Laboratory Services Accreditation

Check in with The Joint Commission.

July 18, 2023

The Joint Commission

What We'll Cover Today –

What current laboratory services customers need to know:

- Learn about standards changes
- What's new or trending in survey process for laboratories
- Most commonly asked questions and RFIs

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Today's Laboratory Services Experts

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Standards Update for Laboratory Services

Department of Standards and Survey Methods Laboratory Updates

CMS

- On May 3, 2023, CMS announced that the Proficiency Testing Final Rule (CMS-3355-F) requirements effective July 11, 2024, will be implemented on January 1,2025:
- https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/administrative/implementation-notification-final-rule-cms-3355-f-clinical-laboratory-improvement-amendments-1988
  (§§ 493.2 and 493.801 through 493.959)
- The final rule in its entirety may be viewed at https://www.federalregister.gov/.
- CMS memo summarizing the new requirements: QSO-22-21-CLIA
- Any Joint Commission Standards revisions/deletions/additions will therefore also be implemented on January 1, 2025.

Department of Standards and Survey Methods Laboratory Updates

29 New Analytes added to subpart I

CLIA Regulation	Analytes
General Immunology § 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry § 493.931	B-natriuretic peptide (BNP) Pro-BNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T

Department of Standards and Survey Methods Laboratory Updates

29 New Analytes added to subpart I (continued)

CLIA Regulation	Analytes
Endocrinology § 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactin Parathyroid hormone Testosterone Vitamin B12
Toxicology § 493.937	Acetaminophen, serum Salicylate Vancomycin

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5 Analytes deleted from subpart I

- LDH isoenzymes
- Ethosuximide
- Quinidine
- Primidone
- Procainamide (and its metabolite, N-acetyl procainamide)

Department of Standards and Survey Methods Laboratory Updates

What's New July 2023 *CAMLAB*

Minor editorial revisions to most chapters in *CAMLAB* to be consistent with current terminology used by CMS which better reflects the full scope of practice of licensed practitioners allowed by their license and permitted by state and federal law and regulation while keeping the intent of the requirement.

Out:

Licensed independent practitioner

Practitioner

In:

Licensed practitioner

Provider

Department of Standards and Survey Methods Laboratory Updates

Standards Simplification Project

- Revised/consolidated/deleted approximately 100 standards through committee work involving DSSM/SIG/ACO/Surveyors.
- Vast majority just consolidated.
- Look for complete information in Joint Commission Pre-Publication and July *Perspective* Articles.
- Implementation Date August 27, 2023.

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Checking in with Survey Process

End of PHE - Recovery…

- We understand that the COVID pandemic had a significant impact on your staffing and laboratory resources.
- We want to continue our partnership with you, our customers and colleagues, to assist you to re-focus priorities in your labs, processes that might have delayed or dropped off during the pandemic.
- We have broad experience and can help you on your journey to excellence and zero harm.

Current Trends

- COVID exacerbated the short staffing situation and impacted the laboratory's ability to maintain good lab practices, effectiveness, and efficiency.
- Human errors are increasing due to staff burnouts and short staffing.
- Unsuccessful Proficiency Testing (PT) and lack of robust investigations and corrective actions are seriously impacting patient care.

Top 10 RFIs related to Proficiency Testing

Standard & Element of Performance (EP)	EP Text
QSA.01.01.01 EP 6	The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation.
QSA.01.02.01 EP 2	The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action
QSA.01.03.01 EP 7	The laboratory staff who performed the proficiency testing along with the laboratory director sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens.

PT Result Review and Investigation – Pre-Analytic

Examples of Pre-Analytic Phase Questions

- Were the PT provider's instructions followed?
- Were the PT kit and all reagents received, stored, and treated according to instructions?
- Were the PT specimen resting too short/too long at room temperature prior to testing?

Common pre-analytic error:

- Specimen handling issues

Suggestions:

- Upon receipt, inspect the integrity of PT material
- Review PT specimen instructions for each shipment prior to testing, this information might change shipment to shipment
- Follow PT instructions for specimen handling
- Have testing personnel follow the proper specimen identification process when testing PT specimen

PT Result Review and Investigation – Analytic

Examples of Analytic Phase Questions

- Is there QC/calibration/correlation issues before and after testing of PT?
- Is there instrument issues before and after testing of PT?
- Is there a documented competency assessment of the individual performing the test?

Common analytic error:

- Instrument issues
- Staff competency

Suggestions:

- Look at a continuous time frame for QC/calibration/correlations, not just the day of PT testing
- Ensure proper training and competency are established for testing personnel

PT Result Review and Investigation – Post-Analytic

Examples of Analytic Phase Questions

- Were there clerical/transcription errors in reporting the results?
- Were there calculation/unit conversion in the testing phase?
- Are the results in the correct format/units required by the PT provider?
- Are the results in the correct method code required by the PT provider?

Common post-analytic error:

- Clerical / Transcription error

Suggestions:

- Interface with LIS and automatic transmission to the PT provider.
- Have a review process for test information.

