



# Weeding Through Waived Testing: Separating the Wheat from the Chaff



Ellis Jacobs, Ph.D., DABCC, FAACC  
Principal, EJ Clinical Consulting, LLC  
Adjunct Associate Professor of Pathology,  
Mount Sinai School of Medicine

# Agenda

- 1 Describe Overarching Federal Regulations/Role of Deemed Agencies**
- 2 Review the Growth of POCT**
- 3 Regulatory Deficiencies in Waived Testing**
- 4 Personnel Training and Competency Assessment Requirements**
- 5 Requirements for Assuring Quality of Examination Procedures**

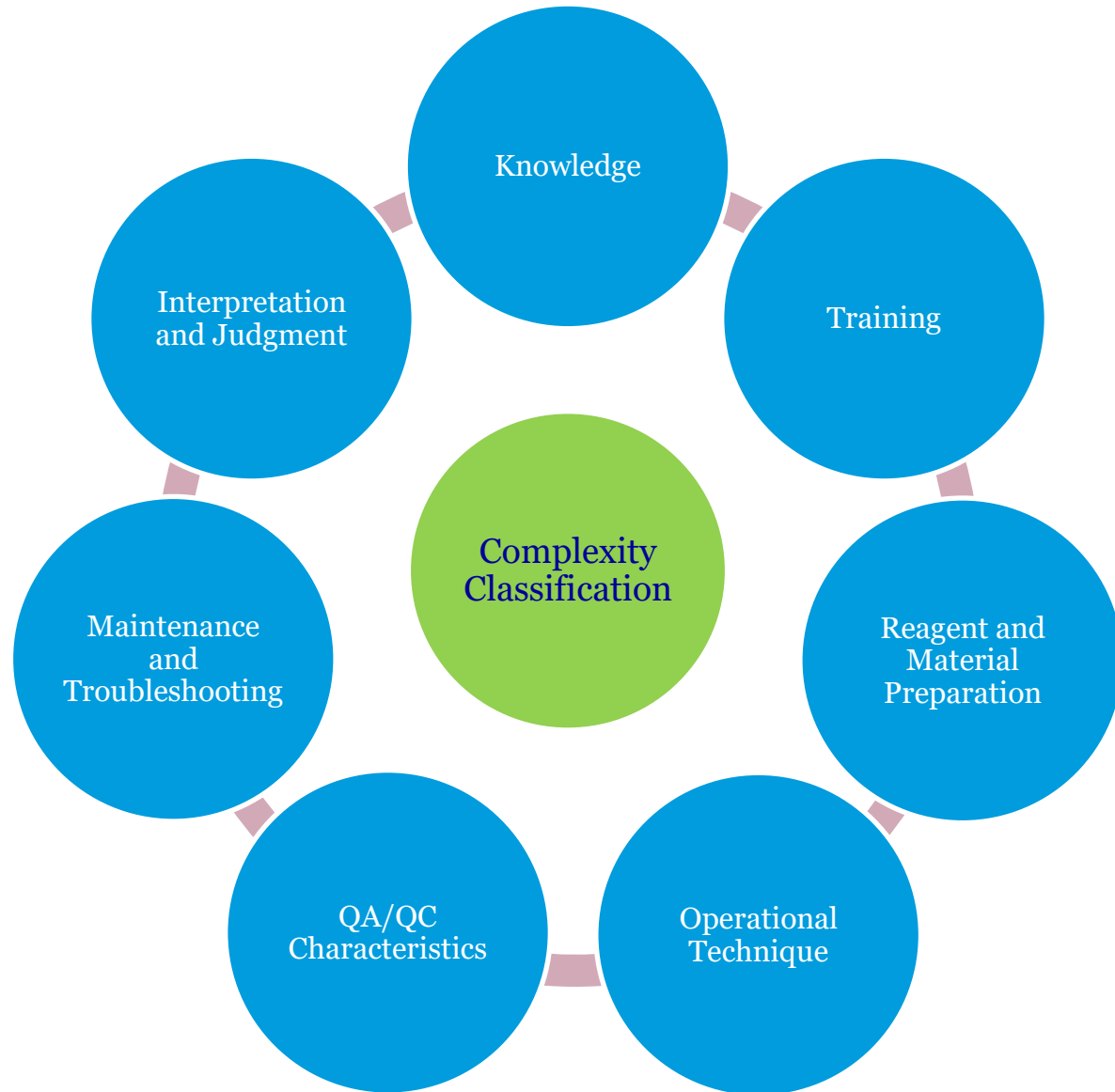
# Clinical Laboratory Improvement Act of 1988 (CLIA 88)

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).

- The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

approximately 260,000 laboratory entities.

