The CLIA World Is Changing

May 8, 2025 ASCLS-ND Spring Symposium

NORTH Dakota | Health & Human Services

1

The North Dakota CLIA State Agency has no conflicts of interest to disclose regarding this presentation.

2

Objectives

- Identify the most common CLIA deficiencies in ND
- Recognize changes in the CLIA regulations
- Evaluate CLIA regulatory updates

3

Top Deficiencies -
03/01/24 through 02/01/25

➢D2016 Successful Participation in Proficiency Testing

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

4

Top Deficiencies -
03/01/24 through 02/01/25

➢D2028 & D2096

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

✓Two consecutive events or

✓Two of three consecutive events

5

Top Deficiencies -
03/01/24 through 02/01/25

➢D2028 Bacteriology

➢D2096 Routine Chemistry

6

Top Deficiencies -
03/01/24 through 02/01/25

➢D6076 Laboratory Director

- Laboratory director must:

✓Meet the qualification requirements
✓Provide overall management and direction

7

Top Deficiencies -
03/01/24 through 02/01/25

➢D6089 Laboratory Director Responsibilities

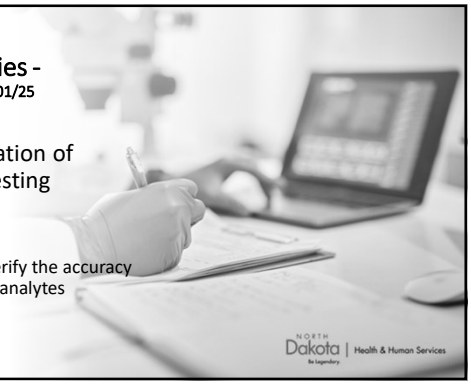
- Ensure the lab participates successfully in proficiency testing

8

Top Deficiencies -
03/01/24 through 02/01/25

➢D5217 Evaluation of Proficiency Testing Performance

- Twice annually verify the accuracy of non-regulated analytes



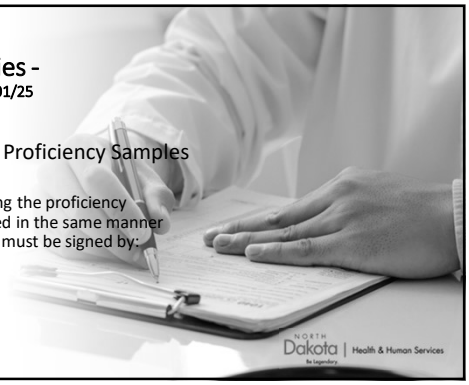
9

Top Deficiencies -
03/01/24 through 02/01/25

➢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



10

Top Deficiencies -
03/01/24 through 02/01/25

❖Attestation Statements

- Lab Director may delegate signing to:

✓Technical Consultant - Moderate Complexity
✓Technical Supervisor - High Complexity

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Top Deficiencies -
03/01/24 through 02/01/25

➢D5449 Quality Control

- For qualitative procedures, perform a positive and negative control each day of patient testing

12

Top Deficiencies -
03/01/24 through 02/01/25

➢D5451 Quality Control

- For test procedures with graded or titered results, perform a negative control and a positive control with graded/titered reactivity each day of patient testing

13

Top Deficiencies -
03/01/24 through 02/01/25

➢D5551 Immunohematology Patient Testing

- The laboratory must perform ABO, Rh, antibody detection, and compatibility testing according to manufacturer's instructions or 21 CFR 606.151 (a-e)

14

Top Deficiencies -
03/01/24 through 02/01/25

➢D5551 Immunohematology Patient Testing

- Compatibility testing must include IgM testing (immediate spin crossmatch)

15

Top Deficiencies -
03/01/24 through 02/01/25

➢D5805 Test Report

- Test report must include the units of measurement

16

CLIA Revisions

➢Effective December 28, 2024 (CMS-Final Rule 3326-F)

- Personnel
- Fees
- Histocompatibility
- Alternative Sanctions for Certificate of Waiver Labs

17

CLIA Revisions

➢Implemented January 1, 2025 (CMS Final Rule 3355-F)

- Proficiency Testing Analytes
- PT Acceptable Performance

18

CLIA Revisions - IGs

- Interpretive guidance added to address:
  - Cybersecurity
  - Data security

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CLIA Revisions - IGs

- D2003 Enrollment in Proficiency Testing
  - For analytes not listed in Subpart I (non-regulated), establish and maintain the accuracy of its testing

20

CLIA Revisions - IGs

- D2003 Enrollment in PT
  - Methods to meet accuracy verification requirements
    - Enroll in PT program
    - Split sampling
    - Blind sampling
  - Must have written procedure (see also D5217)

