What’s New and Improved for the Laboratory Program in 2013
April 23, 2013

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Associate Director
Standards Interpretation Group

Stacy Olea MBA, MT(ASCP), FACHE
Field Director
Objectives

- Learn the new and revised standards that go into effect on July 1, 2013
- Identify how Lab Central Connect will be used in your survey
- List the available resources for your organization
Laboratory Standards Changes
Effective Date July 1, 2013

• 12 New Requirements
• 18 Revised Requirements
• 3 Deleted Redundant Requirements
Process

- Evaluation began August 2011.
- 33 changes submitted for six week field evaluation in June 2012.
- Pilot testing at four medical centers July 2012.
Process (cont.)

- Changes reviewed by Laboratory Professional and Technical Advisory Committee consisting of representatives of major laboratory professional associations.

- Changes approved by Standards and Survey Procedures Committee of the Board of Directors.
Appendix B

- Addresses Laboratory Developed Tests (LDTs)

- The U.S. Food and Drug Administration (FDA) defines LDTs as “a class of in vitro diagnostics that are manufactured, including being developed and validated, and offered, within a single laboratory.”
Appendix B (cont.)

- LDTs are currently CLIA-regulated by both proficiency testing and quality control testing requirements.
- Laboratory Developed Tests are Highly Complex procedures.
QSA.02.01.01 EP 2

- Language change to align with CLIA regulation 42 CFR 493.803.
- Basic requirement for remedial action is unchanged.
- Reference CLIA Brochure #8
CLSI Documents

- 6 footnotes referencing CLSI documents.
- Footnotes are NOT requirements.
- Purchase of CLSI documents is not required.
- References provide as guidance to best practices.
Added procedure requirement - “Precautions for specimen collection, including preventing cross-contamination of primary samples and sample portions shared between testing centers.

Reference : 42 CFR 493.1232
Note: Only the staff authorized by the organization to perform laboratory tests are allowed to modify laboratory test results in a patient’s clinical record.

Emphasizes data ownership in LIS.
Added requirement to validate middleware.

Currently more than 15 middleware systems.

Reference: CLSI document AUTO03-A: Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems
Review of unmodified procedures required every two years.

Reminder: Procedures may be reviewed by the laboratory director or designee with the exception of immuno-hematology procedures which must be reviewed by an individual qualified as a technical supervisor in immuno-hematology.
Added to include ISO definition of quality management system. ……

“a management system to direct and control an organization with regard to quality.”

QSA.02.13.01 EP 9

- Requires documentation of the verification of water quality.

- Certificates of Analysis acceptable.

- Certificates must cover all water quality specifications for procedures.
QSA.04.02.01 EP 4

- Added language “.. and on each new batch of media, and on each new lot number and shipment of antimycobacterial agents(s). ”

- Aligns with language of CLIA Regulation 42 CFR 493.1262.
All stool specimens from patients diagnosed with acute community-acquired diarrhea are simultaneously cultured for O157 Shiga toxin-producing Escherichia coli (STEC) on selective and differential agar and assayed for non-O157 STEC with a test that detects Shiga toxins or the genes encoding these toxins.
Testing may be performed at a reference laboratory.

Reference October 16, 2009 MMWR: http
QSA.04.07.01

- Requires written policies and procedures for the collection, transport, processing, and interpretation of blood cultures.

- EP 1 Define volume of specimen based upon approved clinical guideline (CLSI M44-A), manufacturer’s requirements, and instrument specifications.
QSA.04.07.01 (cont.)

- EP2 Specifies frequency of inspection of manual blood cultures and documentation of inspection results.
- After twelve to twenty-four hours of incubation at 35°C
- Twice daily for days one and two
- Daily for days three to seven
QSA.04.07.01 (cont.)

- Procedures for manual blood culture are required when used as a back-up to an automated system.

- If both automated and manual systems are used, correlations must be performed every six months (QSA.02.08.01)
QSA.04.07.01 (cont.)

- EP 3 requires guidelines for the collection, transport, and processing of blood cultures to minimize contamination and support infection prevention and control activities.

- Incorporate results of PI activities relating to blood culture contamination.
Requires the definition of staff responsible for the provision of blood, blood components, tissue, derivatives, and services.

