

Objectives

2

4

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



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.



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



3

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

- ➤D2096 Routine Chemistry
- ▶D2118 Toxicology
- ➤D2107 Endocrinology
- ➤D2130 Hematology
- ▶D2181 Compatibility Testing



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

- ▶D5421 Verification of **Performance Specifications**
- For each new test/method
- ✓ Nonwaived
- ✓ Unmodified



5 6

Dakota | Health & Human Services

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

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

➤ D5421

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

8

7

Top Deficiencies 01/01/21 through 03/01/23 D6076 Laboratory Director Laboratory director must: Meet the qualification requirements Provide overall management and direction

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

9 10

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

D5447 Control Procedures

• For quantitative test results include 2 controls of different concentrations

D647 Medit à Hunon Services

Nagaria

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

11 12

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

Dakota | Health & Human Services

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

Dakota | Health & Human Services

13 14

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

Dakota be legendary Health & Human Services

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)

Dakota | Health & Human Services

15 16

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

- ➤ D5217 Evaluation of Proficiency Testing Performance
- Twice annually verify the accuracy of non-regulated analytes

Dakota | Health & Human Services

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

Dakota | Health & Human Services

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



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



19 20

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



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)



21 22

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

- ➤D5439 Calibration and Calibration Verification
- Must follow the manufacturer's instructions



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

➤D5551 Immunohematology

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



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?



Impact of D/C PHE

Requirements for SARS-CoV-2 testing

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



25 26

Impact of D/C PHE

Requirements for SARS-CoV-2 testing

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



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



27 28

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



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



Impact of D/C PHE

Requirements for SARS-CoV-2 test result reporting

Will this be rescinded?

Dakota | Health & Human Services

Impact of D/C PHE

Emergency Use Authorization

• What happens to EUAs?

Dakota | Health & Human Services

31 32

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

Dakota | Health & Human Services

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

Dakota | Health & Human Services

33 34

Impact of D/C PHE

EUAs

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

Dakota | Health & Human Services

Impact of D/C PHE

- Remote Review of Pathology Slides
- ✓ Each location performing testing must have their own CLIA certificate
- ✓ Enforcement discretion during PHE

Dakota | Health & Human Services

Hot Topics

Proficiency Testing Analytes Updated

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

Dakota | Health & Human Services

Hot Topics

Proficiency Testing Analytes Updated

- General Immunology
- Anti-HBs
- Anti-HCV

38

CRP (high sensitivity)

Dakota | Health & Human Services

37

Hot Topics

Proficiency Testing Analytes Updated

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

Dakota | Health & Human Services

Hot Topics

Proficiency Testing Analytes Updated

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

Dakota | Health & Human Service

39 40

Hot Topics

Proficiency Testing Analytes Updated

- Endocrinology
- Estradiol
- Folate, serum FSH
- LH Progesterone
- Prolactin
 PTH

- Testosterone
 Vitamin B12

Dakota | Health & Human Services

Hot Topics

Proficiency Testing Analytes Updated

- Toxicology
- · Acetaminophen, serum
- Salicylate
- Vancomycin

Dakota | Health & Human Servi

Hot Topics Proficiency Testing Analytes Deleted LDH isoenzymes Ethosuximide Quinidine Primidone Procainamide/N-acetyl Procainamide

Hot Topics

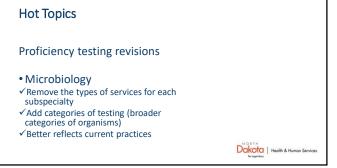
Proficiency testing revisions

• Criteria for acceptable performance updated

✓ Target values

✓ Acceptance Limits

43 44

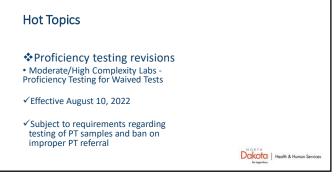


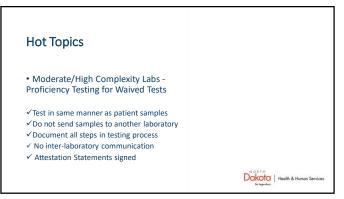
Hot Topics

Proficiency testing revisions

• PT Companies

45 46





47 48

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

Dakota | Health & Human Services

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

50

Dakota | Health & Human Services

49

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/ac counts/USCMS/subscriber/new?t opic_id=USCMS-12461

Dakota | Health & Human Services

CLIA Contact Information

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

Telephone #(701)328-2352

clialab@nd.gov sheilman@nd.gov bweidner@nd.gov

Dakota | Health & Human Services

51 52

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) QS0-22-13-CLIA, 02/28/22;
- 13-CILA, 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

Dakota | Health & Human Services

Happy Medical Laboratory Professionals Week



53 54