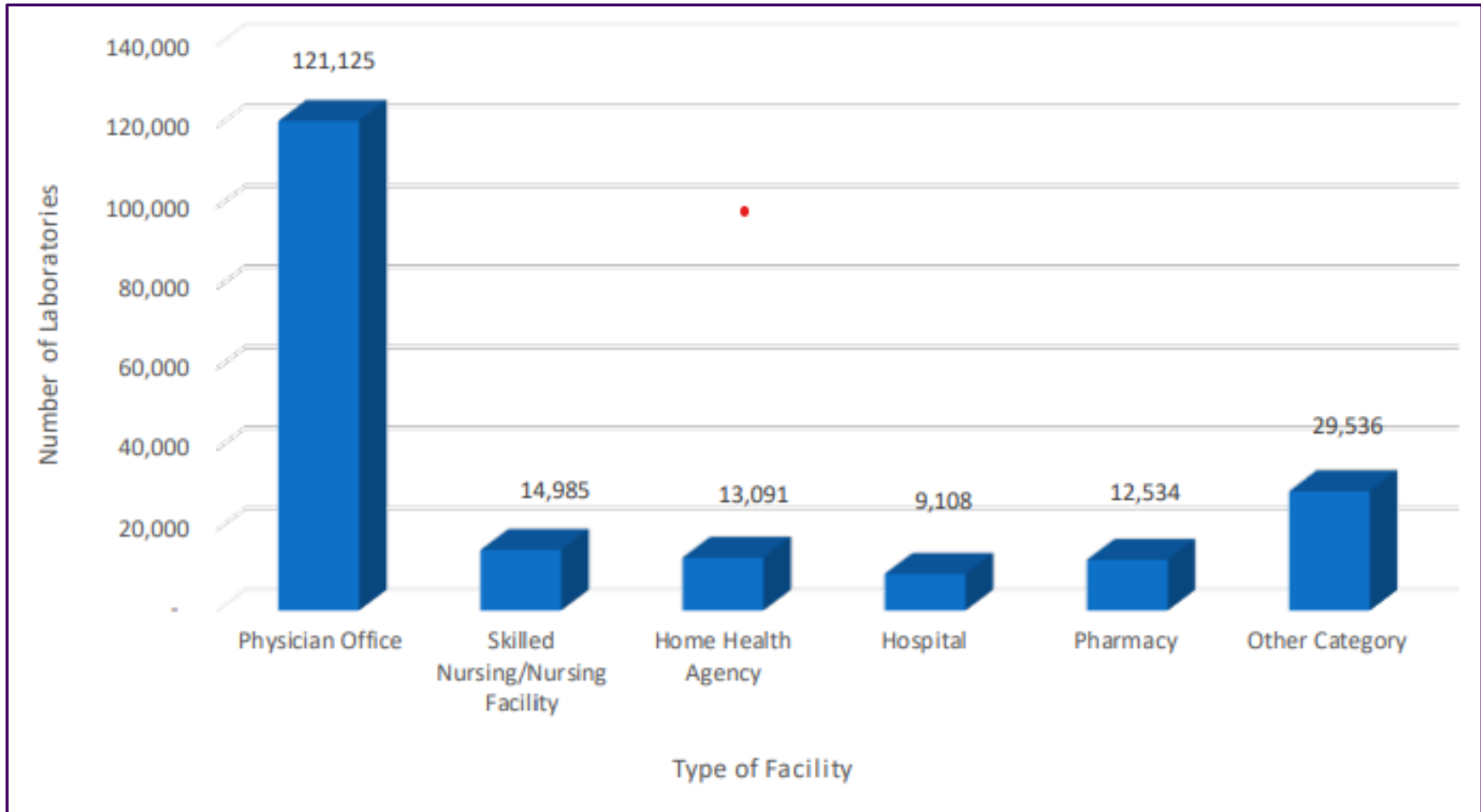
# CLIA Test Complexity Criteria



# CLIA Test Complexity Level

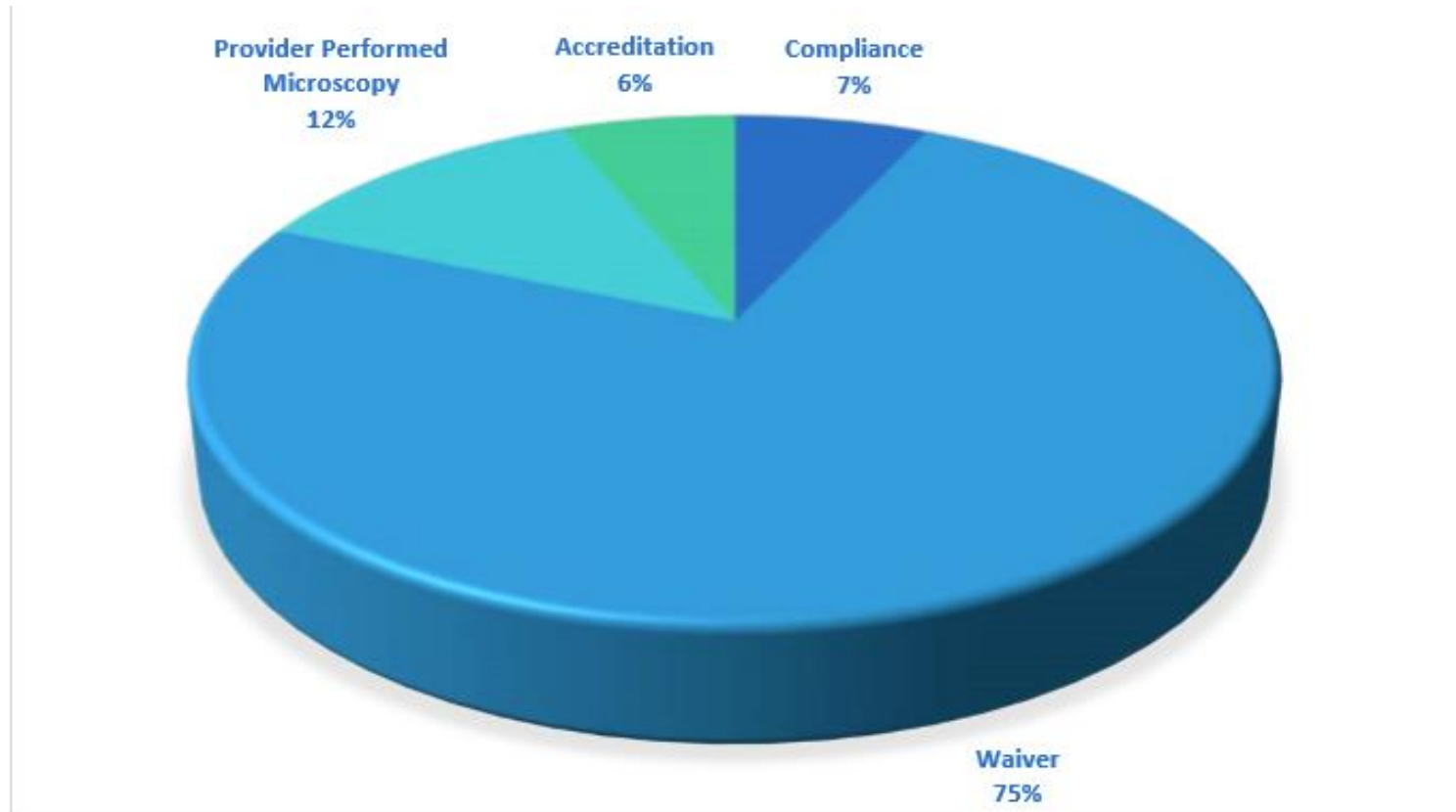
CLIA Requirements	High	Moderate	Waived	PPMP
Personnel	Yes	Yes	No	Yes
QC/QA Practice	Yes	Yes	As per Manufacturer	Yes
PT/EQA	Yes	Yes	No	If available
Routine Inspections	Yes	Yes	No	No
For-cause Inspections	Yes	Yes	Yes	Yes

# CLIA Registered Laboratories



[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

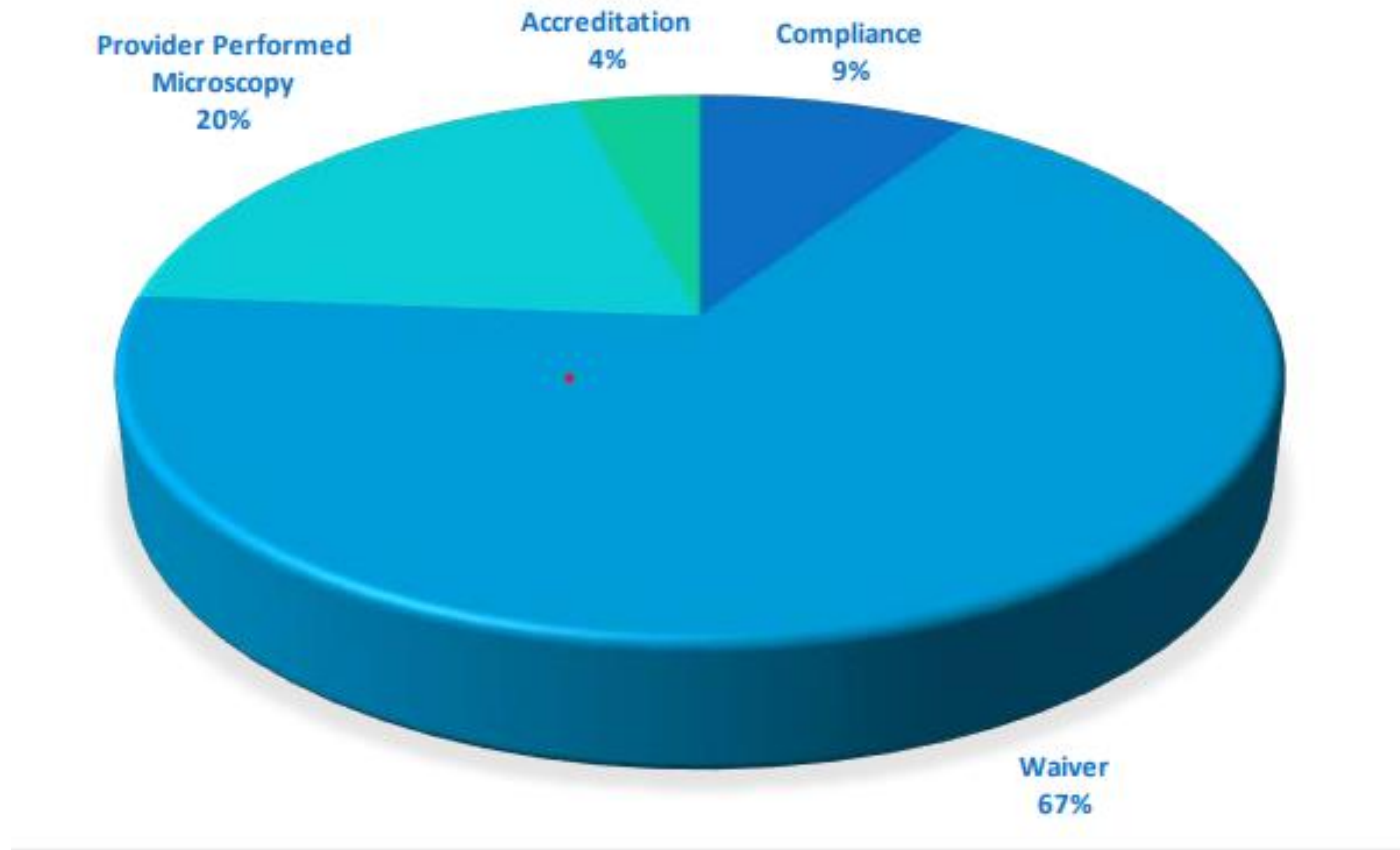
# CLIA Laboratory Certification (Non-Exempt)



COW - 189,978 , PPM - 31,163, CC - 17,594, CA - 15,772

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

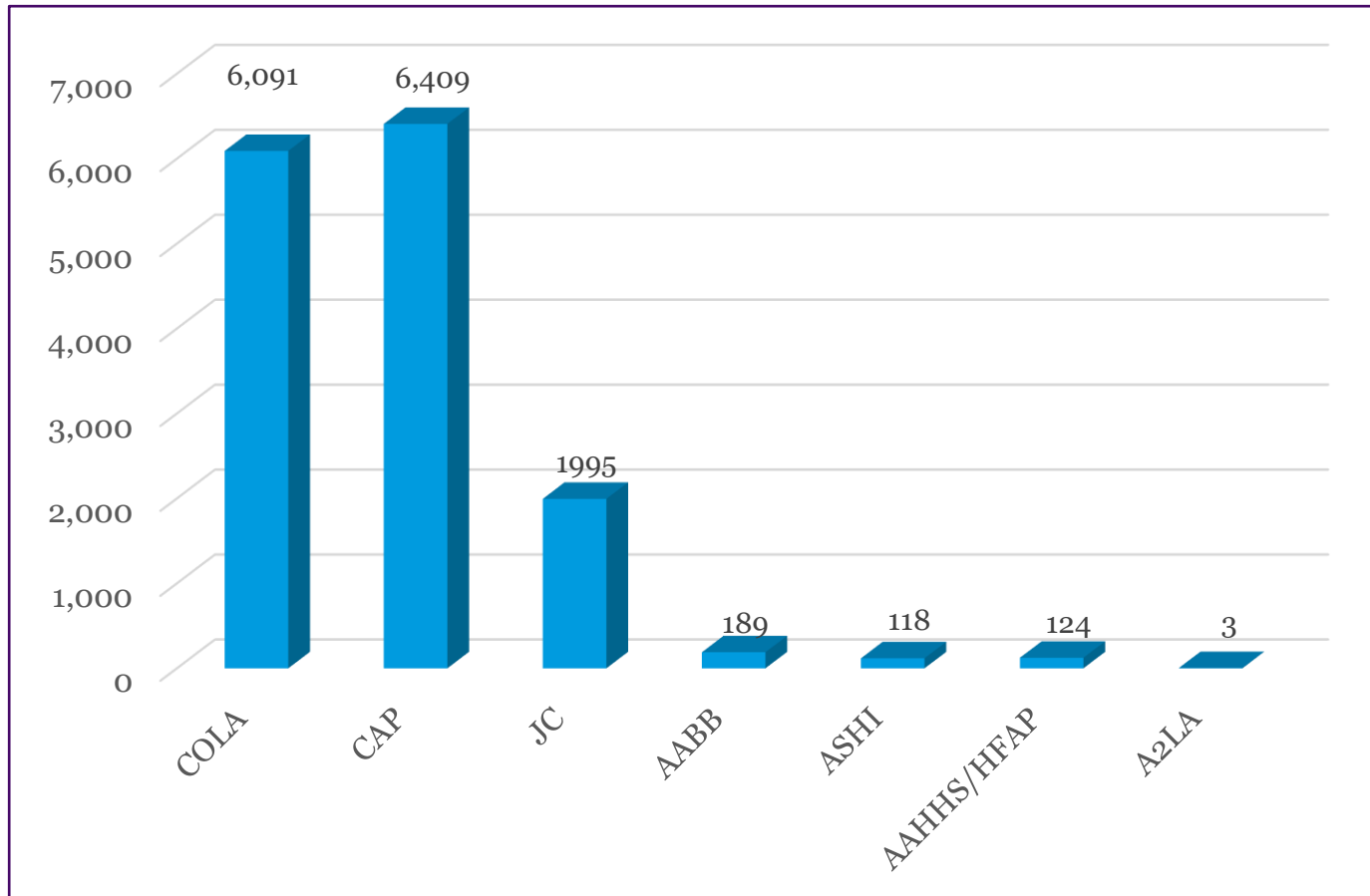
# Physician Office Laboratories CLIA Laboratory Certification



