FIVE ISSUES THAT KEEP NEW CLIA LABORATORY DIRECTORS UP AT NIGHT: COMPLIANCE REQUIREMENTS, CHANGES IN ENFORCEMENT, OVERLOOKED SOURCES OF RISK

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OUTLINE

1. COMMON MISTAKES NEW LAB DIRECTORS MAKE
2. STAYING AHEAD OF PERSONNEL TURNOVER; KEEPING ALL STAFF TRAINED; MAINTAINING COMPETENCY AND RECORDS OF COMPETENCY
3. VARIABILITY IN ACCESSING LABORATORY DEVELOP TESTS FOR VALIDATION
4. ONGOING CHANGES TO CLIA REGULATIONS, INCLUDING HOW CLIA ASSESSORS CHANGE THE EMPHASIS ON THEIR INSPECTIONS FROM ONE YEAR TO THE NEXT (EVEN IF THE REGS ARE UNCHANGED)
5. ACCOUNTABILITY OF CLIA LAB DIRECTOR FOR MEDICAL NECESSITY

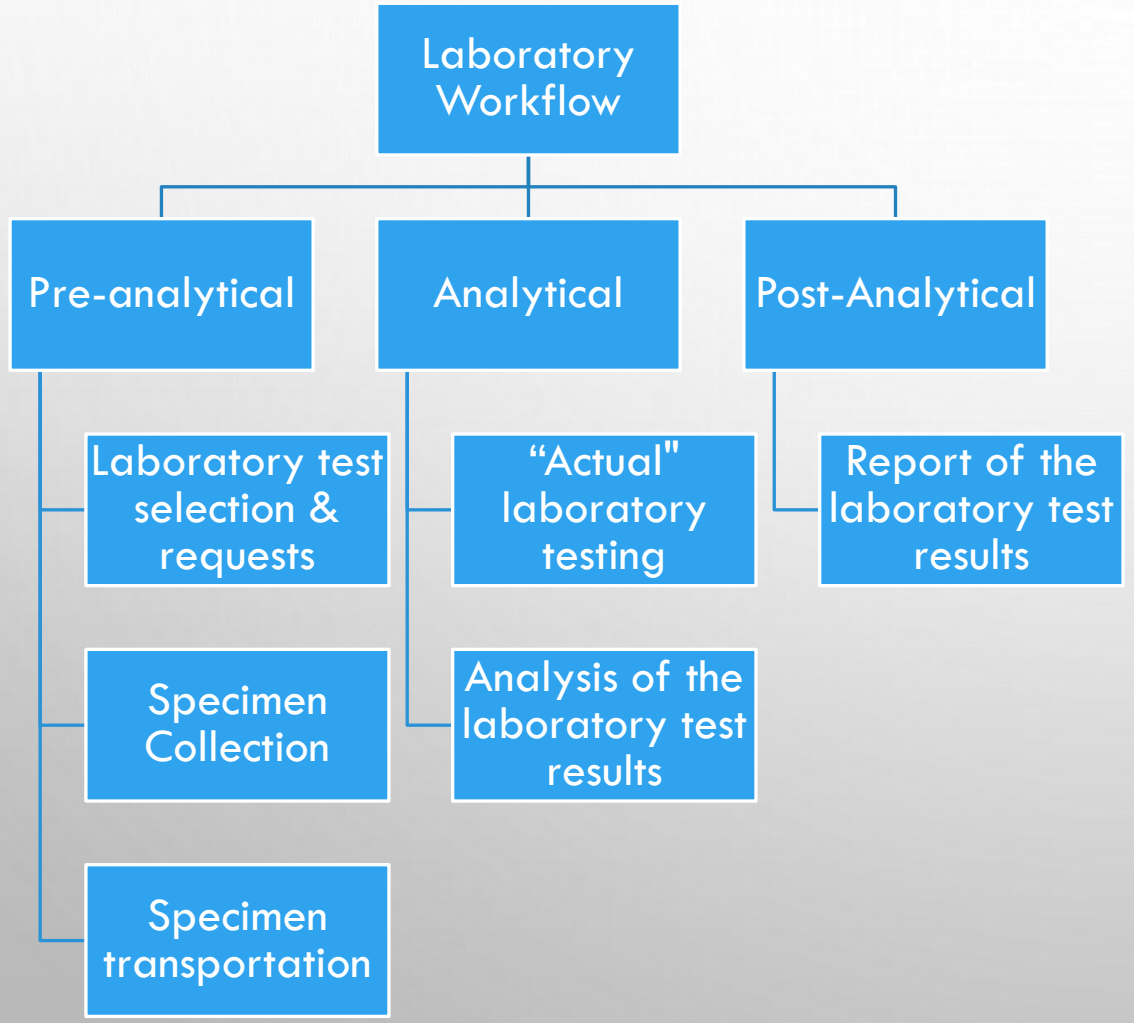
1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

