What We Hear From You! Your Most Frequently Asked Questions Answered

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2020 Laboratory Roundtable Virtual Event
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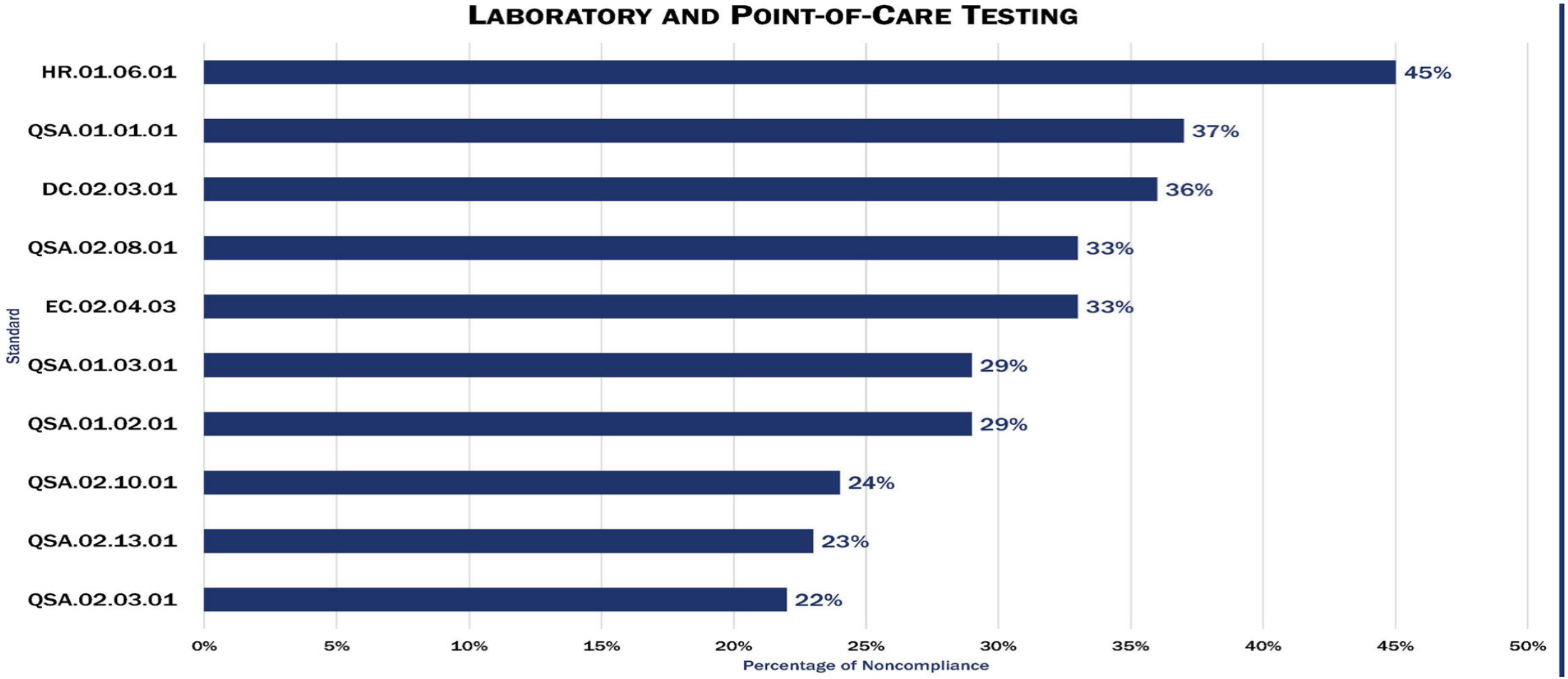
The Joint Commission

Objectives

- Identify top questions to Standards Interpretation Group (SIG)
- Discuss ways to meet competency issues
- Provide tips on how to address standards
- Discuss what is the risk of harm to patients and staff