[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020



# Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organizations

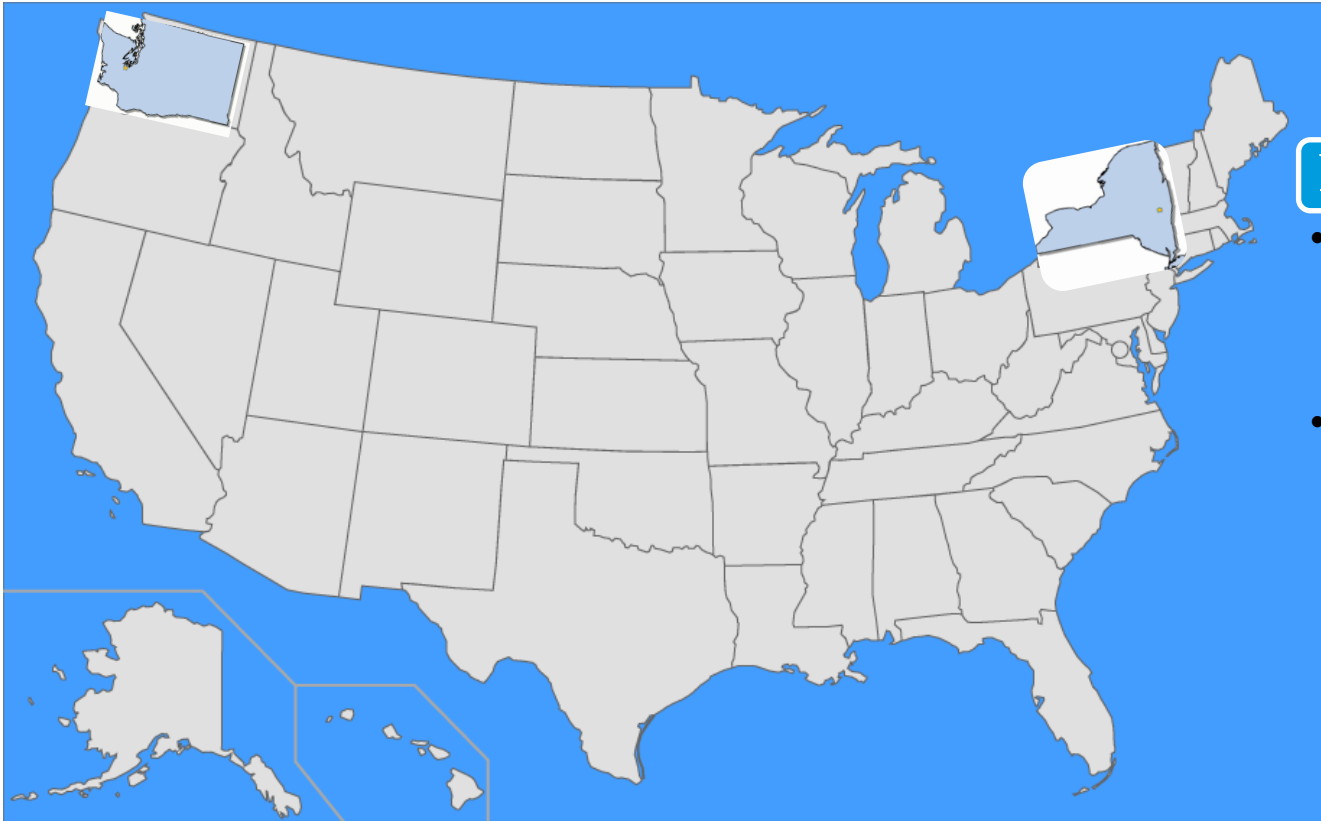


[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

# CLIA Exempt States

## Washington

- HSQA/IIO-Laboratory Quality Assurance
- 4,251



## New York

- Clinical Laboratory Evaluation Program
- 5,518

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

# Waived Tests Definition

Simple laboratory examinations and procedures that are:

- cleared by the Food and Drug Administration (FDA) for home use; or
- employ methodologies that are so simple and accurate as to render likelihood of erroneous results negligible; or
- pose no reasonable risk of harm to the patient if the test is performed incorrectly

# Original Waived Tests: 1992

Urinalysis (non-automated)

Fecal occult blood

Ovulation tests (LH) (visual read)

Urine pregnancy (visual read)

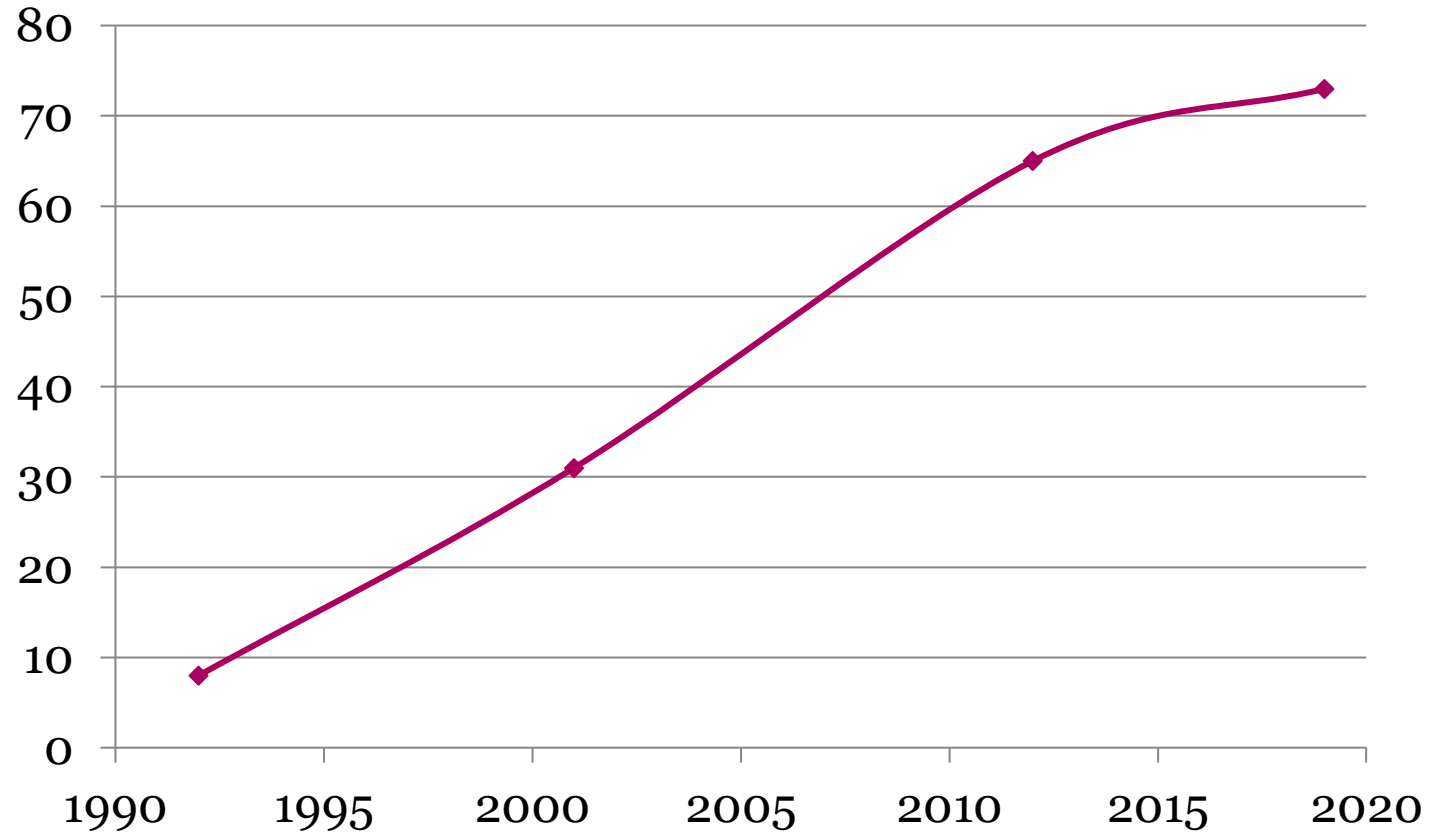
ESR (non-automated)

Hemoglobin (copper sulfate)

Blood glucose (FDA approved for home use)