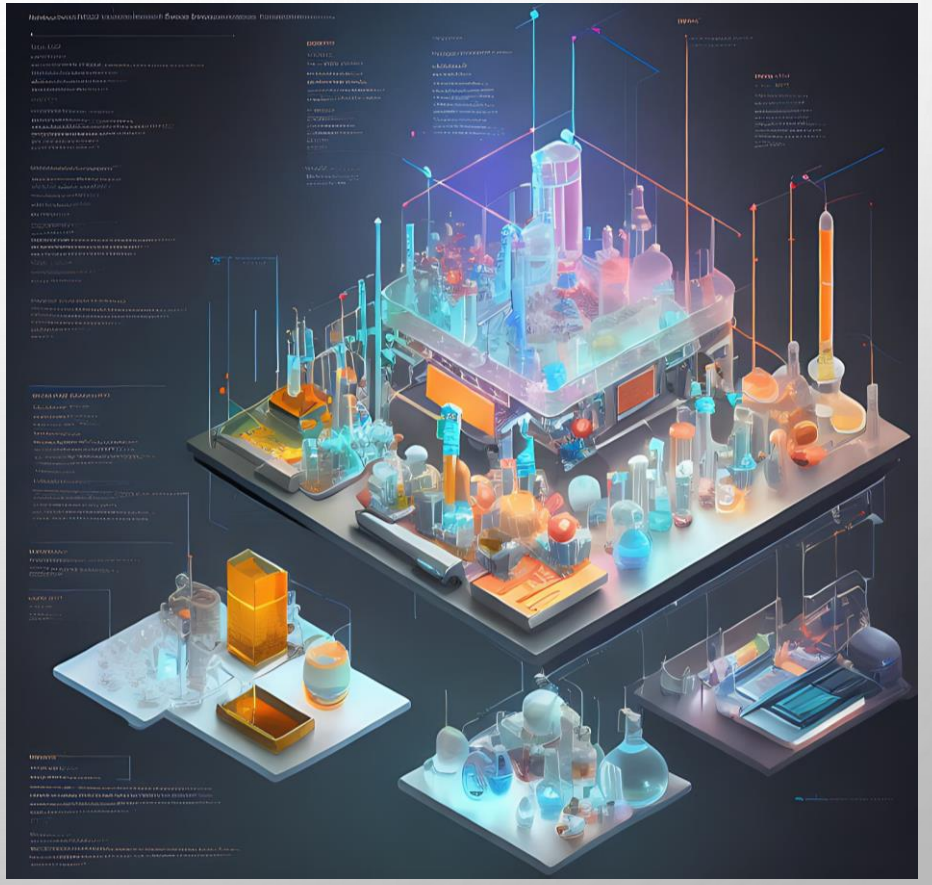
CMS TOP DEFICIENCIES

- PERSONNEL COMPETENCY ASSESSMENT (493.1235)
- ANALYTIC SYSTEMS (493.1252(B))
- GENERAL LAB SYSTEMS (493.1236(C)(1))
- VERIFICATION OF PERFORMANCE SPECIFICATIONS (493.1253(B)(1))
- ANALYTIC SYSTEMS (493.1251(B))
- PROCEDURE MANUAL (493.1251(A))
- ANALYTICAL SYSTEMS (493.1254(A)(1))
- ANALYTICAL SYSTEMS (492.1252(D))
- POST ANALYTIC SYSTEMS (493.1291(C))
- LABORATORY DIRECTOR'S RESPONSIBILITY (493.1407(E)(4)(I))
- *HTTPS://WWW.CMS.GOV/REGULATIONS-AND-GUIDANCE/LEGISLATION/CLIA/DOWNLOADS/CLIATOPTEN.PDF*

