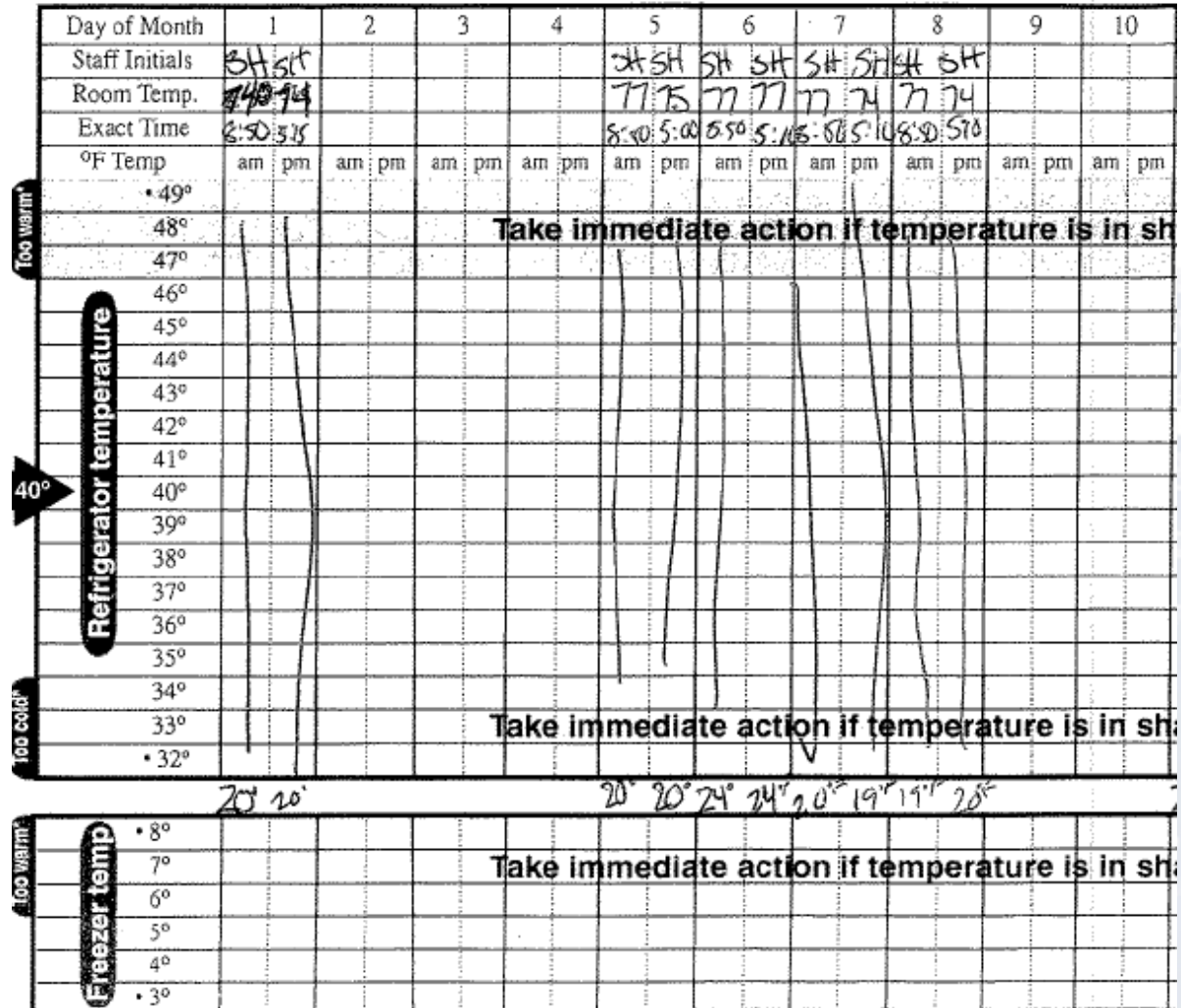
Case Study #4

What is wrong in this picture?