Spun microhematocrit

## # of Waived Analytes



# Current CLIA Waived Tests

Adenovial Antigen

B. burgdorferi

Bilirubin

Bladder Tumor Antigen

BNP

BUN/Creatinine

CBC

Cholesterol (Total, HDL)/Trigs

Drugs of Abuse

Enzymes –

• ALK, ALT, AMS, AST, CK, GGT

Ethanol

Fecal/Gastric Occult Blood

FSH/LH/Estrone 3 glucoronide

Fructosamine

Fructosamine

Glucose

H. pyloris

HgB/Hct

HgB A1C

HIV

Group A Strep

Infectious Mono

Influenza A/B

Ketones

Lead

Lactate

MMP-9 Protein

Na, K, Ca<sup>++</sup>, Cl, CO<sub>2</sub>

Nicotine

Nuclear Matrix Protein

RSV

pH – Body fluids

Pregnancy

Protein, Total

PT/INR

RSV

Sperm Count

T. vaginalis

TSH

Uric Acid

Urinary microalbumin/

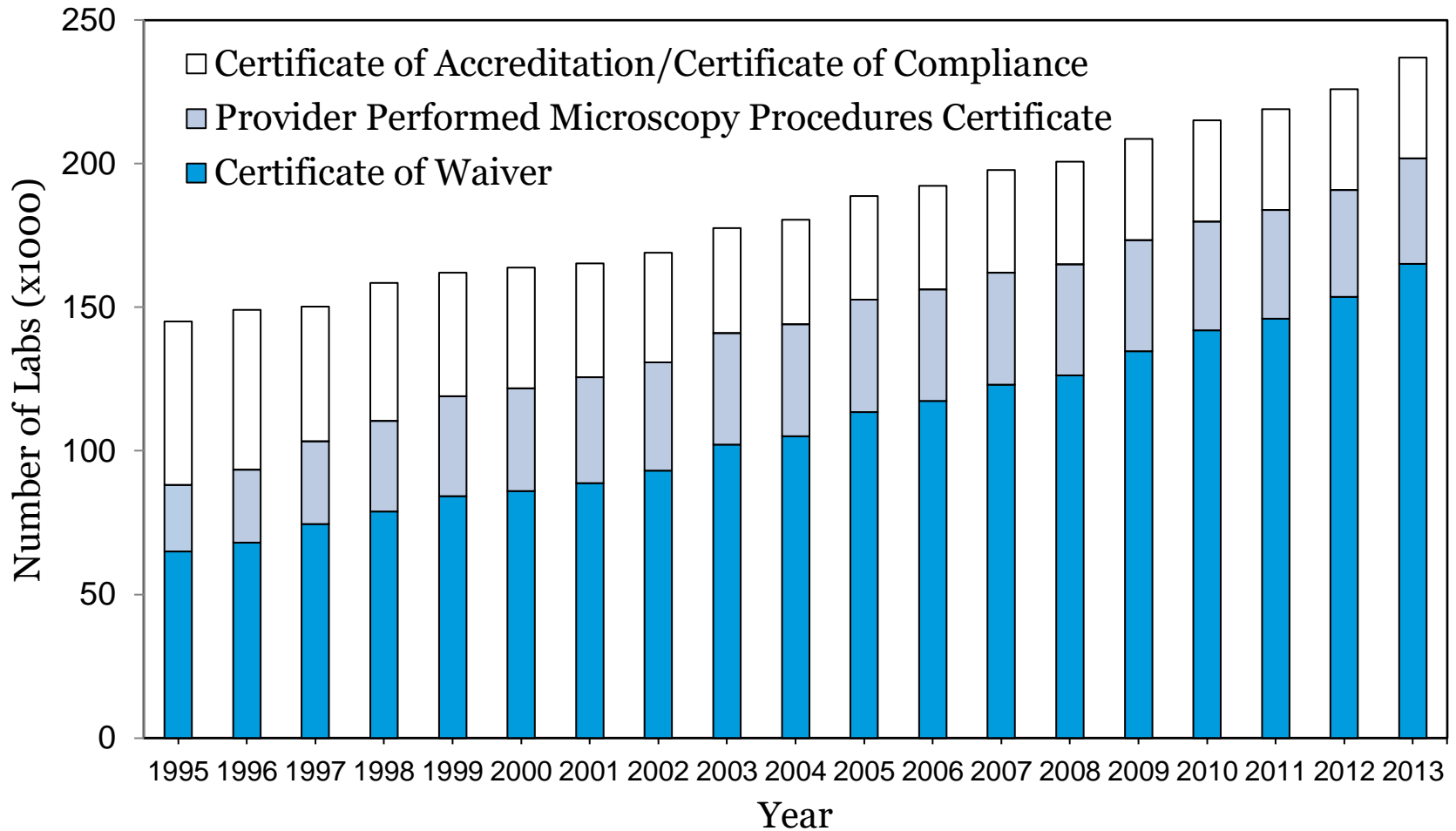
creatinine

Urinalysis/Specific Gravity

Vaginosis

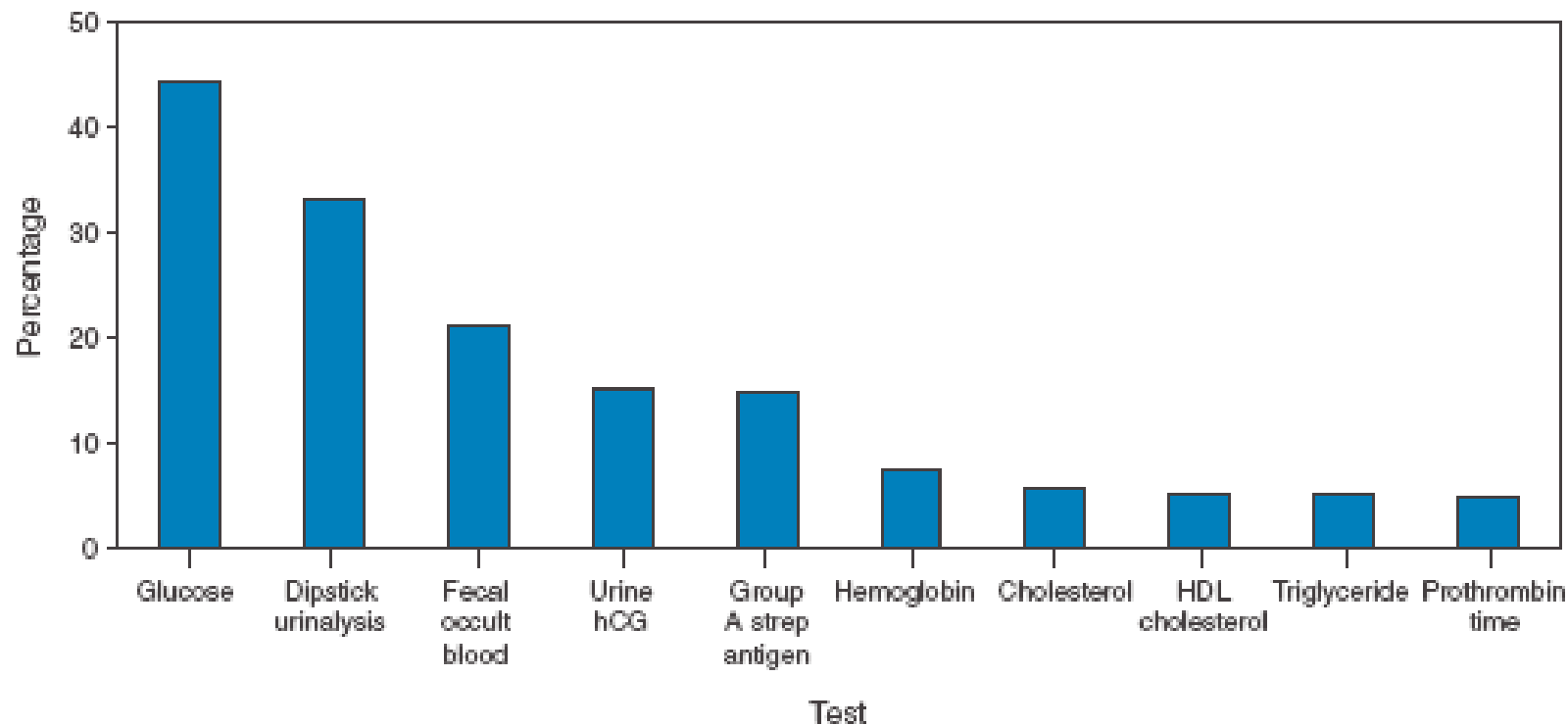
X-linked N teleopeptides

# CLIA Certified Laboratories



[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

# Top Waived Tests 2003-04

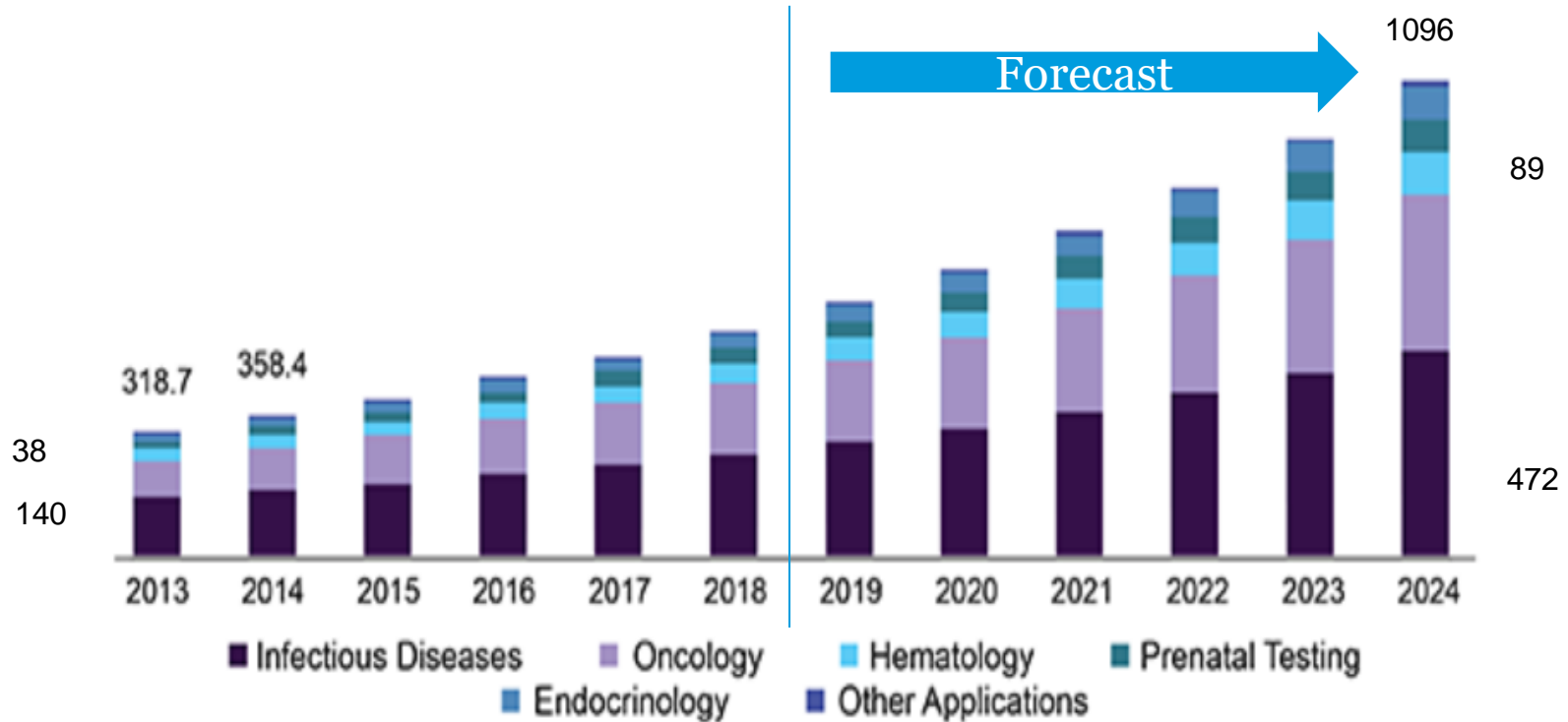


**n = 3,317 sites surveyed by CMS**

***Howerton, et al. MMWR, Recommendations and Reports Nov 11, 2005 / 54(RR13);1-25***



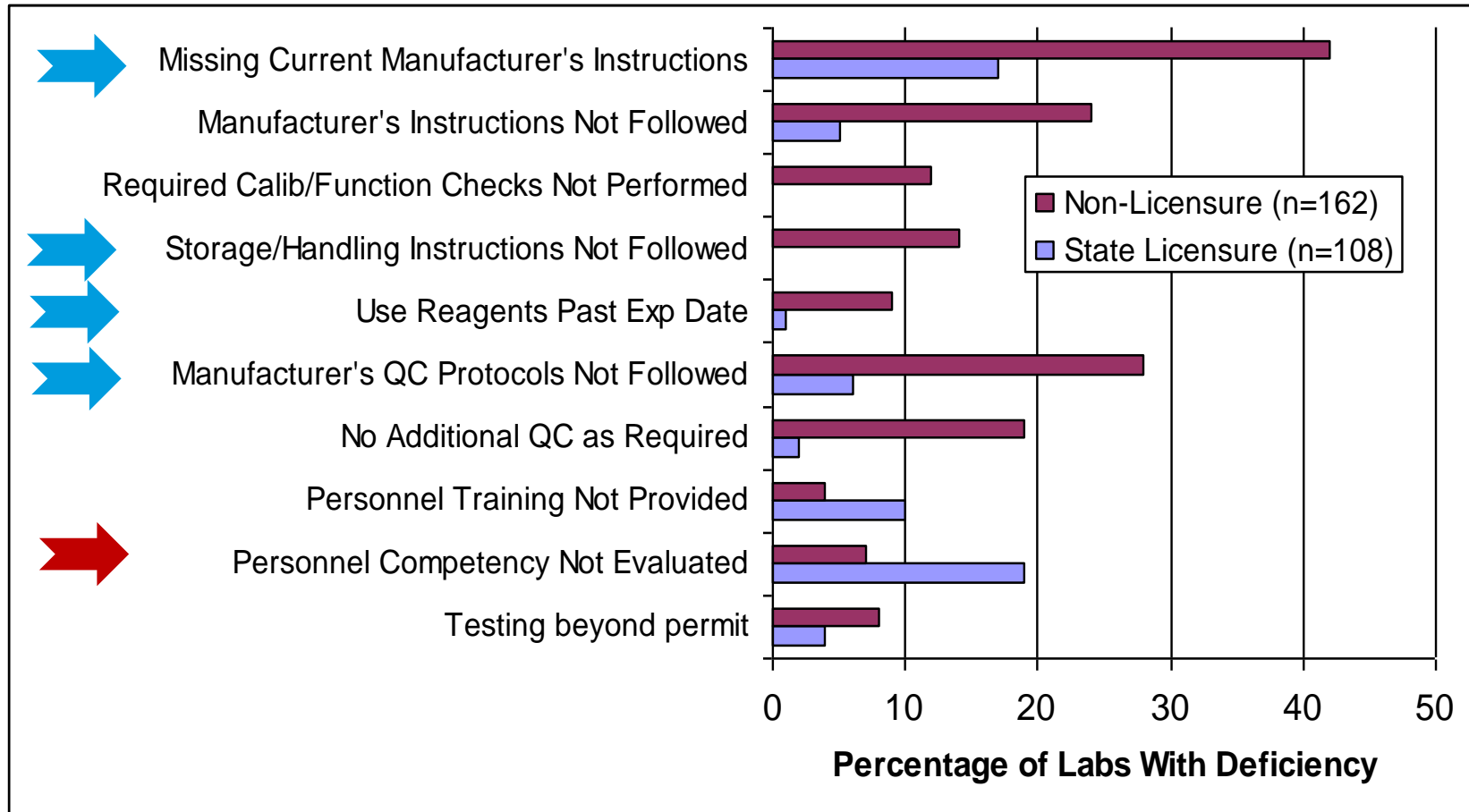
# U.S. Point-of-Care Molecular Dx Market 2013-2024



[www.grandviewresearch.com](http://www.grandviewresearch.com), last accessed 8/4/20

