

Internal Lab Inspections: Are You Inspection Ready?



JOHNS HOPKINS
M E D I C I N E

JOHNS HOPKINS
HEALTH SYSTEM

Presented by: Jeanne Mumford, MT(ASCP)
Manager, Point of Care Testing, JHM

Speaker Introductions

Jeanne Mumford, MT(ASCP)
Manager, Point of Care Testing
Johns Hopkins Medicine

jmumfor3@jhmi.edu

- Quality Oversight of 2 Academic Hospitals and 3 Community Hospitals and 60+ Physician Office Laboratories
- 9 Full Time Point of Care Coordinators
- Standardizing Workflows and Managing Quality Oversight

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

Disclosures

- Nonfinancial - Member of Board of Directors, COLA Resources, Inc, President, KEYPOCC Keystone Point of Care Coordinators; receives no financial compensation
- Financial – Honorarium – Author for AAFP POL Insight 2015A: Quality Assurance Program for Physician Office Laboratories
- Financial – Honorarium – Speaker- AACCC, KEYPOCC

Point of Care Testing

JHM operates six academic and community hospitals.

Hospital	Beds	Glucose Operators
Johns Hospital	1,059	4,313
Bayview	545	1,300
Howard County	267	1,466
Sibley	318	800
Suburban	229	1,343

Johns Hopkins Community Physicians – 39+ sites, 400+ providers, 1,600 glucose operators (primary and specialty care)



