Meeting Dynamic Challenges for Quality and Patient Safety

SHARON S. EHRMEYER, PH.D., MT(ASCP)

PROFESSOR EMERITUS, DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE
SCHOOL OF MEDICINE AND PUBLIC HEALTH
UNIVERSITY OF WISCONSIN, MADISON, WI

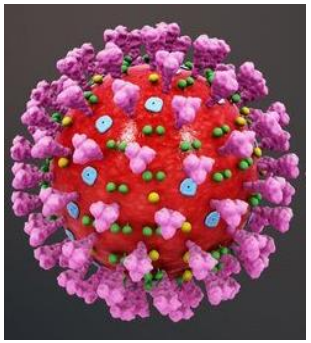
Today's Goal

Developing strategies to meet today's and tomorrow's challenges to enhance POC & laboratory testing's contribution to patient care

Goal: Laboratory & POC Testing

Positive contribution to healthcare team for quality patient care

First: You are – Superheroes!



Hip-hip Hooray!

Quality Results: Part of Solution

Common quote --
60 – 80% of clinical decisions are based on laboratory/POCT results

Tactics:

As a healthcare “team” member -- where to start?

Knowledge is power!

Stay in the "KNOW"

CLIA

The Joint Commission

COLA

COLLEGE of AMERICAN PATHOLOGISTS

A2LA

Don't forget your
state requirements too

CLIA/Your Accrediting Agency

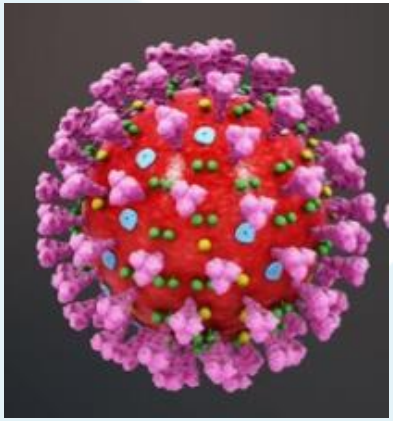
All provide useful information and help!

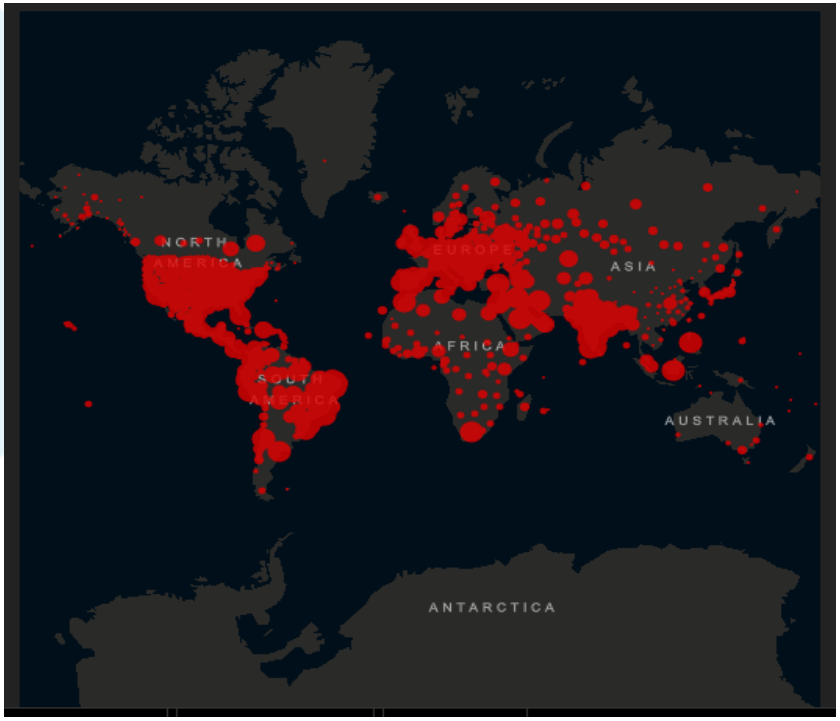
Quality – Complying with Requirements

The established testing regulations, requirements, and standards do represent Good Laboratory Practices (GLP)

- BUT…Always do the “right” thing and this may mean more (e.g., think waived testing as one example)

