CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA Update – Fall 2017

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Centers for Medicare & Medicaid Services

Topics Covered

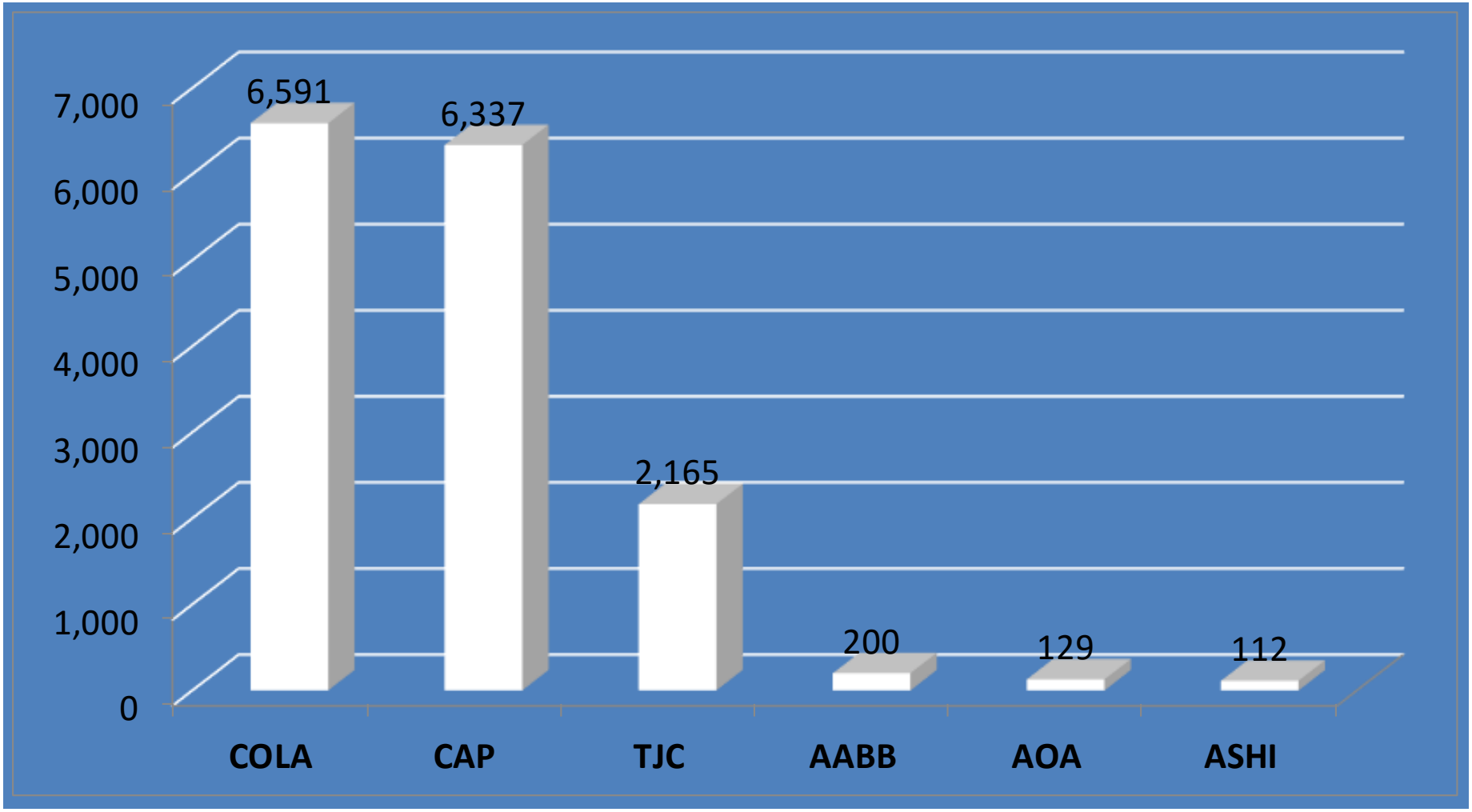
- Statistics
- IQCP Survey Findings – 2016
- CLIA Outreach
- CLIA Virtual Basic Training
- Interagency Coordination

Current Statistics - Enrollment

Total Number of Laboratories	**257,263**
Total Non-Exempt	**248,405**
Compliance	18,082
Accredited	16,248
Waived	180,831
Provider Performed Microscopy	33,244
Exempt	**8,858**
NY	4,807
WA	4,051

CMS data base 6/2017

Certificate of Accreditation Laboratories



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

Top Waived Deficiencies

Deficiency	2012	2013	2014	2015	2016
Not performing QC required by Manufacturer	17%	16%	13%	15%	13.5%
Do not have current package insert	10%	9%	7%	8.5%	7.5%
Not using correct expiration date for storage method	9%	8%	7%	8%	8.4%
Not reporting test results per manufacturer's instructions	5%	5%	5%	5%	3.0%
Not following manufacturer's storage and handling instructions	5%	4%	4%	6%	6.6%