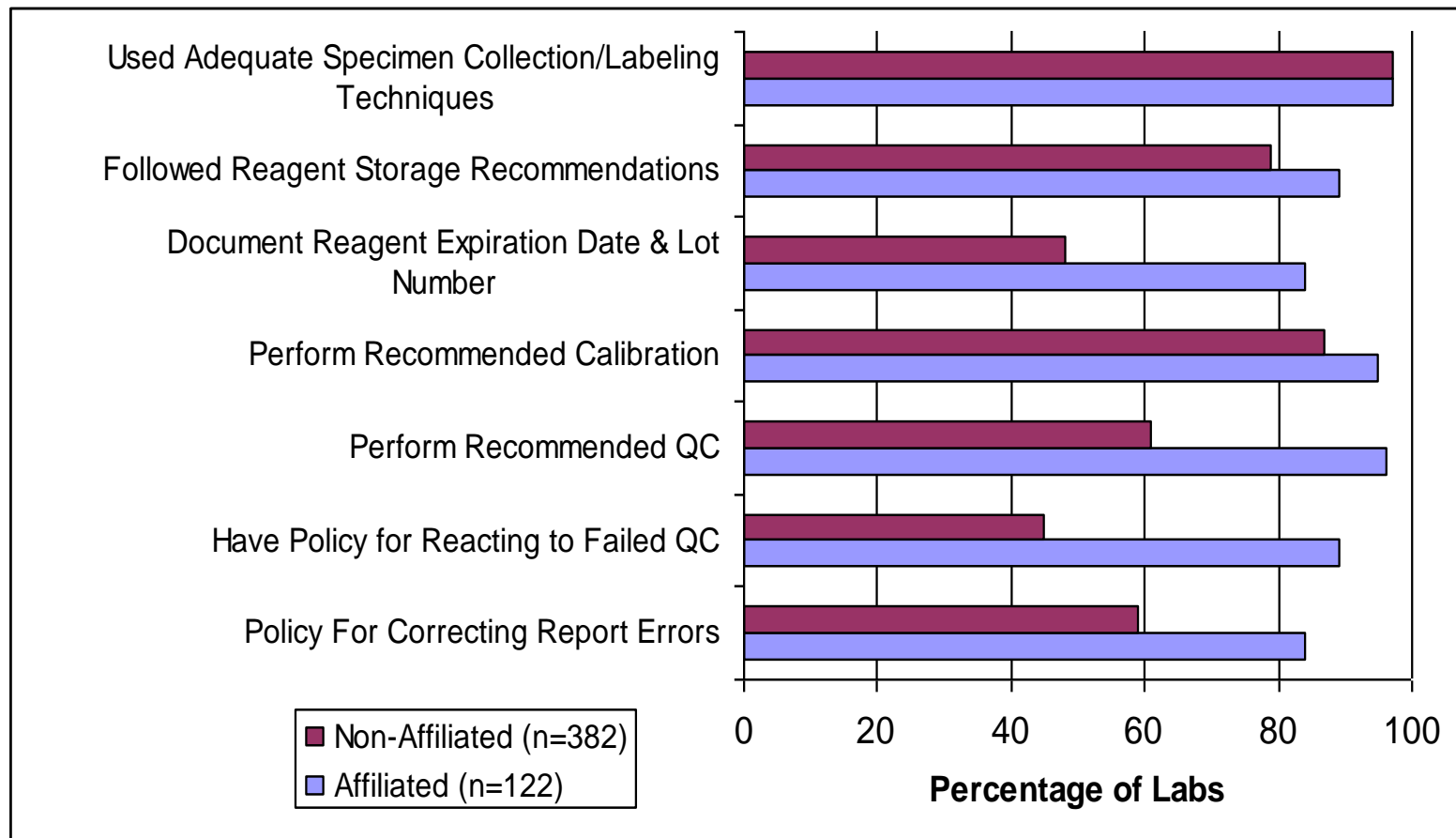
# POCT Deficiencies

# Common Survey Deficiencies in COW Laboratories



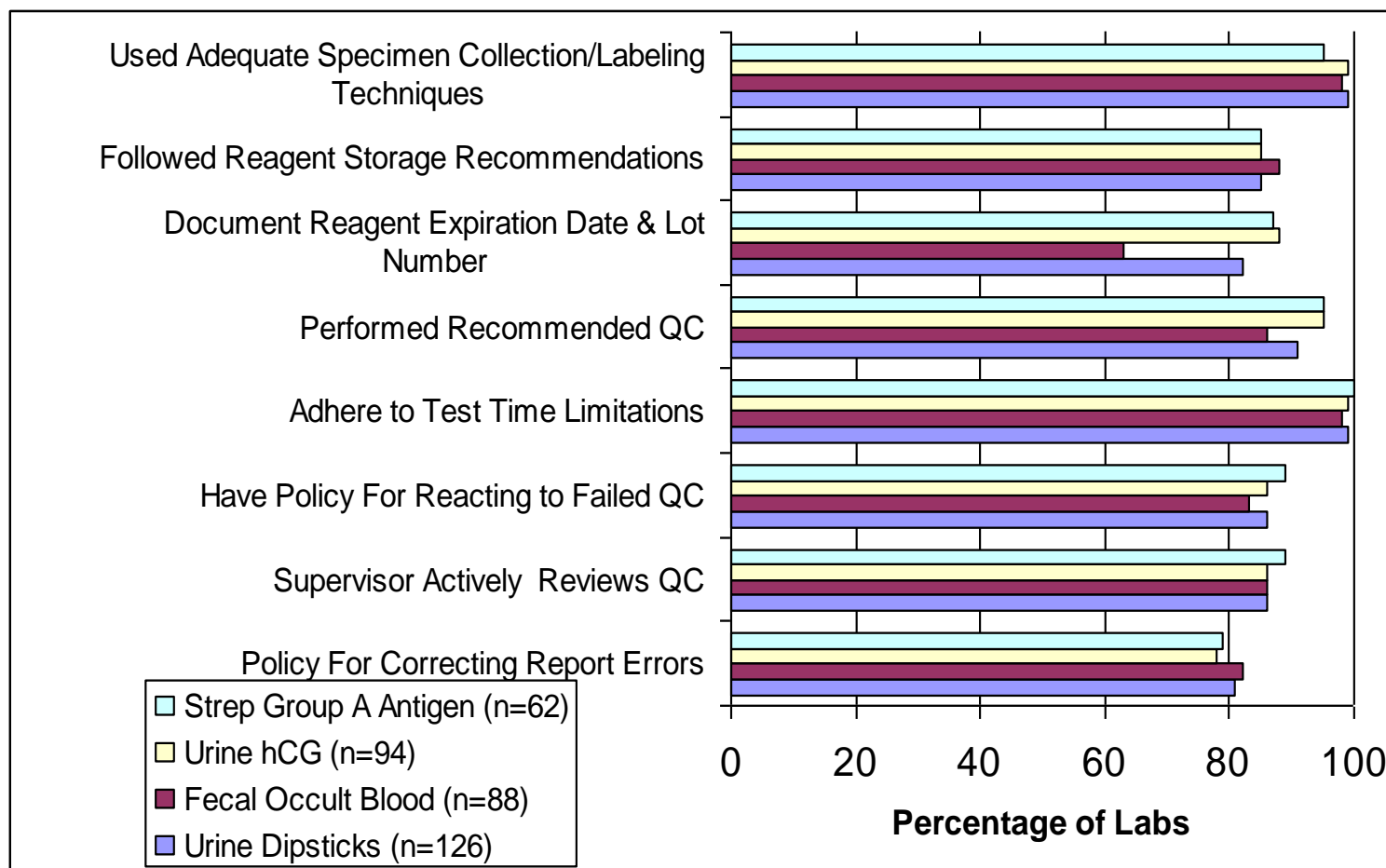
Source: CMS Certificate of Waiver Procedures  
Pilot Project, 2002

# Blood Glucose



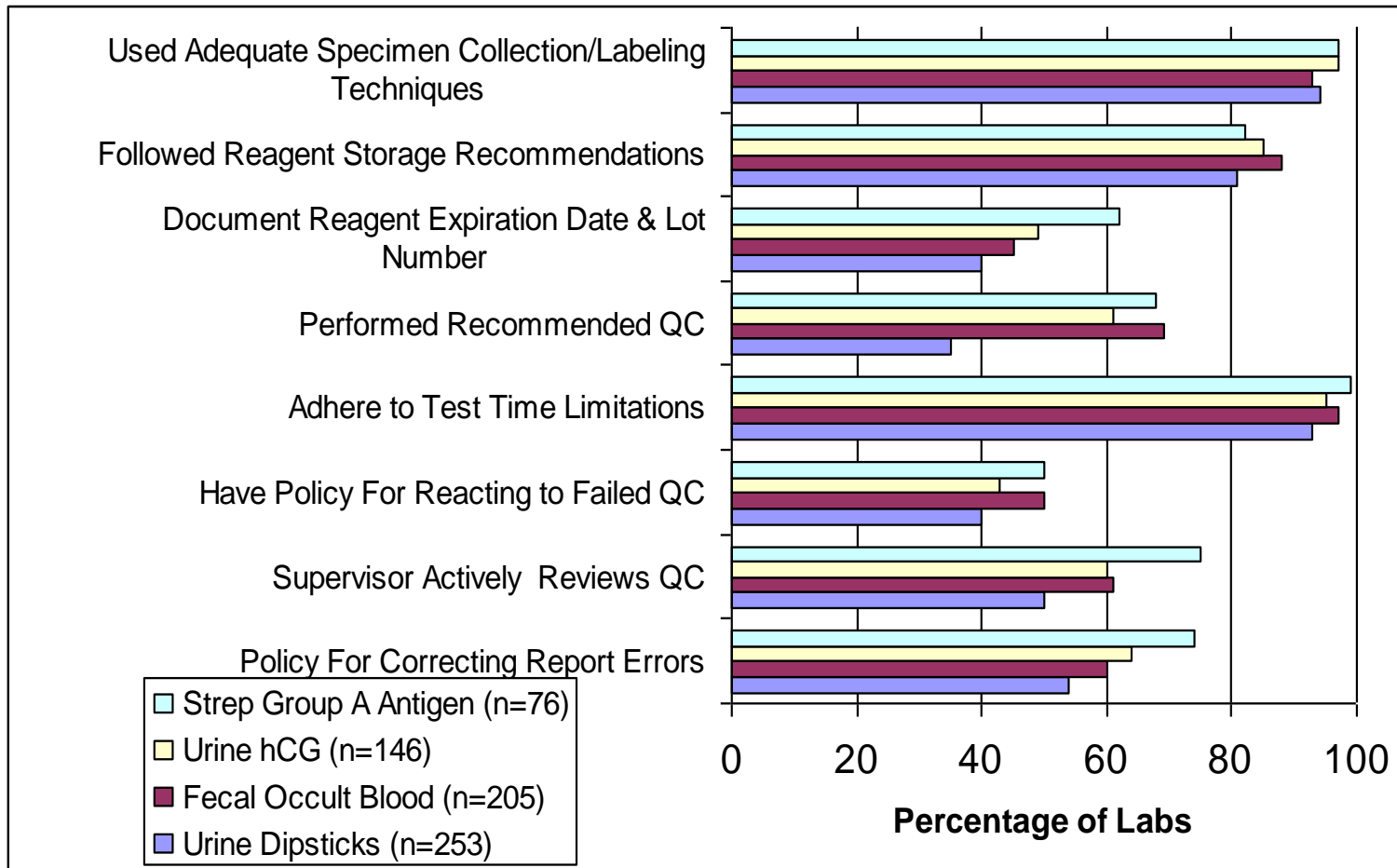
Source: CMS Certificate of Waiver Procedures  
Pilot Project, 2002

# Affiliated Labs



Source: CMS Certificate of Waiver Procedures  
Pilot Project, 2002

# Non-Affiliated Labs



Source: CMS Certificate of Waiver Procedures  
Pilot Project, 2002

# % of Sites Not Conducting Selected Quality Assurance Practices

QA Practice	Affiliated N=78	Non-affiliated N=200
Training documentation	8	22
Assay validation	15	81
SOPM reviews by director	15	81
Staff competency checks	12	46
QC/QA review by director	9	37
Proficiency testing program	46	91

# CMS, CAP, COLA & TJC Top Deficiencies 2016

Error Type	CMS Labs	CMS POL	CAP	COLA	TJC
Testing personnel competency	6	5	1	1,8	1
Activity menu			2		
Procedure manual	1,3	1,3	3		
Instrument correlations	10	10	4		2
SOP manual review			5		
Maintenance records	9	9	6		7
Reagent labeling; expiration	8	7	7		
PT evaluation / Review by lab director			8	3,4	
Method validation approval			10		
PT enrollment				10	4,9
LD not fulfilling his role: QC/QA review				2	5\$,6
Waived testing QC and IQCP				5	10
TC and TS not complying with role and responsibilities				6	5\$
AMR verification problems				9	8
SOP for analytical systems	2	8			
Check test accuracy: 2X/Yr	4	2	9		
Test report content	5	4			3
Test performed manufacturer instructions	7	6			
Lack of cumulative QC				7	

Chittiprol S, Bornhorst, J, Kiechle, FL, Clinical Laboratory News; July 1, 2018



# CLIA Top Ten Deficiencies, 2018

Regulation	Deficiency	%All Labs Cites	% POLs Cited
493.1252(b)	Criteria for reagent and specimen storage; test system operation; test result reporting	4.8	4.6
493.1251(b)	Complete procedure manual	4.6	4.5
493.1236 (c)(1)	At least 2X every year, verify accuracy of tests not enrolled in HHS approved PT	4.3	4.8
493.1235	Policies/procedures followed to assess employee and, if applicable, consultant competency	4.1	4.1
489.1289(a)	Policies/procedures followed to monitor, assess, and correct problems identified in 493.1251-.1283	4	3.8
493.1291(c)	Test report includes all mandated items	3.5	3.6
493.1251(a)	Procedure manual for all tests followed by personnel	3.2	3.2
493.1252(d)	Reagents, solutions, etc. used, not outdated or of substandard quality	3.1	3
493.1254(a)(1)	Maintenance performed at least at manufacturer's stated frequency	3.1	2.8
493.1253(b)(1)	Each lab using unmodified FDA-approved tests must demonstrate attainment of manufacturers' perf. specif.	2.8	2.2

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Statistical\\_Tables\\_Graphs.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html) Accessed 07/14/2020

# Top Deficiencies 2019

Deficiency		CAP	COLA
Testing Personnel Competency		1	1 (18%)
Activity Menu		2	
Instrument/Method Correlations		3 / 4*	
LD not fulfilling PT responsibilities			2 (16%) / 3*
TC/TS not fulfilling responsibilities			3 (13%) / 6*
LD not fulfilling QC/QA responsibilities			4 (12%) / 2*
PT Review documentation			5 (12%) / 4*

\* - ranking in 2016

Make Your Lab Assessment Ready in 2020. Dark Daily. 2/25/20 Webinar.

