CLIAC Update – April 2016

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Current Statistics--Enrollment

Total Number of Laboratories	254,975
Total Non-Exempt	246,650
Compliance	18,385
Accredited	16,441
Waived	177,016
Provider Performed Microscopy	34,808
Exempt	8,325
NY	4,256
WA	4,069

CMS data base 1/2016

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Current Statistics

Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)

- Waiver: 62.8%
- Provider Performed Microscopy: 22.7%
- Compliance: 9.7 %
- Accreditation: 4.8%

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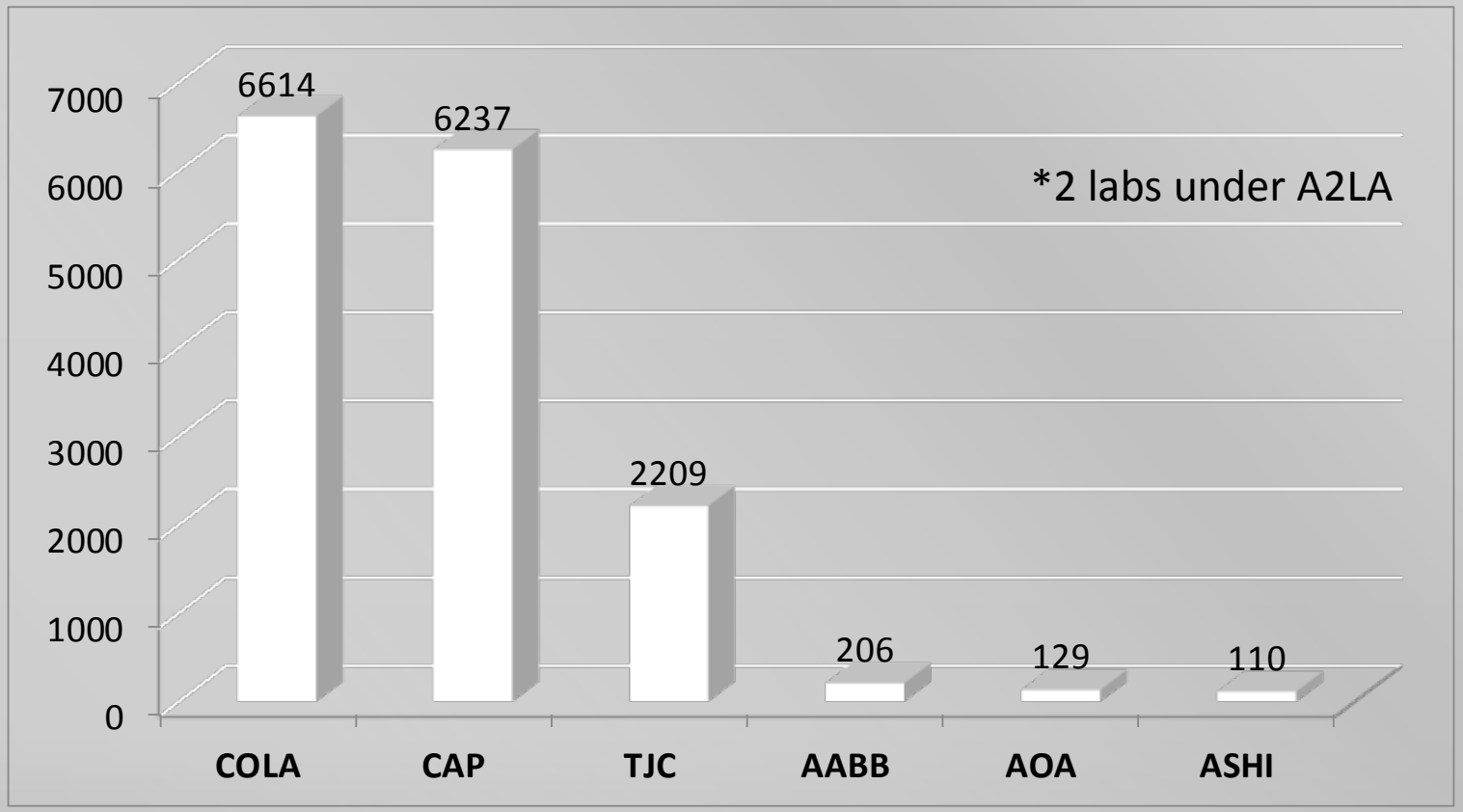
CLIA Certificate of Accreditation Laboratories



CMS data base 1/2016*

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Top 10 Deficiencies

Condition Level Deficiencies
Moderate Complexity Lab Director qualifications
Successful Proficiency Testing Participation
High Complexity Lab Director qualifications
Analytic Systems
Proficiency Testing - enrollment
Moderate Complexity –Technical Consultant
Moderate Complexity – Testing Personnel
Hematology Quality Systems
High Complexity Testing Personnel
High Complexity -Technical Supervisor qualifications

Overall Deficiencies
Proper storage of reagents and specimens
Analytic Systems Quality Assurance
Alternative PT if no PT available
Procedure Manual
Test reports – patient ID
Manufacturer's instructions
Moderate Complexity Lab Director qualifications
Expired reagents
Calibration verification
Successful Proficiency Testing Participation

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Top Waived Deficiencies

Deficiency	2012	2013	2014	2015
Not performing QC required by Manufacturer	17%	16%	13%	15%
Do not have current package insert	10%	9%	7%	8.5%
Not using correct expiration date for storage method	9%	8%	7%	8%
Not reporting test results per manufacturer's instructions	5%	5%	5%	5%
Not following manufacturer's storage and handling instructions	5%	4%	4%	6%

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CLIA Interpretive Guidelines

- Revised guidelines published 01/2016
  - Removal of EQC
  - Addition of IQCP
- Summary of major changes included with S&C:15-17-CLIA

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IQCP

- As of January 1, 2016, labs must be in compliance with their QC choice or deficiencies will be cited

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CMS/FDA Joint Taskforce (Background)

- On October 3, 2014, the FDA submitted its proposed draft guidance for oversight of LDTs to Congress, and subsequently posted a Proposed Notice for Public Comment.