SARS CoV-2 Corona Virus Worldwide Impact





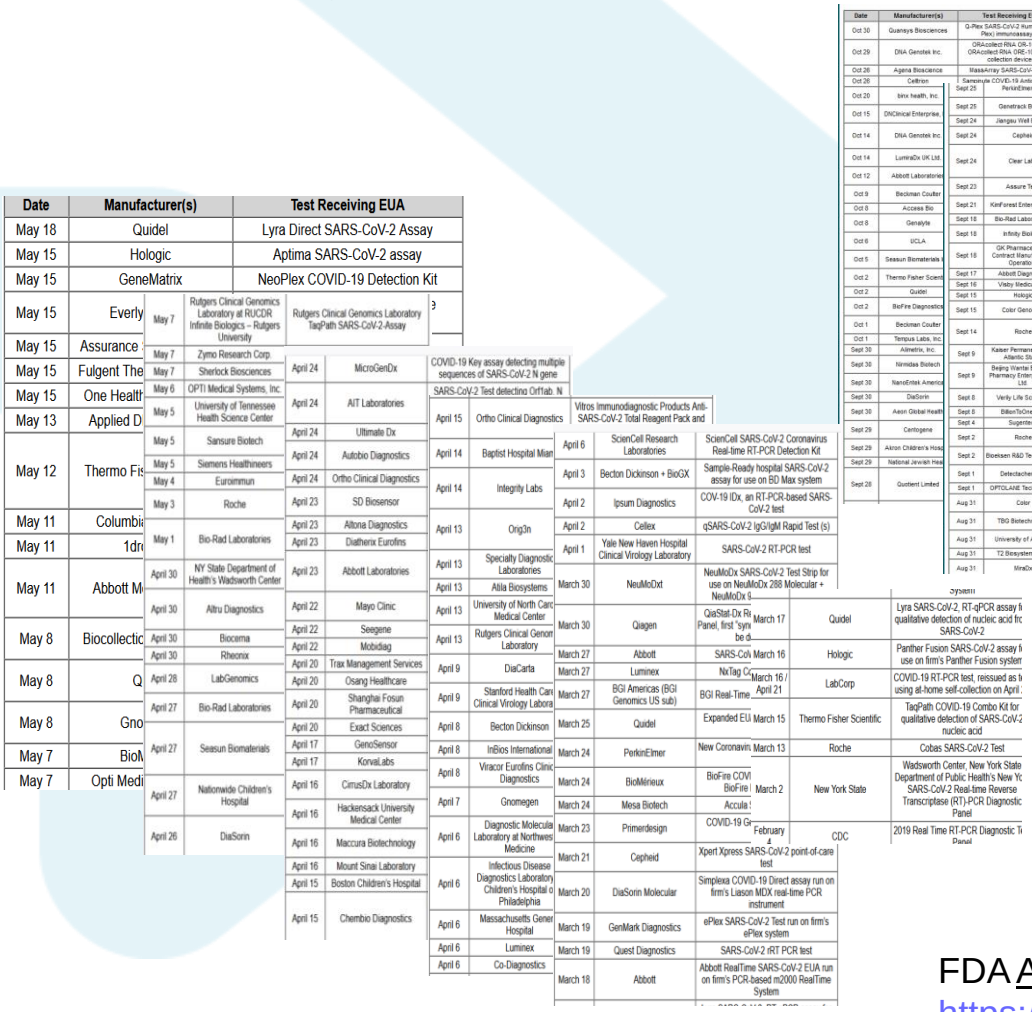
https://www.google.com/search?client=firefox-b-1-d&q=covid+statistics

Nov 20, 2020: 58 M global cases; 1.4 M deaths

Emergency Use Authorization (EUA) Testing* – Confused?

*In emergencies, when no products are available, EUA legally permits FDA to authorize unapproved medical products to diagnose, treat, prevent serious or life-threatening diseases/conditions caused by chemical, biological, radiological, and/or nuclear agents

EUA Tests – March – October 2020
So Many Tests: ~300



FDA Approved Coronavirus Tests. https://www.g2intelligence.com/coronavirus-eua-chart/. Nov. 4, 2020.

Requirements for EUA Testing?

Always, check CLIA and/or your accrediting agency for guidance

CMS: QC/IQCP

15.Can a lab develop an Individualized Quality Control Plan (IQCP) for COVID-19 test systems?

…manufacturer's quality control (QC) instructions for all EUA must be followed, to include QC

…because QC for EUAs must be followed, and no deviations to the QC requirements in the EUA are permitted, IQCP is not applicable to EUAs.

Note: lab director may determine, based on risk assessment that additional QC needs to be implemented above what is required in the EUA Instructions for Use

Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 EmergencyUpdated as of 11/10/2020. https://www.cms.gov/files/document/frequently-asked-questions-faqs-clia-guidance-during-covid-19-emergency.pdf

When EUA is over:

"Regulatory Testing Life" returns to "normal"

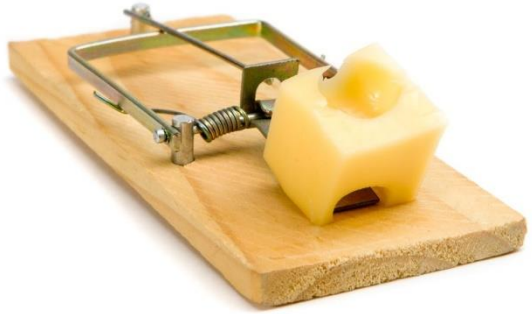
ALL CLIA, COLA, TJC, and CAP regulatory requirements based on test complexity apply

Regulations bring Inspections

Be prepared

Pay attention to frequent deficiencies

Don't fall into the deficiency trap



Regulations bring Inspections

Make sure all testing policies and procedures “line up” with requirements

Make sure all staff are doing what P/P state

CLIA: Top 10 (Oct. 2018) Conditions

(problems with potential to or adversely affect patient test results/care)

Regulation	Deficiency	% All Lab Cited	% POLs Cited
493.1403	Director meets qualifications (493.1405) and provides management/direction (493.1407)	2.5%	2.5%
493.1441	Director meets qualifications (493.1443) and provides overall management/direction (493.1445)	1.6%	0.8%
493.801	Enrolled in HHS approved PT for each specialty and subspecialty tested and tests samples like patients	1.1%	0.9%
493.1250	Nonwaived testing meets requirements (493.1251-.1283); monitor, evaluate quality and correct problems (493.1289)	1.4%	1.2%
493.803	Nonwaived testing enrolled in HHS approved PT; lab successfully passes PT	0.7%	0.7%
493.1409	Lab has qualified technical consultant (493.1411) who provides oversight (493.1413)	1.1%	1.0%
493.1421	Lab has sufficient qualified individuals (493.1423) to perform functions (493.1425)	1.1%	1.0%
493.1415	For hematology testing, meets requirements (493.1230-.1256, 1269, 1281-.1299)	0.4%	0.3%
493.1487	High complexity labs have sufficient qualified individuals (493.1489) to perform functions (493.1495)	0.6%	0.4%
493.1447	High complexity labs have a qualified technical supervisor (493.1449) to perform functions (493.1451)	0.4%	0.2%

