CLIA Update: Spring 2018

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Name Changes

- Division of Clinical Laboratory Improvement and Quality (DCLIQ), formerly the Division of Laboratory Services (DLS)
- Quality, Safety and Oversight Group (QSOG), formerly Survey and Certification Group (SCG)

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Current Statistics--Enrollment

Total Number of Laboratories	**259,967**
Total Non-Exempt	251,009
Compliance	17,967
Accredited	16,074
Waived	184,298
Provider Performed Microscopy	32,670
Exempt	8,958
NY	4,918
WA	4,040

CMS data base 1/2018

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Current Statistics

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

- Waiver: 64.9%
- Provider Performed Microscopy: 21.3%
- Compliance: 9.4 %
- Accreditation: 4.4%

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Growth of Waived Testing

Lab Type	Year	Year	Year	Year	Year	Year	Year
	1993	1995	2000	2005	2010	2015	2017
Compliance	44,762	37,578	25,068	20,480	19,404	18,385	17,967
Waiver	67,294	65,031	85,944	113,445	141,994	177,016	184,298
PPM	16,443	23,089	35,760	39,205	37,795	34,808	32,670
Accredited	23,751	19,426	16,992	15,607	15,864	16,441	16,074

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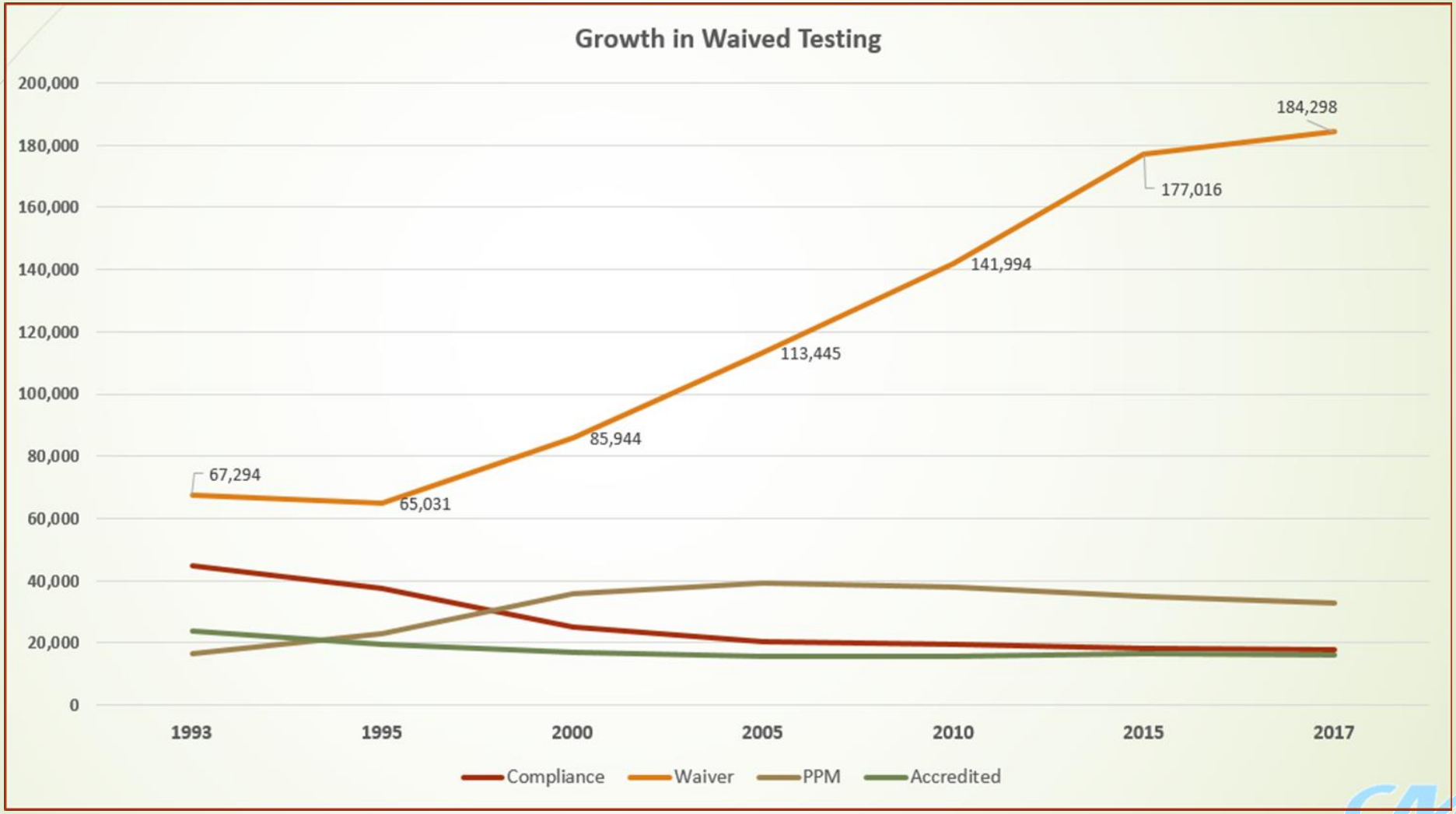
Growth of Waived Testing