# Top Three Deficiencies for CLIA-waived Labs



Not performing QC as required by the manufacturer

Not having a current package insert

Not complying with storage expiration dates

Snyder, MT (ASCP), A. (Speaker) (2015, April 8). CLIA and Point-of-Care Testing. AACC POC Virtual Conference.

# Top 5 CAP POCT Deficiencies – POCT Checklist

1

- POCT.06900 – Competency Assessment

2

- POCT.07300 – Quality Control

3

- POCT.07568 – Comparability on Instruments/ Methods

4

- POCT.07037 – Documentation of QC-Waived Tests

5

- POCT.07512 – QC Handling

# Most Common Waived Testing Citations on TJC surveys

Only one method (instead of two) used to evaluate staff competency

Quality control checks using only one level of control

Control solution for glucometers not dated when opened

Control solution for glucometers used beyond discard date

No confirmatory testing in the policy for glucose testing.

No written policies/procedures for waived testing

BH organizations: not having a CLIA certificate (which can result in Contingent Accreditation)

# Development of POCT Policies

# Development of Policy

## Designate Authority to:

- make and enforce policy
- assign responsibility
- address problems
- make decisions about the program structure
- provide administrative support
- provide quality oversight.

# Development of Policy

## Assign Responsibility for:

- ~~evaluation of instruments~~
- implementation of test methods
- training of personnel
- evaluation of QC results
- maintenance of instruments
- reporting of results
- establishment of procedures based on clinically relevant critical values
- compliance with safety standards
- compliance with regulatory standards
- monitoring of test procedures for accuracy and precision



# Development of Policy

## Assign Responsibility for:

- ~~monitoring of proficiency testing as required for complexity of testing (refer to regulatory requirements)~~
- communicating with instrument operators
- competency evaluation and retraining on an ongoing basis
- quality assurance
- assistance with billing policies
- development of a working relationship with physicians, nursing staff, and/or other individuals involved in POCT
- oversight of the testing methods including troubleshooting and manufacturer relationships.

# Development of Policy

## Maintain Accountability for:

- understanding the principles and limitations of the procedure
- performing and documenting QC
- performing and documenting maintenance
- maintaining proficiency in testing methods
- performing tests and documenting results according to procedure
- following protocols for remedial actions or notification of responsible personnel
- following protocols related to critical (action) values and responses to be taken.

# Personnel Training & Competency Assessment

# Personnel Knowledge/Skill Requirements

The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system (chemistry and detector) and appreciation of the preanalytical aspects of the analysis...

# Personnel – Knowledge/Skill Requirements

sample collection

clinical utility and limitations

expertise in the analytical procedure

reagent storage

quality control and quality assurance

technical limitations of the device;

response to results that fall outside of predefined limits

infection control practices

correct documentation and maintenance of the results.

# Who Approves Training?

**Laboratory Director/  
Technical Consultant**

- The vendor can help with the initial training, but the facility's LD/TC would have to sign off on the training

# Training of Providers

There are records demonstrating that all providers have satisfactorily completed initial training on the performance of the specific tests performed.

- Medical staff credentialing is not an acceptable record of training

CAP POC.09500

# CAP, TJC & COLA

## Specimen Collection Training

### Preamanalytical

There are records that all personnel collecting patient specimens have been trained in collection techniques and in the proper selection and use of equipment/supplies and are knowledgeable about the contents of the specimen collection procedures.

- NOTE: This applies to all personnel who work under a single CLIA license.

All types of specimen collection techniques (e.g. phlebotomy, capillary, arterial, in-dwelling line, phlebotomy during intravenous infusion), as well as non-blood specimens, must be included in the training in accordance with the individuals' duties.

Specimen collection for TJC is done initially(training), and then assessed and documented every 2 years. HR.01.06.01  
Assessing phlebotomy staff competency

COLA includes an initial training, 6 month competency first year, and every year.



# Why are Competency Requirements Confusing?

CLIA  
regulations  
for  
competency  
assessment  
have not  
changed

- Vague language
- Misinterpretation
- Various related requirements are interspersed throughout CLIA regulations
- Requirements are not the same amongst the different inspecting groups

# Definition of Test System for Competency Assessment

CLIA/JC

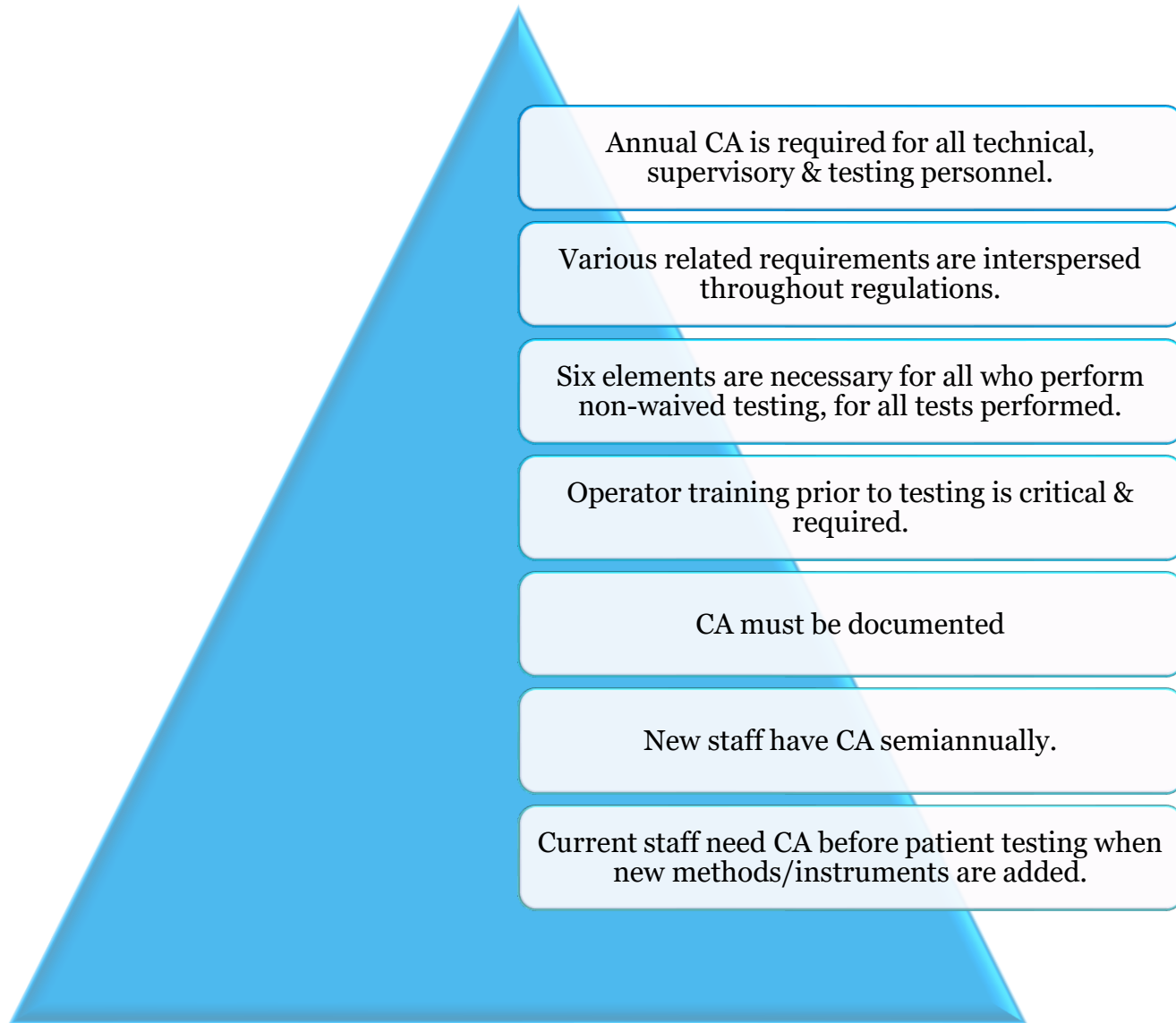
The instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