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

CAP Top Deficiencies (2019 data)

CHECKLIST REQUIREMENT	CAP-WIDE*
COM.10000 Procedure Manual	1
GEN.55500 Competency Assessment -Nonwaived Testing	2
COM.01200 Activity Menu	3
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	4
COM.30600 Maintenance/Function Checks	5
COM.01700 PT and Alternative Performance Assessment Result Evaluation	6
COM.30300 Reagent Labeling	7
COM.04200 Instrument/Equipment Record Review	8
COM.01400 PT Attestation Statement	9
COM.30750 Temperature Checks	10

** Based on 2019 CAP inspection data*

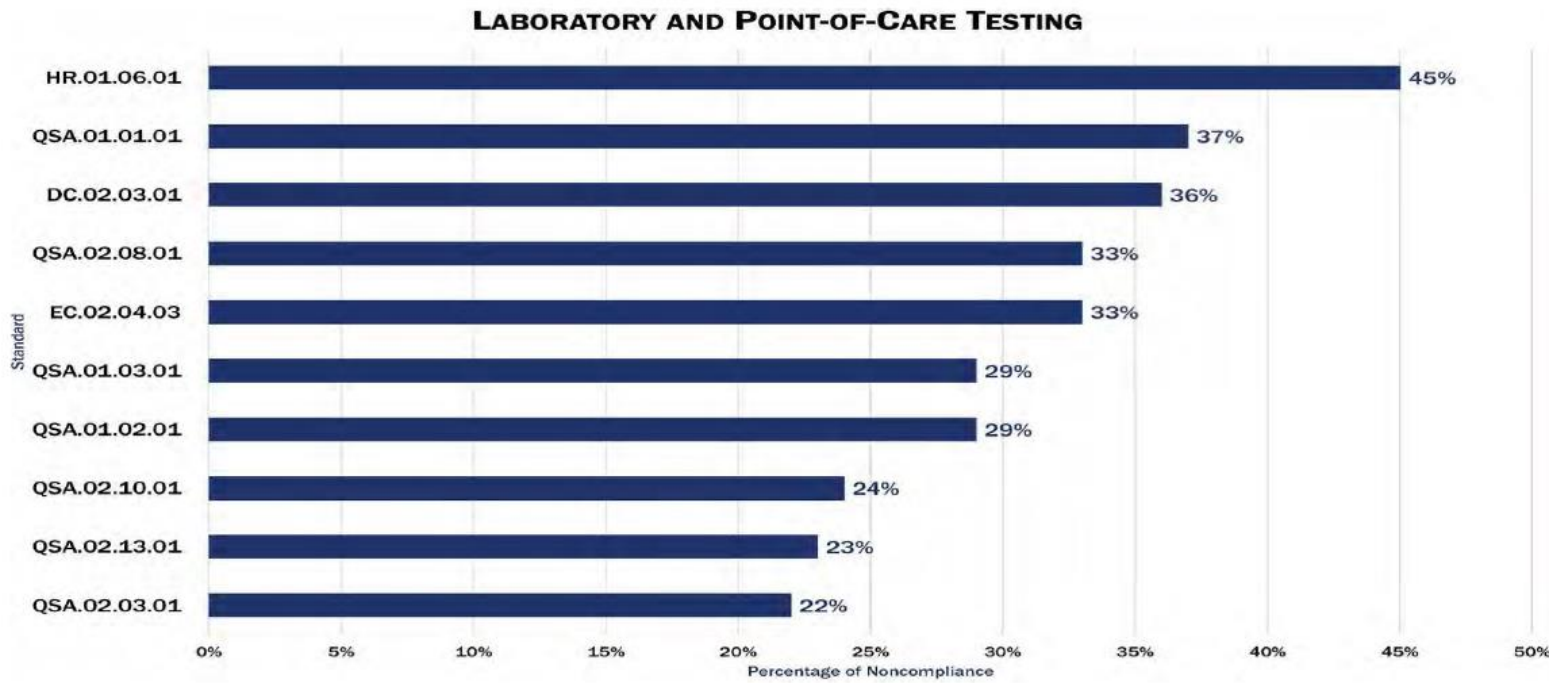
2020 Focus on Compliance. CAP. 6/17/20 Webinar

COLA Top Deficiencies (2019)

RANK	CITATION	#	%	REASON CITED
1	PER 5	658	18%	For not performing or documenting competency assessments as required
2	LDR 4	561	16%	For the Laboratory Director not fulfilling the Proficiency Testing responsibilities of the position
3	PER 4C	472	13%	For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position
4	LDR 5	427	12%	For the Laboratory Director not fulfilling the Quality Control / Quality Assessment responsibilities of the position
5	PT 16	414	12%	For not documenting review of PT scores by the Laboratory Director, supervisory personnel, and testing personnel

