CLIAC Update – Fall 2015

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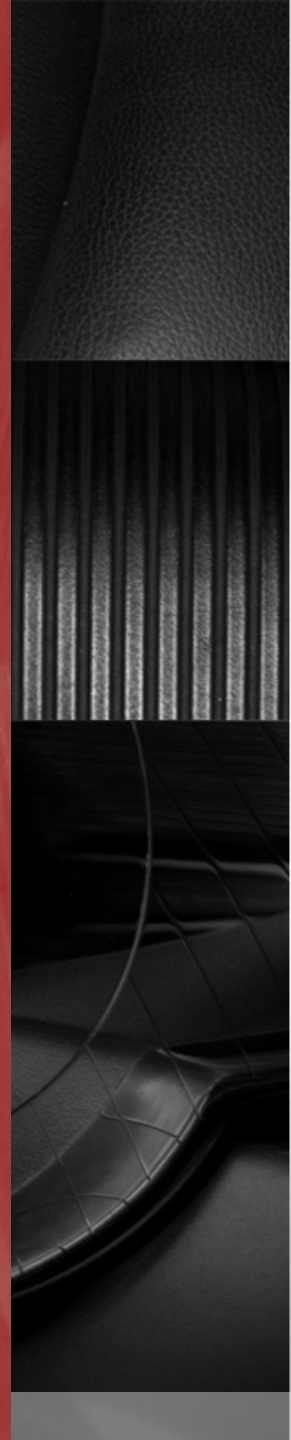

Current Statistics--Enrollment

Total Number of Laboratories	**252,384**
Total Non-Exempt	**244,208**
Compliance	18,505
Accredited	16,431
Waived	174,122
Provider Performed Microscopy	35,180
Exempt	**8,105**
NY	4150
WA	4023

CMS data base 7/2015

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Current Statistics

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)

- Waiver: 62.2%
- Provider Performed Microscopy: 23.1%
- Compliance: 9.8 %
- Accreditation: 4.9%

CMS data base 7/2015

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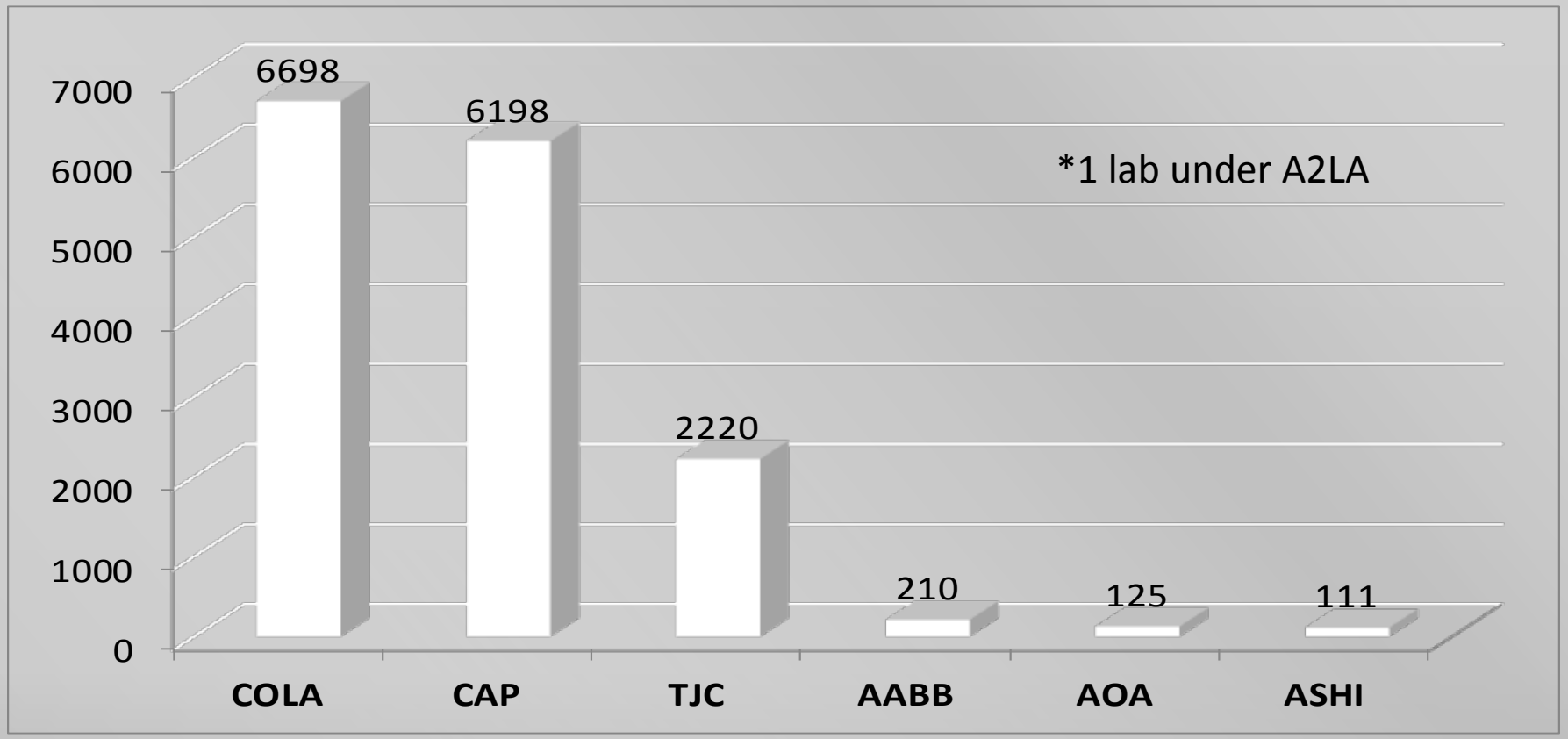
CLIA Certificate of Accreditation Laboratories



