# Meeting Dynamic Challenges for Quality and Patient Safety

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# 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

# 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

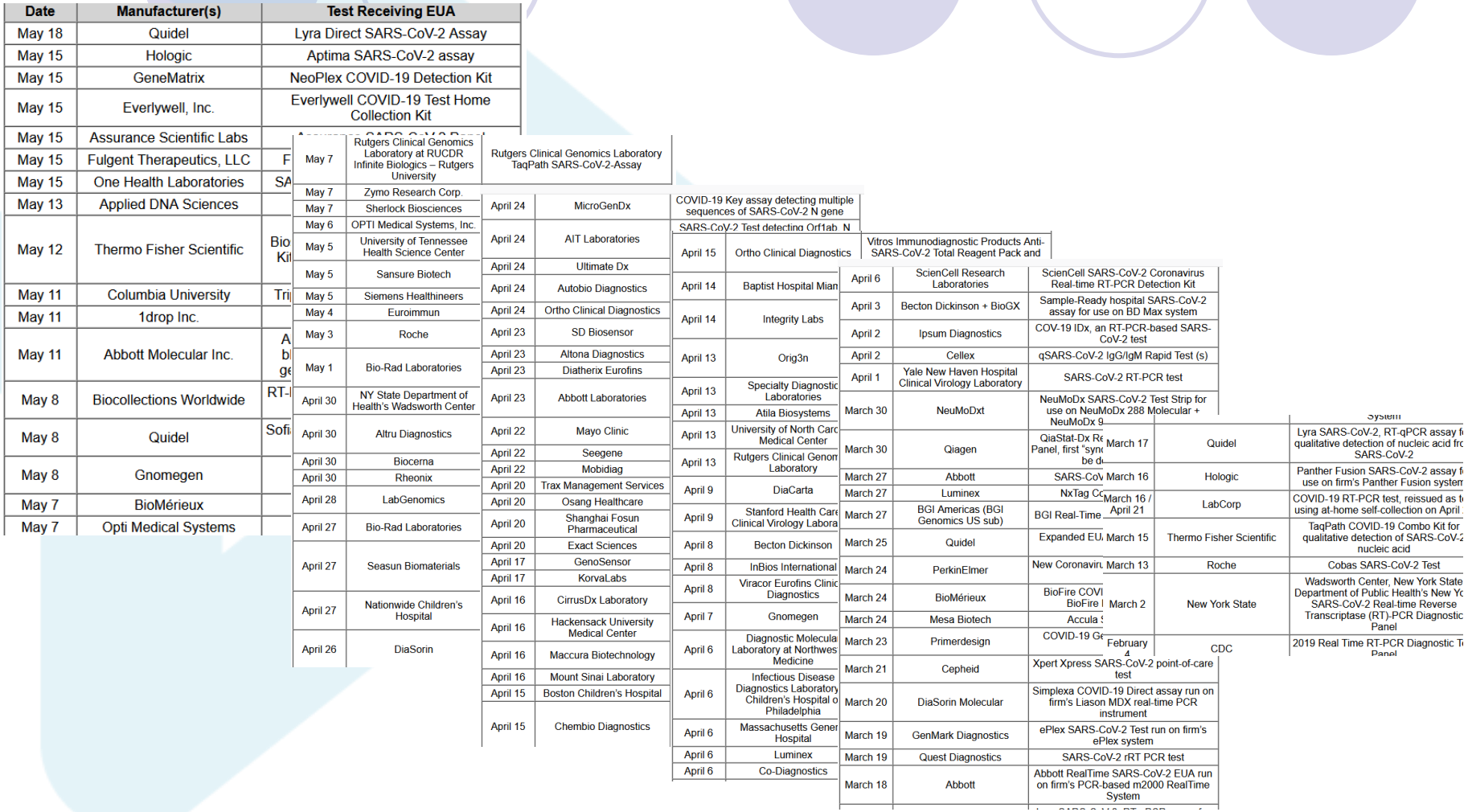
All provide useful information and help!