How to Use Unsatisfactory PT as Lab Improvement

- Monitor and trend the reasons for unsatisfactory PT
- The cause of unsatisfactory PT might indicate a process issue

Example of Unsatisfactory PT	Potential Process Issue
Running the wrong PT specimen	Specimen identification process (downtime or manual test)
Staff competency	Staff competency, especially on low volume/high risk test (such as gram stain, manual fluid count…etc.)
Clerical / Transcription	Manual test result reporting

General Update/Information

COVID-19 vaccination

- The Joint Commission is no longer evaluating compliance with the COVID-19 vaccination requirement.
- While the standard will remain present in the current manual, surveyors have been advised not to evaluate for compliance. The database will be updated and be reflected in the next standards release later this year.

Laboratory Roundtable

- Complimentary laboratory education event
- September 27th & 28th, 2023

The Joint Commission

Standards Interpretation Group

2022 Top Ten Laboratory Standard Observations

Number	Standard and Element of Performance	Requirement
1	QSA.01.02.01 EP 2	Documented corrective action for proficiency testing
2	QSA.02.08.01 EP2	The laboratory performs correlations every six months to evaluate the results of the same test performed with different methodologies or instruments or at different locations.
3	QSA.02.11.01 EP7	The laboratory performs review of other records (work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented.
4	HR.01.06.01 EP18	Non-waived competency assessment includes the required six elements.
5	NPSG.02.03.01 EP2	Implement the procedures for managing the critical results of tests and diagnostic procedures.
6	EC.02.04.03 EP7	The laboratory performs preventive maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.
7	HR.01.06.01 EP3	An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence for non-waived testing.
8	HR.01.06.01 EP20	After the first year of employment, each staff member's competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.
9	LD.04.05.07 EP4	The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.
10	QSA.05.18.01 EP7	The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood administration.

–Topics for today

- QSA.01.02.01
  -QSA.02.08.01

- -End of Public Health Emergency (PHE) but not Emergency use Authorizations (EUA)

Number one most score standard is QSA.01.02.01 EP 2

The standard requires documentation of corrective actions for PT unacceptable results.

It’s more than unsatisfactory or unsuccessful

The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action for the following:
-Individual unacceptable proficiency testing results
-Late submission of proficiency testing results (score is zero)
-Nonparticipation in the proficiency testing event (score is zero; see Note 2)
-Lack of consensus among all laboratories participating in the proficiency testing event (score is ungradable)
These actions are documented.
Note 1: This requirement also applies when the laboratory’s cumulative score for the event meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) requirements for satisfactory performance.
Note 2: Consideration may be given to laboratories failing to participate in a testing event when all the following occur:
- Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results
- The laboratory notifies The Joint Commission and the proficiency testing program provider within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples
- The laboratory participated in the previous two proficiency testing events (See also QSA.01.01.01, EP 5)

80-99

- Remember that you need corrective action on all unacceptable proficiency test results.

- Unacceptable = Anything less than 100%
- Need to review the 80% or better.

No consensus

- PT events with fewer than 10 participants need review and actions
- PT events ungraded need review and actions

Homework

- Record keeping is key for compliance

- Review your processes for your PT review as well as your documents for corrective actions

Correlations

Still on the top ten and moving up.

There are two criteria in the Joint Commission standard QSA.02.08.01 EP 2.

CLIA numbers and the patient population.

More than different CLIAs

- Even if different CLIA numbers if the patient population is the same correlations would be required.

Patient Populations

1. Do the results get entered into the clinical record at the main facility and are clinical decisions based upon those results?

If “yes” the population is not distinct. It’s the same population and correlations are needed.

2. Does the clinic use the main laboratory as a routine backup when instrumentation is down, or when there is insufficient staffing, or during hours when the clinic lab is closed?

If “Yes” the population is not distinct and separate. Correlations are needed.

Homework

Check your testing sites and how those results are used.

The PHE is over but not EUAs

- The U.S. Food and Drug Administration (FDA) has stated that an EUA declaration is distinct from, and not dependent on, U.S. Department of Health and Human Services (HHS) PHE declaration under section 319 of the Public Health Service (PHS) Act, and, therefore, an EUA may remain in effect beyond the duration of the section 319 PHE declaration if all other statutory conditions are met.

EUA still in place

- EUAs may remain authorized and new EUAs may continue being issued (and they have) so long as the applicable EUA declaration and determination remain in effect
- The EUA authorization continues until the test is approved and categorized by the FDA or the FDA ends its 564 emergency declaration.
  - The FDA has indicated they will give 6 months' notice if they end their declaration.
  - FDA will list the expiration date of each EUA assay in the Federal Register and on the FDA Website six (6) months prior to the expiration of the EUA for that test.

Homework

- Keep checking the FDA website and with your manufacturers on changes
- More information on this topic can be found on the FDA website using the search FDA EUA Expiration.
- Remember if the FDA decides not to classify a method and you wish to use that test, it will be a Lab developed test (LDT) that defaults to high complexity.

Wrapping Up

2023 Laboratory Roundtable

- Join us virtually for a complimentary insight-packed event focused on improving laboratory quality and safety and strengthening the patient experience.

- Learn more and register at 2023 Roundtable

The Joint Commission

Thank you for joining us.