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



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

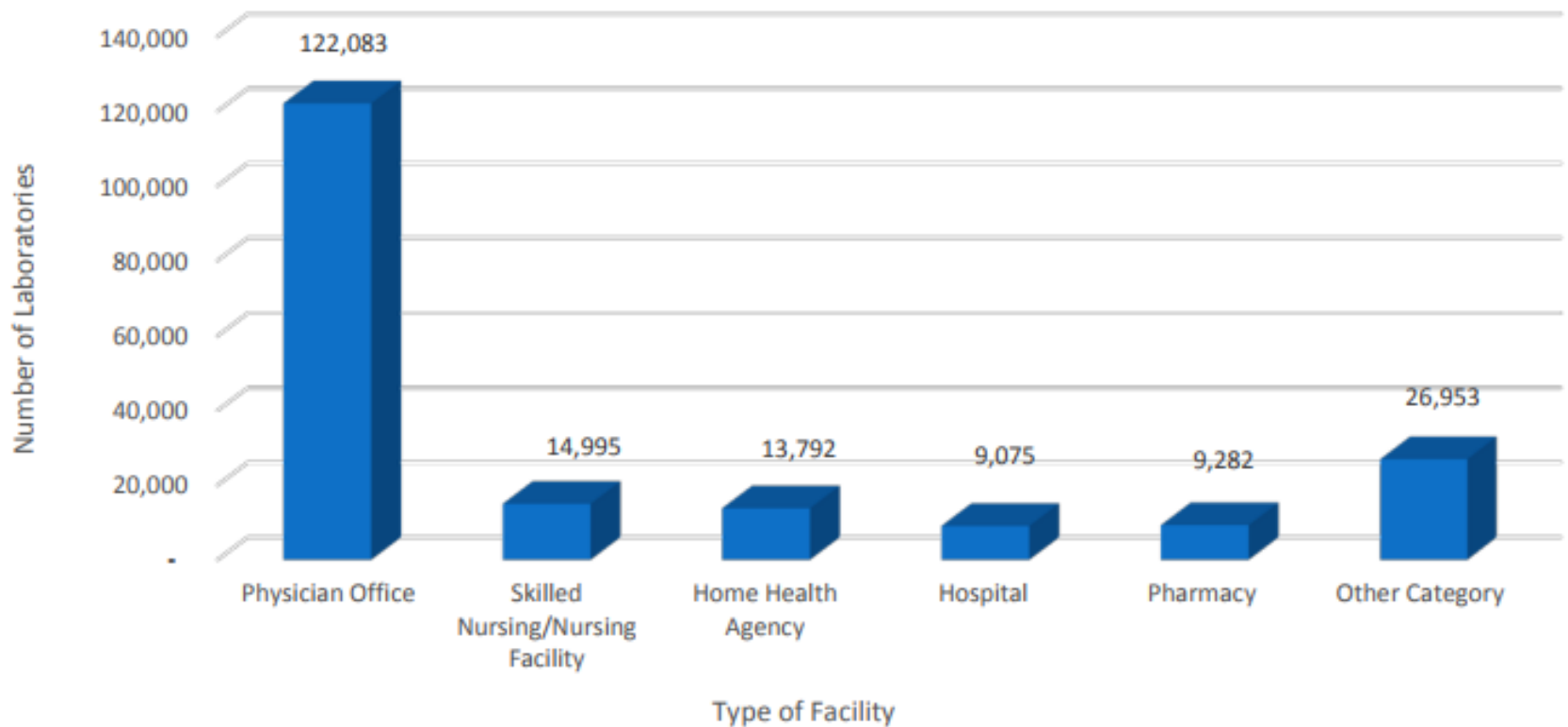
Laboratory Types

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



CLIA UPDATE – July 2017
Division of Laboratory Services
Centers for Medicare & Medicaid Services

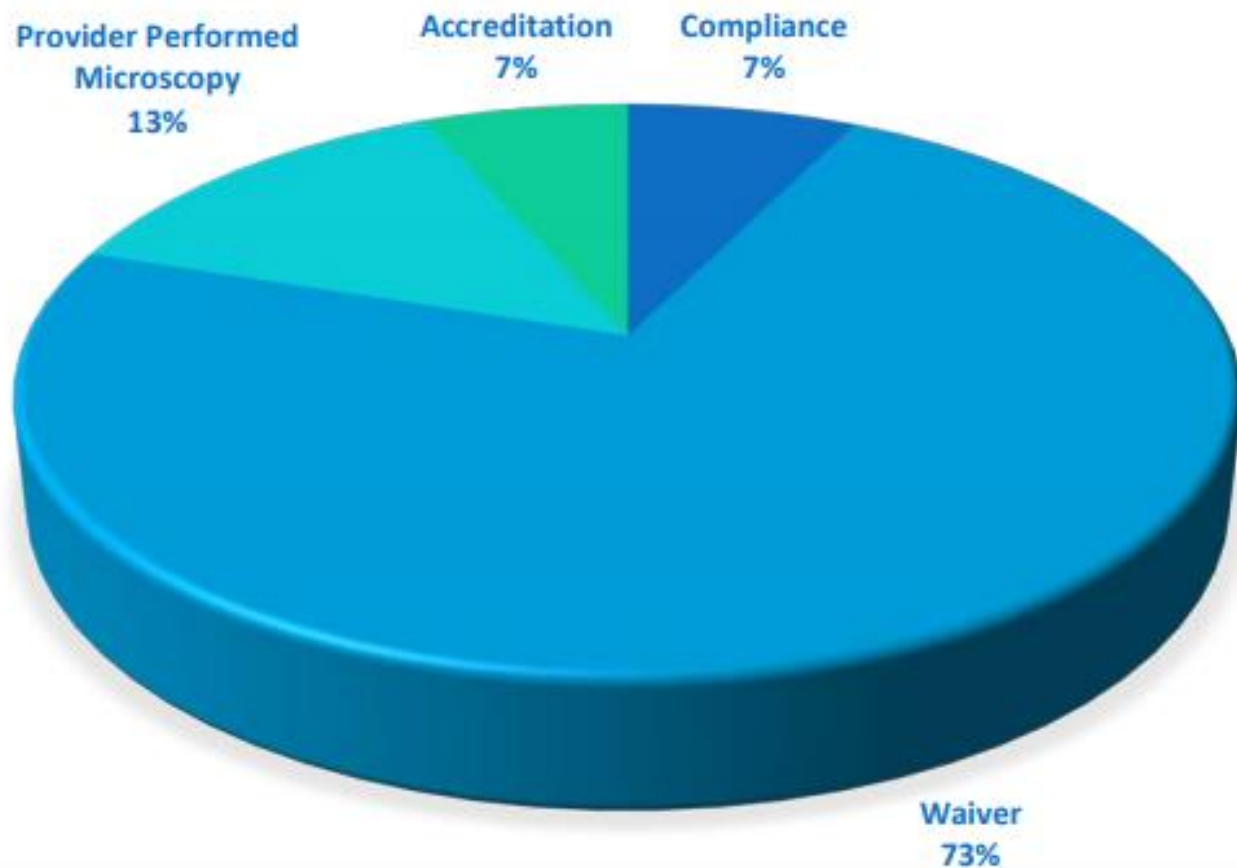
CLIA Laboratory Registration
Self-Selected Laboratory Types