Include contracted staff providing services within the organization.
For contracted labs specify the director, technical supervisor(s), and general supervisor(s).
QSA.05.14.01 EP 8

Deleted – Redundant with QSA.05.09.01 EP 4
QSA.05.14.03  EP 8

- Requires written policies and procedures which address the transfusion of plasma components containing a significant amount of incompatible ABO antibodies or unexpected red cell antibodies.

Requires policies and procedures for neonatal transfusion.

If the organization does not perform neonatal transfusion there must be a policy to address emergency transfusions and for patient referral.
QSA.07.01.01 EP 2

- Requires defined system to address handling, testing, and reporting urine specimens that exceed stability requirements (for example, room temperature urine more than two hours old and refrigerated urine more than four hours old).

- More specific language.
QSA.07.01.01 EP 3

- Requires guidelines and policies to test pediatric urine specimens for reducing substances.
- Assess the clinical need of patient population.
- Policy based on clinical needs assessment
Minor language change. No change in requirements or intent.
The laboratory determines the causes of any cytology discrepancies when comparing the following: A current HSIL, adenocarcinoma, or other malignant with... Replace “histopathology report” with “previous(normal or negative) gynecological specimens from the previous five years.
QSA.08.06.01 EP 2

- Replace “cytotechnologist” with “primary screener”

- Clarify the need to select a minimum of 10% negative GYN cytology cases for quality control.
Clarify the need to correlate nongynecologic cytology findings with histopathology findings.
QSA.08.07.01 EP 1

Clarify that an individual qualified as a cytology technical supervisor (no need to have the title assigned by the organization) reviews and confirms all nongynecologic cytology slides.
QSA.08.08.01 EP 1

Clarifying language relating to the use of standardized nomenclature. No change in requirement or intent.
New standard addressing quality control requirements for chromosomal microarray analysis to include:

1. Probe specificity
2. Assessment of genomic copy number
3. Assay resolution
4. Study limitations
The laboratory interpretive reports for cytogenetic testing include the following information: Band resolution for constitutional cases.
Hematology-specific QC requirements removed.

Requirement moved to QSA.02.10.01 EP 3.

1. Two levels of quality control each day of testing.
2. Levels should cover clinically significant portion of reportable range.
QSA.11.02.01 EP10

- Requires policy and procedure relating for collection of plasma-based coagulation specimens.

QSA.13.04.01 EP 10

- Requires cancer pathology reports in synoptic format.

- Reference: Ensuring Patient-Centered Care by the Commission on Cancer of the American College of Surgeons
Requires the evaluation of semen specimens to be based on approved clinical guidelines. The results are documented.

Lab Central Connect
Why Did We Build This Site?

- Provide a lab-central portal that allows lab users to directly enter their technical information; this replaces e application entry.
- Make survey preparation and process more efficient by storing relevant documents in a central spot that surveyors can access.
- Have a repository available for intracycle monitoring (the new form of PPR) as desired.
- Focus on resolving high risk areas for the lab.
Timelines

- August 21, 2012- site released to all customers at no additional charge
- January 1, 2013- required information must be available by your next full 2013 or 2014 survey to be in compliance

Completed enhancements
- Bulk upload for personnel
- Test Systems manual test entry

In development – Proficiency Testing Summary

Ongoing
- submit updates on Lab Director, test systems.
- Laboratory Operations
- ICM
Required Information

- Personnel for each CLIA:
  - Laboratory Director
  - Technical Consultant (moderate complexity)
  - Technical Supervisor (high complexity)
  - General Supervisor (high complexity)
  - Clinical Consultant (moderate and high)

- Test Systems for each CLIA

- Are you accepting outside specimens for testing?

- Cytology
  - Workload for all personnel performing primary screening
  - Annual statistics
Reviewed Before your Survey

- Does your laboratory accept referral specimens?
- Personnel
- Test Systems
- Cytology: workload and annual statistics
- Document Repository
- Laboratory Operations
Lab Central Connect
Does your laboratory accept referral specimens?
# Personnel List

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<thead>
<tr>
<th>FIRST NAME</th>
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Personnel Education and Experience

Positions Held:
- Laboratory Director
- Laboratory Staff
- Technical Consultant
- General Supervisor
- Other

Highest Education Level Attained:
- MS/MA

Professional Area:
- Medical Technology

Are you licensed/certified in professional area?:
- Yes

Complexity Testing

Waived Testing Only? No

PPMP Only? No

Moderate Complexity Testing

Do you perform moderate complexity testing? Yes

20 CME in laboratory director responsibilities or equivalent training in residency? No

Experience performing, directing, or supervising moderate complexity testing: 7 years 2 months as of 4/15/2013