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

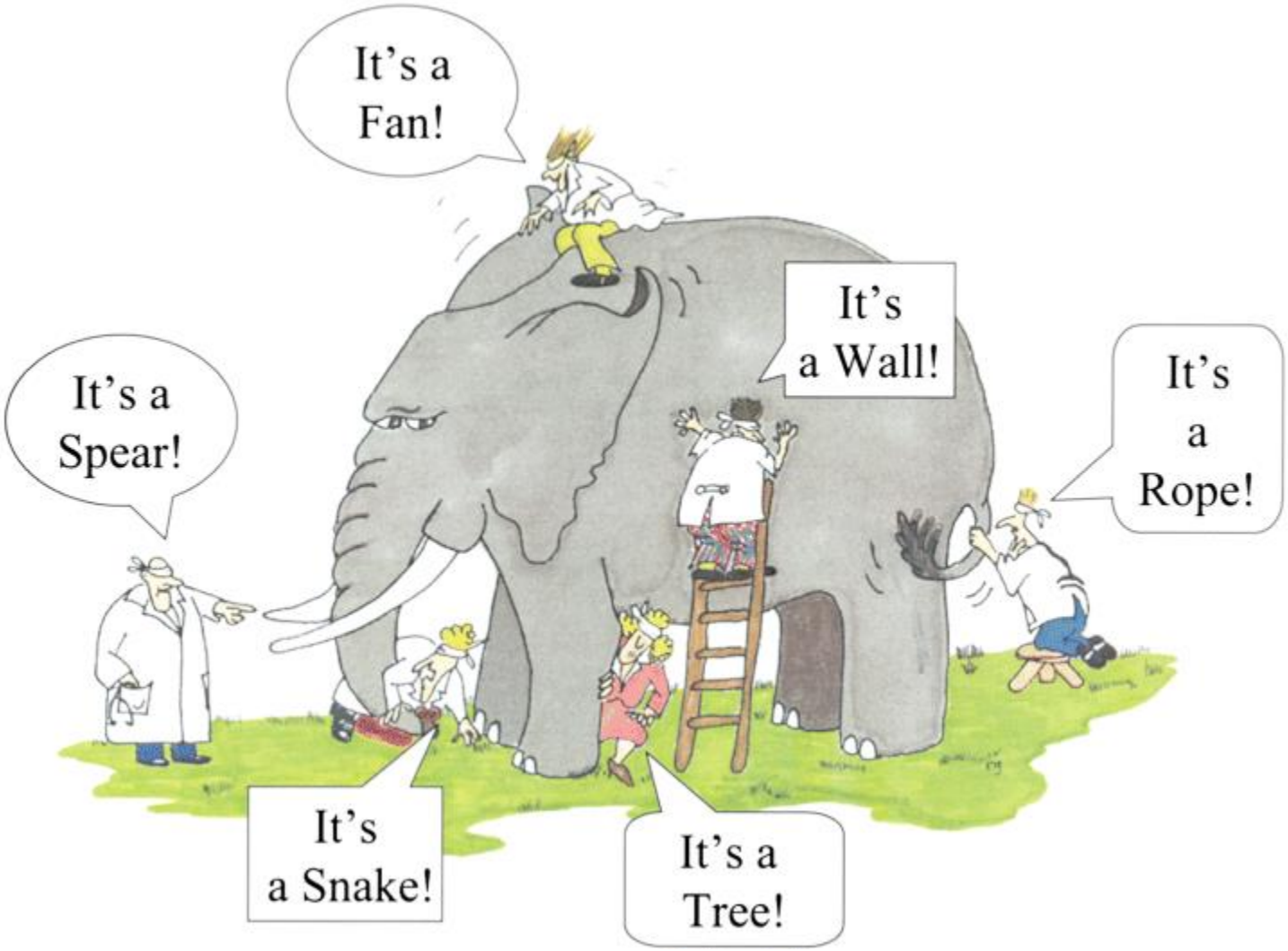
TJC (2019 and so far in 2020) Top Deficiencies



The Joint Commission

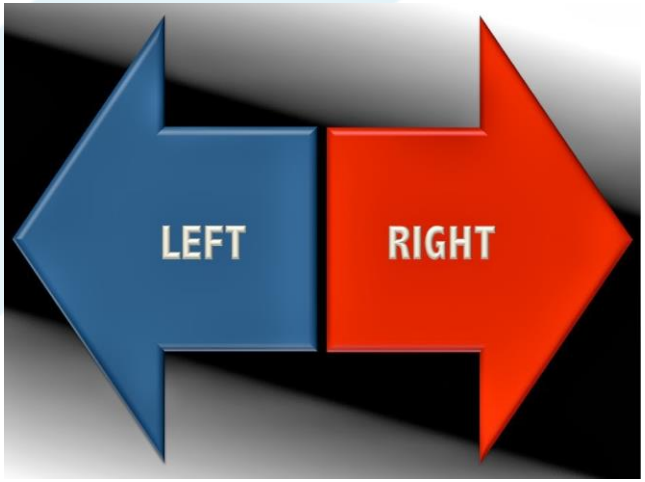
2020 Laboratory Roundtable Virtual Event. The Joint Commission, October 29-30, 2020.

Deficiencies: Common Denominators



Why most deficiencies?

Not having *right* qualified personnel doing the *right* things!



Qualifications/Qualified…Means?