Source: CMS CLIA Data Base

CLIA UPDATE – July 2017
Division of Laboratory Services
Centers for Medicare & Medicaid Services

**CLIA LABORATORIES
BY CLIA CERTIFICATE TYPE
(NON-EXEMPT ONLY)**



MMWR November 2005

CLIA Waiver Project 1999-2001

CMS on site across 10 states

CMS 2002-2004

Additional data from CW sites

CDC funded studies 1999-2003 (LMSMN)

<https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>

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

- Reagent and specimen storage
- Written Policies and Procedures
- Specimen acceptability, prep of materials from manufacturer requirements
- Test report parameters

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf>

Surviving a Laboratory Inspection



JOHNS HOPKINS
MEDICINE

JOHNS HOPKINS
HEALTH SYSTEM

“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

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



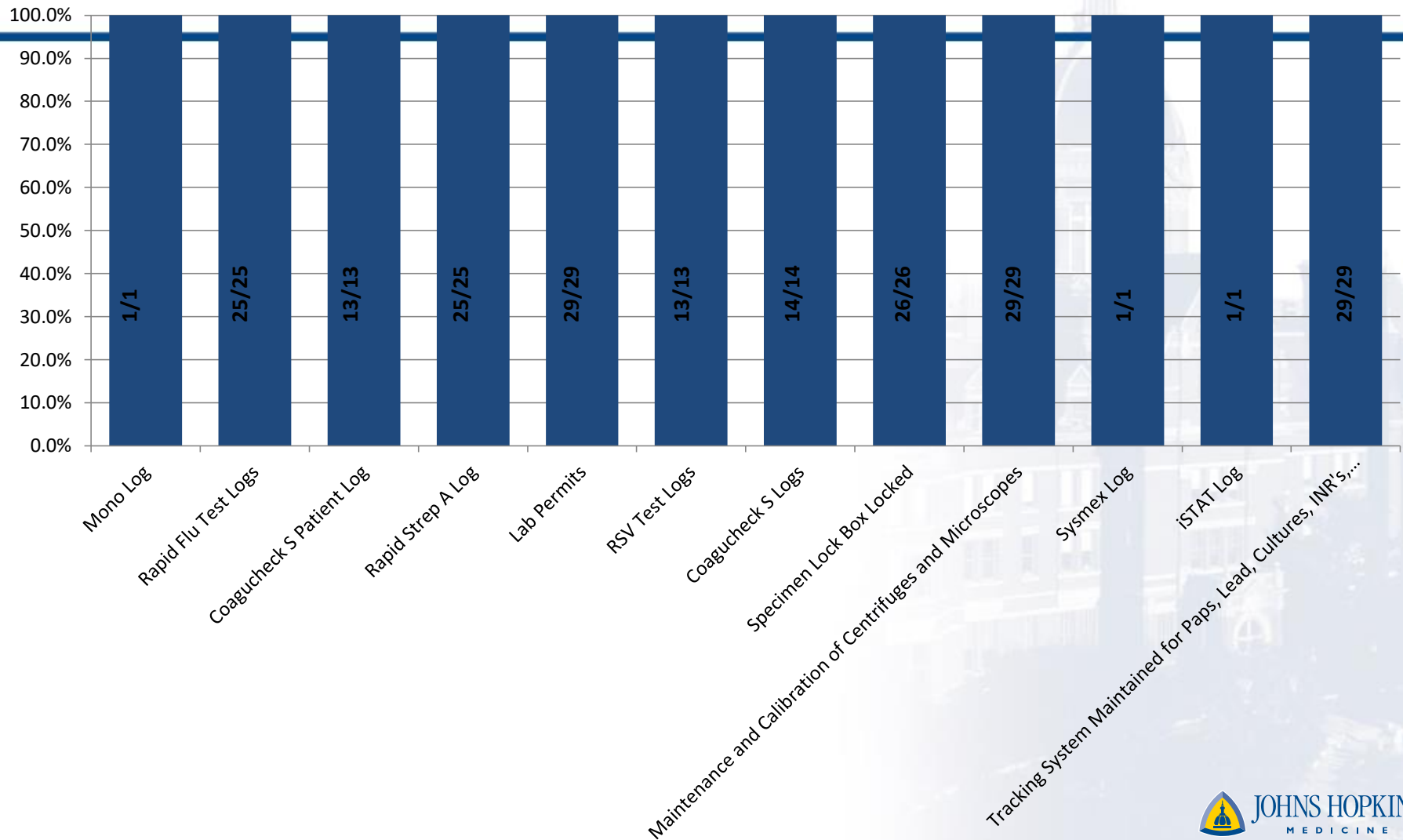
Inspection Reports

The following findings are from
Ambulatory sites

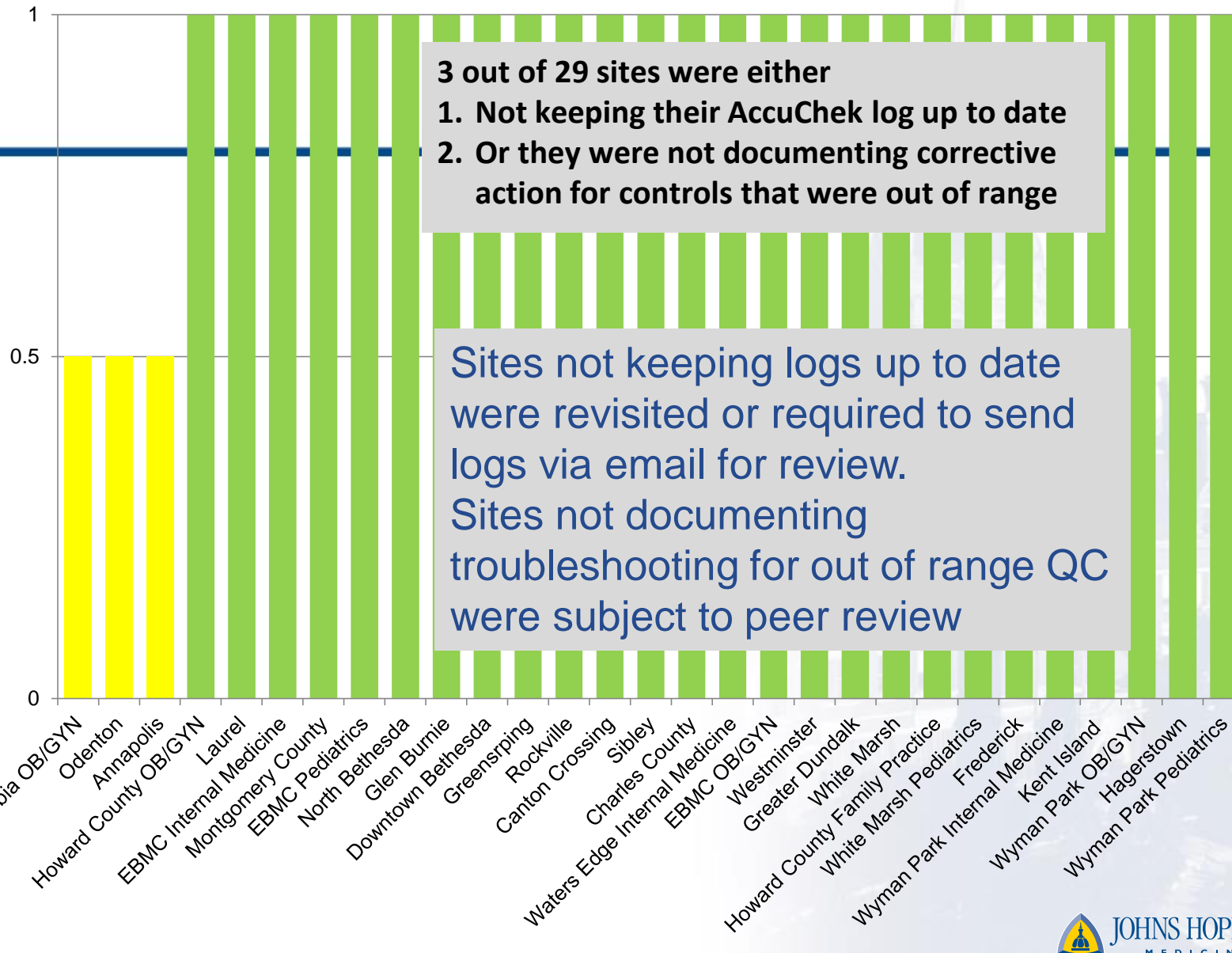
Overall Indicator Percentage Score

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 implemented a 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	-LQC not dated - no daily reports for Feb. filled	-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	-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	- No deficiencies were found		- Will continue to monitor
4/12/07	LAP	Lot # A7JPR010 cuvettes start date was not recorded	-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	Continue to monitor