CMS data base 7/2015*

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Top 10 Deficiencies

Condition Level Deficiencies
Moderate Complexity Lab Director qualifications
Successful Proficiency Testing Participation
High Complexity Lab Director qualifications
Proficiency Testing Enrollment
Analytic System (QC)
Moderate Complexity Testing Personnel
Technical Consultant qualifications
Hematology
High Complexity Testing Personnel
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
Not performing QC required by manufacturer	17%	16%	13%
Does not have current package insert	10%	9%	7%
Not using proper expiration date for storage method	9%	8%	7%
Not reporting patient test results as required by manufacturer	5%	5%	5%
Not following manufacturer's storage and handling instructions	5%	4%	4%

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GPRA Waived Project

Government Performance Review Act

- Goal – improved compliance with CLIA standards
- Measured by- increased percentage of Letters of Congratulations (no problems found) sent to waived (CW) laboratories based on onsite educational visits

GPRA 'Ready, Set, Test!' Waived Project

- 2010 Baseline – 18% received Letters of Congratulations
  - Results from 2011 – 32%
  - Results from 2012 – 44%
  - Results from 2013 – 45%
  - Results from 2014 – 48%

Educational materials like 'Ready, Set, Test' booklet are well-received and serve as an excellent means to improve lab test quality

CLIA Interpretive Guidelines

- Revised guidelines published 01/09/2015
- Summary of major changes included with S&C:15-17-CLIA
- January 2016 revision:

  -Removal of EQC

  -Addition of IQCP

Fecal Occult Blood (FOB) Testing

CMS 3271-P: Proposed rule to amend CLIA regulations by:

- Specifying waived test categorization that applies only to non-automated FOB tests; and
- Removing copper sulfate method from waived list if comments confirm test no longer in use.

This regulatory adjustment gives the FDA flexibility in categorizing FOB tests.

Updating PT Regulations

- On-going Collaboration between CMS and CDC
- Reviewing list of analytes, grading criteria & target values, etc.

Once review is complete, a proposed rule for public comment will be published.

CLIA and FDA Task force - LDTs

- Senior leadership and SMEs from both Agencies
- Effort to identify similarities in regulations
- Streamline requirements for labs regulated by both CMS and FDA
- Public outreach(blog, whitepaper)

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Glucose Meters-Update

S&C Memorandum 15-11, which was previously issued on November 21, 2014, has been withdrawn and reissued in draft-only form in order to:

- Obtain more feedback regarding the use of waived BGMS, the environments in which BGMS are currently used, and any issues that hospitals and other providers have identified with such use
- Promote added education regarding the current CLIA requirements

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Reissued S&C 15-11-CLIA

- Areas of clarification in the reissued memo
  - Regulatory background
  - Manufacturer's instructions
  - Off-Label Use or Test Modification
  - Issues identified on Survey
  - Laboratory options for CLIA Compliance

Lab Excellence Mailbox

- LabExcellence@cms.hhs.gov
- Still accepting comments/questions on S&C:15-11-CLIA

Manufacturer's Package inserts

NOTE: Facilities performing blood glucose testing are held to the intended use, limitations and precautions in the package insert

Manufacturer's Package Inserts

- If the BGMS is used according to the manufacturer's intended use, limitations and precautions, the meter retains its' waived status.

Off-label use

- Using a test outside of FDA approved/cleared intended use, limitations or precautions as indicated in manufacturer's instructions is considered "off-label" use.
- "Off-label use" means the test (whether waived or non-waived) is considered modified and defaults to High Complexity under CLIA

"Off-label" Use

"Off-label" use of a waived test is not prohibited however…..