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CLIA Revisions - IGs

- D2009 Testing of PT Samples
  - Signing of attestation statements
    - Original, inked signatures
    - Secure electronic signatures with date/time stamp
    - Not acceptable: typed names on attestation statement

22

CLIA Revisions - IGs

- D3041 Retention Requirements
  - Must have a procedure for record retrieval when the LIS/EMR are not functioning

23

CLIA Revisions - IGs

- D3041 Retention Requirements
  - Retained copies of pathology reports must include the required personnel identifiers/authorized signatures

24

CLIA Revisions - IGs

➢D5201 Confidentiality

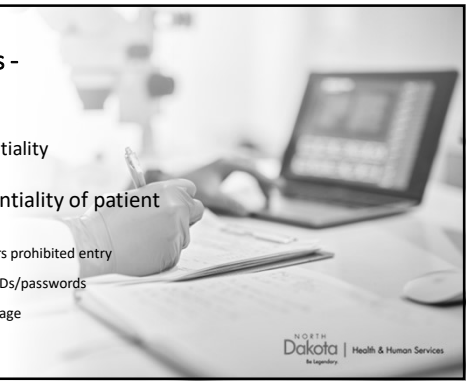
- Control visitor access to:
  - Computer terminals
  - Fax machines/printers
  - Testing areas

25

CLIA Revisions - IGs

➢D5201 Confidentiality

- Ensure confidentiality of patient information:
  - Unauthorized users prohibited entry
  - LIS – unique user IDs/passwords
  - Secure record storage



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CLIA Revisions - IGs

➢D5291 General Lab Systems - Quality Assessment

- Monitoring and evaluating confidentiality of patient information

27

CLIA Revisions - IGs

➢D5403 Procedure Manual

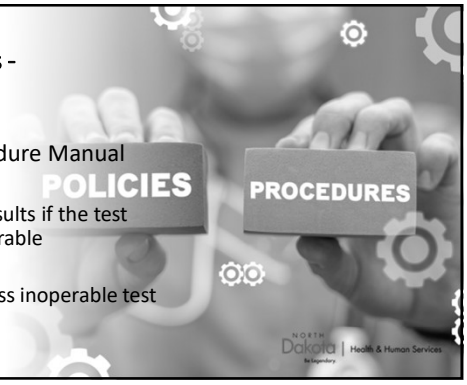
- LIS procedures must be available
- Includes point-of-contact to notify if LIS goes down

28

CLIA Revisions - IGs

➢D5403 Procedure Manual

- Reporting of results if the test system is inoperable
- A plan to address inoperable test systems



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CLIA Revisions - IGs

➢D5413 Test Systems, Equipment, Instruments, Reagents, Material, & Supplies

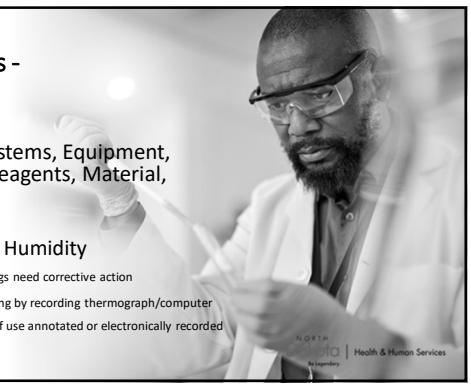
- Water Quality
  - Use appropriate water quality as required by manufacturer
  - Labs producing water should consider: pH, silicon content, particulate matter, bacterial/organic content

30

CLIA Revisions - IGs

➢D5413 Test Systems, Equipment, Instruments, Reagents, Material, & Supplies

- Temperature & Humidity
  - Unacceptable readings need corrective action
  - Continuous monitoring by recording thermograph/computer with date and time of use annotated or electronically recorded



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CLIA Revisions - IGs

➢D5429 Maintenance & Function checks

- Scheduled preventive maintenance
  - Performed by lab (daily, weekly, monthly, etc.)
  - Lab ensures performance of contracted PM services

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CLIA Revisions - IGs

➢D5431 Maintenance & Function checks

- Follow the manufacturer's instruction for installing all software updates (including cybersecurity)

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CLIA Revisions - IGs

➢D5481 Control Procedures Not Available

- Examples of alternative control procedures for PPM tests
  - Two testing personnel review the same slide
  - Have reference material available and ensure testing personnel have demonstrated competency

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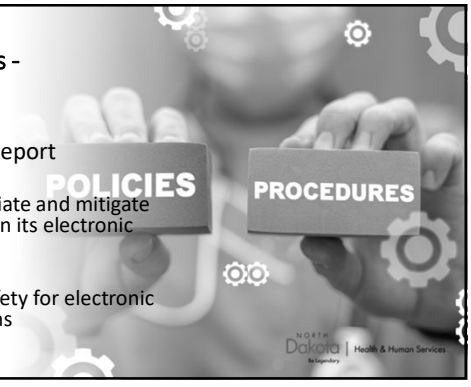
CLIA Revisions - IGs