Review of Greenspring Cardiology Clinic

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

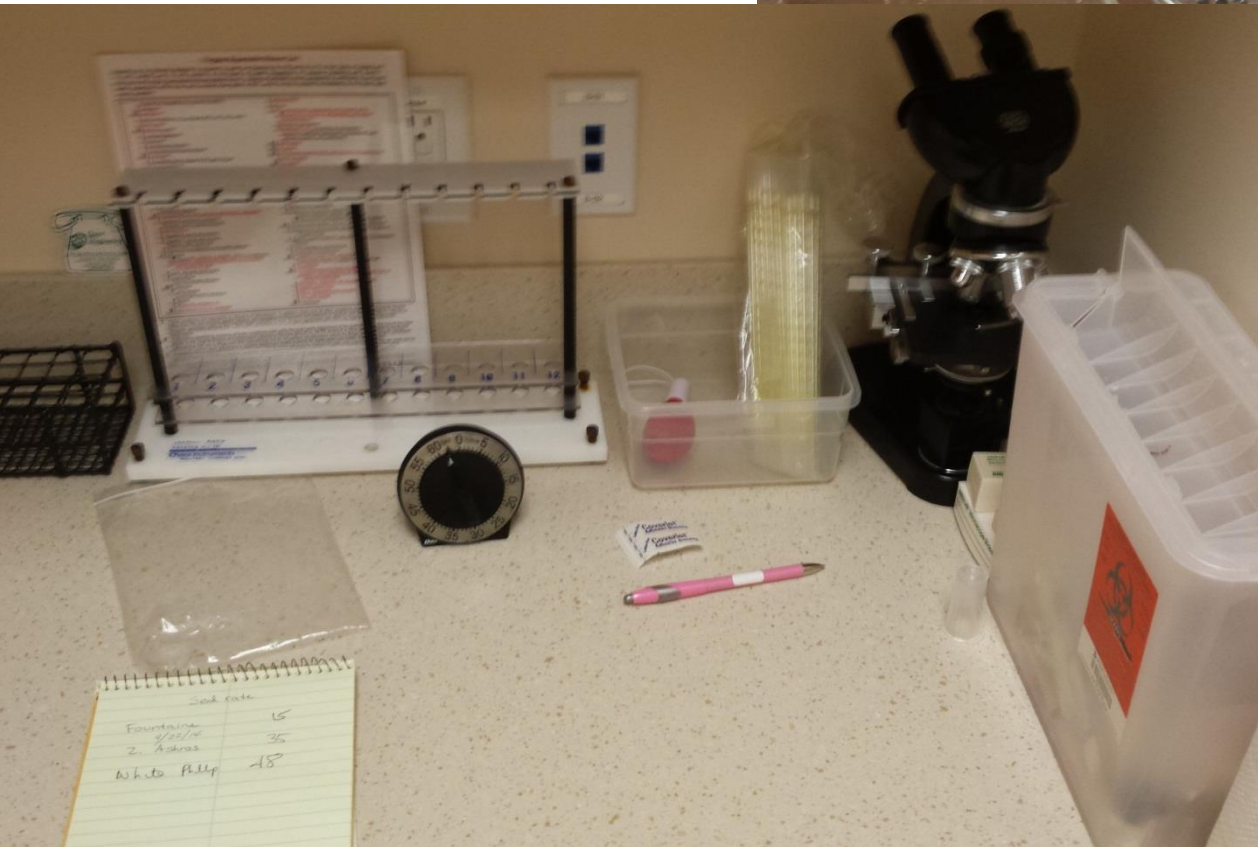
- I. CAP Surveys:
 - a. Worksheets and final reports kept in same binder
 - b. 2004 Surveys - no director review on final summary reports
 - c. 2005 Surveys - summary results for XL-A received. Copy in clinic does not yet have the signature of the director indicating review.
- II. Coumadin Clinic Documents 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

- Observe each of the following slides
- Think of your own policies and procedures
- Do you look for these issues?
- Do your policies and procedures cover the quality oversight of these issues?