1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

UNDERSTAND THE ENTIRE LABORATORY WORKFLOW





1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

PROFICIENCY TESTING (PT)

- ENSURE PT SPECIMENS TESTED AS PATIENT SPECIMENS
- NOT ALL ANALYTES COVERED
- REVIEW/INITIAL/DATE ALL PT REPORTS
- EVALUATE PT TESTING RESULTS
- VARY THE TESTING PERSONAL/INSTRUMENTS
- PT CHECKLIST

American Proficiency Institute

AAB

CAP

WSLH PT

1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

PERSONAL FILE FOLDERS

- JOB DESCRIPTIONS
- RESUME/PROOF OF EDUCATION (PREFER TRANSCRIPT)
- HEPATITIS B VACCINATION ACCEPTANCE/DECLINATION
- FDA MEDICAL DEVICE RELATED INCIDENTS
- TRAINING ANNUAL: SAFETY, OSHA, HIPAA, BBP
- CONTINUING EDUCATION
- 6 MONTH AND ANNUAL COMPETENCY

1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

QUALITY ASSESSMENT (QA) PROGRAM/QUALITY MANAGEMENT SYSTEM (CALENDAR)

QSEs		
Organization	Facilities & Safety	Purchasing & Inventory
Process Management	Information Management	Assessments
Customer Focus	Personnel	Equipment
Documents & Records	Nonconforming Event Management	Continual Improvement

HTTPS://WWW.CDC.GOV/LABQUALITY/QMS-TOOLS-AND-RESOURCES.HTML AND CLSI QMS01 A QUALITY MANAGEMENT SYSTEM MODEL FOR LABORATORY SERVICES, 5TH EDITION

1. COMMON MISTAKES NEW LAB DIRECTORS MAKE

CALIBRATION VERIFICATION

- QUANTITATIVE ASSAYS REQUIRE A MINIMUM OF THREE SPECIMENS, (LOW, MID-POINT, AND HIGH) TO BE PERFORMED AT LEAST EVERY 6 MONTHS

LOT TO LOT VERIFICATION

- REMEMBER TO REVIEW MANUFACTURERS IFU
- USE PATIENT SAMPLES IN ADDITION TO QCS
- NEED GOOD DOCUMENTATION

CLSI EP26-A—USER EVALUATION OF BETWEEN-REAGENT LOT VARIATION

2. STAYING AHEAD OF PERSONNEL TURNOVER; KEEPING ALL STAFF TRAINED; MAINTAINING COMPETENCY AND RECORDS OF COMPETENCY

- DOCUMENT ALL 6 COMPETENCIES
- GENERAL SUPERVISOR, TECHNICAL SUPERVISOR/CONSULTANT AND CLINICAL CONSULTANT REQUIRE OWN COMPETENCIES
- MUST EVALUATE ALL PERSONNEL INVOLVED IN PRE-ANALYTICAL, ANALYTICAL AND POST-ANALYTICAL
- SUGGESTED AND REQUIRED BY MOST ACCREDITING AGENCIES TO PERFORM PT FOR WAIVED TESTING

2. STAYING AHEAD OF PERSONNEL TURNOVER; KEEPING ALL STAFF TRAINED; MAINTAINING COMPETENCY AND RECORDS OF COMPETENCY

STAFF SHORTAGES

- SUGGEST INDIVIDUAL STAFF MEETINGS TO REVIEW:
  - SET EXPECTATIONS AND UPDATE
  - TWO-WAY CONVERSATION
  - CAREER GROWTH PLAN
- REDUNDANCY/CROSS-TRAINING
- CULTURE
  - LUNCH AND LEARN I.E. CONTINUING EDUCATION
  - MEDICAL LABORATORY PROFESSIONALS WEEK
  - WATER COOLER/SNACKS