➢D5801 Test Report

- P&Ps to remediate and mitigate vulnerabilities in its electronic system
- Ensure data safety for electronic communications



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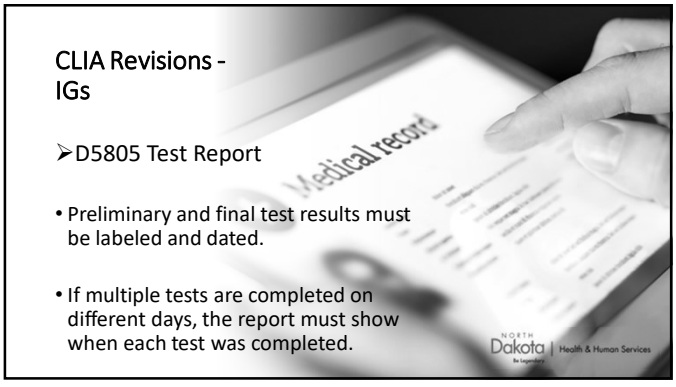
CLIA Revisions - IGs

➢D5805 Test Report

- Preliminary and final test results must be labeled and dated.
- If multiple tests are completed on different days, the report must show when each test was completed.



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CLIA Revisions - IGs

➢D5805 Test Report

- Lab must convey updates of analysis/interpretation software to the individual ordering/using the test results

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CLIA Revisions - IGs

➢D5811 Test Report

- Lab must ensure that only authorized individuals can access a patient's results

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CLIA Revisions - IGs

➢D5815 Test Report

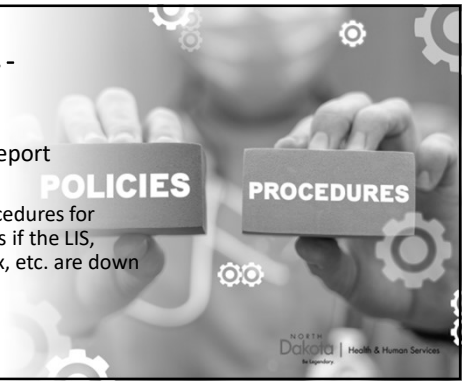
- If delays would negatively impact patient care, the lab must have an alternative method to report results

39

CLIA Revisions - IGs

➢D5815 Test Report

- Must have procedures for reporting results if the LIS, EMR, phone, fax, etc. are down



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CLIA Revisions - IGs

➢D5807 Test Report

- Interpretive guidance added to:
  - Use the race-free equation for eGFR (estimated Glomerular Filtration Rate)

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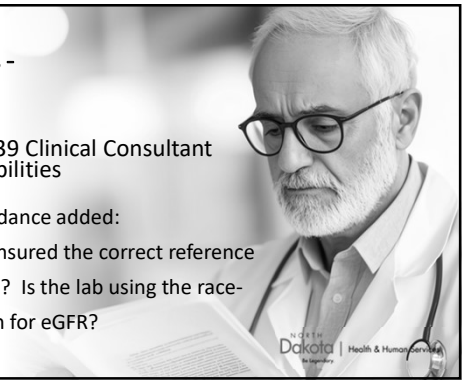
CLIA Revisions - IGs

➢D6061 &D6139 Clinical Consultant (CC) Responsibilities

- Interpretive guidance added:
  - Has the CC ensured the correct reference range is used? Is the lab using the race-free equation for eGFR?



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CLIA Revisions - IGs

➢D3025 & D5559 Requirements for transfusion services/investigation of transfusion reactions

- FDA must be notified of transfusion related fatalities
  - Email (recommended) *fatalities2@fda.hhs.gov*
  - Telephone *240-402-9160*
  - Fax 301-837-6256 Attn: CBER Fatality Program Manager

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CLIA Revisions - IGs

➢D3025 & D5559 Requirements for transfusion services/investigation of transfusion reactions

- FDA must be notified of transfusion related fatalities
  - Express mail
    Office of Compliance & Biologics Quality/CBER
    Attn: Facility Program Manager
    10903 New Hampshire Ave, Bldg 71, Rm 3128
    Silver Spring, MD 20993-000

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CLIA Revisions - IGs

➢D3025 & D5559 Requirements for transfusion services/investigation of transfusion reactions

- Send reports of fatal transfusion reactions to CMS (State Agency)
- For ND labs, email clialab@nd.gov

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CLIA Revisions - IGs

➢Quality Assessment

- D5221 General Laboratory Systems
- D5391 Preanalytic Systems
- D5791 Analytic Systems
- D5891 Postanalytic Systems

