



CLIA: Lab Quality Enhances Patient Care
 April 26, 2024 ASCLS-ND Spring Symposium



1



Objectives

- Identify the most common CLIA deficiencies in ND
- Evaluate CLIA hot topics

2



Top Deficiencies -
 03/01/23 through 02/29/24

➤ D2016 Successful Participation in Proficiency Testing

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

3



Top Deficiencies -
 03/01/23 through 02/29/24

➤ D2028, D2096, D2107

- Unsuccessful proficiency testing performance – failure to achieve a satisfactory score for:
- ✓ Two consecutive events or
 - ✓ Two of three consecutive events

4



Top Deficiencies -
 03/01/23 through 02/29/24

- D2028 Bacteriology
- D2096 Routine Chemistry
- D2107 Endocrinology

5



Top Deficiencies -
 03/01/23 through 02/29/24

➤ D6076 Laboratory Director

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

6

Top Deficiencies -
03/01/23 through 02/29/24

➤ **D6102 Laboratory Director Responsibilities**

- Ensure new testing personnel are trained and competent before performing patient testing
- Training must be documented




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Top Deficiencies -
03/01/23 through 02/29/24

➤ **D6094 Laboratory Director Responsibilities**

- Ensure the lab establishes and follows quality assessment P&Ps to assure quality and to identify failures
- To help prevent subsequent PT failures



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Top Deficiencies -
03/01/23 through 02/29/24

➤ **D5217 Evaluation of Proficiency Testing Performance**

- Twice annually verify the accuracy of non-regulated analytes



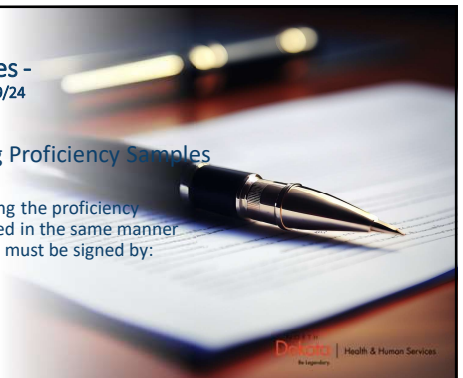
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Top Deficiencies -
03/01/23 through 02/29/24

➤ **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 -
03/01/23 through 02/29/24

❖ **Attestation Statements**

- Lab Director may delegate signing to:
 - ✓ Technical Consultant - Moderate Complexity
 - ✓ Technical Supervisor - High Complexity (pathologist for immunohematology)



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Top Deficiencies -
03/01/23 through 02/29/24

➤ **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 -
03/01/23 through 02/29/24

➤ D5413 Test Systems, Equipment, Instruments, Reagent

- Proper storage

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Top Deficiencies -
03/01/23 through 02/29/24

➤ D5413 Test Systems, Equipment, Instruments, Reagent

- Reagents labeled

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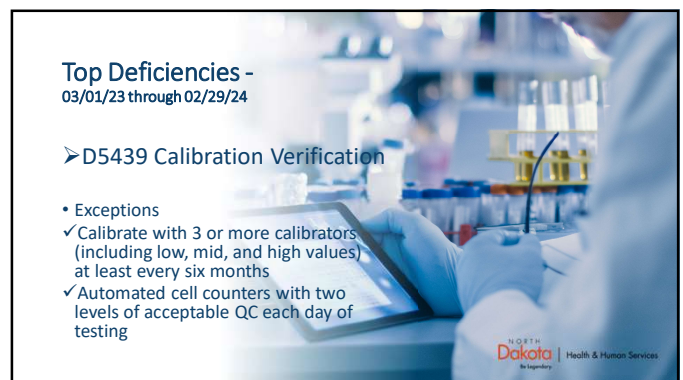
Top Deficiencies -
03/01/23 through 02/29/24