Education

Training

Competency (Assessment)

AND

Fulfillment of responsibilities

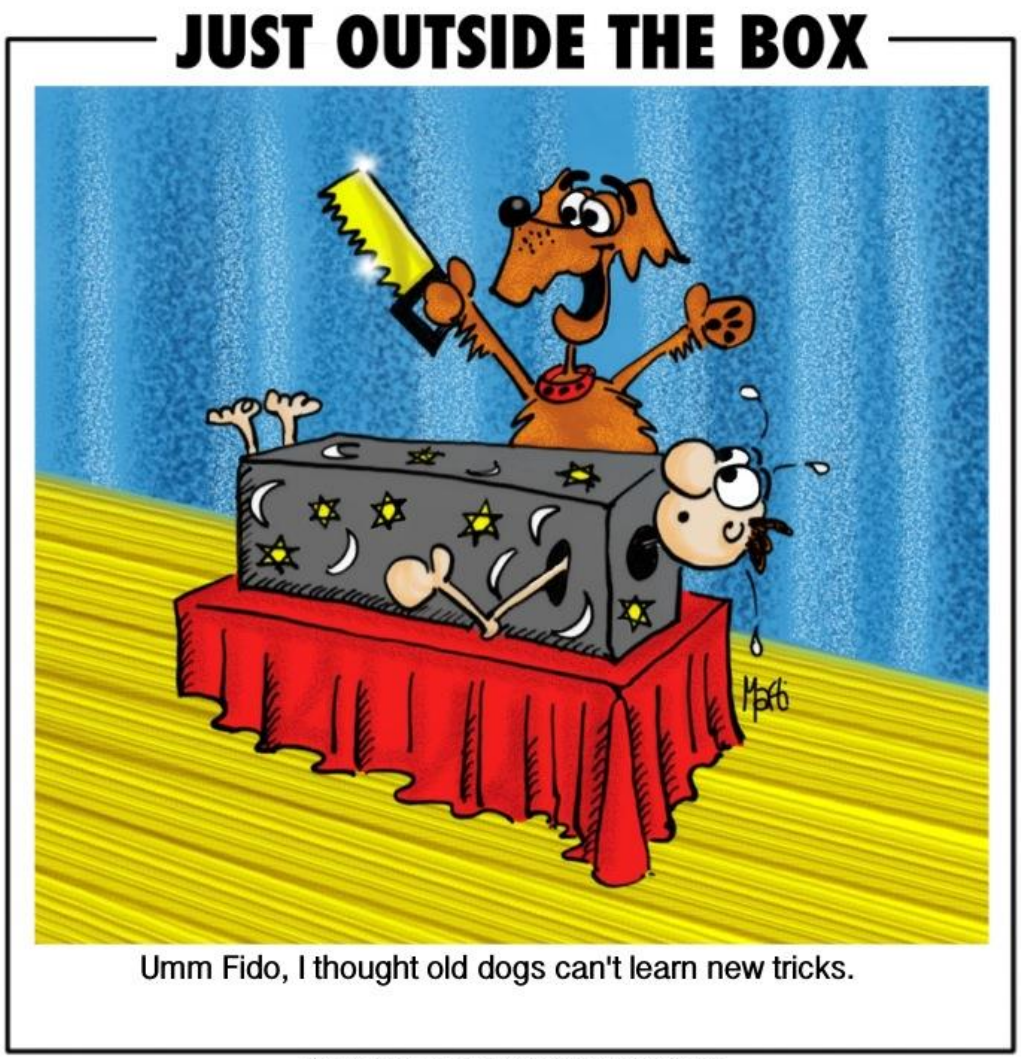
Best Practices for establishing a quality laboratory

- Established and well-defined quality management plan
- Laboratory director involvement
- Thorough training and competency assessment program
- Clear policies/procedures for all staff

Jean Ball. Best Practices and Common Deficiencies in Point of Care Testing. Whitehat Webinar. October 8, 2020

Deficiency Avoidance

New Tricks? REALLY!



Important Mantras for Avoidance

Check, check, check

Train, train, train

Assess, assess, assess

Remind, remind, remind

Check Personnel Credentials to fulfill Requirements:

- Moderate complexity testing (CLIA Subpart M, §§493.1403 – .1425)
  - Director
  - Technical Consultant
  - Clinical Consultant
  - Testing Personnel
- High complexity testing (CLIA Subpart M, §§493.1441 - .1495)
  - Director
  - Technical Supervisor
  - Clinical Consultant
  - General Supervisor
  - Testing Personnel

Director *Requirements* – Mod. Complex

□ 1. M.D., D.O. with current medical license to practice in State of laboratory's location **and** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications. Doctors of Optometry can serve for testing in their specialty area. Optometrists may perform waived or moderately complex tests when tears are the specimen.

□ 2. M.D., D.O., or D.P.M (after September 1, 1993). with current medical license to practice in State of laboratory's location **and** laboratory training/experience consisting of (check one):

- □ a. 1 year directing or supervising nonwaived tests.
- □ b. 20 CME credit hours in laboratory practice commensurate with director responsibilities.
- □ c. Equivalent laboratory training (20 CMEs) obtained during medical residency.

□ 3. Doctorate in chemical, physical, biological or clinical laboratory science **and** certification by HHS-approved Board.

□ 4. Doctorate in chemical, physical, biological or clinical laboratory science **and** 1 year directing or supervising nonwaived testing.