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CLIA Revisions - IGs

➢Quality Assessment
The laboratory must –

- Establish written P&Ps to prevent recurrence of problems identified
- Communicate the P&Ps to staff, clients, etc. as appropriate
- Document that P&Ps to prevent recurrence had been followed

47

CLIA Revisions – Revised Dtags

➢Lab Director Qualifications (moderate complexity)

- D6003 – state licensed physician board-certified in anatomic or clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology
- Or

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (moderate complexity)
  - D6003 – state licensed physician with:
    - One year directing/supervising non-waived testing
    - 20 CE credits in laboratory director responsibilities

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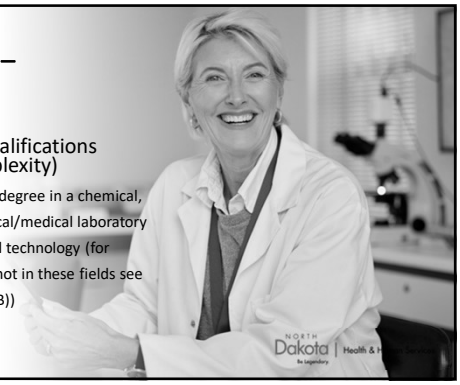
CLIA Revisions – Revised Dtags



- Lab Director Qualifications (moderate complexity)
  - D6003 – Doctoral degree in a chemical, biological, or clinical/medical laboratory science or medical technology (for doctoral degrees not in these fields see 493.1405(b)(3)(i)(B))

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (moderate complexity)
  - D6003 – Doctoral degree
    - Board-certified
    - 20 CE credits in LD responsibilities
    - One year supervising/directing non-waived testing

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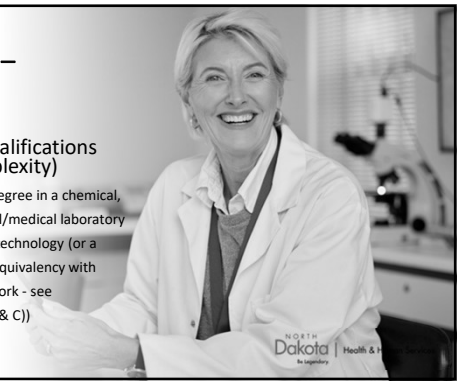
CLIA Revisions – Revised Dtags



- Lab Director Qualifications (moderate complexity)
  - D6003 – Master's degree in a chemical, biological, or clinical/medical laboratory science or medical technology (or a bachelor's degree equivalency with additional course work - see 493.1405(b)(4)(i)(B & C))

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (moderate complexity)
  - D6003 – Master's degree
    - One year training/experience in non-waived testing
    - One year supervisory experience in non-waived testing
    - 20 CE credits in LD responsibilities

53

CLIA Revisions – Revised Dtags

- Lab Director Qualifications (moderate complexity)
  - D6003 – Bachelor's degree in a chemical, biological, or clinical/medical laboratory science or medical technology (for bachelor's degrees not in these fields see 493.1405(b)(5)(i)(B))

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (moderate complexity)
  - D6003 – Bachelor's degree
    - Two years training/experience in non-waived testing
    - Two years supervisory experience in non-waived testing
    - 20 CE credits in LD responsibilities

55

CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (moderate complexity)
  - D6005 – LD must:
    - Be onsite at least once every six months (at least four months between).
    - Document the visits.

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CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (moderate complexity)
  - D6005 – Onsite Visits:
    - Supplement interactions between off-site directors and the lab
    - Cannot be delegated

57

CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (moderate complexity)
  - D6005 – Onsite Visits:
    - LD determines the type of documentation
    - May include: sign in/out logs, meeting minutes, notes of observations, & travel vouchers

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CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (moderate complexity)
  - D6020 –

    Ensure QC and QA programs are established and maintained to assure quality and identify failures

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CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (moderate complexity)
  - D6024 – added:

    Ensure patient test results are reported only when the test system is functioning properly.

60

CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – state licensed physician board-certified in anatomic or clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology or

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CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – state licensed physician with:
    - One year training/experience in non-waived testing in designated specialty/subspecialty

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CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – Doctoral or Master's degree in a chemical, biological, clinical/medical science or medical technology:
    - Or meet the requirements at 493.1405(b)(3)(i)(B) or (b)(4)(i)(B or C) and
    - One year training/experience in non-waived testing in designated specialty/subspecialty

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CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – Bachelor's degree in a chemical, biological, clinical/medical science or medical technology:
    - Or meet the requirements at 493.1405(b)(5)(i)(B) and
    - Two years training/experience in non-waived testing in designated specialty/subspecialty

