Time To Catch Up With CLIA

April 27, 2023 ASCLS-ND Spring Symposium

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Objectives

- Identify the most common CLIA deficiencies in ND
- Recognize the lab implications of the Public Health Emergency (PHE) discontinuance
- Evaluate CLIA hot topics

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Top Deficiencies -
01/01/21 through 03/01/23

➢D2016 Successful Participation in Proficiency Testing

- Labs performing non-waived testing must successfully participate in an approved proficiency testing program.

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Top Deficiencies -
01/01/21 through 03/01/23

➢D2096, D2118, D2107, D2130, D2181

Unsuccessful proficiency testing performance – failure to achieve a satisfactory score for:

✓Two consecutive events or
✓Two of three consecutive events

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Top Deficiencies -
01/01/21 through 03/01/23

➢D2096 Routine Chemistry
➢D2118 Toxicology
➢D2107 Endocrinology
➢D2130 Hematology
➢D2181 Compatibility Testing

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5421 Verification of Performance Specifications

- For each new test/method

✓Nonwaived
✓Unmodified

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5421

• Obtain performance specifications comparable to the manufacturer for:
✓Accuracy
✓Precision
✓Reportable Range
✓Verify Reference Interval

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5421

• Required for:
✓New testing platform
✓Addition of tests to existing platform
✓Qualitative tests

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Top Deficiencies -
01/01/21 through 03/01/23

➢D6076 Laboratory Director

• Laboratory director must:
✓Meet the qualification requirements
✓Provide overall management and direction

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5451 Control Procedures

• For tests with graded/titered results, include a negative control and one with graded/titered results each day of testing

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5447 Control Procedures

• For quantitative test results include 2 controls of different concentrations

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Top Deficiencies -
01/01/21 through 03/01/23

➢D6087 Laboratory Director Responsibilities

• Ensure tests are performed as required for accurate and reliable results
✓Correct ISI and Pt N Mean for INRs

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Top Deficiencies -
01/01/21 through 03/01/23

➢D6094 Laboratory Director Responsibilities

- Lab establishes and follows quality assessment P&Ps to assure quality and to identify failures

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Top Deficiencies -
01/01/21 through 03/01/23

➢D2000 Enrollment and Testing of Proficiency Samples

- Labs must test proficiency samples in the same manner as patient samples.
- Proficiency samples must not be sent to another lab for testing = PT Referral

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Top Deficiencies -
01/01/21 through 03/01/23

➢D2009 Testing Proficiency Samples

- Statements attesting the proficiency samples were tested in the same manner as patient samples must be signed by:

✓Lab director
✓Testing Personnel

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Top Deficiencies -
01/01/21 through 03/01/23

❖Attestation Statements

- Lab Director may delegate signing to:

✓Moderate Complexity – Technical Consultant
✓High Complexity – Technical Supervisor (pathologist for immunohematology)

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5217 Evaluation of Proficiency Testing Performance

- Twice annually verify the accuracy of non-regulated analytes

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5417 Test Systems, Equipment, Instruments, Reagent

- Reagents/supplies must not be used when outdated

✓Stain
✓Non-automated methods

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5439 Calibration Verification

- Required at least every six months
- After major preventive maintenance
- When reagents are completely changed
- Uncorrectable QC trends/shifts
- Lab's established schedule

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5439 Calibration Verification

- Exceptions

✓Calibrate with 3 or more calibrators (including low, mid, and high values) at least every six months

✓Automated cell counters with two levels of acceptable QC each day of testing

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5439 Calibration Verification

- Exceptions

✓Automated chemistry analyzers with three levels of acceptable QC more than once each day of testing

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5439 Calibration Verification

- Exceptions

✓Instruments factory/manufacturer calibrated

✓Tests considered non-quantitative (e.g. Protime, PTT)

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5439 Calibration and Calibration Verification

- Must follow the manufacturer's instructions

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Top Deficiencies -
01/01/21 through 03/01/23

➢D5551 Immunohematology

- For compatibility testing - must perform an IgM immediate spin compatibility test

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Impact of D/C PHE

Public Health Emergency ends on May 11, 2023

How does this affect:
- SARS-CoV-2 testing?
- SARS-CoV-2 reporting requirements?
- Emergency Use Authorizations for SARS-CoV-2 tests?