□ 5. Master's in clinical laboratory science, medical technology or chemical, physical or biology science **and** 1 year laboratory training/experience in nonwaived testing **and** 1 year supervisory experience in a laboratory in nonwaived testing.

□ 6. Bachelor's in clinical laboratory science, medical technology or chemical, physical or biological science **and** 2 years laboratory training/experience in nonwaived testing **and** 2 years supervisory experience in a laboratory in nonwaived testing.

□ 7. **ON OR BEFORE 2/28/92** qualified or could have qualified as a director under the laboratory regulations published March 14, 1990 (see § 493.1406).

□ 8. **ON OR BEFORE 2/28/92** qualified as a director by the State in which the laboratory is located.

CLIA Personnel Requirements. In: Ehrmeyer S. New Poor Labs' Guide to the Regulations. Westgard QC. 2019

Train, Train, Train*
Assess, Assess, Assess*

- Training provides essential knowledge, skills and behaviors for analysts to meet policies and procedures. Must be done before testing and with changes. Records must be maintained.

- Competency of analysts is the correct application of knowledge, skills and behaviors.

- Competency assessment *confirms* that application of knowledge, skills and behaviors is correct. CA must be performed at prescribed intervals and records maintained.

*Waived Testing – training/CA varies with accrediting agency

Competency Assessment Includes:
Technical Consultant's Responsibility (Mod. Complex)

(1) Direct observations of routine patient test performance, including patient preparation (if applicable), specimen handling, processing and testing;

(2) Monitoring recording and reporting of test results;

(3) Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records;

(4) Direct observation of performance of instrument maintenance and function checks;

(5) Assessment of test performance through testing -- previously analyzed, internally blind, or external PT samples; and

(6) Assessment of problem-solving skills.

TIPs from COLA for CA

Free webinar addressing meaningful CA:

https://outlook.office.com/mail/inbox/id/AAMkAGYxYzQyYjE5LWFiZTktNGM2OC04OTY2LTVhYzgyZGNjNWViMABGAAAAAACtvT04z%2FyySoX9RoxKu%2FOrBwBYhY5fsGZ6RpiqDTiwseFNAAAAAAENAABYhY5fsGZ6RpiqDTiwseFNAAYtdFEKAAA%3D

- Competency assessment does not have to be done all at once.
- Keep a running file on each person and add to it as they resolve problems, perform PT, etc.
- Include copies of documentation in the file, for example a write-up of a non-conforming event where the testing personnel resolved the situation. Include copies of routine maintenance logs, documentation of critical value communication, etc.

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

CAP's Common CA Deficiencies

- **Incomplete documentation of all 6 elements**
  - Each test system/method must have all 6 elements assessed for all non-waived testing
- **Ineligible competency assessor**
  - For all moderately complex testing, must meet technical consultant qualifications
    - Must have a bachelor's degree in a chemical, physical, biologic or laboratory science
    - Must have at least two years of experience in the same complexity of testing
    - Must be delegated in writing

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

Jean Ball, MBA, MT(HHS), MLT(ASCP), "Preparing for Your CAP POC Inspection"

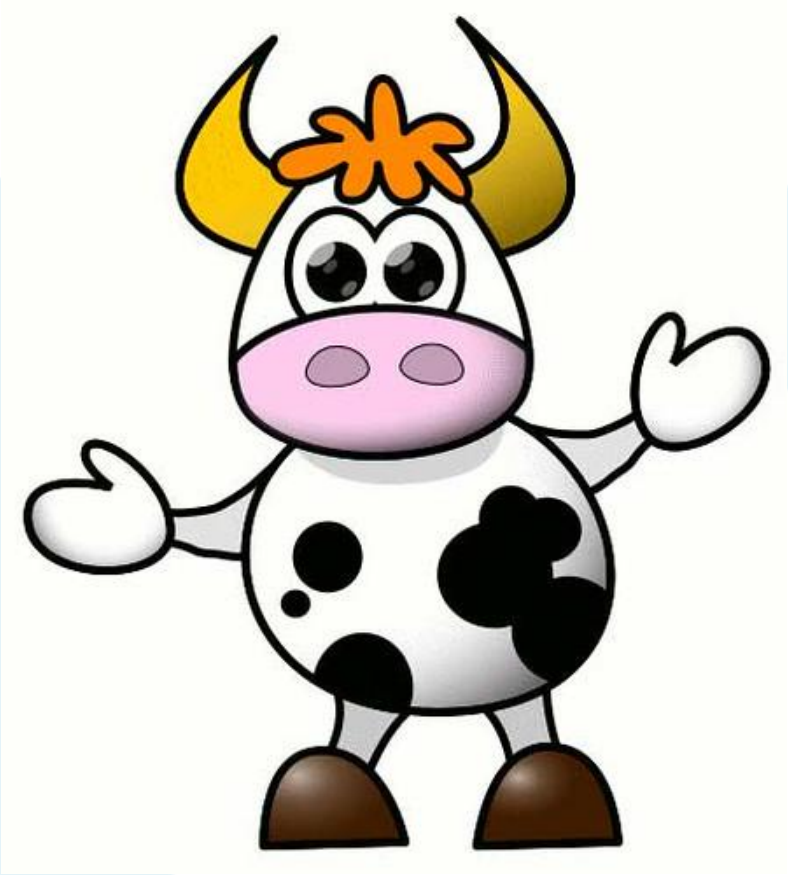
- Wonderful!!