# 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)

# Confused?: Many Tests with EUA



| Date | Manufacturer(s) | Test Receiving EUA |
|---|---|---|
| May 18 | Quidel | Lyra Direct SARS-CoV-2 Assay |
| May 15 | Hologic | Aptima SARS-CoV-2 assay |
| May 15 | GeneMatrix | NeoPlex COVID-19 Detection Kit |
| May 15 | Everlywell, Inc. | Everlywell COVID-19 Test Home Collection Kit |
| May 15 | Assurance Scientific Labs | |
| May 15 | Fulgent Therapeutics, LLC | F |
| May 15 | One Health Laboratories | SA |
| May 13 | Applied DNA Sciences | |
| May 12 | Thermo Fisher Scientific | Bio Kit |
| May 11 | Columbia University | Tri |
| May 11 | 1drop Inc. | |
| May 11 | Abbott Molecular Inc. | A b g |
| May 8 | Biocollections Worldwide | RT- |
| May 8 | Quidel | Sofi |
| May 8 | Gnomegen | |
| May 7 | BioMérieux | |
| May 7 | Opti Medical Systems | |
| May 7 | Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics – Rutgers University | Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay |
| May 7 | Zymo Research Corp. | |
| May 7 | Sherlock Biosciences | |
| May 6 | OPTI Medical Systems, Inc. | |
| May 5 | University of Tennessee Health Science Center | |
| May 5 | Sansure Biotech | |
| May 5 | Siemens Healthineers | |
| May 4 | Euroimmun | |
| May 3 | Roche | |
| May 1 | Bio-Rad Laboratories | |
| April 30 | NY State Department of Health's Wadsworth Center | |
| April 30 | Altru Diagnostics | |
| April 30 | Biocerna | |
| April 30 | Rheonix | |
| April 28 | LabGenomics | |
| April 27 | Bio-Rad Laboratories | |
| April 27 | Seasun Biomaterials | |
| April 27 | Nationwide Children's Hospital | |
| April 26 | DiaSorin | |
| April 24 | MicroGenDx | COVID-19 Key assay detecting multiple sequences of SARS-CoV-2 N gene |
| April 24 | AIT Laboratories | SARS-CoV-2 Test detecting Orf1ab, N |
| April 24 | Ultimate Dx | |
| April 24 | Autobio Diagnostics | |
| April 24 | Ortho Clinical Diagnostics | |
| April 23 | SD Biosensor | |
| April 23 | Altona Diagnostics | |
| April 23 | Diatherix Eurofins | |
| April 23 | Abbott Laboratories | |
| April 22 | Mayo Clinic | |
| April 22 | Seegene | |
| April 22 | Mobidiag | |
| April 20 | Trax Management Services | |
| April 20 | Osang Healthcare | |
| April 20 | Shanghai Fosun Pharmaceutical | |
| April 20 | Exact Sciences | |
| April 17 | GenoSensor | |
| April 17 | KorvaLabs | |
| April 16 | CirrusDx Laboratory | |
| April 16 | Hackensack University Medical Center | |
| April 16 | Maccura Biotechnology | |
| April 16 | Mount Sinai Laboratory | |
| April 15 | Boston Children's Hospital | |
| April 15 | Chembio Diagnostics | |
| April 15 | Ortho Clinical Diagnostics | Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and |
| April 14 | Baptist Hospital Mian | |
| April 14 | Integrity Labs | |
| April 13 | Orig3n | |
| April 13 | Specialty Diagnostic Laboratories | |
| April 13 | Atila Biosystems | |
| April 13 | University of North Carc Medical Center | |
| April 13 | Rutgers Clinical Genom Laboratory | |
| April 9 | DiaCarta | |
| April 9 | Stanford Health Care Clinical Virology Labora | |
| April 8 | Becton Dickinson | |
| April 8 | InBios International | |
| April 8 | Viracor Eurofins Clinic Diagnostics | |
| April 7 | Gnomegen | |
| April 6 | Diagnostic Molecula Laboratory at Northwes Medicine | |
| April 6 | Infectious Disease Diagnostics Laboratory Children's Hospital o Philadelphia | |
| April 6 | Massachusetts Gener Hospital | |
| April 6 | Luminex | |
| April 6 | Co-Diagnostics | |
| April 6 | ScienCell Research Laboratories | ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR Detection Kit |
| April 3 | Becton Dickinson + BioGX | Sample-Ready hospital SARS-CoV-2 assay for use on BD Max system |
| April 2 | Ipsum Diagnostics | COV-19 IDx, an RT-PCR-based SARS-CoV-2 test |
| April 2 | Cellex | qSARS-CoV-2 IgG/IgM Rapid Test (s) |
| April 1 | Yale New Haven Hospital Clinical Virology Laboratory | SARS-CoV-2 RT-PCR test |
| March 30 | NeuMoDxt | NeuMoDx SARS-CoV-2 Test Strip for use on NeuMoDx 288 Molecular + NeuMoDx 9 |
| March 30 | Qiagen | QiaStat-Dx Re Panel, first "sync be d |
| March 27 | Abbott | SARS-CoV |
| March 27 | Luminex | NxTag Co |
| March 27 | BGI Americas (BGI Genomics US sub) | BGI Real-Time |
| March 25 | Quidel | Expanded EU |
| March 24 | PerkinElmer | New Coronaviru |
| March 24 | BioMérieux | BioFire COVI BioFire |
| March 24 | Mesa Biotech | Accula |
| March 23 | Primerdesign | COVID-19 Ge |
| March 21 | Cepheid | Xpert Xpress SARS-CoV-2 point-of-care test |
| March 20 | DiaSorin Molecular | Simplexa COVID-19 Direct assay run on firm's Liason MDX real-time PCR instrument |
| March 19 | GenMark Diagnostics | ePlex SARS-CoV-2 Test run on firm's ePlex system |
| March 19 | Quest Diagnostics | SARS-CoV-2 rRT PCR test |
| March 18 | Abbott | Abbott RealTime SARS-CoV-2 EUA run on firm's PCR-based m2000 RealTime System |
| March 17 | Quidel | Lyra SARS-CoV-2, RT-qPCR assay f qualitative detection of nucleic acid fr SARS-CoV-2 |
| March 16 | Hologic | Panther Fusion SARS-CoV-2 assay f use on firm's Panther Fusion system |
| March 16 / April 21 | LabCorp | COVID-19 RT-PCR test, reissued as t using at-home self-collection on April |
| March 15 | Thermo Fisher Scientific | TaqPath COVID-19 Combo Kit for qualitative detection of SARS-CoV-2 nucleic acid |
| March 13 | Roche | Cobas SARS-CoV-2 Test |
| March 2 | New York State | Wadsworth Center, New York State Department of Public Health's New Yo SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel |
| February 4 | CDC | 2019 Real Time RT-PCR Diagnostic T Panel |