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IQCP SURVEY FINDINGS - 2016

IQCP Survey Findings*
(*Surveys from 1/1/16 – 12/31/16)

Laboratories surveyed	9241	
Labs implementing IQCP	761	8%
Labs with IQCP Citations	154	1.7%
Percent of labs implementing IQCP with IQCP citations		20%

IQCP Survey Findings

IQCP Citation Category	Number of Labs Cited
Reduced QC w/o IQCP	69
Risk Assessment Citations	64
Quality Control Plan Citations	43
Quality Assurance Citations (inadequate/missing)	24
Lab Director Signature missing	18
Total	**218**

IQCP Survey Findings

Risk Assessment Citation	Number of Labs cited
RA not performed	35
Data Issues	12
Not all 5 components assessed for risk	6
Not all phases of testing assessed	5
Miscellaneous RA citations	4
Documentation Issues	2

IQCP Survey Findings

Quality Control Plan (QCP) Citations	Number of labs cited
No QCP	16
QCP – no specific number, type or frequency of Controls	13
QCP not followed	9
Miscellaneous QCP	3
QCP less than manufacturer's instructions	2

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CLIA OUTREACH

CLIA Outreach

The Division of Laboratory Services (DLS) created the CLIA Outreach Program – Academic (COPA) in the summer of 2016 and had its formal GO-Live in February of 2017

CLIA Outreach - COPA

DLS began with a pilot program for only local schools to gauge the interest and acceptance for the program.

- 11 schools were contacted within 120 miles of Baltimore.
- 6 schools showed interest in our CLIA 101 presentation
- 5 events were scheduled for Maryland schools.

COPA Target Audience

- Allied health students of 2 to 4 year degree programs in local or regional universities and community colleges.

- Associate Degree – Medical Laboratory Technician (MLT) / Clinical Laboratory Technician (CLT)

- Bachelor's Degree – Medical Laboratory Scientist (MLS) / Clinical Laboratory Scientist (CLS)

Goals of COPA

- Promote Clinical Laboratory Science as a career at universities and community colleges.

- Educate students of Clinical Laboratory Science programs about the Clinical Laboratory Improvement Amendment of 1988 (CLIA) and how its regulations promote and ensure high quality test results

Goals of COPA

- Describe how the Centers for Medicare and Medicaid Services (CMS) work with State governments and Accreditation Organizations to monitor the certification and survey of clinical laboratories in the US and overseas.
- Describe the aspects of CLIA for test complexity, certification and testing requirements/regulations

COPA Presentation Schedules -2017

Academic Program	INSITUTION NAME	CITY	DATE
MLT/CLT	Anne Arundel Community College	Arnold, MD	Mar '17
MLT/CLT	Community College of Baltimore County	Rosedale, MD	Sep '17
MLT/CLT	Fortis College - Landover	Landover, MD	Mar '17
MLS/CLS	George Washington University	Foggy Bottom, DC	Nov '17
MLT/CLT	Howard Community College	Columbia, MD	Feb '17
MLS/CLS	Salisbury University	Salisbury, MD	Feb '17
MLS/CLS	Stevenson University	Owings Mills, MD	Sep '17
MLS/CLS	Walter Reed National Military Medical Ctr.	Bethesda, MD	Apr '17

Evaluations and Feedback

- Evaluations of the program content and presenters scored HIGH; average 4.8 points out of 5.0!
  - *"Expand this information to high school and middle school students"*
  - *"Excellent and informative presentation. More on job options "*
  - *"…move along faster leaving more time for job info "*
  - *"Educated and knowledgeable speakers "*
  - *"use more examples and personal stories"*
- <u>In all situations</u> the schools have asked us to come back!
- Challenge to vary the presentation method form live to on-line audio-visual options to better reach the off-campus students.

COPA Expansion Ideas

- The current program materials are being offered to CMS CLIA Regional Staff and/or State Agencies to present to their area's academic institutions - 2017
- In development: design presentations for local high school science programs: junior and senior students -2018
- Collaboration with Healthcare Students of America (HOSA), an organization that focuses on high schools using a state chapter system across the country -2018
- Given the growth of Point of Care Testing (POCT) expand the proposed mailing list to offer the COPA to Nursing/Medical schools -2019

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VIRTUAL BASIC TRAINING

CLIA Virtual Basic Training

- All Surveyors (RO and SA) are required to take the virtual training courses
- New surveyors (those with less than 2 years experience) have 3 months to complete the training
- Remaining surveyors have up to one year to complete the training

CLIA Virtual Basic Training Update

- Go live date was May 2017
- Basic made up of 14 Lessons, with a total of 24 modules
- All modules available 24/7
- There is a Pre / Post Test for each module
- Includes a short video that covers the entire survey process

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TRI-AGENCY COORDINATION

Interagency Coordination

- CMS, along with CDC and the FDA, formed a tri-agency response team to keep each agency informed of potential issues involving CLIA laboratories
- Develop process where by each agency informs the other of potential issues so that response can be proactive rather than reactive.
- Allows CLIA to determine the immediate need for sending surveyors into the laboratory .

