POINT-OF-CARE TESTING and the CLIA SURVEY

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CLIA
Regulatory Requirements

- Waived Tests:
  - 42 CFR § 493.15(e)(1)
    - Follow manufacturers' instructions for performing the test

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Regulatory Requirements

- Non-Waived Tests (Moderate, PPMP, and High):
  - Proficiency Testing (42 CFR § 493.801)
  - Facility Administration (42 CFR § 493.1100)
  - General Systems (42 CFR § 493.1230)
  - Preanalytic Systems (42 CFR § 493.1240)
  - Analytic Systems (42 CFR § 493.1250)
  - Postanalytic Systems (42 CFR § 493.1290)
  - Personnel (42 CFR § 493.1351)

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CMS' Current Survey Approach

- Survey approach remains educational, but deficiencies identified are cited
  - Laboratory has opportunity to correct
  - Regulatory explanation &/or resources provided
- In 2006, GAO stated survey consistency concerns
- Training & guidance provided to surveyors
- "Mandatory" citations determined
- Accelerated enforcement for repeat offenders
- Slight increases in citations occurred
  - Due to mandatory citations & areas of training focus

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CMS' Current Survey Approach

- The primary objective of the CLIA survey process is to determine whether or not the laboratory meets the CLIA requirements.

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CMS' Current Survey Approach

- The surveyor meets this objective by employing an outcome-oriented survey process or approach.
  - The intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

ONSITE CLIA SURVEYS

- NOT subject to biennial inspections:
  - Certificate of Waiver
  - Certificate of PPMP
- Subject to biennial inspections:
  - Certificate of Compliance
  - Certificate of Accreditation

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ONSITE CLIA SURVEYS
Certificate of Waiver/PPMP

- Pursuant to 42 CFR § 493.1775(b):
  - CMS/agent may conduct an inspection to:
    - Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health
    - Evaluate a complaint

ONSITE CLIA SURVEYS

Certificate of Waiver/PPMP

- Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory
- Collect information regarding the appropriateness of tests specified as waived tests or PPMP

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ONSITE CLIA SURVEYS
Certificate of Compliance

- The inspection sample for review may include testing in the categories of waived tests and PPMP.

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ONSITE CLIA SURVEYS
Regulatory Requirements

- Non-Waived Tests (Moderate, PPMP, and High):
  - Proficiency Testing (42 CFR § 493.801)
  - Facility Administration (42 CFR § 493.1100)
  - General Systems (42 CFR § 493.1230)
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  - Analytic Systems (42 CFR § 493.1250)
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FACILITY ADMINISTRATION

- Facilities
- Requirements for transfusion services
- Retention requirements

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FACILITY ADMINISTRATION
Retention Requirements

- Test Reports:
  - Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting
    (42 CFR §493.1105(a)(6))
    - A copy, *either paper or electronic*, includes all information sent to the individual requesting the test or using the test result(s).

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PROFICIENCY TESTING

- CLIA proficiency testing requirements pertain to non-waived tests only.
- Proficiency is required for only the test system, assay, or examination used as the primary method for patient testing during the proficiency testing event.
  (42 CFR § 493.801(b)(6))

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PROFICIENCY TESTING

- If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (42 CFR § 493.1281(a))

PROFICIENCY TESTING

- Each laboratory must enroll in a proficiency testing program that meets the criteria in subpart I.
- At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I. (42 CFR § 493.1236(c)(1))

GENERAL SYSTEMS

- Confidentiality of patient information
- Specimen identification and integrity
- Complaint investigations
- Communications
- Personnel competency assessment policies
- Evaluation of proficiency testing
- Quality assessment program

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GENERAL SYSTEMS
Specimen Identification and Integrity

- The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. (42 CFR § 493.1232)

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GENERAL SYSTEMS

Personnel Competency Assessment Policies

- As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to asses employee and, if applicable, consultant competency. (42 CFR § 493.1235)

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PREANALYTIC SYSTEMS

- Test requisition
- Specimen submission, handling, and referral policies and procedures
- Quality assessment program

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PREANALYTIC SYSTEMS
Test Requisitions

- Test requisitions must include:
  - The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen. . .