Remember when EUA is over, "testing life" returns to "normal"



FDA Approved Coronavirus Tests. https://www.g2intelligence.com/coronavirus-eua-chart/. May 19 2020.

# TJC COVID-19: QC Testing

**What are the quality control requirements I must follow for COVID-19 tests ?**

Back to FAQs

*Any examples are for illustrative purposes only.*

During the COVID-19 emergency, external quality control for COVID-19 tests may be performed less frequently than The Joint Commission and CLIA normally require. Quality control for COVID-19 testing must be performed at least as frequently as stated in the manufacturer's package insert, and an individual quality control plan (IQCP) is not required at this time.

After the emergency is resolved and the Emergency Use Authorizations (EUA) are rescinded, laboratories MUST return to the full frequency required for quality control by The Joint Commission standards and CLIA regulations.

April 8, 202. https://www.jointcommission.org/standards/standard-faqs/laboratory/quality-system-assessment-for-nonwaived-testing-qsa/000002296/

# TJC COVID-19: Validation of Testing

**My laboratory wants to begin testing for COVID-19, what is required for validation of this test?**

Back to FAQs

*Any examples are for illustrative purposes only.*

Laboratories who elect to conduct COVID-19 testing must follow the guidance released by the FDA, CDC, and CLIA (CMS). Since this is an emergent and changing situation, it's best to review those websites often. The FDA is allowing for an abbreviated validation process, but laboratories must follow those FDA guidelines.

The manufacturer should also be able provide additional information.

The Joint Commission is following the guidance from FDA, CDC, and CLIA (CMS) as follows:

1. If the laboratory is using a CDC-developed Emergency Use Authorization (EUA) assay, the instructions provided with the procedure must be followed.

2. If the laboratory is using an Emergency Use Authorization (EUA) assay not developed by CDC but approved by the FDA, the laboratory director must determine the number of positive and negative specimens needed to verify performance and must follow manufacturer's instructions.