Interagency Coordination

- CMS, CDC and the FDA, have formed an additional tri-agency workgroup that will review EUAs for emergent diseases.

- Standardization of information, policies and procedures for EUAs to assist laboratories and surveyors.

Emergency Use Authorization (EUA) Authority (FD&C Act § 564)

- A legal mechanism that allows the FDA to strengthen the nation's public health protections against Chemical, Biological, Radiologic, and Nuclear (CBRN) threats.

- Facilitates the availability of Medical Counter Measures (MCM). The term MCM means the medical products that might be needed during public health emergencies to diagnose, prevent, or treat diseases or other conditions resulting from CBRN emergencies.

- HHS Secretary has to make a declaration of emergency or threat justifying emergency use.

EUA Authority (FD&C Act § 564)

- With an EUA, FDA can authorize:
  (a) the use of an unapproved MCM or
  (b) the unapproved use of an approved MCM during an emergency.

- When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act.

FDA List of EUAs

This FDA page lists current and terminated Emergency Use Authorizations that Make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies

https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm

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Next Generation Sequencing (NGS) Multi-Site Testing and CLIA Applicability

Objectives

1) Background
2) Current Multi-Site Testing Models
3) Examples
4) Questions

TRADITIONAL TESTING MODEL

- All phases of a single laboratory test (i.e. preanalytical, analytical, and postanalytical) are or have been performed and reported out by one CLIA laboratory. (Example: Point-Of-Care testing)

- A single entity is responsible for the entire patient test, from beginning to end of the testing process.

PRESENT- NON-TRADITIONAL TESTING MODELS

- Testing models have changed!
  - Becoming more common to split functions of a test procedure and outsource it to contractors.
  - Advances in computer systems, Wi-Fi, global communication, etc.
  - Advances in science, bioinformatics, etc. (e.g. NGS genetic testing)
  - Improved accessibility, and use of digital data

NGS Testing Model 1: Traditional CLIA Setup

- Model 1 involves only 1 testing site; requires a CLIA certificate.
  - Traditional laboratory workflow- all parts of the test performed by 1 facility.
  - Patient report is generated and sent to the provider by the one CLIA facility.
- NGS test systems tend to be high complexity tests.
- All CLIA requirements, high complexity testing personnel qualifications, etc. would apply.

Legend: green box= indicates “wet process” (i.e. bench work flow)
orange box= indicates “dry process” (i.e. data analysis/evaluation and interpretation)

NGS Testing Model 2: Non-traditional, multiple site testing

- Model 2 involves 2 sites.
  - Non-traditional laboratory workflow; parts of test performed by more than 1 facility.
  - Site 1, performs the "wet process"; requires a CLIA certificate.
  - CLIA Site 1 has a *contract* with Site 2 to perform a part of the test procedure; use of external outsourced services.
- Site 2 generally *receives the electronic data/image*, performs the analysis and interpretation via a computer and software, and sends the test result and test report back to CLIA Site 1, or
  - Site 2 can instead send the test report to the provider.
  - Site 2 may or may not be a CLIA laboratory.
- Other examples of test systems using this model: sanger sequencing, digital cytogenetics, digital toxicology, digital pathology

Questions

1. What specialties/subspecialties have parts of test systems that can be outsourced to another facility?

a) Examples: Sequencing tests (e.g. sanger and NGS), flow cytometry, cytogenetics, digital pathology, digital toxicology

b) Others-Anything we missed?

2. What other types of non-traditional business models are you aware of between the laboratory and the outsource facility providing the testing service?

3. What difficulties are encountered with non-traditional testing models?

Questions

4. What criteria/requirements should be included in the contract with an outsource facility?

5. In regards to bioinformatics, how does the laboratory/laboratory director ensure the outsource facility and its computer/software is providing accurate and reliable information or results?

6. How does the laboratory ensure the outsource facility is fulfilling its responsibilities in the contract (particularly if the outsource facility is not under the same business/organizational entity)?

7. Other questions to consider?

Where to Obtain Information

CLIA Website:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

CLIA Central Office: **410-786-3531**

CLIA Mailbox: LabExcellence@cms.hhs.gov

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Thank you!