64

CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – Associate degree in medical laboratory science/technology or clinical laboratory science:
    - And four years training/experience in non-waived testing in designated specialty/subspecialty

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CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – Training/Experience
  - Medical technology internship – need verification from program director of hours or weeks
  - Clinical in nature - performance of non-waived testing of human specimens to aid in diagnosis, treatment, and monitoring of patients

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CLIA Revisions – Revised Dtags

- Technical Consultant Qualifications (moderate complexity)
  - D6035 – Training/Experience
  - Experience in each specialty/ subspecialty may be acquired concurrently
  - Waived testing experience is not accepted

67

CLIA Revisions – Revised Dtags

- Technical Consultant Responsibilities (moderate complexity)
  - D6036 – responsible for the technical and scientific oversight of the lab
  - Not required to be on-site at all times testing is performed, but must be available for consultation

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6064 – state licensure if required
  - For questions, contact the North Dakota Board of Clinical Laboratory Practice at www.ndclinlab.com

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6065 – state licensed physician
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6065 – Doctoral, Master's, or Bachelor's degree in a chemical, biological, clinical/medical science or medical technology or nursing from an accredited institution:
  - Or meet the requirements at 493.1405(b)(3)(i)(B), (b)(4)(i)(B or C), or (b)(5)(i)(B)
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6065 – Associate degree in a chemical, biological, clinical/medical laboratory science/technology or nursing
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6065 – High school graduate (or equivalent) with completion of an official military medical laboratory procedures course
  - See 493.1423(b)(5) for more details
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6065 – High school graduate (or equivalent) with appropriate training
  - D6066 - See 493.1423(b)(6)(ii)(A-H) for training requirements

74

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6190 – For blood gas analysis:
  - Qualified for moderate complexity testing under (b)(1-6)
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6190 – For blood gas analysis:
  - Bachelor's degree in respiratory therapy or cardiovascular technology from accredited institution and
  - One year of experience/training in blood gas analysis
  - Or

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CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (moderate complexity)
  - D6190 – For blood gas analysis:
  - Associate degree related to pulmonary function from accredited institution and
  - Two years of experience/training in blood gas analysis

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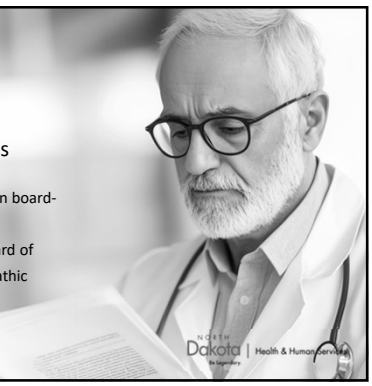
CLIA Revisions – Revised Dtags



- Lab Director Qualifications (high complexity)
  - D6078 – state licensed physician board-certified in anatomic or clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology
  - Or

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 - state licensed physician with:
  - Two years directing/supervising high complexity non-waived testing
  - 20 CE credits in laboratory director responsibilities

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Doctoral degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution
  - For doctoral degrees not in these fields see 493.1443(b)(3)(i)(B)(1 & 2)
  - And

80

CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Doctoral degree
  - Certified by an HHS-approved board
  - And

81

CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Doctoral degree HHS-approved boards:
    - ABB, ABB, ABCC, ABFT, ACHI, ABMGG, ABMLI, ABMM, DMLI, and NRCC
    - See regulations at 493.1443(b)(3)

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CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Doctoral degree
  - At least two years of –
    - Lab training/experience
    - Experience directing/supervising high complexity testing
  - And

83

CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Doctoral degree
  - 20 CE credits in laboratory director responsibilities

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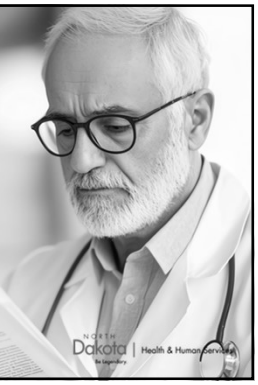
CLIA Revisions – Revised Dtags

- Lab Director Qualifications (high complexity)
  - D6078 – Oral Pathology Subspecialty
  - Certified by:
    - American Board of Oral Pathology
    - American Board of Pathology
    - American Osteopathic Board of Pathology



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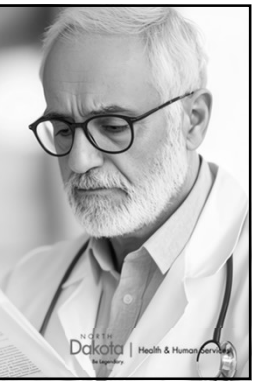
CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (high complexity)
  - D6079 LD delegation of duties, in writing:
    - Technical Supervisor – 493.1445(e) (3-7,12-14)
    - Clinical consultant – 493.1445(e)(8-9)
    - General supervisor – 493.1463(b)(1-4)



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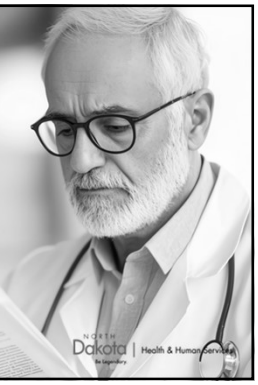
CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (high complexity)
  - D6080 – LD must:
    - Be onsite at least once every six months (at least four months between).
    - Document the visits.