After the emergency is resolved and the EUA's are rescinded, laboratories must validate methods as required for the complexity of testing. (Joint Commission standard QSA.02.01.01 EP 1 for moderate complexity and EP 2 for high complexity.) If the EUA's are rescinded and the FDA has not assigned a complexity to the method, laboratories must validate the method as a high complexity laboratory developed test. (Joint Commission Standard QSA.02.01.01 EP 2.)

April 8, 202. https://www.jointcommission.org/standards/standard-faqs/laboratory/quality-system-assessment-for-nonwaived-testing-qsa/000002296/

# QC and Method Validation Guidance

## Check Westgard.com

WESTGARD WEB

**A Review of Predictive Value of Laboratory Tests**

Expanding on a previous lesson on Clinical Agreement, Dr. Westgard discusses the Predictive Value of a Laboratory Test

Continue Reading

**Sprinting into a Marathon: Striving for Quality in the Covid19 Crisis**

**A few months into the Covid19 crisis, we need to stop treating it as a short-term crisis and start preparing it like it's a long-term emergency.**

Continue Reading

**Key Facts in Covid-19 Testing**

**Wayne Dimech provides a useful overview of SARS-Cov-2 testing and the COVID-19 illness. Wayne Dimech is Executive Manager, Scientific and**

**Estimating Clinical Agreement for a Qualitative Test: A Web Calculator for 2x2 Contingency Table**

**How do you validate a qualitative test? Here's an introduction to a tiny little tool you might find useful for virus assay validation**

Continue Reading

**2019 CLIA Proposed Acceptance Limits for Proficiency Testing**

CLIA has posted a proposed set of new quality

**Covid-19 Testing: Maintaining Quality in a State of Emergency**

**Wayne Dimech examines the quality - or lack thereof - of SARS-Cov-2 testing. Wayne Dimech is Executive Manager, Scientific and Business Relations at NRL, Australia (NRL) in Melbourne. He is a recognized expert in infectious disease serology and laboratory quality.**

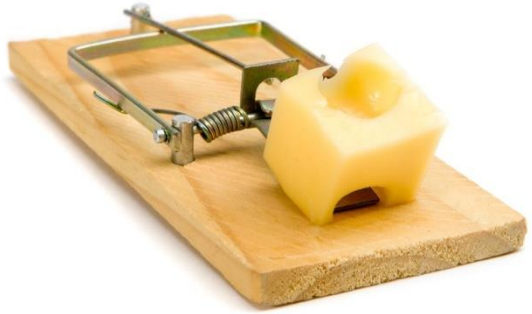
Continue Reading

**MIOT Hospital Sigma metric Verification of Performance**

# 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) Deficiencies

| Regulation | Deficiency | % All Lab Cited | % POLs Cited |
|---|---|---|---|
| 493.1252(b) | Criteria for reagent and specimen storage; test system operation; test result reporting | 4.8% | 4.6% |
| 493.1289(a) | Policies/procedures followed to monitor, assess, and correct problems identified in 493.1251-.1283 | 4.0% | 3.8% |
| 493.1251(b) | Complete procedure manual | 4.6% | 4.5% |
| 493.1251(a) | Procedure manual for all tests followed by personnel | 3.2% | 3.2% |
| 493.1236(c)(1) | At least 2X every year, verify accuracy of tests not enrolled in HHS approved PT | 4.3% | 4.8% |
| 493.1291(c) | Test report includes all mandated items | 3.5% | 3.6% |
| 493.1235 | Policies/procedures followed to assess employee and, if applicable, consultant competency | 4.1% | 4.1% |
| 493.1252(d) | Reagents, solutions, etc. used, not outdated or of substandard quality | 3.1% | 3.0% |
| 493.1254(a)(1) | Maintenance performed at least at manufacturer's stated frequency | 3.1% | 2.8% |
| 493.1253(b)(1) | Each lab using unmodified FDA-approved tests must demonstrate attainment of manufacturers' perf. specif. | 2.8% | 2.2% |

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

# 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 (2018 data)

| CHECKLIST REQUIREMENT | CAP-WIDE* |
|---|---|
| **GEN.55500** Competency Assessment | **1** |
| **COM.01200** Activity Menu | **2** |
| **COM.04250** Comparability of Instruments and Methods – Nonwaived Testing | **3** |