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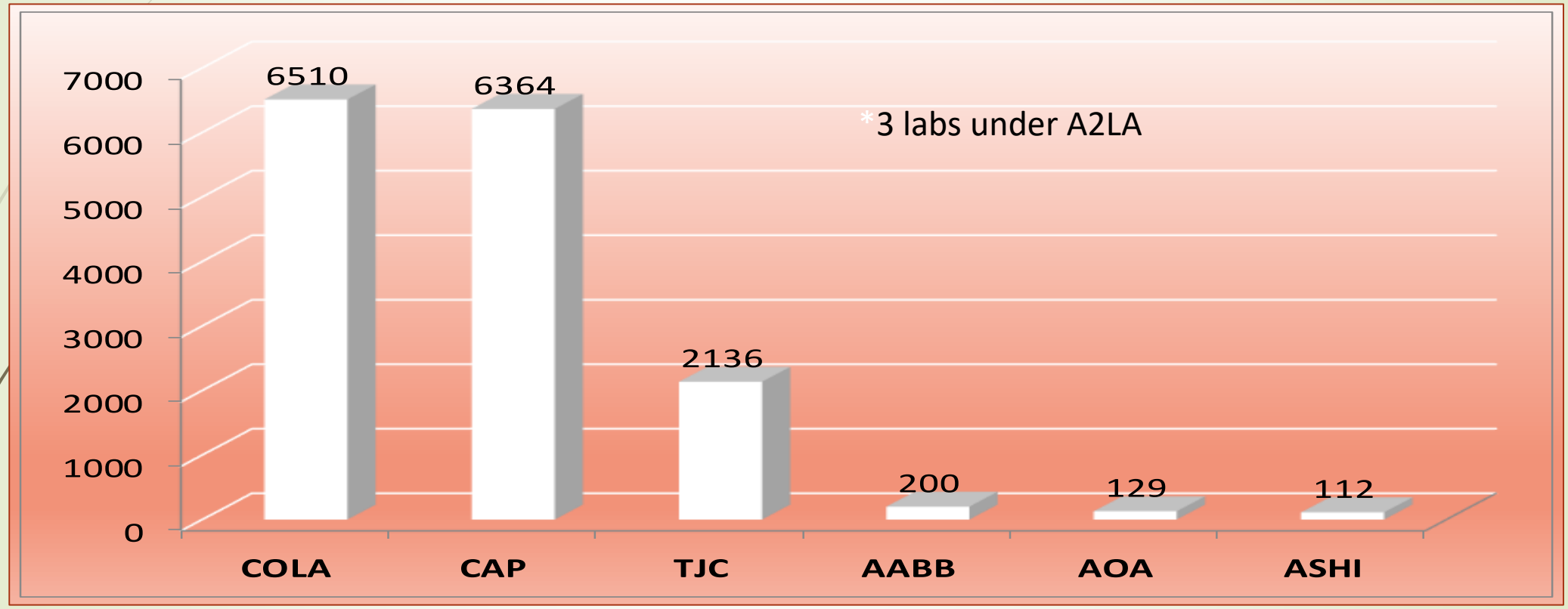
Certificate of Accreditation Laboratories



CMS data base 1/2018

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
• Procedure Manual
• Alternative PT if no PT available
• Test reports – patient ID • Competency
• Manufacturer's instructions
• Expired reagents
• Maintenance and function checks
• Calibration verification

Request for Information (RFI) CMS-3326-NC

- Published January 9, 2018
- Comments due by March 12, 2018
- Comments requested on questions related to:
  - Personnel
  - Proficiency Testing Referral
  - Histocompatibility
  - CLIA fees

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RFI - Personnel

- Nursing degree: equivalent to Biological Science degree or add as separate qualifying degree
- Physical Science degree: should be considered as educational background appropriate for qualifying to meet CLIA educational requirements
- Competency: Should General supervisor with AA degrees be allowed to perform competency for moderate complex testing personnel in labs performing mod and high complex testing.