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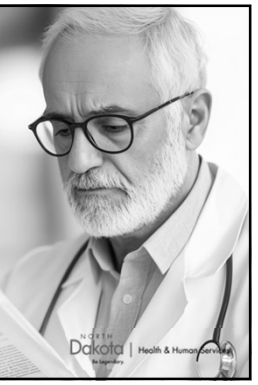
CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (high complexity)
  - D6080 – Onsite Visits:
    - Supplement interactions between off-site directors and the lab
    - Cannot be delegated



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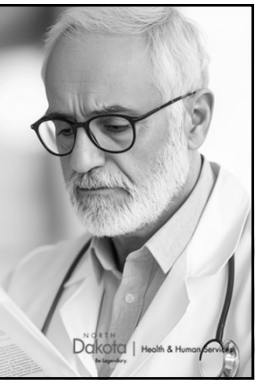
CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (high complexity)
  - D6080 – Onsite Visits:
    - LD determines the type of documentation
    - May include: sign in/out logs, meeting minutes, notes of observations, & travel vouchers



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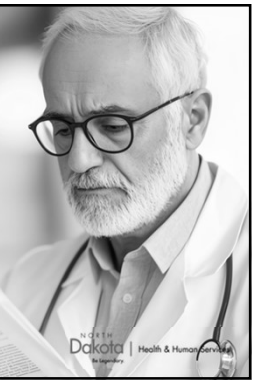
CLIA Revisions – Revised Dtags

- Lab Director Responsibilities (high complexity)
  - D6093 –

    Ensure QC and QA programs are established and maintained to assure quality and identify failures



90

CLIA Revisions – Revised Dtags

- Technical Supervisor Qualifications (high complexity)
  - D6111 – state licensed physician board-certified in anatomic and clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology

91

CLIA Revisions – Revised Dtags

- Technical Supervisor Qualifications (high complexity)
  - D6111 – state licensed physician with:
  - One year training/experience in non-waived testing in designated specialties of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology
  - For micro – one year in micro specialty and at least six months within each subspeciality (bacteriology, mycobacteriology, mycology, parasitology, and virology)

92

CLIA Revisions – Revised Dtags

- Technical Supervisor Qualifications (high complexity)
  - D6111 - Doctoral degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution
  - For doctoral degrees not in these fields see 493.1443(b)(3)(i)(B)
  - And

93

CLIA Revisions – Revised Dtags

- Technical Supervisor Qualifications (high complexity)
  - D6111 - One year training/experience in non-waived testing in designated specialties of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology
  - For micro – one year in micro specialty and at least six months within each subspeciality (bacteriology, mycobacteriology, mycology, parasitology, and virology)

94

CLIA Revisions – Revised Dtags

- Technical Supervisor Qualifications (high complexity)
  - D6111 - Master's degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution (or a bachelor's degree equivalency with additional course work - see 493.1449(c)(4)(i)(B & C))
  - And

95

CLIA Revisions – Revised Dtags

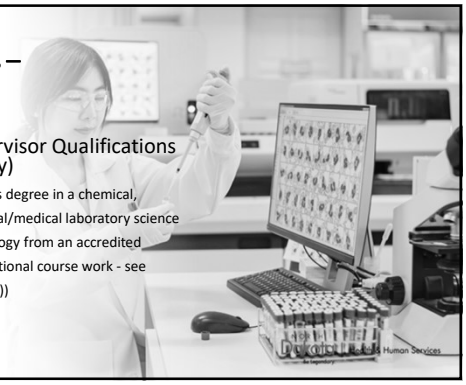
- Technical Supervisor Qualifications (high complexity)
  - D6111 - Two years training/experience in non-waived high complexity testing in designated specialties of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology
  - For micro – two years in micro specialty and at least six months within each subspeciality (bacteriology, mycobacteriology, mycology, parasitology, and virology)

96

CLIA Revisions – Revised Dtags

➢Technical Supervisor Qualifications (high complexity)

- D6111 - Bachelor's degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution (or additional course work - see 493.1449(c)(5)(i)(B))
- And