- Whitehat Communications:

  Thursday, October 8, 2020 Point of Care Group Webinars 2020

  https://www.whitehatcom.com/POC_Group_Webinars_2020.htm

Remind Staff:
Yes, Responsible for Responsibilities



Who Me?

Not fulfilling/providing required responsibilities remains a major deficiency!

Our Goal

Positive contribution to healthcare team for quality patient care

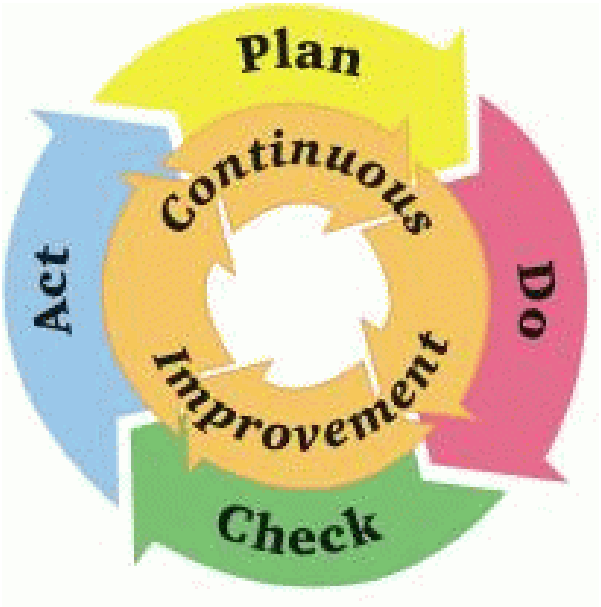
UALITY → **Patient Safety**

Failure to recognize lack of quality and Improve quality in the *entire testing* process can jeopardize patients' safety

Need effective quality management

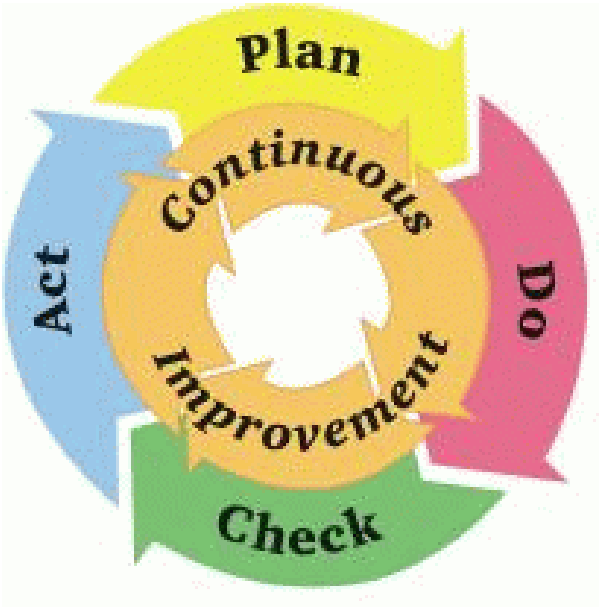
Quality Assessment/Assurance: Monitor & Improve

- Continually and *seriously* be involved to ensure (*ongoing)* effectiveness
  - Think monitoring
  - Think problem investigation
  - Think corrective actions
  - Think quality improvement



Quality Assessment/Assurance: Monitor & Improve

- Continually and *seriously* be involved to ensure (*ongoing)* effectiveness
  - Think monitoring
  - Think problem investigation
  - Think corrective actions
  - Think quality improvement



Quality Improvement: How?

Consequences: § 493.1812: Action when deficiencies pose immediate jeopardy

CMS requires immediate action to remove jeopardy due to condition level deficiencies

- ≥1 or more sanctions may be imposed

If jeopardy is not eliminated, CMS suspends/limits CLIA certificate (can be revoked later, if necessary)

When activity is a significant hazard to public health

- CMS can seek temporary injunction/restraining order regardless of CLIA certificate and State-exemption status.

e-CFR data is current as of October 2, 2017. https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

CAP: Investigating non-conforming Events

CAP's revised (2020) GEN.20208 QM Patient Care/Client Services

The QM program includes a process to identify and evaluate non-conforming events -- errors and incidents that may interfere with patient care/client services

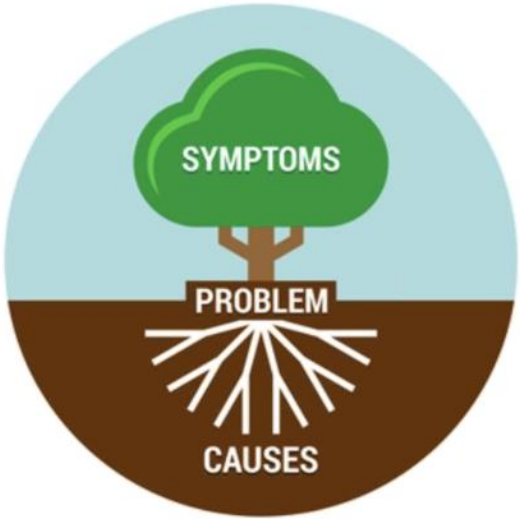
CAP's new (2020) GEN.20310 Investigation of Non-conforming Events

QM program requires a **RCA** when a non-conforming event occurs that results in death, permanent harm or severe temporary harm (e.g., sentinel event). For nonconformances that … are not sentinel events (e.g., near misses), QM program includes a process to define the scope and extent of the investigation required.