If the laboratory chooses to use the test "off label", CLIA regulations at §493.1253(b)(2) require establishment of performance specifications for that test

CLIA Survey Process

- CMS is not “targeting” BGMS
- CMS following its Outcome Oriented Survey process for CLIA surveys

IQCP Education &Transition Period

E&T Period – ends Dec.31, 2015

CMS certified labs should be in the final stages of:

- Decision to implement IQCP or default QC
- Planning & completing their transition, phasing out EQC (if using it)

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IQCP Facts

- As of January 1, 2016, labs must be in compliance with their QC choice or deficiencies will be cited
- IQCP is optional; the default is the regulation at §493.1256(d)

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IQCP Facts

- Series of IQCP webinars held Nov. 4-6
- Intended for RO/SA surveyors
- Refresher training on IQCP prior to end of Education and Transition period.

IQCP & Accredited Labs

AOs with approved IQCP procedures:

- CAP—3/12/15
- COLA- 5/20/14
- NY State - 6/6/14
- WA State - 2/27/15
- Joint Commission – 6/18/15
- AOA – 10/20/15

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IQCP Educational Outreach

- IQCP Workbook is here!
  - Published on 5/15/15
  - Focus geared primarily towards Physician Office Laboratories (POLs) & other smaller labs

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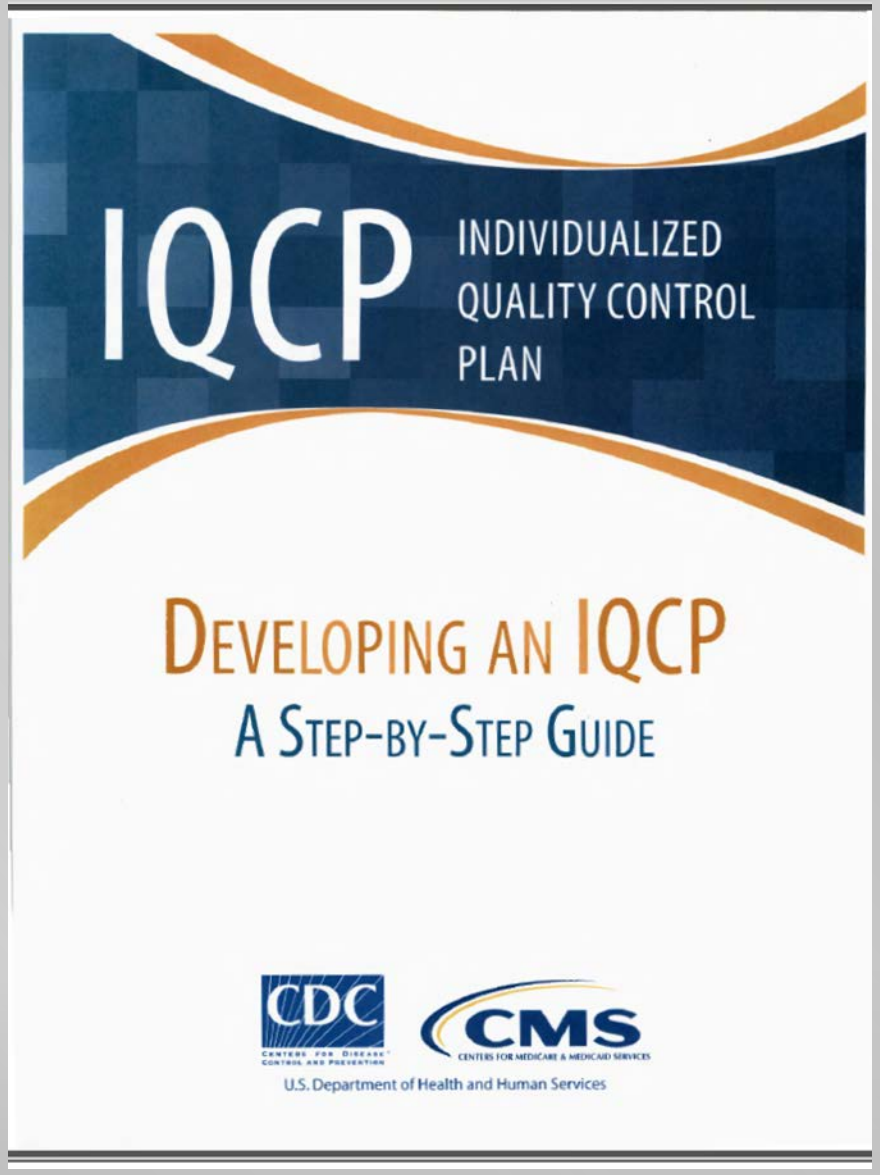
IQCP
INDIVIDUALIZED
QUALITY CONTROL
PLAN
DEVELOPING AN IQCP
A STEP-BY-STEP GUIDE
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
U.S. Department of Health and Human Services

IQCP Communications

- CLIA website (www.cms.gov/clia/)
- IQCP Mailbox : IQCP@cms.hhs.gov
- IQCP workbook: http://wwwn.cdc.gov/CLIA/Resources/IQCP/

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