97

CLIA Revisions – Revised Dtags

➢Technical Supervisor Qualifications (high complexity)

- D6111 - Four years training/experience in non-waived high complexity testing in designated specialties of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology
- For micro – four years in micro specialty and at least six months within each subspeciality (bacteriology, mycobacteriology, mycology, parasitology, and virology)

98

CLIA Revisions – Revised Dtags

➢Technical Supervisor Qualifications (high complexity)

- D6111
  - Cytology – see 493.1449(e)
  - Histopathology – see 493.1449(f)
  - Oral Pathology – see 493.1449(g)
  - Histocompatibility – see 493.1449(h)
  - Clinical cytogenetics – see 493.1449(i)

99

CLIA Revisions – Revised Dtags

➢Technical Supervisor Responsibilities (high complexity)

- D6127 – Competency Evaluations at least semi-annually the first year of testing
- Semi-annual evals can now be delegated (in writing) to a general supervisor

100

CLIA Revisions – Revised Dtags

➢General Supervisor Qualifications (high complexity)

- D6143 – qualified as a:
  - High complexity lab director or
  - High complexity tech supervisor or
  - State licensed physician or podiatrist or

101

CLIA Revisions – Revised Dtags

➢General Supervisor Qualifications (high complexity)

- D6143 – qualified as a:
- Doctoral, master's, or bachelor's degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution and
- One year training/experience in non-waived high complexity testing
- Or

102

CLIA Revisions – Revised Dtags

- General Supervisor Qualifications (high complexity)
  - D6143 – qualified as:
  - High complexity testing personnel (see 493.1489(b)(3)
  - Two years of laboratory training/experience in high complexity testing

103

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6170 – state licensure if required
  - For questions, contact the North Dakota Board of Clinical Laboratory Practice at www.ndclinlab.com

104

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6171 – state licensed physician or podiatrist
  - Or

105

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6171 – Doctoral, Master's, or Bachelor's degree in a chemical, biological, clinical/medical laboratory science or medical technology from an accredited institution
  - Or meet the requirements at 493.1443(b)(3) or 493.1449(c)(4)
  - Or

106

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6171 – Associate degree in laboratory science or medical laboratory technology
  - Or meet the requirements at 493.1489(b)(3)
  - Or

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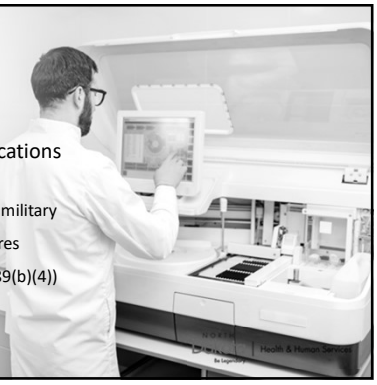
CLIA Revisions – New/Revised Dtags



- Testing Personnel Qualifications (high complexity)
  - D6171 – Completion of U.S. military medical laboratory procedures training course (see 493.1489(b)(4))

108

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6171 – high complexity blood gas analysis (see 493.1489(b)(6))

109

CLIA Revisions – New/Revised Dtags

- Testing Personnel Qualifications (high complexity)
  - D6171 – high complexity histopathology (see 493.1489(b)(7))

110

CLIA Revisions – Revised Dtags

- Grandfathering Provision for CLIA positions (moderate & high complexity)

  If qualified and serving in the CLIA position in a CLIA-certified lab as of Dec. 28, 2024, and continuously employed since Dec. 28, 2024.

111

CLIA Revisions – Revised Dtags

- Grandfathering Provision

  "Continuously employed" – no more than a six month (cumulative) break in the position in a two-year period.

112

CLIA Revisions – Revised Dtags

- Grandfathering Provision

  Responsibility of the individual to provide documentation showing their eligibility.

113

CLIA Revisions – New & Revised Dtags

- Histocompatibility
  - D5729 – use a continuous monitoring and alert system for F/F storage of specimens and reagents.
  - D5731 – P&Ps for storage and retention of specimens; easily retrievable; and emergency plan for alternate storage.
  - D5735 – quality control procedures for reagents used to facilitate/enhance isolation/identification of lymphocytes/ lymphocyte subsets.

