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

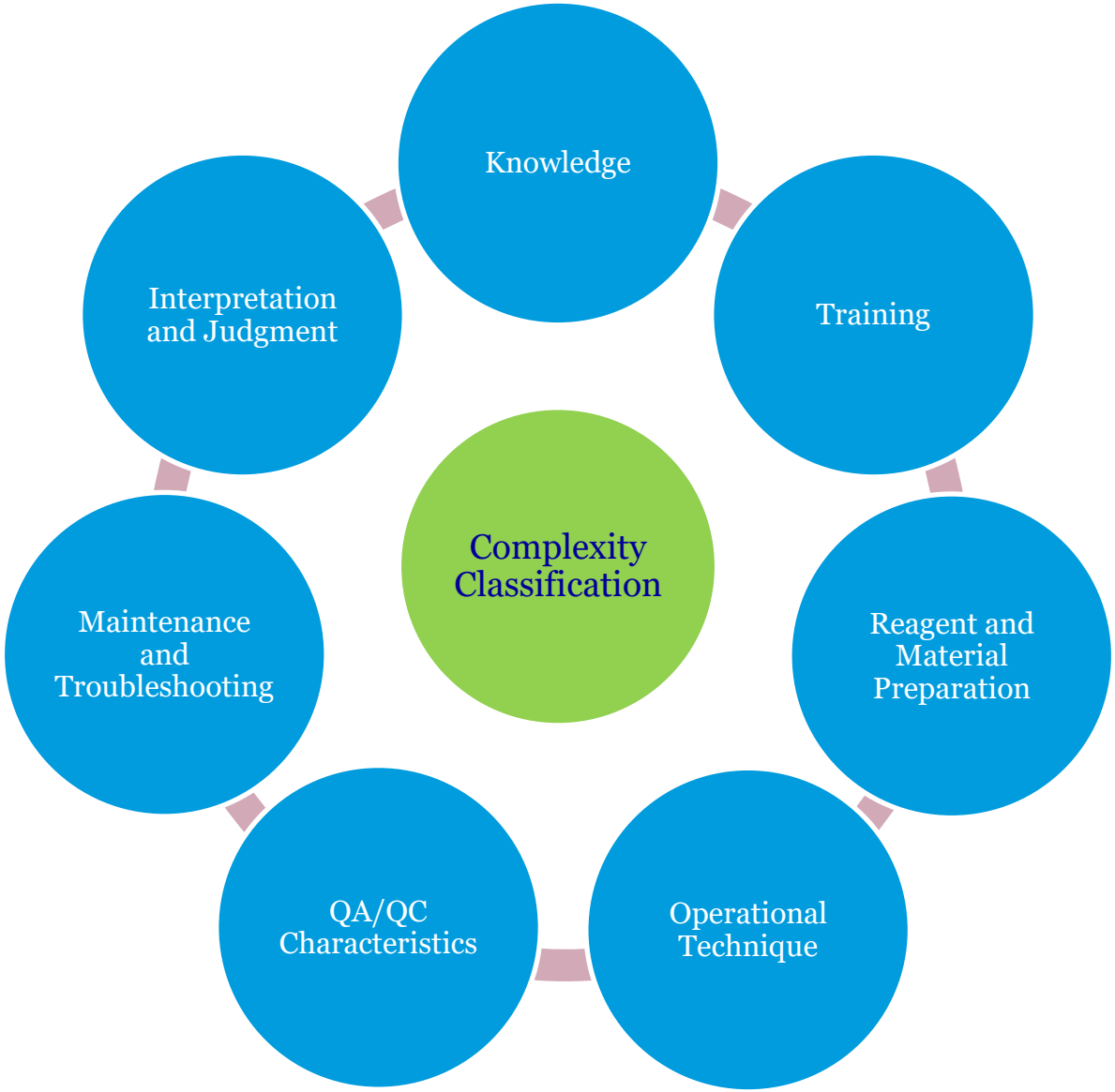
Clinical Laboratory Improvement Act of 1988 (CLIA 88)

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.