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

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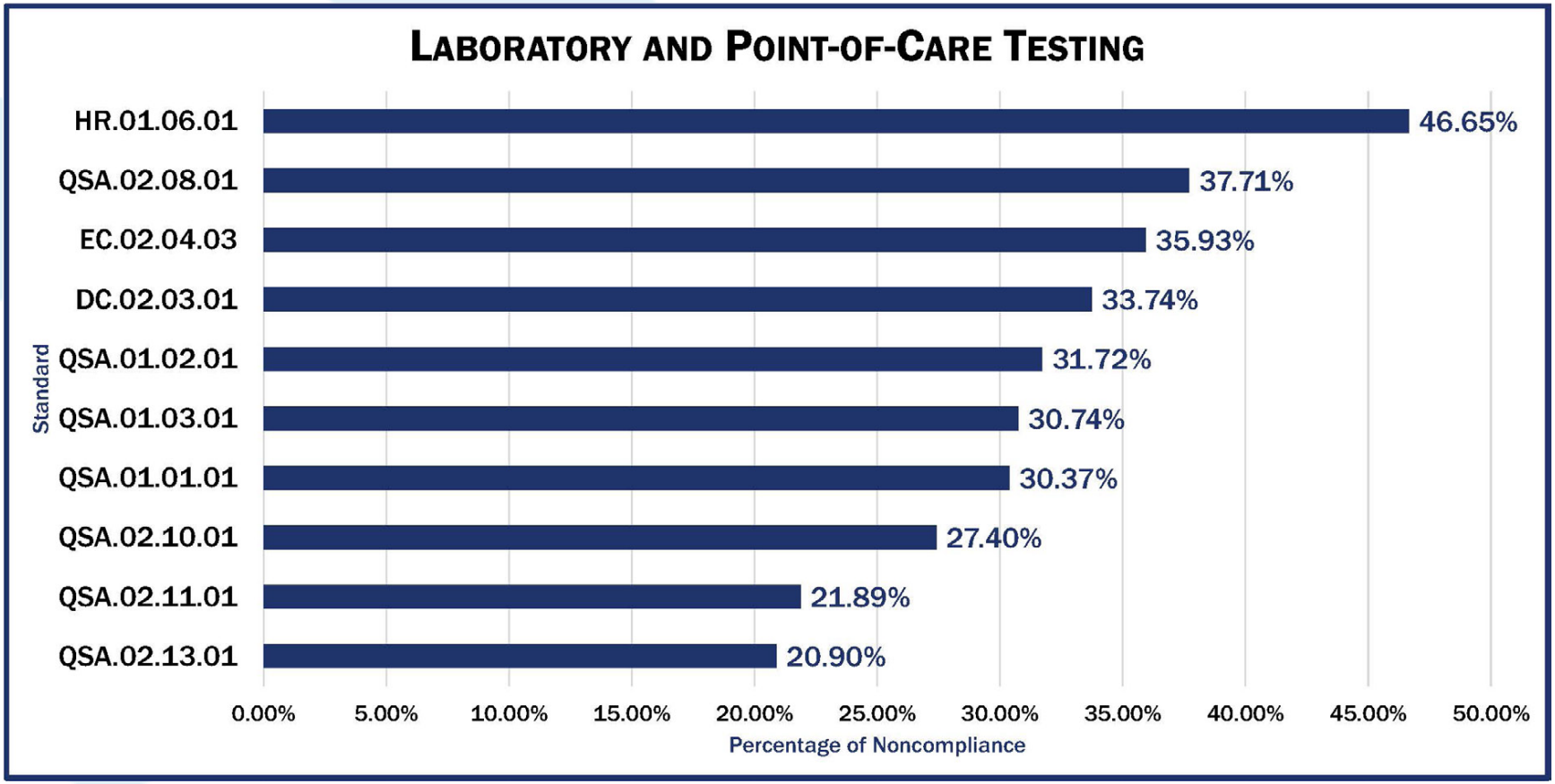
# TJC (2018) Top Deficiencies






Perspectives. The Joint Commission. April 2019 l Volume 39 | Number 4

# Deficiencies: Common Denominators

# CLIA: Top 10 (Oct. 2018) Conditions

(Note number of deficiencies focused on personnel)