    (42 CFR § 493.1241(c)(1))

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PREANALYTIC SYSTEMS
Test Requisitions

- 42 CFR § 493.1241(c)(1) Interpretation:
  - The test requisition must provide the information necessary to identify and send test results to the individual who ordered the test (the **authorized person**), or, where applicable, to the authorized person's **agent**.

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PRETANALYTIC SYSTEMS
Test Requisitions

- "Authorized person"
  - An individual authorized under State law to order tests or received test results, or both
- "Agent"
  - An individual or entity legally acting on behalf of the authorized person to receive test results

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ANALYTIC SYSTEMS

- Procedure manual
- Test systems, equipment, instruments, reagents, materials, and supplies
- Performance specifications
- Maintenance and function checks
- Calibration and calibration verification procedures
- Control procedures
- Test records
- Quality assessment program

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ANALYTIC SYSTEMS
Performance Specifications

- 42 CFR § 493.1253:
  - Establishment and Verification of Performance Specifications
    - VERIFICATION
    - ESTABLISHMENT

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ANALYTIC SYSTEMS
Performance Specifications

- VERIFICATION of Performance Specifications
  - Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

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ANALYTIC SYSTEMS
Performance Specifications

- Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:
  - Accuracy
  - Precision
  - Reportable range of test results for the test system.
- Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

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ANALYTIC SYSTEMS
Performance Specifications

- ESTABLISHMENT of Performance Specifications
  - Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures)., OR. . .

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ANALYTIC SYSTEMS
Performance Specifications

. . .uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

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ANALYTIC SYSTEMS
Performance Specifications

- Accuracy
- Precision
- Analytical sensitivity
- Analytical specificity to include interfering substances
- Reportable range of test results for the test system
- Reference intervals (normal values)
- Any other performance characteristics required for test performance.

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ANALYTIC SYSTEMS
Performance Specifications

- Establish/Verify Performance Specification:
  - When MULTIPLE INSTRUMENTS (including the same make and model, e.g., point-of-care instruments) are used to perform the same test, the laboratory must establish or verify, as applicable, performance specifications for each instrument.

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ANALYTIC SYSTEMS
Performance Specifications

- When a temporary replacement (loaner) instrument is received which is identical (i.e., same make and model, and method for the same analyte) to the instrument which is being replaced. . .

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ANALYTIC SYSTEMS
Performance Specifications

. . .the laboratory must verify comparable performance by comparing, at a minimum, results of two or more levels of controls AND either previously tested proficiency testing samples or previously tested patient specimens.

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ANALYTIC SYSTEMS
Quality Control Procedures

- Quality Control Procedures must detect immediate errors that occur due to:
  - Test System Failures
  - Environmental Conditions
  - Operator Performance

(42 CFR § 493.1256(c)(1))

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ANALYTIC SYSTEMS
Quality Control Procedures

- Test System Failures
  - Reagent contamination or deterioration
  - Reagent lot variation
  - Reaction temperature fluctuations
  - Inadequate sampling
  - Improper or loss of calibration
  - Electronic or mechanical failure
  - Power supply variances

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ANALYTIC SYSTEMS
Quality Control Procedures

- Environmental Condition Changes
  - Temperature
  - Airflow
  - Light intensity
  - Humidity
  - Altitude

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ANALYTIC SYSTEMS
Quality Control Procedures

- Operator Performance
  - Improper specimen preparation and handling
  - Incorrect test interpretation
  - Failure to follow the manufacturer's test system instructions

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ANALYTIC SYSTEMS
Quality Control Procedures

- Operator training prior to testing is critical and competency assessment over time is necessary to ensure continued appropriate test performance.