➤ 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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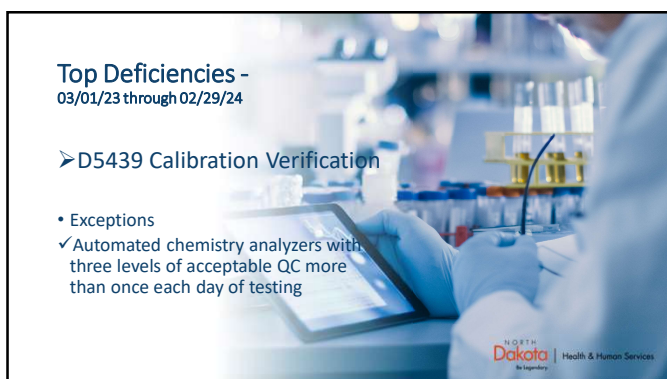
Top Deficiencies -
03/01/23 through 02/29/24

➤ 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 -
03/01/23 through 02/29/24

➤ 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 -
03/01/23 through 02/29/24

➤ D5439 Calibration Verification

- Exceptions
 - ✓ Instruments factory/manufacture calibrated
 - ✓ Tests considered non-quantitative (e.g. Protime, PTT)

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Top Deficiencies -
03/01/23 through 02/29/24

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

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Top Deficiencies -
03/01/23 through 02/29/24

- D6046 Technical Consultant Responsibilities
- Competency evaluations:
 - ✓ All non-waived testing personnel
 - ✓ All platforms
 - ✓ Annually

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Top Deficiencies -
03/01/23 through 02/29/24

- D5891 Post Analytic Quality Assessment
- Test report assessments

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Laboratory Quality Assessment

- Robust QA program -->
- Accurate & reliable results -->
- Quality patient care

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Hot Topics – PT Analytes Updated

- Proficiency Testing analytes updated effective July 11, 2024
- Implementation date: January 1, 2025

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Hot Topics – PT Analytes Updated

Based on:

- Current availability of PT samples
- Volume of patient testing nationally

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Hot Topics – PT Analytes Updated

Based on:

- Impact on patient/public health
- Cost and feasibility of implementation

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Hot Topics – PT Analytes Updated

General Immunology

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

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Hot Topics – PT Analytes Updated

Routine Chemistry

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

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Hot Topics – PT Analytes Updated

Routine Chemistry cont.

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

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Hot Topics – PT Analytes Updated

Endocrinology

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

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Hot Topics – PT Analytes Updated

Toxicology

- Acetaminophen, serum
- Salicylate
- Vancomycin

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Hot Topics – PT Analytes Updated

Analytes Deleted:

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

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Acceptable Performance Criteria changes
 - ✓ From standard deviations to percentage-based

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Acceptable Performance Criteria changes
 - ✓ Analytes with lower concentrations graded on percentages or fixed acceptance limits
 - ✓ See Attachment 1 of CMS QSO-22-21-CLIA

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Hot Topics – Proficiency Testing

Revisions & Requirements

- 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 & Requirements

- Microbiology - Miscellaneous
 - ✓ Report proficiency results to the highest level reported for patients
 - ✓ Percentage of mixed cultures for bacteriology, mycobacteriology, and mycology will decrease from 50% to 25%

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Bacteriology
 - ✓ Gram stains – morphology will be graded
 - ✓ Bacterial Toxin Detection – required

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Bacteriology
 - ✓ New criteria for grading direct bacterial antigen detection
 - ✓ Detection of presence/absence of bacteria with or without ID

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Bacteriology
 - ✓ Antimicrobial susceptibility testing – at least two samples per event
 - ✓ Annual program includes: aerobic and anaerobic bacteria for gram neg bacilli and cocci; and gram pos bacilli and cocci

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Mycobacteriology
 - ✓ Acid fast stain
 - ✓ Detection of presence/absence of mycobacteria with or without ID

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Mycobacteriology
 - ✓ Annual program includes: *Mycobacterium tuberculosis complex* and *Mycobacterium other than tuberculosis*

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Mycology
 - ✓ Direct fungal antigen detection
 - ✓ Detection of presence/absence of fungi and aerobic actinomycetes with or without ID