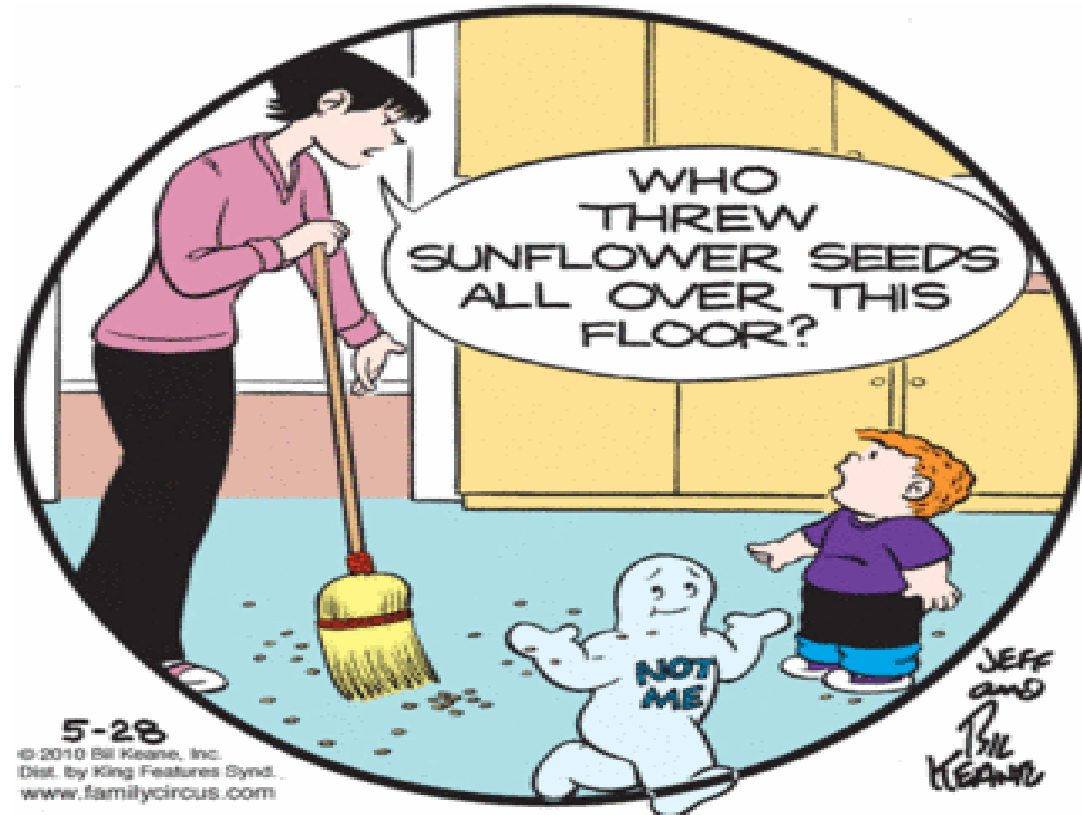
Are any of these things preventable? (Procedure, training, self checks)

Corrective Action Plan

Put yourself in the shoes of your inspector, how would you react if you found this during an inspection?



Case Study #5



5-28
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“Not me!”

Challenges faced

Ambulatory Sites

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
- Significant responsibilities with patient care documentation

Geographically Challenging

- Cover the whole state of Maryland (Northern Virginia)

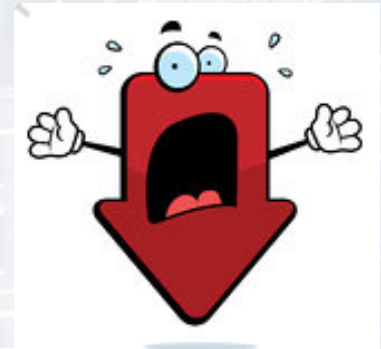
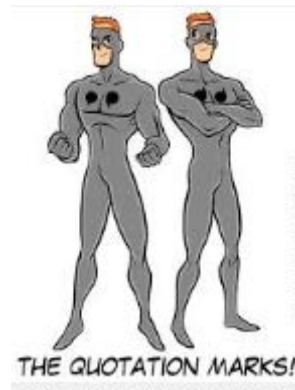
Ambulatory Sites

Laboratory Director

- Learning how to share responsibilities with the Office Medical Director who are the Laboratory Directors
- Communicating in a busy environment
- Corrective Action Plans and follow up
- Proficiency testing results
- PPM Module Completion
- Review and Sign Documents

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



Hospital Units

- Glucometer control stains on glucometers
- Not labeling solutions with both open and expiration dates
- Not keeping back up batteries on charger
- Not docking devices after user periodically
- Ordering or starting POCT without consulting POC office
- Using patient glucometer when staff are locked out of hospital device



Corrective action plan Plan of Required Improvement Requirements for Improvement

Where to Start?

- When CLIA, CAP, COLA or TJC require corrective action plans (CAP), they outline the specific need in the inspection report including the regulation reference number
- Written action plans are suggested for all internal inspections/audits

- 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

Hospital Unit Findings

Date	Coordinator	Problems Noted	Items Performed	Suggestions for next visit
2/22/2007	LAP	<ul style="list-style-type: none"> -LQC not dated - no daily reports for Feb. filled 	<ul style="list-style-type: none"> -dated QC -filed faxed daily reports -filed overlay reports in binders -noted that CLIA certificate is posted and current -found competency records for 7/05 and 2006 in file cabinet -removed outdated procedure 	<ul style="list-style-type: none"> -make new folder for competency records - review survey results for attestation signatures -make cheat sheet for printing reports -take QC and reagents
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“Communication is fundamental to achieving the desired improvements.”

Point of Care Testing. James H Nichols, PhD, DABCC, FACB. Clinics in Laboratory Medicine. 2007



Summary

A comprehensive self conducted inspection process includes:

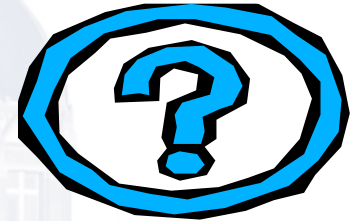
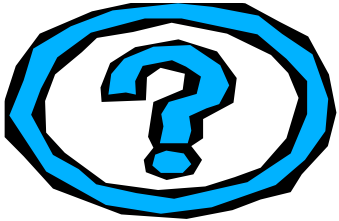
- Developing a Quality Assurance Program to support the inspection process
- Ongoing monitoring
- Corrective action plans
- Compliance with federal and local regulations

All of which are strategies to keep you
Inspection Ready!

Resources

- [Medical Laboratory Observer - CLIA Inspection Deficiencies: What they mean and how to avoid them 2012](#)
- [Advance: CRI Lab Quality Advisor - Top 5 Deficiencies for Laboratories 2014](#)
- [CAP Today: QC for accreditation: CMS validation inspections](#)

Questions



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