Label Here

Johns
Hopkins
Medicine
E-Req



148266783

Ordering Site Information:

Department ID: JH-661

Department Name: Women's Services at Odenton

Address:

City, State Zip:

Phone:

Fax:

Physician Information:

Ordering

Provider: [redacted] RN

NPI: [redacted]

Encounter

Provider: [redacted] PA-C

Not Doc



JOHNS HOPKINS
MEDICINE

JOHNS HOPKINS
HEALTH SYSTEM

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

Temperature Log for Vaccines (Fahrenheit)

Using this temperature log: Check the temperatures in both the freezer and refrigerator compartments of your vaccine storage units at least twice each 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.

Month/Year: Aug 2011 Days 1-15

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
• 49°															
48°															
47°															
46°															
45°															
44°															
43°															
42°															
41°															
40°															
39°															
38°															
37°															
36°															
35°															
34°															
33°															
• 32°															

Refrigerator temperature

Too warm*

Too cold*

Aim for 40°

Take immediate action if temperature is in shaded section*

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	21206600	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
425	21214611	9/2013	10/10/12	8:09A	JMB	1.2	—	
426	21214611	9/2013	10/10/12	8:19A	JMB	1.2	3.0	⊗

New
controls

test
bottle -
Gray cap
not seated
tight on
bottle
when opened

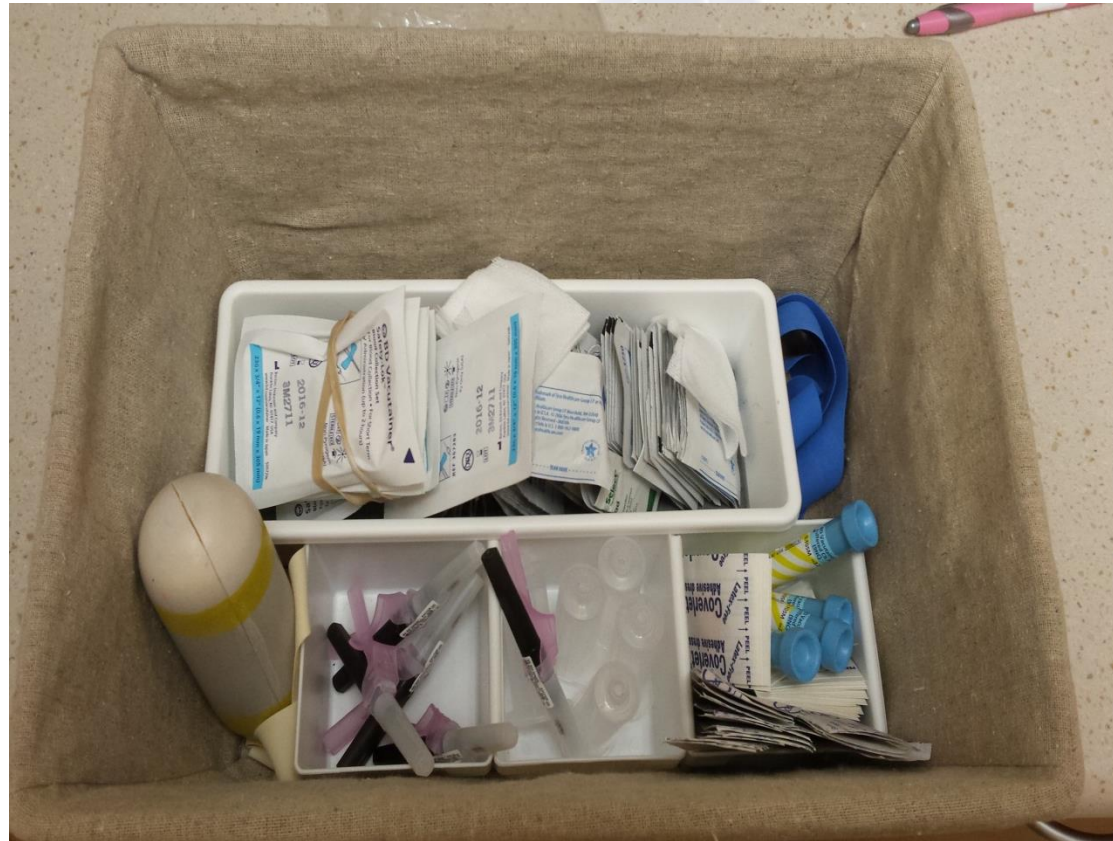
Case Study #1

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?



