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”

Don’t forget your state requirements too
CLIA/Your Accrediting Agency

All provide useful information and help!
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Manufacturer(s)</th>
<th>Test Receiving EUA</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 18</td>
<td>Quidel</td>
<td>Lyra Direct SARS-CoV-2 Assay</td>
</tr>
<tr>
<td>May 15</td>
<td>Hologic</td>
<td>Aptima SARS-CoV-2 assay</td>
</tr>
<tr>
<td>May 15</td>
<td>GeneMatrix</td>
<td>NeoPlex COVID-19 Detection Kit</td>
</tr>
<tr>
<td>May 15</td>
<td>EveryWell, Inc.</td>
<td>EveryWell COVID-19 Test Home Collection Kit</td>
</tr>
<tr>
<td>May 15</td>
<td>Assurex Scientific Labs</td>
<td></td>
</tr>
<tr>
<td>May 15</td>
<td>Fulgent Therapeutics, LLC</td>
<td></td>
</tr>
<tr>
<td>May 15</td>
<td>One Health Laboratories</td>
<td></td>
</tr>
<tr>
<td>May 13</td>
<td>Applied DNA Sciences</td>
<td></td>
</tr>
<tr>
<td>May 12</td>
<td>Thermo Fisher Scientific</td>
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</tr>
<tr>
<td>May 11</td>
<td>Columbia University</td>
<td></td>
</tr>
<tr>
<td>May 11</td>
<td>1drop Inc.</td>
<td></td>
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<tr>
<td>May 11</td>
<td>Abbott Molecular Inc.</td>
<td></td>
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<tr>
<td>May 8</td>
<td>Biocollections Worldwide</td>
<td></td>
</tr>
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<td>Quidel</td>
<td></td>
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<tr>
<td>May 8</td>
<td>NanoGenom</td>
<td></td>
</tr>
<tr>
<td>May 7</td>
<td>BioMérieux</td>
<td></td>
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<tr>
<td>May 7</td>
<td>Opti Medical Systems</td>
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COVID-19 Key assay detecting multiple sequences of SARS-CoV-2 N gene

Remember when EUA is over, “testing life” returns to “normal”

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

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.
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.)

QC and Method Validation Guidance
Check Westgard.com
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

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

## CLIA: Top 10 (Oct. 2018) Conditions
(problems with potential to or adversely affect patient test results/care)

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<tbody>
<tr>
<td>493.1403</td>
<td>Director meets qualifications (493.1405) and provides management/direction (493.1407)</td>
<td>2.5%</td>
<td>2.5%</td>
</tr>
<tr>
<td>493.1441</td>
<td>Director meets qualifications (493.1443) and provides overall management/direction (493.1445)</td>
<td>1.6%</td>
<td>0.8%</td>
</tr>
<tr>
<td>493.801</td>
<td>Enrolled in HHS approved PT for each specialty and subspecialty tested and tests samples like patients</td>
<td>1.1%</td>
<td>0.9%</td>
</tr>
<tr>
<td>493.1250</td>
<td>Nonwaived testing meets requirements (493.1251-1283); monitor, evaluate quality and correct problems (493.1289)</td>
<td>1.4%</td>
<td>1.2%</td>
</tr>
<tr>
<td>493.803</td>
<td>Nonwaived testing enrolled in HHS approved PT; lab successfully passes PT</td>
<td>0.7%</td>
<td>0.7%</td>
</tr>
<tr>
<td>493.1409</td>
<td>Lab has qualified technical consultant (493.1411) who provides oversight (493.1413)</td>
<td>1.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>493.1421</td>
<td>Lab has sufficient qualified individuals (493.1423) to perform functions (493.1425)</td>
<td>1.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>493.1415</td>
<td>For hematology testing, meets requirements (493.1230-1256, 1269, 1281-.1299)</td>
<td>0.4%</td>
<td>0.3%</td>
</tr>
<tr>
<td>493.1487</td>
<td>High complexity labs have sufficient qualified individuals (493.1489) to perform functions (493.1495)</td>
<td>0.6%</td>
<td>0.4%</td>
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<tr>
<td>493.1447</td>
<td>High complexity labs have a qualified technical supervisor (493.1449) to perform functions (493.1451)</td>
<td>0.4%</td>
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## CAP Top Deficiencies (2018 data)