114

CLIA Revisions – New & Revised Dtags

➢Histocompatibility

- D5737 – participate in a cell exchange program to validate interlaboratory reproducibility. Assess by test techniques.
- D5739 – use the current WHO nomenclature for HLA typing.
- D5749 – have written criteria for determining when antigen and allele typing are required

115

CLIA Revisions – New & Revised Dtags

➢Histocompatibility

- D5757 - for potential transplant recipients, have specimens available monthly for periodic testing
- D5763 – written criteria for each method of crossmatching

116

CLIA Revisions – New & Revised Dtags

➢Histocompatibility

- D5765 – written criteria for:
  - ✓ Defining donor & recipient HLA antigens, alleles, & antibodies to be tested;
  - ✓ Defining criteria to assess a recipient's alloantibody status;
  - ✓ Assessing recipient antibody presence/absence on an ongoing basis;
  - ✓ Typing the donor, to include HLA antigens to which antibodies have been identified in the potential recipient;

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CLIA Revisions – New & Revised Dtags

➢Histocompatibility

- D5765 – written criteria for: (continued)
  - ✓ Circumstances when pre- and post-transplant confirmation of donor and recipient specimens is required;
  - ✓ Donor and recipient test results are available to the transplant team;
  - ✓ Immunologic assessments are based on test results from a CLIA-certified lab;
  - ✓ Define time limits between recipient testing and performance of a crossmatch.

118

CLIA Revisions – New & Revised Dtags

➢Histocompatibility

- D5767 – test report specifies type of crossmatch
- D5769 – P&Ps specifying the histocompatibility testing to use for each type of cell, tissue, or organ
- D5773 – Document all control procedures performed

119

Hot Topics – Proficiency Testing

Revisions & Requirements

- Microbiology - Miscellaneous
  - ✓Report proficiency results to the highest level reported for patients
  - ✓Gram stains – morphology will be graded
  - ✓Bacterial Toxin Detection – required

120

Hot Topics – Proficiency Testing

Revisions & Requirements

- Coagulation

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

121

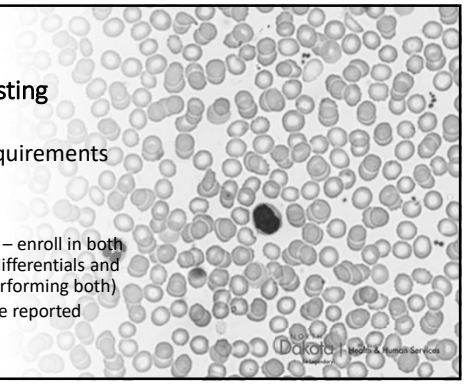
Hot Topics – Proficiency Testing

Revisions & Requirements

- Hematology

✓WBC Differentials – enroll in both automated WBC differentials and blood cell ID (if performing both)

✓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%

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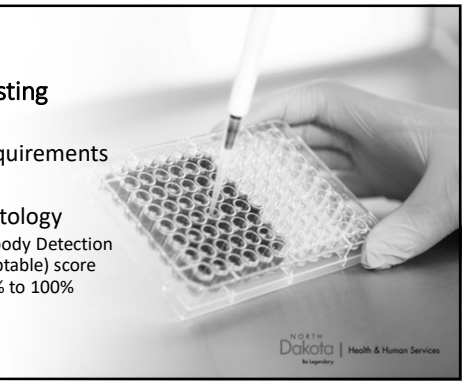
Hot Topics – Proficiency Testing

Revisions & Requirements

- Immunohematology

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



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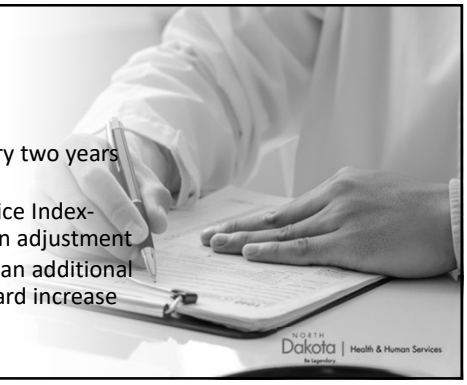
Hot Topics – Fee Changes

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

127

Hot Topics – Fee Changes

- Fees will be assessed for issuing:

✓ Replacement certificates
✓ Revised certificates

128

Hot Topics – Fee Changes

- Following activities will be assessed additional fees based on resources/time:

✓ Performing follow-up (revisit) surveys to verify correction of deficient practices

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Hot Topics – Fee Changes

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

130

Hot Topics – Fee Changes

✓ Performing a complaint survey for all certificate types, if substantiated

131

Hot Topics – Fee Changes

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

132

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

133

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

135

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

136

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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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 (until 06/05/25)
kimllarson@nd.gov
bweidner@nd.gov

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Sources

- The advance copy of the revised Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services is available at:
  - https://www.cms.gov/files/document/qso-25-10-clia.pdf

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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-22-21-CLIA, 07/11/22; Admin Info-23-07-CLIA, 05/03/23; QSO-24-03-CLIA, 12/28/23; QSO-25-10-CLIA.
- 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
- 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/clia-laboratories

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Happy Belated Medical Laboratory Professionals Week April 20-26, 2025

LAB WEEK
MEDICAL LABORATORY PROFESSIONALS WEEK

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