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

# CAP Top Deficiencies ( from 2018 data)

| CHECKLIST REQUIREMENT | CAP-WIDE* |
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| **GEN.55500** Competency Assessment | 1 |
| **COM.01200** Activity Menu | 2 |
| **COM.04250** Comparability of Instruments and Methods – Nonwaived Testing | 3 |

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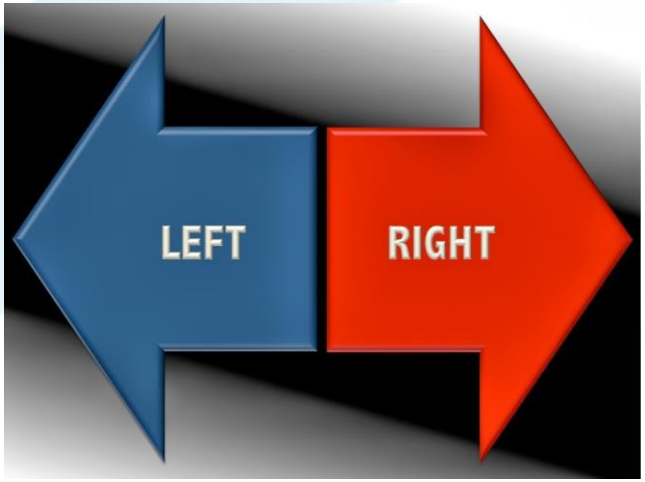
# TJC's #1 Deficiency

| | |
|---|---|
| HR.01.06.01 | Determine that staff are competent to perform their responsibilities |

Perspectives. The Joint Commission. April 2019 l Volume 39 | Number 4

# Why most deficiencies?

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



# Qualifications/Qualified…Means?

Education

Training

Competency (Assessment)

AND

Fulfillment of responsibilities

# Deficiency Avoidance

# New Tricks? REALLY!

# Important Mantras for Avoidance

Check, check, check

Train, train, train

Assess, assess, assess

Remind, remind, remind

# Check Personnel Credentials

- 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.

# 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

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# TIPs from COLA for CA

- 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.

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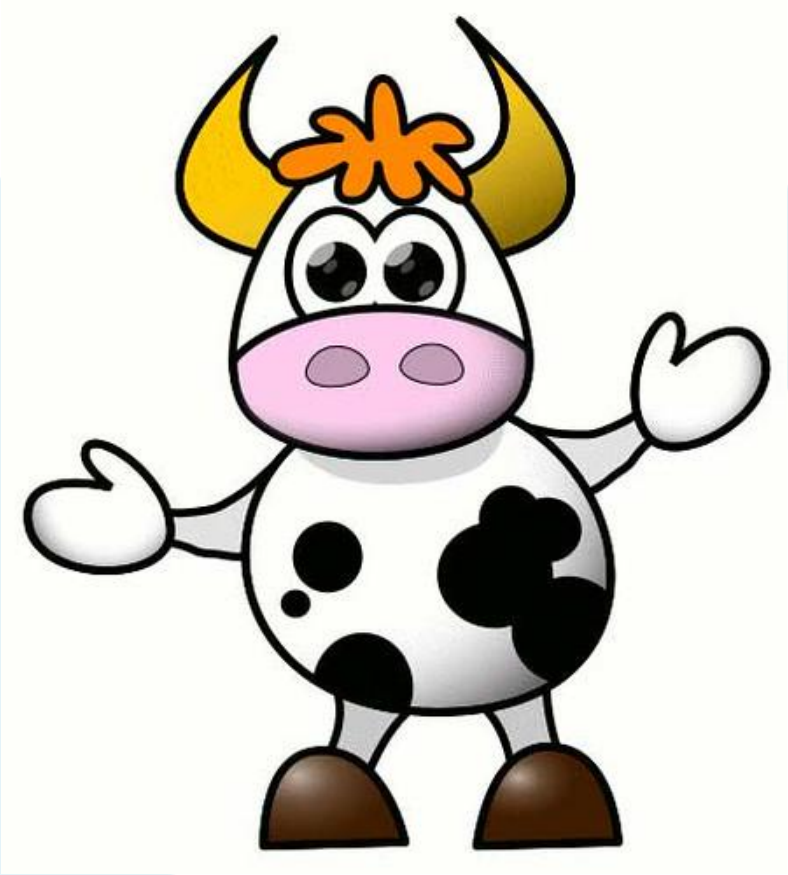
# Remind Staff:
# Yes, Responsible for Responsibilities



Who Me?