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RFI – Personnel

- What is appropriate lab training, experience and skills when determining qualifications necessary to meet CLIA requirements?
- Should non-traditional degrees, such as a Regents Bachelor of Arts, be considered to meet requirements for chemical, physical, biological, clinical chemistry, and/or medical technology degrees.

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RFI – Proficiency Testing Referral

- Comments regarding application of discretion in situations where a laboratory has referred PT to another laboratory and reported that lab's results as its' own
- Under what circumstances should the discretion be applied?
- Should alternative sanctions rather than principle sanctions be an option for PT referral for waived laboratories?

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RFI - Histocompatibility

- Comments related to CLIAC recommendations that:
  - Virtual crossmatch should be an acceptable alternative to physical crossmatch
  - Under what criteria and decision-making algorithms virtual crossmatching would be an appropriate substitute for physical crossmatching

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RFI – CLIA Fees

- Comments on methodology to set reasonable and fair fees for revised certificate requests
- Alternative, standardized method for determining hourly rates for entities (§493.649(b))
- Updating fees for program compliance as well as additional fees to accredited labs (§493.649(b))
- Assessing other fees for compliance activities

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CLIA Outreach (COPA) Update

- The Division of Clinical Laboratory Improvement and Quality (DCLIQ) created the CLIA Outreach Program – Academic (COPA) in the summer of 2016

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COPA Goals

- Connect with college and university Medical Laboratory Science programs and their students to increase their knowledge of and visibility of CMS/CLIA.
- Demonstrate the direct link between compliance with CLIA regulations and high quality laboratory testing and
- Promote medical laboratory science as an important, dynamic and desirable career

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COPA Update

- The CLIA 101 Presentation has reached 8 campuses, 113 students and 25 faculty in Maryland and Virginia
- In 2018 outreach efforts have expanded to events planned by Healthcare Occupation Students of America (HOSA) in DC and TX
- COPA plans an event in DC at the USA Science and Engineering Festival in April 2018 which is designed for high school age students

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COPA Schedule -2018

Academic Program	INSITUTION NAME	CITY	DATE
MLT/CLT	Fortis College - Landover	Landover, MD	Feb '18
MLS/CLS	George Washington University	Ashburn, VA	Nov '17
HOSA	Healthcare Occupation Students of America	District of Columbia	Mar '18
HOSA	Healthcare Occupation Students of America	Dallas, Texas	June '18
MLS/CLS	Walter Reed National Military Medical Ctr.	Bethesda, MD	Apr '18
STEM	USA Science & Engineering Festival	District of Columbia	Apr '18

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COPA Expansion: Ideas

- Completion of two new presentation for the 2018 season will focus on high school science programs: junior and senior students
- Collaboration with Healthcare Students of America (HOSA) state chapters could result in COPA presentations in DE, WV and VA - 2018
- Given the growth of Point of Care Testing (POCT) expand the proposed mailing list to offer the COPA to Nursing/Medical schools -2019
- The current program materials will be offered to CMS CLIA Regional Staff and/or State Agencies to present to their area's academic institutions

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CLIA Oversight and Nontraditional Testing Models

Traditional Testing Model

- All phases of laboratory test performed and reported out by one CLIA laboratory
- A single entity is responsible for the entire test from start to finish of the testing process
- All CLIA requirements apply

CLIA Oversight and Nontraditional Testing Models

Testing models have changed:

- Common to split test functions and outsource to contractors
- Advances in communications and scientific knowledge
- Improved accessibility and use of digital data

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Examples of Non-traditional Testing Models

- Sanger sequencing: sequencing, data analysis, genotyping, interpretation
- Next Generation Sequencing: sequencing, data analysis (primary, secondary, tertiary analysis), bioinformatics, interpretation
- Telepathology (anatomic pathology): slide grossing by cytotechnologist, slide examination by Pathologist
- Toxicology: Mass spec reactions, data analysis, interpretation

CLIAC Workgroup Request-April 2018

- Provide input to CLIAC for consideration in making recommendations to HHS regarding the need for optimal oversight by CLIA and best methods for such oversight in non-traditional testing models such as:
  - Telemedicine (i.e. remote review/reporting of laboratory results, pathology etc.)
  - Bioinformatics facilities (ex. Cloud based programming)
  - NGS testing, sequencing
  - Toxicology

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Where to Obtain Information

CLIA Website: www.cms.hhs.gov/clia/

CLIA Central Office: 410-786-3531

CLIA Mailbox: LabExcellence@cms.hhs.gov

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