3. VARIABILITY IN ACCESSING LABORATORY DEVELOP TESTS FOR VALIDATION

- DETERMINE TEST COMPLEXITY: CLIA FDA DATABASE
- NEED ACCEPTABILITY CRITERIA
- VERIFICATION STUDIES: MODERATE COMPLEXITY
  - ACCURACY
  - PRECISION
  - REPORTABLE RANGE
  - REFERENCE INTERVAL

HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDRH/CFDOCS/CFCLIA/SEARCH.CFM

3. VARIABILITY IN ACCESSING LABORATORY DEVELOP TESTS FOR VALIDATION

- LABORATORY DEVELOPED TEST (LDT): TEST DESIGNED AND USED IN A SINGLE LAB
- MODIFIED FDA CLEARED OR APPROVED TEST
  - VALIDATION STUDIES: HIGH COMPLEXITY
    - ACCURACY (METHOD COMPARISON)
    - PRECISION
    - REPORTABLE RANGE/LINEARITY (QUANTITATIVE)
    - REFERENCE INTERVAL
    - ANALYTICAL SENSITIVITY (LIMIT OF DETECTION)
    - ANALYTICAL SPECIFICITY (CROSS-REACTIVITY (EXCLUSIVITY), INTERFERING SUBSTANCES AND INCLUSIVITY
    - CARRYOVER
    - SPECIMEN STABILITY

3. VARIABILITY IN ACCESSING LABORATORY DEVELOP TESTS FOR VALIDATION

- CLSI GUIDELINES (HTTPS://CLSI.ORG/)
- ISO
- WESTGUARD (HTTPS://WWW.WESTGARD.COM/)
- AMP (HTTPS://WWW.AMP.ORG/RESOURCES/VALIDATION-RESOURCES/)
- BURD EM. VALIDATION OF LABORATORY-DEVELOPED MOLECULAR ASSAYS FOR INFECTIOUS DISEASES. CLIN MICROBIOL REV. 2010 JUL;23(3):550-76. DOI: 10.1128/CMR.00074-09. PMID: 20610823; PMCID: PMC2901657.
- EP EVALUATOR
- ACCREDITING AGENCY WEBSITES (CAP, CMS, COLA AND JC)

4. ONGOING CHANGES TO CLIA REGULATIONS

- PT CHANGES JULY 2022 CMS-3355-F (EFFECTIVE JULY 11, 2024)
  - CMS SANCTIONS RELATING TO PROFICIENCY TESTING (PT) SHARING OR IMPROPER PT REFERRAL WILL NOW ALSO APPLY TO PROFICIENCY TESTING PERFORMED ON WAIVED TESTS (EFFECTIVE AUGUST 10, 2022).
    - PT STILL NOT REQUIRED FEDERALLY FOR WAIVED TESTING BUT HIGHLY SUGGESTED
  - IMMUNOHEMATOLOGY CHANGES: ACCEPTABLE SCORE FOR UNEXPECTED ANTIBODY DETECTION (ANTIBODY SCREEN) WILL BE 100%.
  - HEMATOLOGY CHANGES: LABORATORIES PERFORMING BOTH AUTOMATED DIFFERENTIALS AND MANUAL DIFFERENTIALS WILL BE REQUIRED TO ENROLL BOTH IN PT
  - CHEMISTRY, TOXICOLOGY, ENDOCRINOLOGY AND IMMUNOLOGY CHANGES: CMS HAS APPROVED SEVERAL ADDITIONS TO LIST OF REGULATED ANALYTES AND REMOVED SOME
  - MICROBIOLOGY CHANGES: COVER MORE ORGANISMS/TYPE

HTTPS://PUBLIC.POWERDMS.COM/COLAMD/DOCUMENTS/1137841/ AND HTTPS://WWW.CMS.GOV/FILES/DOCUMENT/QSO-22-21-CLIA.PDF AND HTTPS://WWW.CMS.GOV/MEDICAREPROVIDER-ENROLLMENT-AND-CERTIFICATIONSURVEYCERTIFICATIONGENINFOPOLICY-AND-MEMOS-STATES-AND/FINAL-RULE-CLINICAL-LABORATORY-IMPROVEMENT-AMENDMENTS-1988-CLIA-PROFICIENCY-TESTING-ANALYTES-AND