Not fulfilling/providing required responsibilities remains a major deficiency!

# Our Goal

*Positive contribution to healthcare team for quality* patient care

UALITY

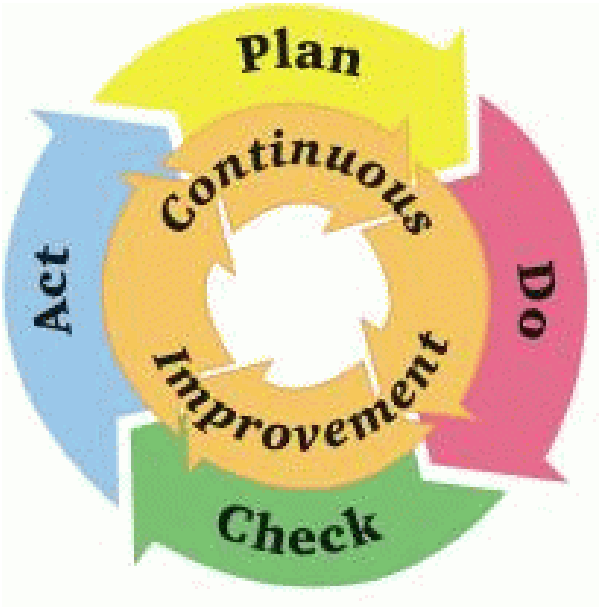
**Patient Safety**

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



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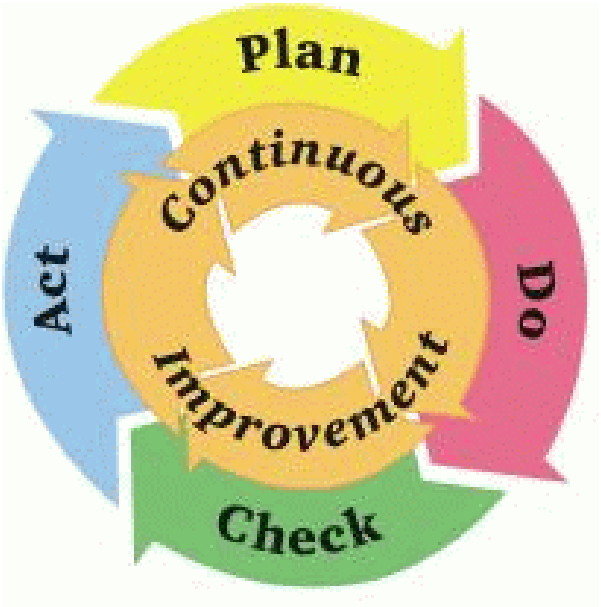


# Quality Improvement: How?

Definition of Insanity?

# 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 (2019) GEN.20208 QM Patient Care/Client Services

QM program includes a process to identify/evaluate errors, incidents and other problems that may interfere with patient care/client services

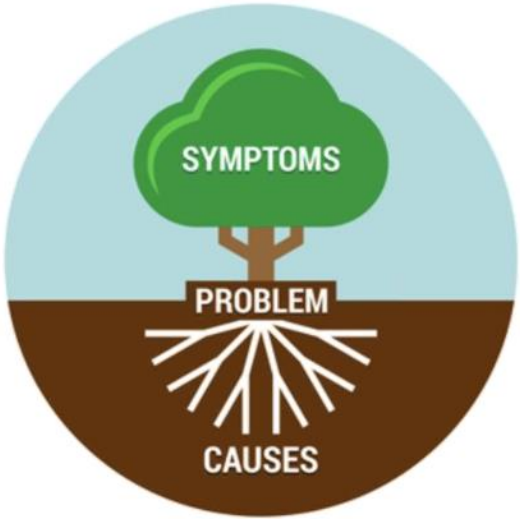
## CAP's new (2019) GEN.20310 Investigation of Non-conforming Events

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?*

# Some 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, FAACC // **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=7E78A5E00567C7CF43426F122319139838 87E0CF

# Planning Guidance

## Lab Preparedness During the COVID-19 Pandemic

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

# Superheroes!

Thanks to all of you!