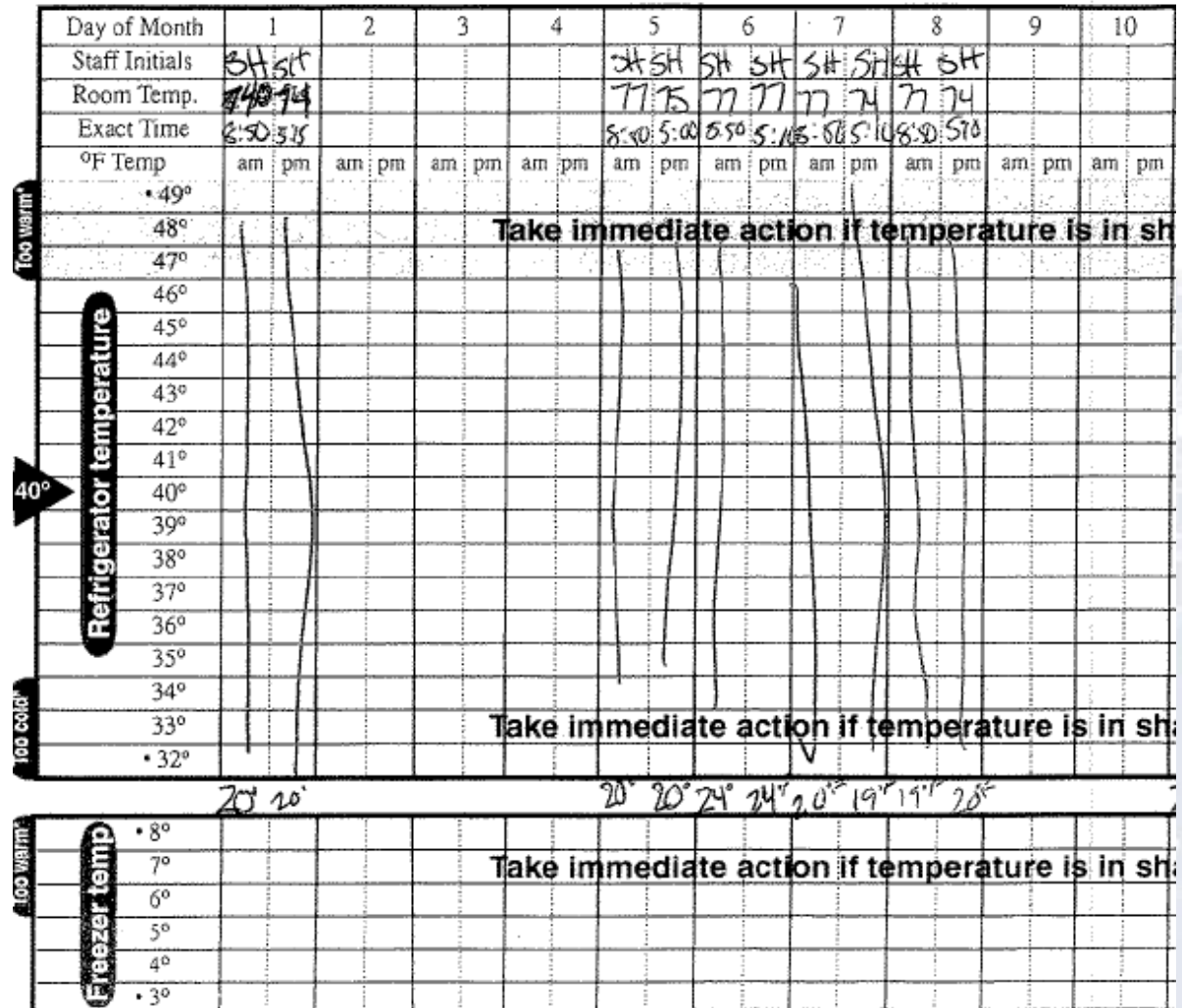
Case Study #4

What is wrong in this picture?