4. ONGOING CHANGES TO CLIA REGULATIONS

GUIDANCE ON SUBMISSIONS FOR CHANGES TO CMS-116

- RETAIN 7 YEARS
- LABORATORY CHANGES THAT REQUIRE NEW CMS-116
  - INITIAL
  - SURVEY, INITIAL OR RECERTIFICATION
  - CERTIFICATE TYPE CHANGE
  - REINSTATEMENT
  - OWNER/DIRECTOR CHANGE
  - ADDING MULTIPLE SITE EXCEPTION

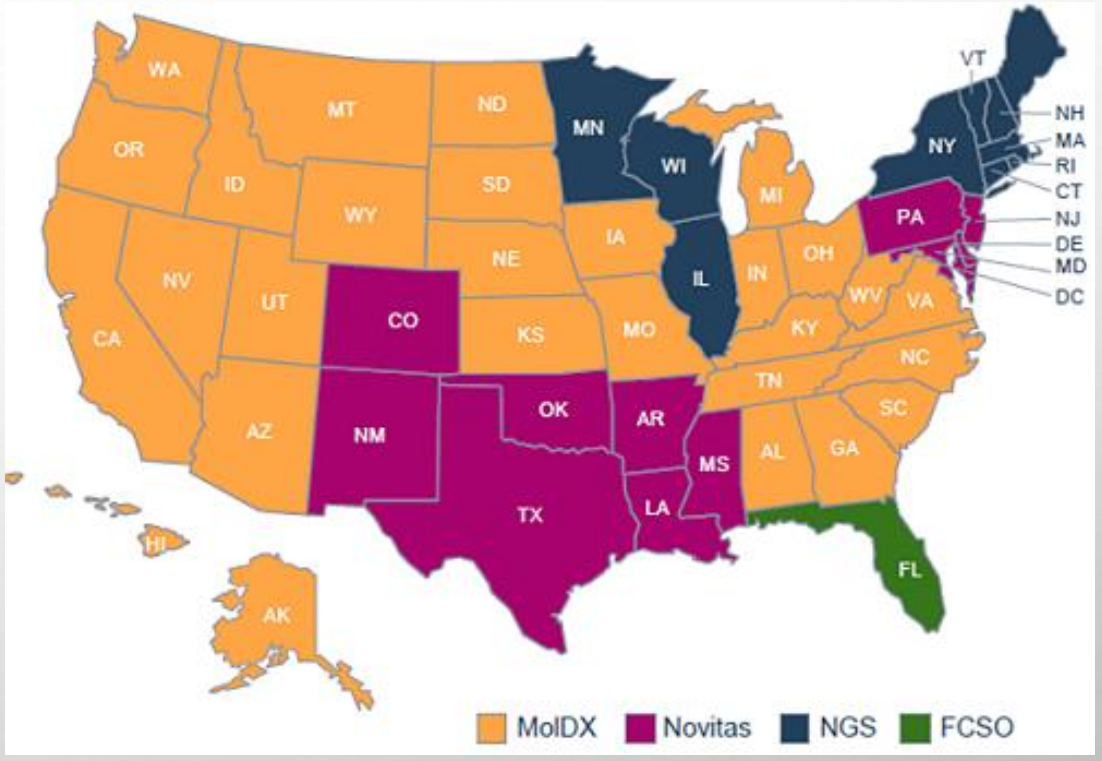
HTTPS://WWW.CMS.GOV/FILES/DOCUMENT/ADMIN-INFO-23-05-CLIA.PDF

4. ONGOING CHANGES TO CLIA REGULATIONS

- MOLECULAR
  - SPECIMEN STABILITY DONE WITH GENOMIC REFERENCE MATERIALS
  - *IN-SILICO* CROSS-REACTIVITY
  - LOT TO LOT VERIFICATION OF CRITICAL COMPONENTS
  - CONTROLS NEEDED (DON'T HAVE TO BE SEPARATE CONTROLS)
    - EXTRACTION CONTROL (MANUAL EXTRACTION)
    - REVERSE TRANSCRIPTION CONTROL
    - INTERNAL CONTROL IF REACTION INHIBITION IS A SIGNIFICANT SOURCE OF FALSE NEGATIVE RESULTS