Top Ten 2019 and so far in 2020



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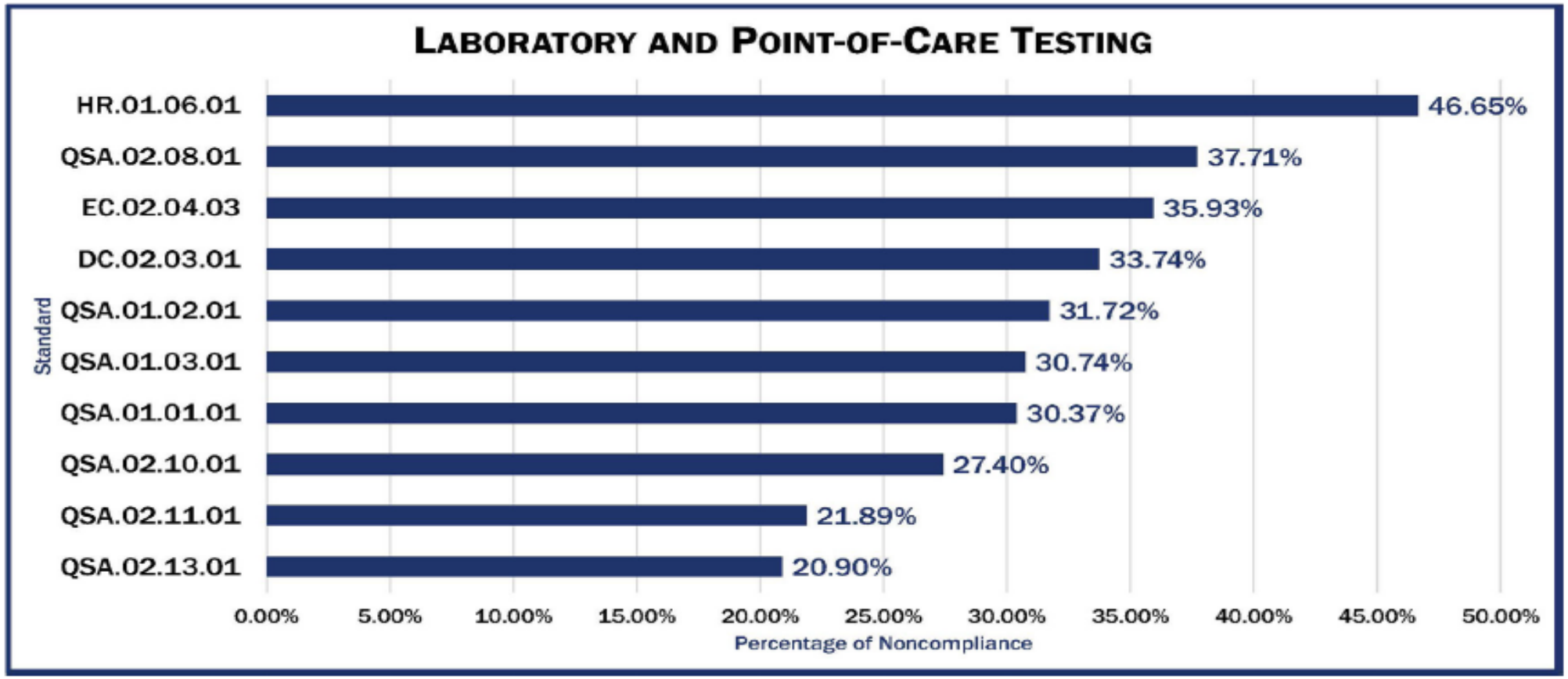
Top Ten 2018



Note: *The data included for the laboratory program were derived from an average of 721 applicable surveys.*

Survey Analysis for Evaluating Risk™ (SAFER™)

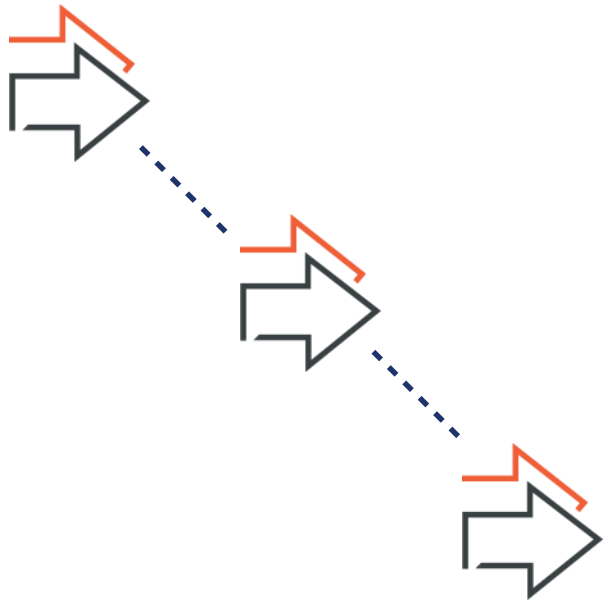
- A transformative approach for identifying and communicating risk levels associated with deficiencies cited during surveys
- Helps organizations prioritize and focus corrective actions
- Provides one, comprehensive visual representation of survey findings
- Implemented: January 2017