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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Mycology
 - ✓ Annual program includes: yeast or yeast like organisms; molds including dematiaceous fungi, dermatophytes, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes


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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Parasitology
 - ✓ Direct parasite antigen detection
 - ✓ Detection of presence/absence of parasites with or without ID



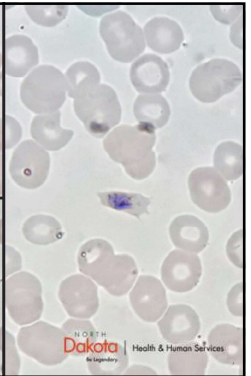
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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Parasitology
 - ✓ Annual program includes: intestinal parasites and blood/tissue parasites



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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Virology
 - ✓ Viral antigen detection
 - ✓ Detection and ID of viruses



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Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology – Virology
 - ✓ Annual program includes: respiratory viruses, herpes viruses, enterovirus, and intestinal viruses



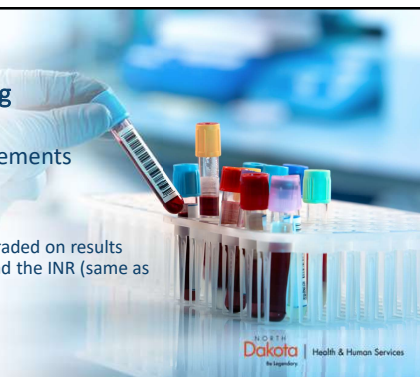
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Hot Topics – Proficiency Testing

Revisions & Requirements

- Coagulation
 - ✓ Prothrombin Time - Graded on results reported in seconds and the INR (same as patients)




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Hot Topics – Proficiency Testing

Revisions & Requirements

- Hematology
 - ✓ WBC Differentials – enroll in both automated WBC differentials and blood cell ID (if performing)
 - ✓ Both scores will be reported



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Hot Topics – Proficiency Testing

Revisions & Requirements

- Hematology
 - ✓ Blood cell ID satisfactory (acceptable) score changed from 90% to 80%



49

Hot Topics – Proficiency Testing

Revisions & Requirements

- Toxicology
 - ✓ Samples must cover the full range that could occur in patient samples




50

Hot Topics – Proficiency Testing

Revisions & Requirements

- Immunochemistry
 - ✓ Unexpected Antibody Detection satisfactory (acceptable) score changed from 80% to 100%



51

Hot Topics – Proficiency Testing

Revisions & Requirements

- Revised approval/reapproval process of PT companies



52

Hot Topics – Proficiency Testing

- 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



53

Hot Topics – Proficiency Testing

- 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



54

Hot Topics – Fee Changes

CLIA fee changes effective -
January 27, 2024

- Certificate of Waivers increased by \$25 to offset program FDA costs for categorizing tests
- Increased fees 18% across the board

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Hot Topics – Fee Changes

Increases every two years based on:

- ✓ Consumer Price Index-Urban inflation adjustment
- ✓ If applicable, an additional across the board increase

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Hot Topics – Fee Changes

- Certificate fees
 - ✓ Waiver - \$248
 - ✓ PPM - \$297

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Hot Topics – Fee Changes

- CLIA fees based on volume for:
 - ✓ Compliance
 - ✓ Registration
 - ✓ Accreditation

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Hot Topics – Fee Changes

- CLIA fees – 2 part:
 - ✓ Compliance (for surveys)
 - ✓ Certificate (for CLIA certificate)
- Assessed every two years

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Hot Topics – Fee Changes

- CLIA fees – see the ND State CLIA Agency website for a breakdown of the fees

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

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Hot Topics – Fee Changes

- Following activities will be assessed fees:
 - ✓ Issuing a replacement certificate
 - ✓ Issuing a revised certificate



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Hot Topics – Fee Changes

Fees for revised/replacement certificates:

- ✓ Waiver - \$95
- ✓ PPM - \$150
- ✓ Accreditation - \$95



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Hot Topics – Fee Changes

Fees for revised/replacement certificates:

- ✓ Registration - \$150
- ✓ Compliance - \$150



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Hot Topics – Fee Changes

- Following activities will be assessed additional fees based on resources/time:
 - ✓ Performing follow-up/revisit surveys to determine correction of deficient practices



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Hot Topics – Fee Changes

- ✓ Conducting desk reviews of unsuccessful proficiency testing performance in compliance labs



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Hot Topics – Fee Changes

- ✓ Performing a substantiated complaint survey for all certificate types



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Hot Topics – Fee Changes

- ✓ Adding a new specialty and determining compliance outside of the routine survey cycle for compliance labs

67

Hot Topics – QCOR website

The Centers for Medicare & Medicaid Services' website "Quality, Certification and Oversight Report" lists all CLIA certified laboratories

https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp

68

Hot Topics – QCOR website

- Use this website to verify CLIA certification
- Updated with new information entered in the CLIA database

69

Hot Topics – QCOR website

Using the website:

- Find "Tool" in upper left corner
- Select "CLIA Laboratory Lookup"
- Search by CLIA number, facility name, city, state, etc.

70

Hot Topics – QCOR website

- Information available:
 - ✓ Name of facility
 - ✓ Laboratory Director
 - ✓ Address
 - ✓ Phone number

71

Hot Topics – QCOR website

- Information available:
 - ✓ Certificate type
 - ✓ Effective date
 - ✓ Expiration date
 - ✓ Facility type

72

Hot Topics – QCOR website

- Screen is printable
- Is not a copy of the actual CLIA certificate



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Hot Topics – Electronic CLIA Certificates

- Opt in to receive email notifications using the CLIA application form

EMAIL ADDRESS

RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

- Or request by emailing clialab@nd.gov



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Hot Topics – Electronic CLIA Certificates

- Emailed CLIA fee coupons
- Emailed link to access CLIA certificate
- Next cycle CLIA certificate available about 30 days before expiration date

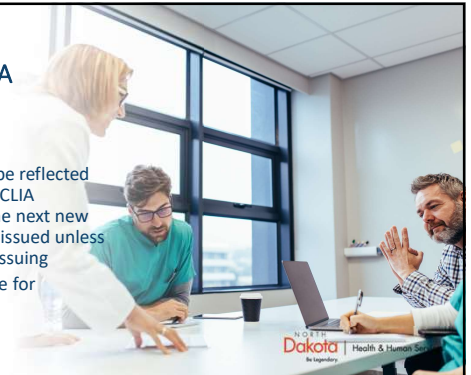


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Hot Topics – Electronic CLIA Certificates

- Changes will not be reflected on the electronic CLIA certificate until the next new CLIA certificate is issued unless fee is paid for re-issuing
- Use QCOR website for verification



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Hot Topics - Impact of D/C PHE

Public Health Emergency ended 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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Hot Topics - Impact of D/C PHE

EUAs

- Not dependent on PHE declaration (see Section 564 of the Federal Food, Drug, and Cosmetic Act)
- FDA working with manufacturers to transition




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Hot Topics - Impact of D/C PHE

- Laboratories must ensure their testing:
 - ✓ Has an EUA in effect or
 - ✓ Has been categorized by the FDA



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Hot Topics – CLIA Communications

- ❖ 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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80

CLIA Contact Information

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

Telephone #(701)328-2352

cialab@nd.gov
sheilman@nd.gov
bweidner@nd.gov



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81

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-22-21-CLIA, 07/11/22; Admin Info-23-07-CLIA, 05/03/23; QSO-24-03-CLIA, 12/28/23
- Centers for Medicare and Medicaid Services (CMS) CLIA website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>;
- U.S. Food & Drug Administration's website at <https://www.fda.gov>.
- ASPEN Central Office Tag Summary Report
- CLIA final rule at <https://www.federalregister.gov/>
- ND State CLIA Agency website at <https://www.hhs.nd.gov/health/regulation-licensure-and-certification/health-facilities-unit/cli-laboratories>



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Happy Belated Medical Laboratory Professionals Week



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83