CAP

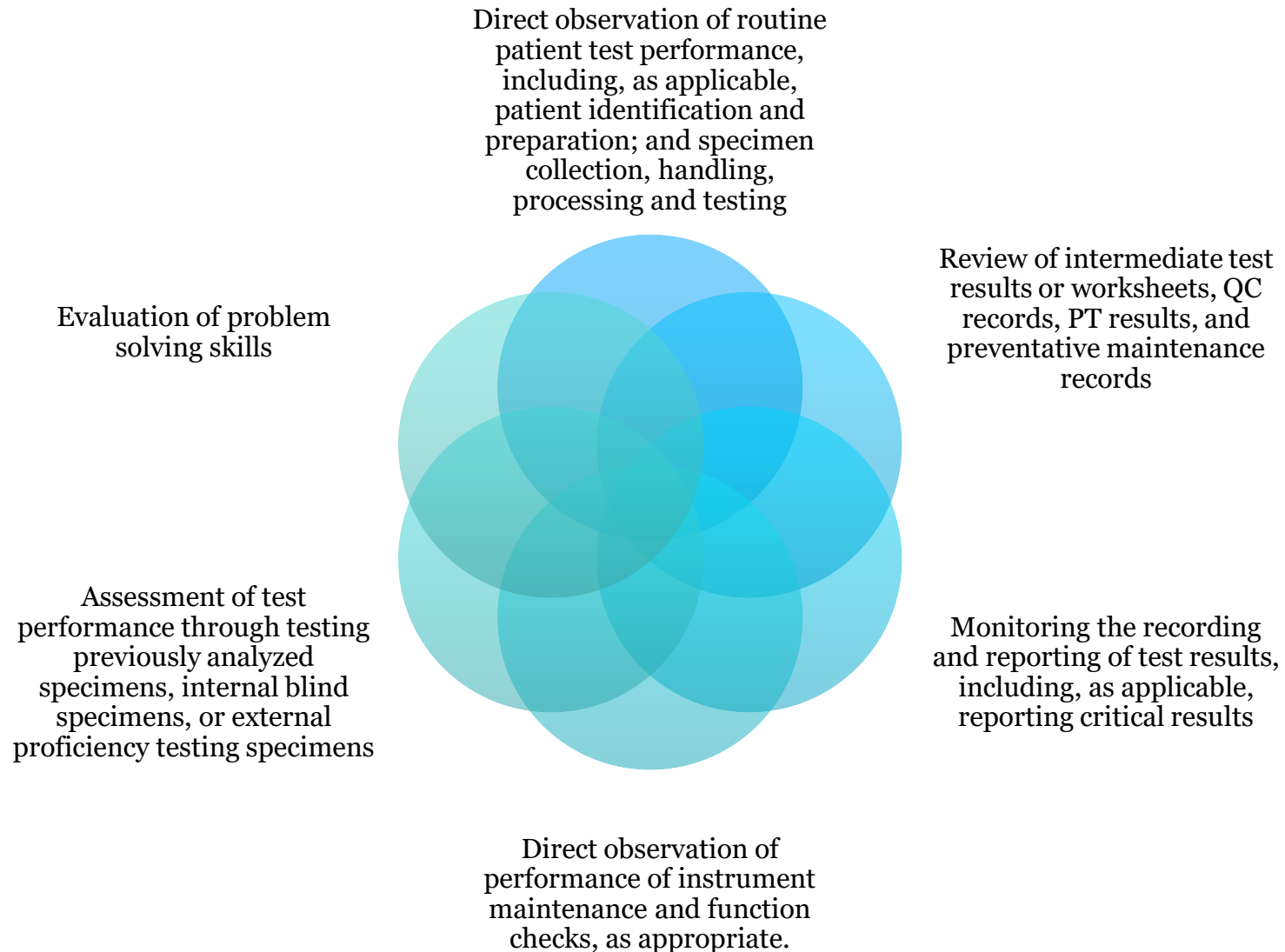
The process that includes pre-analytical, analytical, and post-analytical steps used to produce a test result or set of results.

may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results

# CLIA Competency Assessment Policy



# Six Elements for Non-Waived Testing




## Does CLIA Require Competency for Waived Testing ?

**NO COMPETENCY ASSESSMENT** is required for personnel who only perform waived testing in a CLIA laboratory.

Personnel involved in pre- or post-analytical processes are not required to undergo CA.

Waived testing personnel, non-testing pre/post analytical & those not in regulatory positions aren't subject to CA.

# CAP Waived Testing Competency



It is not necessary to assess all 6 elements for each assessment event: The POC program may select which elements to assess. Selected elements for CA include but are not limited to the 6 elements required for non-waived testing.

A laboratory must evaluate and document the competence of all testing personnel for each test system

Any personnel whose work is part of the testing process (including pre-analytical)

CA performed after initial training and then annually

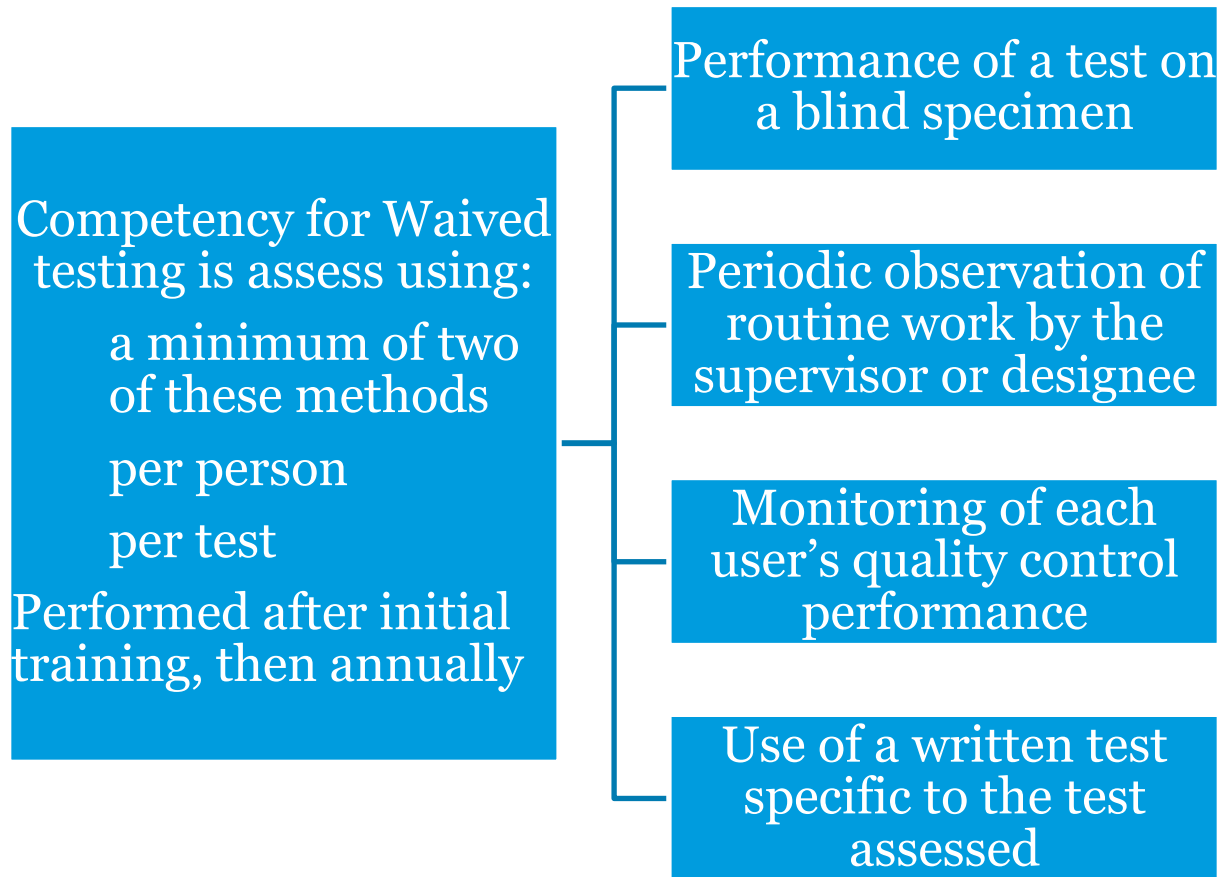
# COLA Waived Competency Assessment

Should  
include Pre-  
analytical  
and Post-  
analytical of  
each test  
performed

Initial  
Competency

6 Months  
Later after  
initial  
competency,  
and  
annually  
thereafter

# JC Waived Testing Competency





# Assuring Quality of Examination Procedure

# POCT Equipment

**The laboratory director, or designated suitably qualified person, shall be responsible for the selection criteria and for the procurement of equipment, materials, and reagents.**

- There shall be written procedures for the maintenance and operation of POCT equipment
- The management group shall recommend that any POCT device or system be withdrawn from service if critical requirements are not met or safety becomes an issue.
- A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed.

# Assuring Quality of Examination Procedure

## The laboratory director shall validate the following processes for service provision

- Trueness and precision and, where appropriate, linearity of the instrument response shall be verified by the QC program.
- Split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites.
- Frequency of internal QC should be specified for each device.
- Corrective action to be taken for out-of-control results shall be documented.
- Action taken on nonconforming QC results shall be documented.
- QC results shall be recorded for regular review by the quality manager or designated person.
- Process control for consumable supplies and reagents shall be documented and monitored.
- In-patient self-testing using POCT devices, if allowed, shall be monitored to validate the accuracy and comparability of the results to those of the central laboratory.

# CAP & COLA Waived Testing QC Requirements

QC is performed based on manufacturer's instructions for quality control.

## Internal Controls (CAP)

- Acceptable control results must be recorded, at a minimum, once per day of patient testing for each device.
- Acceptable internal control results need not be recorded, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results.

# Joint Commission Waived Testing QC Requirements

Approved QC plan based on specified rationale:

- How the test is used
- Reagent stability
- Manufacturers' recommendations
- The organization's experience with the test
- Currently accepted guidelines

For non-instrument-based waived testing, QC is performed based on manufacturer recommendation

For instrument-based waived testing:

- QC is performed on each instrument
- Two levels of QC, if commercially available

# Calibration & Verification

## Waived Tests (CAP)

For waived tests, the POCT program follows manufacturer instructions for calibration, calibration verification, and related functions.

### Evidence of Compliance:

- Written procedure consistent with the manufacturer's instructions for each waived test AND
- Records for calibration/calibration verification-related functions as required by the manufacturer AND
- Records of recalibration or other appropriate corrective action when calibration verification is unacceptable

# Summary

The majority of POCT is classified as Waived Testing.

Only QC, as recommended by manufacturer, is federally required for waived testing. However, deemed accrediting agencies may have additional requirements.

Competency assessments are not federally required for waived POCT, but are by deemed accrediting agencies.

Oversight makes a difference.

Testing sites need guidance.

We have unlimited educational opportunities.

*Thank  
You*

Questions?

[ellisjacobs1@gmail.com](mailto:ellisjacobs1@gmail.com)