Root Cause Analysis Approach

- **Root cause analysis**: A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

- **In more general terms:**
  - Looking deeply into problems to find out why they are happening.
  - Uncovering causes that are not obvious.



RCA's in-depth look often requires a cultural change

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

Culture Change for Quality and Patient Safety

Quality/Safety: Requires "Right" Culture

"Quality and Patient Safety *NOT* associated with mismanagement, hostilities, "in-fighting," incompetence, disorganization"

Anne Belanger, former inspector and Laboratory Accreditation director, The Joint Commission

TJC enhanced focus: Culture of Safety and Zero Harm

Leadership (LD) standards…[for] a just and learning culture to reach zero harm

(LD.03.01.01, LD.03.09.01, LD.03.02.01, PI.01.01.01)

Leaders have essential role…with consistent activities…

- Leadership participation is crucial to …facilitate transparent, non-punitive approach to reporting and learning from adverse events, close calls, and unsafe conditions

Surveyors look for engaged leadership and their participation in developing/sustaining a culture of safety.

https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/lab-focus/lab-focus--issue-2-2019/

COLA's Quality and Safety View:
Testing is more than Compliance; its Culture

…Within total healthcare system…[there is] awareness of importance of accurate lab information to improve patient outcomes

…we know that accuracy emerges through relevant, practical, quality and safety-centered processes combined with a continuous "quality-on-the-mind" focus during daily actions of caring for patients…

Beigel DA, COLA 2017 Laboratory Accreditation Manual.

*Leadership** is required for lab safety (and patient safety)

- Building a culture of safety
- Encouraging openness and transparency
- Ensuring safety competency
- The incident management plan
- Process for incident investigation

*Irwin Rothenberg. Technical writer/quality advisor: COLA Resources, Inc.

MLO. Achieving a culture of safety with competency and commitment. (Oct 2017) https://www.mlo-online.com/ebook/1gmmj/0A1gmn1/MLO201710/html/index.html?page=24&origin=reader

“Right” Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Who did it?	What happened? Why?
Punitive	Fair and just
Bad people	Bad systems
Penalize the reporter	Thank the reporter
Confidential	Transparent learning
Investigation	Root cause analysis
Independent silos; no/little communication	Inclusive and interdisciplinary team; lots of communication

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

“Right” Culture Requires Shift in Thinking

Not Effective Thinking	Effective Thinking
Thinking errors are rare	Realizing errors are everywhere
Great care	Great care in a high-risk environment
Lack of direction; staff make it up as they go along	Principles of fair and just culture, guidelines algorithms, flow charts
Risk of disclosure/confidentiality	Moral duty, risk of non-disclosure
Great staff; poor systems	Great staff; great systems
Deliver care to patients	Partner with team, patients and families

http://www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

“Effective” Thinking for The Right Culture

Summary of Today, we addressed

- Tactics based on survey/inspection findings to be aware and avoid deficiencies
- Quality assessment and quality improvement techniques for quality results and patient safety
- Importance of the “right” laboratory culture for quality and patient safety

What about Tomorrow?

Who knows?

- Keep current, keep “ear to ground”, be in the know
- Be flexible
- Be ready for the next “*surprise*”

But how?

Planning Guidance

Lab Preparedness During the COVID-19 Pandemic

Strategies for curtailing test menus, implementing social distancing, and supporting staff morale in response to a surge in testing and staffing shortages

Author: Jonathan Hoyne, PhD, DABCC, FACC // **Date:** MAY.1.2020 // **Source:** Clinical Laboratory News

Topics: Lab Management, Change Management, Emergency Preparedness/Response, Lab Safety, Personnel Management, Test Utilization

The past few months have been a whirlwind of news about, and activities in response to, the emergence and spread of the novel coronavirus, SARS-CoV-2. As this pandemic unfolds, laboratory personnel are key to the efforts to halt the virus's spread and treat patients.

The consequences of the pandemic on laboratories are likely to go beyond those of more familiar emergencies, like floods or hurricanes. In addition to a possibly overwhelming surge in patients with COVID-19 illness, we might experience planned reductions in other patient populations, a changed patient mix to mostly or nearly all COVID-19 patients, supply shortages, and staff shortages as team members need to self-quarantine or stay home to care for family members.

https://www.aacc.org//media/Files/CLN/2020/CLN_May2020.pdf?la=en&hash=7E78A5E00567C7CF43426F12231913983887E0CF

My last Word on Quality and Safety -- Continue to:

Superheroes!

Thanks to all of you!

References

Policy for Coronavirus Disease-2019 tests During the Public Health Emergency (revised). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised

https://www.cdc.gov/coronavirus

https://www.cdc.gov/cornavirus/2019-ncov/lab/faqs.html#general-Guidance-and-Regulatory-Requirements

https://www.coms.gov/files/document/clia-laboatory-covid-19-emergency-frequently-asked-questions.pdf

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-caretesting.html

Laboratory Data Reporting. COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115. https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

CMS Laboratory Quick Start Guide to CLIA Certification. https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf

Standards and Certification: Laboratory Requirements (42CFR 493). https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

COLA website AND Laboratory Accreditation Manual (2020). www.COLA.org

The Joint Commission website AND Comprehensive Laboratory Accreditation Manual for Laboratory and POCT (2020). www.jointcommission.org

CAP website AND Checklists (2020). www.CAP.org