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<tr>
<th>CHECKLIST REQUIREMENT</th>
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<tr>
<td>GEN.55500 Competency Assessment</td>
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<tr>
<td>COM.01200 Activity Menu</td>
<td>2</td>
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<tr>
<td>COM.04250 Comparability of Instruments and Methods – Nonwaived Testing</td>
<td>3</td>
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## COLA Top Deficiencies (2019)

<table>
<thead>
<tr>
<th>RANK</th>
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<th>REASON CITED</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>PER 5</td>
<td>658</td>
<td>18%</td>
<td>For not performing or documenting competency assessments as required</td>
</tr>
<tr>
<td>2</td>
<td>LDR 4</td>
<td>561</td>
<td>16%</td>
<td>For the Laboratory Director not fulfilling the Proficiency Testing responsibilities of the position</td>
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<tr>
<td>3</td>
<td>PER 4C</td>
<td>472</td>
<td>13%</td>
<td>For the Technical Consultant or Technical Supervisor not fulfilling the responsibilities of the position</td>
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<td>4</td>
<td>LDR 5</td>
<td>427</td>
<td>12%</td>
<td>For the Laboratory Director not fulfilling the Quality Control / Quality Assessment responsibilities of the position</td>
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<td>5</td>
<td>PT 16</td>
<td>414</td>
<td>12%</td>
<td>For not documenting review of PT scores by the Laboratory Director, supervisory personnel, and testing personnel</td>
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TJC (2018) Top Deficiencies

**Laboratory and Point-of-Care Testing**

- **HR.01.06.01**: 46.65%
- **QSA.02.08.01**: 37.71%
- **EC.02.04.03**: 35.93%
- **DC.02.03.01**: 33.74%
- **QSA.01.02.01**: 31.72%
- **QSA.01.03.01**: 30.74%
- **QSA.01.01.01**: 30.37%
- **QSA.02.10.01**: 27.40%
- **QSA.02.11.01**: 21.89%
- **QSA.02.13.01**: 20.90%

Percentage of Noncompliance

Perspectives. The Joint Commission. April 2019 | Volume 39 | Number 4
Deficiencies: Common Denominators
## CLIA: Top 10 (Oct. 2018) Conditions
(Note number of deficiencies focused on personnel)

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TJC’s #1 Deficiency

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

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
Culture Change for Quality and Patient Safety
“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.

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


“Right” Culture Requires Shift in Thinking

<table>
<thead>
<tr>
<th>Not Effective Thinking</th>
<th>Effective Thinking</th>
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<tbody>
<tr>
<td>Who did it?</td>
<td>What happened? Why?</td>
</tr>
<tr>
<td>Punitive</td>
<td>Fair and just</td>
</tr>
<tr>
<td>Bad people</td>
<td>Bad systems</td>
</tr>
<tr>
<td>Penalize the reporter</td>
<td>Thank the reporter</td>
</tr>
<tr>
<td>Confidential</td>
<td>Transparent learning</td>
</tr>
<tr>
<td>Investigation</td>
<td>Root cause analysis</td>
</tr>
<tr>
<td>Independent silos; no/little communication</td>
<td>Inclusive and interdisciplinary team; lots of communication</td>
</tr>
</tbody>
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“Right” Culture Requires Shift in Thinking

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<thead>
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<tr>
<td>Thinking errors are rare</td>
<td>Realizing errors are everywhere</td>
</tr>
<tr>
<td>Great care</td>
<td>Great care in a high-risk environment</td>
</tr>
<tr>
<td>Lack of direction; staff make it up as they go along</td>
<td>Principles of fair and just culture, guidelines algorithms, flow charts</td>
</tr>
<tr>
<td>Risk of disclosure/confidentiality</td>
<td>Moral duty, risk of non-disclosure</td>
</tr>
<tr>
<td>Great staff; poor systems</td>
<td>Great staff; great systems</td>
</tr>
<tr>
<td>Deliver care to patients</td>
<td>Partner with team, patients and families</td>
</tr>
</tbody>
</table>

“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


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.

Planning Guidance

Lab Preparedness During the COVID-19 Pandemic

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

MAKE
things
Happen

RIGHT
Superheroes!

Thanks to all of you!