- Opponents of the proposed guidance have argued that the CMS' CLIA program already sufficiently regulates LDTs, and the FDA's LDT proposal would only add undue burden for the laboratories, as well as claiming that both agencies have many duplicative requirements regarding LDT regulations.

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Background(cont.)

- Opponents have also argued that laboratories do not function nor have activities like manufacturers, and therefore, the FDA has no authority over these laboratories.
- Both the CMS and the FDA have explained the different statutory authority and responsibilities on numerous occasions.

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CMS/FDA JOINT AGENCY TASK FORCE

- Posted FAQs on the CLIA website regarding CLIA and FDA oversight responsibilities for LDTs,
- Posted a joint agency blog regarding a FDA/CMS LDT Quality Task Force. This task force has been working together this spring to review both the FDA's Quality System requirements and the CLIA requirements in an attempt to identify any duplication and streamline the LDT oversight process if possible.

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CLIA MODERNIZATION PROPOSALS

- CMS is aware of four proposals being developed for legislative consideration concerning the CMS CLIA program.
- These proposals have been put forth by:
  1) American Medical Association (AMA),
  2) Association for Molecular Pathology (AMP),
  3) College of American Pathologists (CAP), and
  4) Diagnostic Test Work Group (DTWG).

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MODERNIZATION PROPOSALS (cont.)

- These proposals differ in their risk based classification of the LDTs, which oversight responsibilities should be covered by CMS versus the FDA, and implementation time frames.
- The House Energy and Commerce Committee held a hearing in November of 2015, in which both CMS and FDA representatives answered questions regarding their respective oversight authority and responsibilities regarding LDTs.

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COMMON PROPOSAL THEMES

- Similar themes:

  1) Revision/enhancement of the CLIA ‘88 regulations,

  2) Shift in the oversight responsibility for manufacturing requirements of the Laboratory Developed Tests (LDTs) from the FDA to CMS,

  3) Requirement of both analytical and clinical validation data for LDTs,

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COMMON PROPOSAL THEMES (CONT.)

4) Less stringent LDT review/approval process than the current FDA's 510K/PMA review/approval process, and

5) A publically accessible database of all LDTs being offered by CLIA laboratories.

Note: Each of these proposals differs on what CLIA updates are needed and how to regulate LDTs.

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PRECISION MEDICINE INITIATIVE

- Seeks to enhance disease prevention and treatment by taking into account individual variability in genes, environment, and lifestyle.
- Presidential initiative to build a large research cohort of one million Americans.
- Employs genomic technologies, data collection and storage, computation analysis, and mobile health applications.

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PRECISION MEDICINE INITIATIVE

- Plans to engage cohort members using a highly interactive and proactive participation model.
- CLIA issue: researchers wish to provide participants with genomic test results that were obtained in non-CLIA certified research laboratories.
- CLIA certification is intended to ensure accurate test results. Without CLIA certification, patients and health care providers cannot be assured of the test result's analytic validity, potentially leading to misdiagnosis and treatment.

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QUALITY CONTROL

- Acceptable control materials will now include on-board controls.
- Certain instruments have introduced the use of on-board controls, i.e., ampules or cartridges containing the same QC material that would traditionally be considered as external QC.
- Instrument/electronic function checks and procedural controls do not fulfill the regulatory requirement for testing control materials.

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QUALITY CONTROL (CONTINUED)

- The laboratory director is responsible for the determination of what control materials to use in his/her laboratory.
- Surveyors will ensure that the laboratory is following its own established policies, specifically its QC procedures, in the context of the Outcome Oriented Survey Process.
- Laboratories that intend to perform less QC than the regulatory requirements must develop and implement an IQCP that supports their QC plan.

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Primary Source Verification (PSV)

- PSV is the process of confirming an applicant's credentials by verifying that a degree, certificate, or diploma was received, that licenses were granted, and by confirming reported work history.
- Verifications are obtained either directly from an institution, former employers, or their authorized agents.
- The use of Primary Source Verification (PSV) is optional for the laboratory.

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Primary Source Verification (PSV)

- It is the Laboratory Director's (LD) responsibility to ensure that personnel qualifications are met.
- CLIA personnel regulations and the policy on mandatory citations are not changing.
- Both the condition level AND standard level deficiencies must be cited when noncompliance with personnel regulations is found.

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CLIA Basic Training Update

- Transition Face-to-Face to Virtual On-line Training
- Available for surveyors 24/7
- Modules built on content from face-to-face CLIA Basic Training
- Training developed by group consisting of Central Office and Regional Office Staff

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CLIA Basic Training Update

- Modules will be interactive-knowledge point questions built in
- Professional voice-over for all modules
- Expected completion for pilot early Summer 2016

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Resources

- CLIA website:

  https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

- IQCP Mailbox : IQCP@cms.hhs.gov

- LabExcellence: LabExcellence@cms.hhs.gov

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