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ANALYTIC SYSTEMS
Quality Control Procedures

- In general, at least ONCE each day patient specimens are assayed or examined perform the following for –
  - Each quantitative procedure, include 2 control materials of different concentrations;
  - Each qualitative procedure, include a negative and positive control material;
  - Test procedures producing graded/titered results, include a negative control material and a control material with graded/titered reactivity respectively. (42 CFR § 493.1256(d)(3)(i-iii))

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ANALYTIC SYSTEMS
Quality Control Procedures

- For CLIA purposes, “control materials” are defined as:
  - **External** quality control materials
  - Have a similar matrix to that of patient specimens
  - Treated in the same manner as patient specimens
  - Go through all analytic phases of testing

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- However, a laboratory can perform EQUIVALENT QUALITY TESTING (EQC) as specified in Appendix C of the State Operations Manual (CMS Pub.7)

  (42 CFR § 493.1256(d))

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- EQC may only be used for laboratory testing subject to the following control procedure requirements:
  - 42 CFR § 493.1256(d)(3)(i-iii)
  - 42 CFR § 493.1256(d)(3)(iv) – test procedures that include an extraction phase (limited to Options 1 and 2)
  - 42 CFR §§ 493.1267 to 493.1269 – control requirements for routine chemistry and hematology (limited to Options 1 and 2)

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- OPTION **1** – Test system uses one or more internal/procedural control(s) to monitor all of its analytic components
  - Evaluation Process:
    - For **ten** (10) consecutive days of testing, perform the test system's internal control procedures per the manufacturer's instructions and test two levels of external control material daily. If acceptable. . .
    - The laboratory may reduce the frequency of testing two levels of external control material from daily to once per calendar **month**.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- OPTION **2** – Test system uses some internal/procedural controls to monitor only certain components
  - Evaluation Process:
    - For **thirty** (30) consecutive days of testing, perform the test system's internal control procedures per the manufacturer's instructions and test two levels of external control material daily. If acceptable. . .
    - The laboratory may reduce the frequency of testing two levels of external control material from daily to once per calendar **week**.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- OPTION **3** – Test systems without internal/procedural controls
  - Evaluation Process:
    - For **sixty** (60) consecutive days of testing, perform the test system's control procedures per the manufacturer's instructions and, at a minimum, test two levels of external control material daily. If acceptable. . .
    - The laboratory may reduce the frequency of testing two levels of external control material from daily to once per calendar **week**.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- If any internal/external control results are unacceptable during the evaluation process OR after the laboratory has reduced the frequency for testing external control materials, the laboratory must repeat the testing of the unacceptable control.
  - If repeat control result is acceptable, no further corrective action is necessary. Resume evaluation process or reduced external control testing frequency.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- If repeat control result is NOT acceptable, the laboratory must:
  - Identify the problem and take appropriate corrective action.
  - Evaluate all patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been adversely affected. (42 CFR 493.1282(b)(2))
  - Restart and successfully complete the evaluation process before reducing the frequency of testing external control materials.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- Remember, the following ongoing assessment activities are also required:
  - Proficiency testing results MUST demonstrate acceptable/satisfactory performance
  - Analytic system quality assessment activities must demonstrate problems are not occurring
  - Competency assessment evaluations must demonstrate testing personnel are accurately performing testing

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- If unacceptable results are obtained for any of these assessment activities, the laboratory must:
  - Investigate
  - Identify the problem
  - Document the corrective action(s) taken
  - RESTART the evaluation process

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

- If the laboratory chooses to implement the reduced QC frequency (EQC) for MULTIPLE INSTRUMENTS (including the same make and model used to perform the same test) a successful evaluation process must be performed for each instrument for which the QC frequency applies.

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ANALYTIC SYSTEMS
Quality Control Procedures - EQC

OTHER POSSIBLE OPTIONS???

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POSTANALYTIC SYSTEMS
Test Reports

- The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. (42 CFR § 493.1291(a))

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POSTANALYTIC SYSTEMS
Test Reports

- Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

  (42 CFR § 493.1291(f))

POSTANALYTIC SYSTEMS
Test Reports

- 42 CFR § 493.1291(f) Interpretation:
  - Test results must be released to the authorized person, or, if applicable, their agent.
  - Test results must also be released to any additional individuals/entities designated on the test requisition.
    - These entities are understood to be "responsible for using" the test results.

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POSTANALYTIC SYSTEMS
Test Reports

- For CLIA purposes, when the authorized person, designated agent, or individual responsible for using the test result receives the results, whichever is last, the laboratory's CLIA responsibility ends.

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CLIA WEBSITE

Information can be found at the CMS Website:
www.cms.gov/clia