High Complexity Testing

Do you Direct/Perform/Supervise high complexity testing? Supervise

If you direct, supervise, or perform high complexity tests, fill in your experience (include laboratory internships):

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>> Add Another
### Education Documentation

#### Document Repository:

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Diploma

University Diploma

Master of Science in Clinical Laboratory Science

Awarded to Suzie Smyth
### Test Systems - FDA

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Test Systems:

This is the Test Systems feature in Lab Central. This area allows you to create/view a list of the various Test Systems you are running in your Laboratory. You can Add Tests and remove them over the course of time using this feature. This will serve as your test analyzer list for The Joint Commission rather than the e application.

Please note that entry of waived testing is optional, although you may choose to enter those systems if you elect to utilize the operations modules in Lab Central.

For helpful hints on entering Test Systems and answers to the most frequently asked Questions, please see our website. You can access by clicking this link: Helpful Hints: Test Systems.

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### Document Repository

**Survey Docs**

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- **POCT Staff**
- **CLIA/State License**
- **Proficiency Testing**
- **Cytology**

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Cytology
Workload and Annual Statistics

Cytology Workload for Sara Slide

Cytology Annual Statistics
Proficiency Testing
PT Investigation

PT investigation Bilirubin Event 1 2012
CLIA Certificates and Licenses
CLIA Certificate
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Document Repository:

Search By Keyword:

Filter by Tag:

Competency

Add Document

DATE | DOC NAME | DESCRIPTION | TAG | ACTIONS
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Competency Documentation

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# Document Tags

Document Repository:

**Survey Docs**
- Employee
- POCT Staff
- CLIA/State License
- Proficiency Testing
- Cytology

**Search By Keyword:**

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- CLIA License
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- Correlations
- Education
- EOC/Safety
- Evaluations
- Org chart
- Orientation
- PI
- PT Attestation
- PT Remedial Action Unsatisfactory
- PT Remedial Action Unsatisfactory
- Safety
- Workload

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Correlations

Chemistry Correlations January 2012
Welcome

This is the Lab Operations Tool Suite. This Tool Suite is geared toward providing you with a set of Modules you can use to help manage your daily Laboratory activities. Competency Assessment Tracking, Inventory Management, Equipment Management, Environmental Monitoring documentation, QC documentation, and Data logging tools are all provided here.

Competency
- Keep track of your Competency Assessment testing schedule.
  - Personnel Tracked: 2
  - Status Overview:
    - 3
    - 0
    - 0
    - 0
    - 5
    - 0

Inventory
- Record and store data on any testing materials and supplies.
  - Total Items: 0
    - ADD an Item >>

Equipment
- Document any equipment (e.g., analyzer, etc.) that you want to track.
  - Total Items: 1
    - ADD an Item >>

Environmental
- Record temperature/humidity of any laboratory locations that require close attention.
  - Locations Monitored: 0
    - ADD a Location >>

Quality Control
- Document & report on Quality Control procedures within the Laboratory.
  - Total Items: 0
    - ADD a Control >>

Logs
- Record and report on critical data for a variety of logging types.
  - Total Items: 0
    - ADD a Log >>
Resources
Take 5 with The Joint Commission Podcast Series

Monday April 8, 2013

Hear the first podcast in the Take 5 series. Pat Adamski, director of The Joint Commission’s Standards Interpretation Group, talks about alarm safety challenges and offers practical advice.

Listen to podcast
Accreditation – Laboratory Services

Laboratory Services Accreditation

Why Should Pathologists Consider Joint Commission Lab Accreditation?

Reasons pathologists should choose Joint Commission accreditation: Learn More

Download PDF

Accreditation Information

- 2013 Survey Activity Guide
- Calculating your Lab Application Due Date
- Tracer Methodology 101
- From Survey Report to Accreditation Decision

Forms

- Laboratory Organization Update Form
- Standards Online Question Form

Labs: Claim your rightful place as partners in patient safety
### Previous Teleconferences

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<th>Topic Library Resources</th>
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<td>Slides from the September 12, 2012 Webinar: Introducing the new Joint Commission Lab Central Connect Portal</td>
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Standards Information
Standards FAQs

Select a manual to view FAQs. Want to be alerted to updates to the Standards FAQs? Sign Up. The Joint Commission standards are NOT available on this website. The standards are available in print and electronic formats and can be purchased from Joint Commission Resources.