4. ONGOING CHANGES TO CLIA REGULATIONS

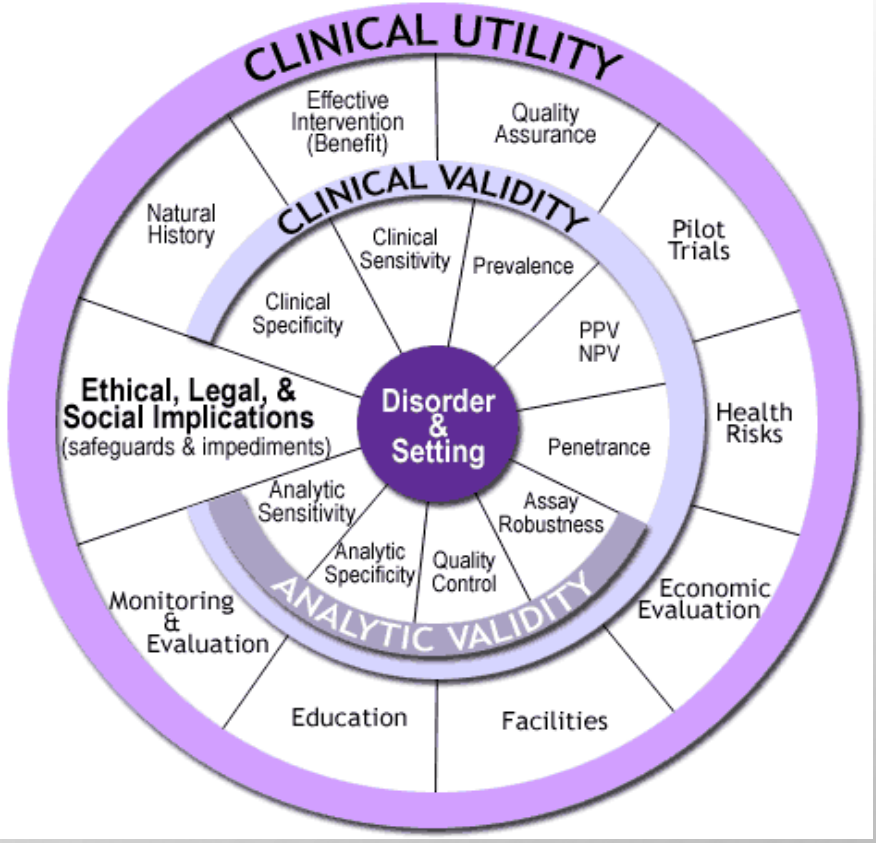
- THE MOLECULAR DIAGNOSTIC SERVICES (MOLDX) PROGRAM
  - PROVIDES UNIFORM POLICIES FOR 28 STATES, ACROSS FOUR MEDICARE ADMINISTRATIVE CONTRACTORS (MACS)
  - INFECTIOUS DISEASE PANELS PERFORMED AND BILLED IN MOLDX JURISDICTIONS ARE SUBJECT TO LCD



4. ONGOING CHANGES TO CLIA REGULATIONS

TECHNICAL ASSESSMENT REQUIREMENTS

- ANALYTICAL VALIDATION
- CLINICAL VALIDITY: ACCURACY WITH WHICH A TEST PREDICTS THE PRESENCE OR ABSENCE OF A CLINICAL CONDITION OR PREDISPOSITION
- CLINICAL UTILITY: VALUE OR BENEFIT ASSIGNED TO A PARTICULAR OUTCOME OR STATE



https://www.cdc.gov/genomics/gtesting/file/images/ACCE_wheel.gif

4. ONGOING CHANGES TO CLIA REGULATIONS

CLIAC WORK GROUP RECOMMENDED CLIA UPDATES (NO CHANGES 2023)

- MAIN SUGGESTIONS
  - NEED CLIA TO DEFINE DATA AS SPECIMEN
  - NEW CLIA CERTIFICATE FOR ENTITIES THAT WORK WITH LAB DATA
  - ALLOW REMOTE TESTING ACTIVITIES
- OTHER SUGGESTIONS
  - FDA SHOULD INCLUDE CONTROLS FOR SELF COLLECTION DEVICES
  - CLIA SHOULD DEFINE NEW PERSONNEL ROLES
  - NEW SPECIALTY ADDITIONS (NGS)