Survey Analysis for Evaluating Risk™ (SAFER™)

Risk

Likelihood to Harm a Patient/Staff/Visitor:

- Low: harm could happen, but would be rare
- Moderate: harm could happen occasionally
- High: harm could happen any time



Scope

- Limited
- Pattern
- Widespread

Aggregate SAFER™ Data

Requirements for Improvement (RFI) Distribution

For Full and Initial Laboratory surveys from 01/01/2019 through 06/30/2019 (n=380)

Likelihood to Harm Patient/Staff/Visitor	Immediate Threat to Health or Safety 0.00%			
HIGH	3.75%	1.64%	0.72%	6.11%
MODERATE	23.94%	21.32%	5.04%	50.30%
LOW	21.32%	17.04%	5.23%	43.59%%
	49.01% LIMITED	40.00% PATTERN	10.99% WIDESPREAD	
		Scope		

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Test Complexity

- Tests approved by FDA — assigns test complexity
  - Waived
    - CLIA waived does NOT mean CLIA exempt
    - FDA cleared does NOT mean CLIA waived
  - Moderate
  - High

- Test complexity determines personnel, Quality Control (QC), and inspection/accreditation requirements

HR.01.06.01 — the Number 1 Standard Questions

- Always in the top scored too
- Moderate Risk

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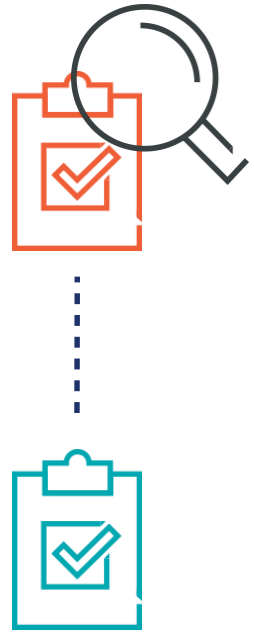
What We See Missing or HR.01.06.01

- Missing elements in competence assessment
- Competence assessment not done or late
- Competence performed by person who is not qualified according to CLIA
- Missed locations outside of the lab performing non-waived testing (POC and PPMP)



Who Can Do Competence Assessments?

- The Joint Commission follows CLIA subpart M
- Moderate complexity requires a Technical Consultant
- High complexity requires a Technical Supervisor or delegation to a general supervisor
- For moderate complex testing a TC cannot delegate to a general supervisor

Tips for Compliance

- Collect your data, observations all year long and assess at the annual due date.
- QSA.02.11.01 addresses a process to review results, quality control (QC), and so on. Use this information as part of your competence assessment program.

Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing.

- This observation can be made at any time during the one-year assessment period.
- Many supervisors randomly watch staff perform testing and document acceptability of such testing.

Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing.

- Incorporate as part of rounding
- Have the person performing the assay from receiving the sample through the release and filing of results in the LIS
- Was appropriate QC used? Was the expiration checked? Was QC stored correctly?
- Follow P&Ps for delta checks and critical result reporting

Monitoring, Recording, and Reporting of Test Results

- This is best performed across the assessment period.
- QSA.02.11.01 requires daily review of patient results. If an employee exhibits issues with recording and reporting results, these issues will be evident if the records reviewed cover all testing personnel.
- Daily review of results
- Pull the results of the person for review. Routine review can often reveal issues related to competence — investigate.

Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance

- All these records require regular review throughout the assessment period. If an employee exhibits problems with any of these activities, notation can be made over the course of the year.

Direct observation of performance of instrument maintenance function checks and calibration.

- Observation of these functions can occur at any time during the assessment period. Performance can be noted.

Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)

- Records can be maintained of proficiency test results, blind testing sample results, or the results of previously analyzed specimens throughout the year.

Problem-solving Skills as Appropriate to the Job

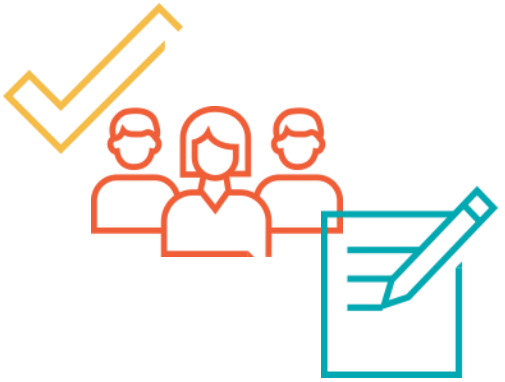
- When there are QC problems or instrument function problems or specimen acceptability problems, the ability of an employee to resolve these problems can be noted. Some laboratories develop a test with examples of problems for the employee to resolve.