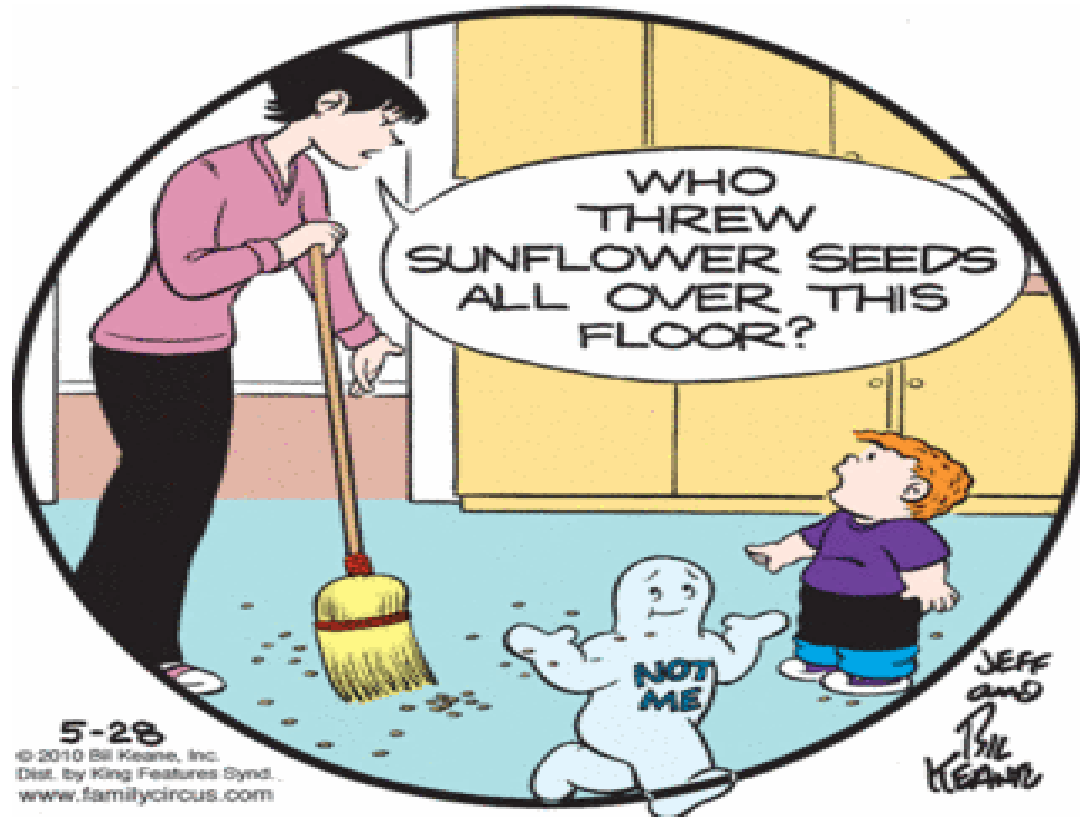
Are any of these things preventable? (Procedure, training, self checks)

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
© 2010 Bill Keane, Inc.
Dist. by King Features Synd.
www.familycircus.com

"Not me!"

Challenges faced

Challenges, Continued

Medical Office Assistants

- Often not trained to perform POC tests in school
- Balancing patient workload with regulatory requirements
- Significant responsibilities with patient care documentation

Geographically Challenging

- Cover the whole state of Maryland (Northern Virginia)

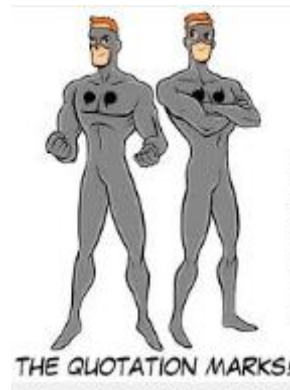
Challenges, Continued

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 Unit Challenges

- Glucometer control stains on glucometers
- Open and expiration dates
- Not keeping back up batteries on charger
- Not docking devices after use, periodically
- Ordering or starting POCT without consulting POC office
- Using patient glucometer when staff are locked out of hospital device
- Who to communicate the Results of Audit

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
- Anything graded less than 100%

- 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	-LQC not dated - no daily reports for Feb. filled	-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	-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	- No deficiencies were found		- Will continue to monitor
4/12/07	LAP	Lot # A7JPR010 cuvettes start date was not recorded	-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	Continue to monitor

“Communication is fundamental to achieving the desired improvements.”

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



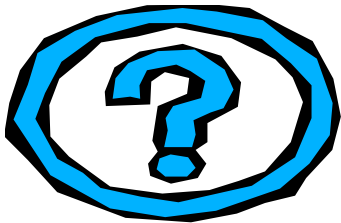
Summary

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!

Questions



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