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Impact of D/C PHE

Requirements for SARS-CoV-2 testing

- Approved/categorized by the FDA or
- Have emergency use authorization (EUA)

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Impact of D/C PHE

Requirements for SARS-CoV-2 testing

- Follow the manufacturer's instructions
- Enforcement discretion for use on asymptomatic individuals

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Impact of D/C PHE

Requirements for SARS-CoV-2 test result reporting

- Effective August 26, 2020

- 493.41 [D1002] for waived labs
- 493.110(a) [D3000] for non-waived labs

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Impact of D/C PHE

Requirements for SARS-CoV-2 test result reporting as of 04/04/22

➢ CoW and PPM labs report:
- + antigen results
- + molecular (NAAT) results

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Impact of D/C PHE

Requirements for SARS-CoV-2 test result reporting as of 04/04/22

➢ Moderate/High Complexity labs report:
- + antigen results
- + molecular (NAAT) results if waived
- +/= molecular (NAAT) results for non-waived

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Impact of D/C PHE

Requirements for SARS-CoV-2 test result reporting

Will this be rescinded?

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Impact of D/C PHE

Emergency Use Authorization

- What happens to EUAs?

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Impact of D/C PHE

EUAs

- Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows FDA to issue EUAs
- FDA assurance

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Impact of D/C PHE

EUAs

- Not dependent on a PHE declaration
- SARS-CoV-2 EUAs will continue until the HHS (Health & Human Services) Secretary terminates

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Impact of D/C PHE

EUAs

- HHS will publish advance notice of termination 180 days prior
- FDA working with manufacturers to transition

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Impact of D/C PHE

❖Remote Review of Pathology Slides

✓Each location performing testing must have their own CLIA certificate

✓Enforcement discretion during PHE

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Hot Topics

Proficiency Testing Analytes Updated

- Effective July 11, 2024
- First update since 1992
- Final rule found at https://www.federalregister.gov/

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Hot Topics

Proficiency Testing Analytes Updated

- General Immunology
  - Anti-HBs
  - Anti-HCV
  - CRP (high sensitivity)

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Hot Topics

Proficiency Testing Analytes Updated

- Routine Chemistry
  - BNP
  - Pro BNP
  - CA125
  - Carbon dioxide
  - CEA
  - LDL Cholesterol (direct measurement)
  - Ferritin

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Hot Topics

Proficiency Testing Analytes Updated

- Routine Chemistry cont.
  - GGT
  - Hgb A1c
  - Phosphorus
  - PSA, total
  - TIBC (direct measurement)
  - Troponin I
  - Troponin T

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Hot Topics

Proficiency Testing Analytes Updated

- Endocrinology
  - Estradiol
  - Folate, serum
  - FSH
  - LH
  - Progesterone
  - Prolactin
  - PTH
  - Testosterone
  - Vitamin B12

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Hot Topics

Proficiency Testing Analytes Updated

- Toxicology
  - Acetaminophen, serum
  - Salicylate
  - Vancomycin

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Hot Topics

Proficiency Testing Analytes Deleted

- LDH isoenzymes
- Ethosuximide
- Quinidine
- Primidone
- Procainamide/N-acetyl Procainamide

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Hot Topics

Proficiency testing revisions

- Criteria for acceptable performance updated

✓Target values
✓Acceptance Limits

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Hot Topics

Proficiency testing revisions

- Microbiology

✓Remove the types of services for each subspecialty
✓Add categories of testing (broader categories of organisms)
✓Better reflects current practices

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Hot Topics

Proficiency testing revisions

- PT Companies

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Hot Topics

❖Proficiency testing revisions

- Moderate/High Complexity Labs - Proficiency Testing for Waived Tests

✓Effective August 10, 2022

✓Subject to requirements regarding testing of PT samples and ban on improper PT referral

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Hot Topics

- Moderate/High Complexity Labs - Proficiency Testing for Waived Tests

✓Test in same manner as patient samples
✓Do not send samples to another laboratory
✓Document all steps in testing process
✓ No inter-laboratory communication
✓ Attestation Statements signed

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Hot Topics

❖ Electronic CLIA Certificate

• Opt on the CLIA application form to receive email notifications

EMAIL ADDRESS

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

• Emailed link to access CLIA certificate within 30 days of current expiration date

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Hot Topics

❖ Electronic CLIA Certificate

• Welcome email sent on Feb 8, 2023

• Email request to your CLIA State Agency to receive electronic notifications

• clialab@nd.gov

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Hot Topics

❖ Would you like to receive email updates from CLIA?

Sign up for the CLIA Communications Email List with this link:

https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS-12461

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CLIA Contact Information

https://www.hhs.nd.gov/health/regulation-licensure-and-certification/health-facilities-unit/clia-laboratories

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Sources

• Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories;
• Centers for Medicare and Medicaid Services (CMS) QSO-21-10-CLIA, revised 04/15/22;
• Centers for Medicare and Medicaid Services (CMS) QSO-22-13-CLIA, 02/28/22;
• Centers for Medicare and Medicaid Services (CMS) CLIA website at https://www.cms.gov/Regulations-andGuidance/Legislation/CLIA;
• U.S. Food & Drug Administration's website at https://www.fda.gov.
• ASPEN Central Office Tag Summary Report 03/01/23

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Happy Medical Laboratory Professionals Week

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