Assessment

- Now take all the data and assess by qualified person per CLIA

Tips for Compliance

- Check your state regulations for laboratory personnel
- Work with your Human Resources department
- Written Documentation Checklist



Competency Requirements Tip Sheet

TIP: Competency Requirements

Joint Commission Requirement	Nonwaived Testing including PPMP	Waived Testing
Methods	Use 6 methods (if applicable) 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of quality control performance by each user 4. Problem-solving skills 5. Direct observation of instrument checks 6. Monitoring result reporting	Use 2 of 4 methods 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of quality control performance by each user 4. Written test
Initial Training and Annual Assessment	Yes Semiannual in the first year	Yes
Signatures	Both the director/supervisor/consultant *and* the employee must sign that the individual has received training and is competent prior to performing testing independently.	No signature is required, but the director/designee must assess competency.

*table available on page WT-12 of the January 2020 CAMLAB

QSA.02.08.01

- Correlations
- Moderate risk
- Fourth commonly scored from Joint Commission survey

What We See for QSA.02.08.01

- Not done every six months or at all
- Failure to correlate automated and manual differentials
- Failure to correlate POC or ER with main lab
- Data collected but failure to be reviewed
- Lacking criteria for acceptability
- What samples to use

Tips for Compliance

- Check all your methods
- Make a schedule/reminder
- Do it along the way

Waived Testing

- SIG gets lots of questions for waived testing across all programs
- On and off the most frequently standards list
- Low to moderate risk

CLIA Certificate

- Each physical address must have its own CLIA certificate
  - Exceptions decided by state CMS office; certificate will specify multisite or mobile (not common):
    - Contiguous buildings on hospital campus
    - Certain nonprofit, public health testing
    - Mobile laboratories

- Lack CLIA certificate
  - Connected to PDA decision rule

Point-of-Care Tests (POCT) but not waived

- PPMP
  - Fern, KOH, Wet Prep
  - Urine Microscopic
- Non-waived
  - iSTAT
  - ABG analyzers
  - ACT analyzers
  - TEG
  - Mohs Testing
  - AmniSure

Policy and Practices for Waived Tests

- The Joint Commission currently surveys manufacturer suggestions and recommendations as requirements.
- Confirmatory testing, QC, temperatures requirements, and so on.

WT.03.01.01 – Competence

- For instrument-based waived testing
  - Staff must have specific training and documented competency for that instrument
  - Includes ALL testing personnel
  - Glucose meters, Coaguchek, Clinitek 100, DCA 100

- Competency assessed at time of orientation and at least once every year for each WT
  - Different from hospital HR standards, which generally allow triennial competency assessment
  - Can we assess just the high-risk and low-volume tests? No.
  - Can we alternate which tests we assess each year? No.

Methods to Assess Waived Competence

- Methods to assess current competency must include at least two of the following:
  - Performing a test on an unknown (blind) specimen
    - Unknown = has a known value which is not known to the testing personnel
  - Direct observation of routine testing
  - Monitoring each user's quality control performance
  - Written testing specific to the method assessed

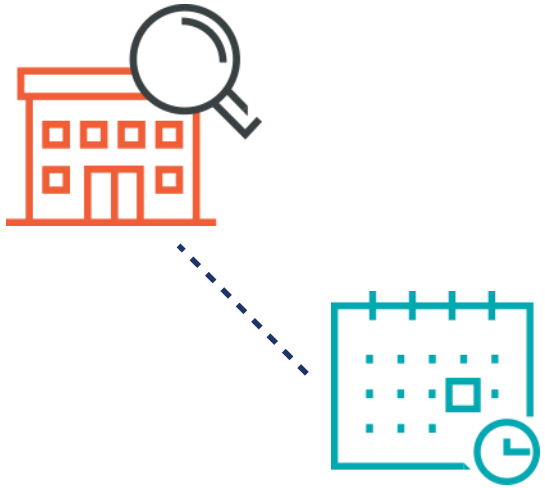

Non-instrument-based Waived Tests

- Competence still required for staff BUT there is one exception
  - For credentialed staff (physicians, LIPs), privileging process may be used in lieu of competency assessments if **non-instrument** waived test that is within their scope of practice
  - Common for occult blood

Remember PPMP is not a waived test; you must do full lab competence with six methods.