Laboratory Services (CAMLAB)

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Standards Online Question Form

Do You Have a Question about Joint Commission Standards?

There are four options for submitting questions.

1. **Online form**
   Complete the [standards online question form](#). An e-mail response may require up to 5 business days.

2. **Telephone**
   Call the Standards Interpretation Group at 630-792-5900, 8:30 a.m. - 5:00 p.m. CT. All telephone inquiries will be responded to within two business days, not including weekends and holidays.

3. **Fax**
   Fax your question to 630-792-5942. A written response may require up to 5 business days from the time of receipt. All faxes must include the following:
   - Your full name
   - Name of your Health Care Organization
   - Manual(s) under which you are accredited
   - Full address including City, State and Zip Code
   - Phone Number (with time and date when you can be reached by phone)
   - Fax Number

4. **U.S. Mail**
   A written response may require up to 5 business days from the time of receipt. Send your question with the same information noted above to:
   - Standards Interpretation Group
   - The Joint Commission
   - Ono Renaissance Blvd.
   - Oakbrook Terrace, IL 60181

Thank you for your cooperation with these procedures.

We recommend that you browse the [standards FAQs section](#) of our website before submitting your question. The answer you are seeking may already be addressed.
Lab Central Connect

Lab Central Connect™ is the new customer portal which provides a convenient location to store all of your survey related documents. It provides standardized entry of information required on survey to minimize errors or surprises when the surveyors arrive.

Resources and Tools

- CLIA Personnel Requirements
- Lab Central Connect Frequently Asked Questions
- Lab Central Connect Helpful Hints

Questions about Lab Central Connect?

Contact:
Jennifer Rhamy, Executive Director
630-792-5754
jrhamy@jointcommission.org

Tuesday 4:10 CST, April 16, 2013
Resources Available to Joint Commission Accredited Laboratories
Educational Resources

Calibration Verification

The link below will take you to a video presentation regarding Calibration Verification. In addition to the video, there are slides and a script for you to customize to deliver continuing education customized to your own lab.

www.jointcommission-ims.org/downloads/LabCentral/Calibration-Verification/player.html

Laboratory Educational Resources:
Previous teleconference slides, CLIA Resources and News Releases.
http://www.jointcommission.org/accreditation/laboratory_educational_resources.aspx

Center for Transforming Healthcare:
Established in 2009, the Joint Commission Center for Transforming Healthcare aims to solve healthcare's most critical safety and quality problems.
http://www.centerfortransforminghealthcare.org

JCR Publications/Resources:
Joint Commission Resources has a vast array of products and services to help you with your accreditation needs.
http://www.jcrinc.com/LAB-Resources/
Lab Central Personnel Resources

Personnel:

The Personnel Section tracks pertinent laboratory staffing information. Contact information, complexity testing experience, and documents such as CE Certificates can be stored and managed here. Please complete staffing information for personnel in the following categories:

- Laboratory Director (if changed from who is currently listed)
- Technical Supervisor (high complexity)
- General Supervisor (high complexity)
- Technical Consultant (moderate complexity)
- Clinical Consultant (high and moderate complexity)

All other staff listings are encouraged, but optional.

For additional guidance, the following three resources are designed to help you complete the Personnel section:

- CLIA Regulations for Personnel
- Joint Commission Info Sheet
- Joint Commission Presentation on CLIA Requirements

To upload multiple contacts at one time, please use our bulk process by downloading the spreadsheet below:

- Bulk Upload Spreadsheet
- Bulk Upload User Guide
Lab Central Support Center

Resources

Lab Central Self Help Guide

This is the full version of the Lab Central Help Guide. The file size is almost 12MB and depending on your internet connection may take several minutes to open.

Still have questions about Lab Central Connect? Contact your Account Executive who will be happy to assist you. For general comments or concerns about Lab Central, you can send an email to qualitylabs@jointcommission.org

Helpful Hints Sheets

The Joint Commission has developed Helpful Hints Sheets to assist you with your data entry. There are two sheets: Test Systems Helpful Hints and General Frequently Asked Questions. The General sheet has information about referral testing, cytology workload and other subjects. To access the sheets, click below.