4. ONGOING CHANGES TO CLIA REGULATION

FDA, CMS AND CDC ARE CURRENTLY RESPONSIBLE FOR OVERSEEING CLIA

- FDA HAS NOT REGULATED LDTS AND INSTEAD LEFT CMS TO REGULATE THESE TESTS THROUGH CLIA
  - VERIFYING ACCURATE, LEADING-EDGE IVCT DEVELOPMENT (VALID) ACT
  - VERIFIED INNOVATIVE TESTING IN AMERICAN LABORATORIES (VITAL) ACT
  - SIGNS FDA IS PREPARED TO USE THE FEDERAL RULEMAKING PROCESS TO IMPOSE NEW LDT REGULATIONS.

5. ACCOUNTABILITY OF CLIA LAB DIRECTOR FOR MEDICAL NECESSITY

- LABORATORY MEDICAL DIRECTORS DO NOT DETERMINE MEDICAL NECESSITY
- OIG COMPLIANCE GUIDANCE
- FRAUD AND ABUSE LAWS SHOULD BE FAMILIAR WITH AND TRAIN EMPLOYEES ON
  - PATIENT PRIVACY (HIPAA, HITECH AND 42 CFR PART 2)
  - FALSE CLAIMS ACT
  - STARK
  - ANTI-KICKBACK STATUTE
  - ELIMINATING KICKBACKS IN RECOVERY ACT
  - SUNSHINE
  - STATE LAW COUNTERPARTS

STORIES FROM THE ROAD

WHY ALL OF THIS MATTERS?

- TOP REASONS WHY LABS FAIL A CLIA INSPECTION:
  - LACK OF STAFF FOCUS ON REGULATORY ISSUES
  - RETIREMENT OR MEDICAL ISSUES FOR KEY PERSONNEL
  - LACK OF INSTITUTIONAL SUPPORT
  - LACK OF A SOLID ONGOING PLAN FOR REGULAR TIMELY COMPLIANCE
  - LACK OF SUFFICIENT KNOWLEDGE/INVOLVEMENT BY THE CLIA LAB DIRECTOR

CONSEQUENCES CAN BE SEVERE

- DEPENDING ON TYPE OF DEFICIENCIES CITED
  - STANDARD- INVOLVES ONLY A COMPONENT OF A CLIA STANDARD
  - CONDITIONAL- INVOLVES A CLIA STANDARD
  - CONDITIONAL, IMMEDIATE JEOPARDY – INVOLVES A CLIA STANDARD AND COULD LEAD TO INJURY OF HARM- MOST SEVERE

PENALTIES MAY INCLUDE:

- PRINCIPAL SANCTION-SUSPENSION, LIMITATION OR REVOCATION OF THE CLIA CERTIFICATE
- FINES
- LOSS OF ABILITY TO DIRECT A CLIA LABORATORY FOR TWO YEARS

HOW CAN THE CLIA LAB DIRECTOR MAKE A DIFFERENCE?

- TOP REASONS WHY LABS FAIL A CLIA INSPECTION:
  - LACK OF STAFF FOCUS ON REGULATORY ISSUES- ***REGULAR CHECK-IN MEETINGS WITH STAFF***
  - RETIREMENT OR MEDICAL ISSUES FOR KEY PERSONNEL- ***INSIST ON CONSISTENCY AND COMMUNICATION ACROSS THE LAB SO THAT OTHERS CAN STEP IN***
  - LACK OF INSTITUTIONAL SUPPORT- ***ADVOCATING TO THE INSTITUTION FOR RESOURCES***
  - LACK OF A SOLID ONGOING PLAN FOR REGULAR, TIMELY COMPLIANCE- ***DEVISE, CHECK ON AND UPDATE THE PLAN REGULARLY***
  - LACK OF SUFFICIENT KNOWLEDGE/INVOLVEMENT BY THE CLIA LAB DIRECTOR- ***BE INFORMED AND INVOLVED!***

THANK YOU!