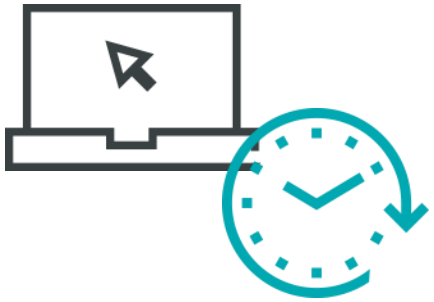
Tips for Compliance

- Check all your locations
- Check medical records for test results
- Make a schedule/reminder
- Work with all locations and individuals doing waived testing



COVID-19

- The Joint Commission has resources on its website
- Office hours
- CDC and FDA



Remember this is only during the period that the Emergency Use Authorization (EUA) is effective.

CMS Waivers

Currently CMS/CLIA has not allowed any waivers for competence, calibration verifications, correlations, and so on.

Therefore, at this time The Joint Commission has not been notified that CMS/CLIA has changed any requirements for compliance with CLIA/Joint Commission standards.

Please note that The Joint Commission is working with CMS/CLIA and any changes will be made available on the Joint Commission's website.

Will This be Part of our Lab Survey?

- If the Public Health Emergency is in effect at the time of the survey, COVID-19 testing will be reviewed to determine that there is a valid CLIA Certificate and that there is compliance with all of the manufacturers' instructions.

- If the Public Health Emergency and Emergency Use Authorizations have been rescinded, COVID-19 testing will be included in the survey process and surveyed to the standards relating to the complexity assigned by the FDA. Those methods without complexity assignments will be surveyed as high complexity Laboratory Developed Tests.

Complexity of COVID Testing

- The settings in which an EUA-authorized test may be used are described in the Letter of Authorization. When the FDA authorizes point of care tests (including SARS-CoV-2 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance.

- *FDA website has the list*

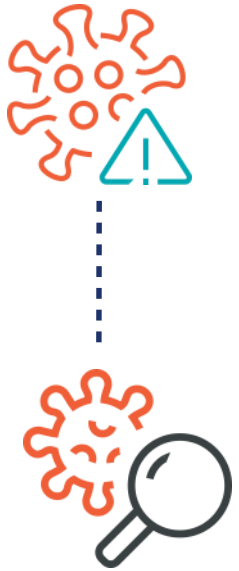
Method Validation for COVID Tests

- 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:
  - If the laboratory is using a CDC-developed Emergency Use Authorization (EUA) assay, the instructions provided with the procedure must be followed.
  - If the laboratory is using an 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 EUAs are rescinded, laboratories must validate methods as required for the complexity of testing.

Quality Control for COVID Testing

- 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 EUAs are rescinded, laboratories must perform quality control as required for the complexity and specialty of testing.

PT for COVID Testing

- Any test granted Emergency Use Authorization by the FDA does not require proficiency testing (PT) because these tests have not been classified by the FDA as waived or non-waived nor have CLIA specialties been assigned.

- Any regulated analytes that required PT testing prior to the Public Health Emergency declaration continue to require proficiency testing.

Covid-19 Reporting Test Results

- Beginning on October 15, 2020, all CLIA-certified organizations that perform or analyze any test intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report all positive and negative test results to the appropriate state or local public health department.
- These new CLIA requirements apply to all laboratories performing SARS-CoV-2 testing, regardless of the type of CLIA certificate issued (Certificate of Accreditation, Compliance, Register or Waiver, and Provider-Performed Microscopy).
- However, if specimens are referred to another laboratory for testing, the testing laboratory is required to report results.

Resources at The Joint Commission

- *Comprehensive Accreditation Manual for Laboratory and Point of Care Testing*
- Account Executive (AE)
- *The Joint Commission Perspectives*
- Standards FAQs
- Standards Interpretation Group (SIG)
- On-site Laboratory Surveyor

Resources

- Test complexity/FDA site; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm

- Centers for Medicare and Medicaid Services (CMS) www.cms.hhs.gov/clia

Resources for COVID

- The Joint Commission: https://www.jointcommission.org/covid-19/?utm_source=TJCWebsite&utm_medium=Slider&utm_campaign=TJCCovid-19
- CDC : https://www.cdc.gov/coronavirus/2019-ncov/index.html
- FDA : https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices

THANK YOU

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Questions ?