Lab Central Frequently Asked Questions: General
Lab Central Helpful Hints: Test Systems
Lab Central Support Center

Other Resources

Resources for the Clinical Laboratory

Industry Reference Documents for Laboratory Accreditation

Regulatory Information

Both state and federal regulators provide information about the Clinical Laboratory Improvement Amendments (CLIA) and related state laws. The Centers for Medicare and Medicaid Services (CMS) and individual State Health Departments are free sources for information on regulations and inspections.

Centers for Medicare and Medicaid Services (CMS)
www.cms.gov
877-267-2323

CLIA Program
www.cms.hhs.gov/clia

CLIA Regulations for Personnel
http://www.cdc.gov/clia/regs/subpart_m.aspx

CLIA Form 116: Application For Certification

Below is a link the FDA Biological Deviation Form.
www.fda.gov/downloads/AboutFDAReportsManualsForms/Forms/UCM061463.pdf

Occupational Safety & Health Administration (OSHA)
www.osha.gov
202-693-2100

Centers for Disease Control and Prevention (CDC)
www.cdc.gov
800-311-3435
Lab Central Support Center

Newsletters

There are several clinical laboratory magazines that cover topics in laboratory medicine.

Advance for Administrators of the Laboratory
www.advanceforal.com
800-355-6627

Advance for Medical Laboratory Professionals
www.advanceformlp.com
800-355-6627

American Association of Physician Offices and Laboratories
www.aapil.com
800-470-5605

Clinical Laboratory News
www.aacc.org
800-892-1400

Clinical Laboratory Strategies
www.aacc.org
800-892-1400

Medical Laboratory Observer (MLO)
www.mlo-online.com
941-959-9521

Phlebotomy Newsletter (Center for Phlebotomy Education, Inc.)
www.phlebotomy.com
812-633-4636

Physician Office Lab News
www.decisionhealth.com
877-397-1496

Professional Management Organizations
There are several organizations that focus on management of a clinical laboratory.

Medical Group Management Association (MGMA)
www.mgma.org
877-275-6462
## LEADING PRACTICE LIBRARY™ DOCUMENTS

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Targeted Solutions Tool

The View From The Joint Commission

By Mark G. Pellettier, R.N., M.S.

Get an inside look at the latest news in health care from Mark G. Pellettier, R.N., M.S., interim chief operating officer, in an environment which welcomes open discussion, sharing, questions, feedback and more.

Have you heard about the Targeted Solutions Tool™ (TST)?

Developed by the Joint Commission Center for Transforming Healthcare, the Targeted Solutions Tool™ (TST) is a unique online application that helps Joint Commission accredited organizations solve some of the most persistent health care quality and safety problems. The TST is easily accessible on Joint Commission Connect™, accredited health care organizations' secure extranet. The TST uses a step-by-step process to guide organizations in accurately measuring their actual performance, identifying their barriers to excellent performance, and then directing them to proven solutions that are customized to address each organization's particular barriers.

This free tool also provides tips for sustaining a comprehensive improvement process. The TST tool is currently available for three projects:
What's New and Improved for the Laboratory Program in 2013

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Standards BoosterPaks™

Quality Improvement Tools

Standards BoosterPaks™

- **NEW** - Use of Restraint and Seclusion for Organizations Using Joint Commission Accreditation for Deemed Status * (New - 2/14/13)
- Management of Hazardous Waste in Health Care Facilities *
- Environment of Care (EC.04.01.01, EC.04.01.03, EC.04.01.05) *
- Sample Collection *
- Suicide Risk (NPSG.15.01.01) *
- MM.03.01.01 *
- Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation (FPPE/OPPE) *

*Requires Adobe Reader*

FAQs about the BoosterPak

What is a BoosterPak?
A BoosterPak is a searchable document intended to provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or non-compliance scores in the hospital field.

The BoosterPak concept was developed as one method to address the issue of consistency of standards interpretation.

BoosterPaks contain:

1. Description of Standard and Implementation Suggestions
2. Frequently Asked Questions, Definitions, and Additional Information about Specific Topics
3. Supporting Documentation, Evidence, Value, Historical Information, and Additional References and Links
Review

✓ Learned the new and revised standards that go into effect on July 1, 2013
✓ Identified how Lab Central Connect will be used in your survey
✓ Listed the available resources for your organization
Questions