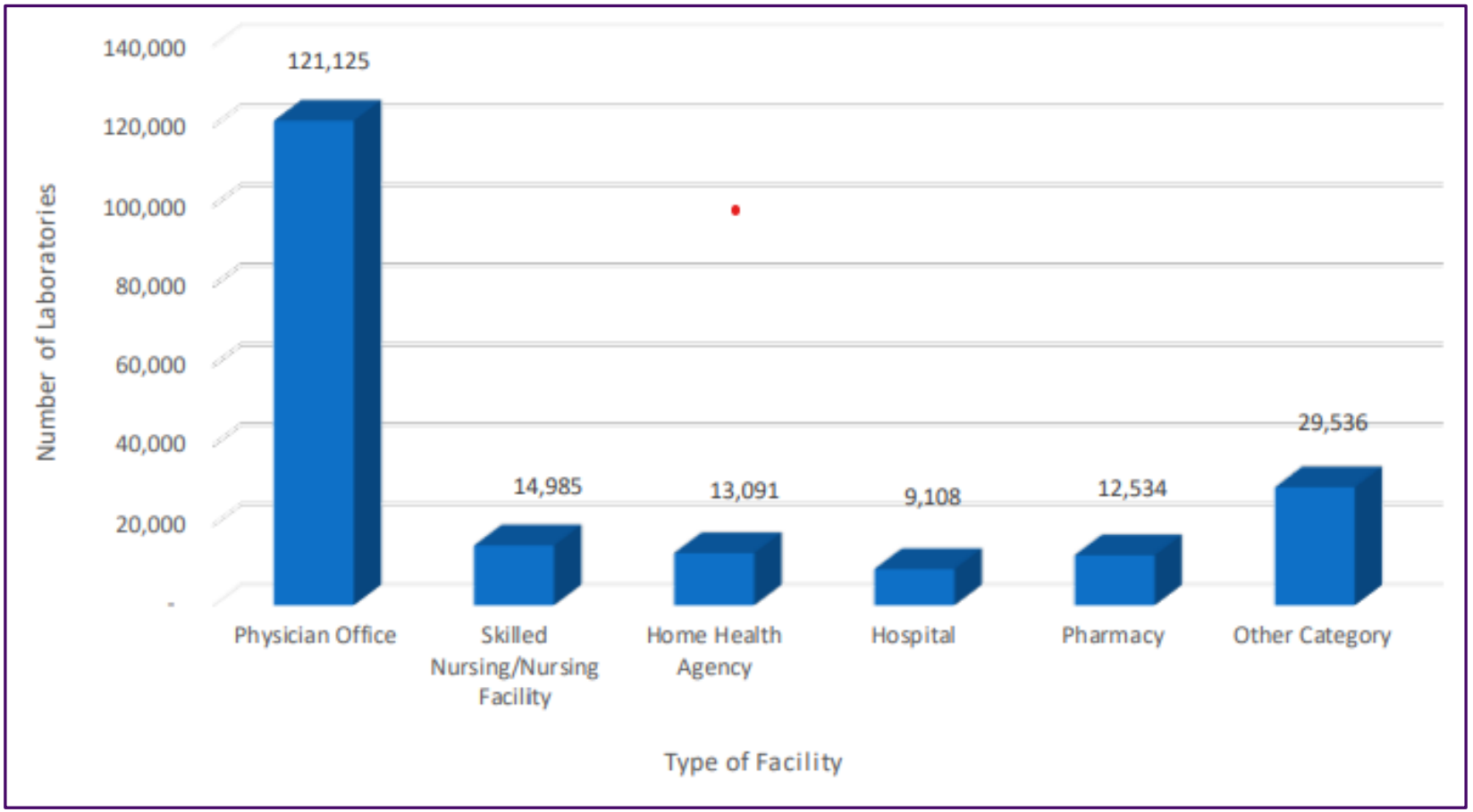
CLIA Test Complexity Criteria



CLIA Test Complexity Level

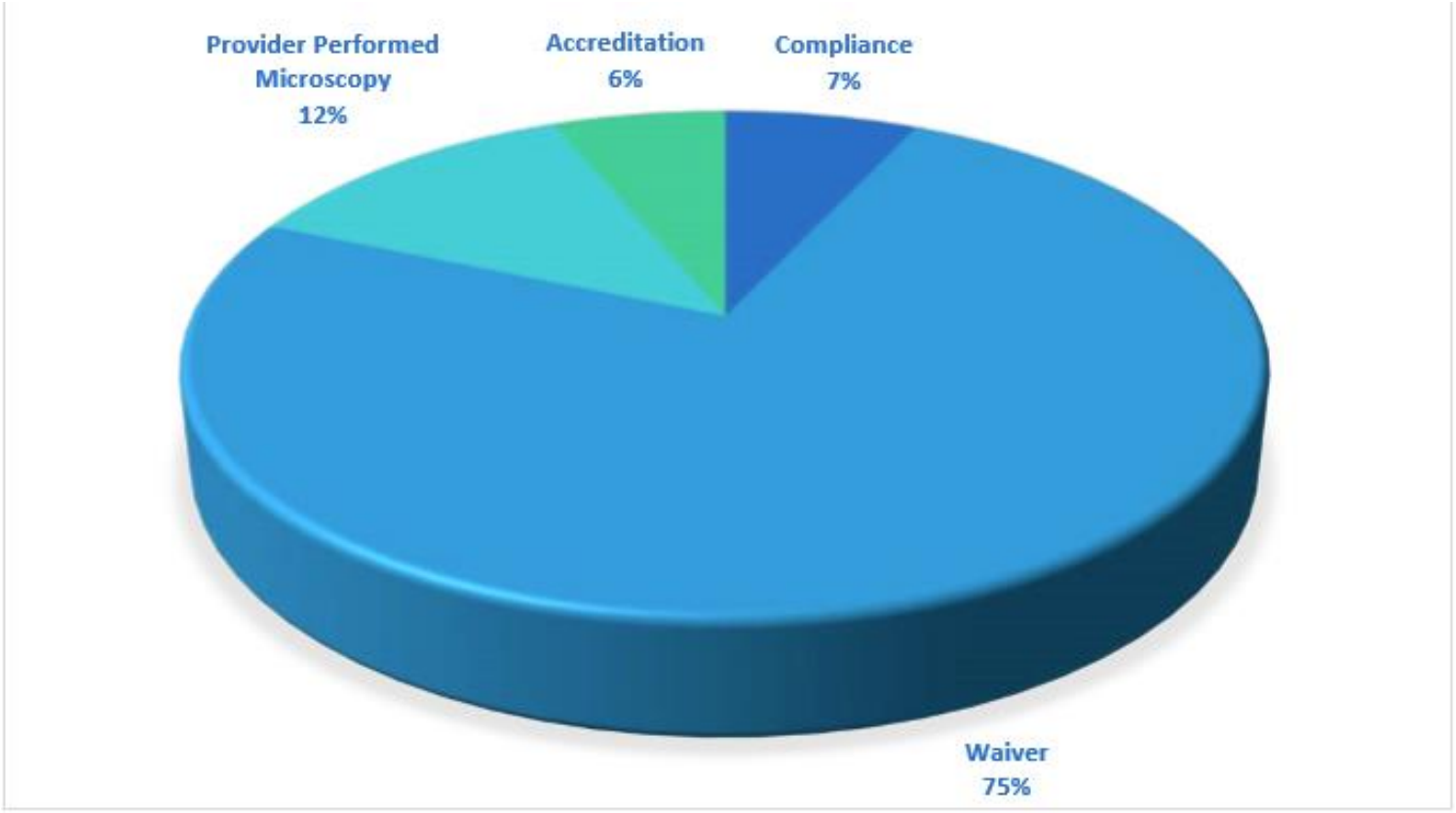
CLIA Requirements	High	Moderate	Waived	PPMP
Personnel	Yes	Yes	No	Yes
QC/QA Practice	Yes	Yes	As per Manufacturer	Yes
PT/EQA	Yes	Yes	No	If available
Routine Inspections	Yes	Yes	No	No
For-cause Inspections	Yes	Yes	Yes	Yes

CLIA Registered Laboratories



https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html Accessed 07/14/2020

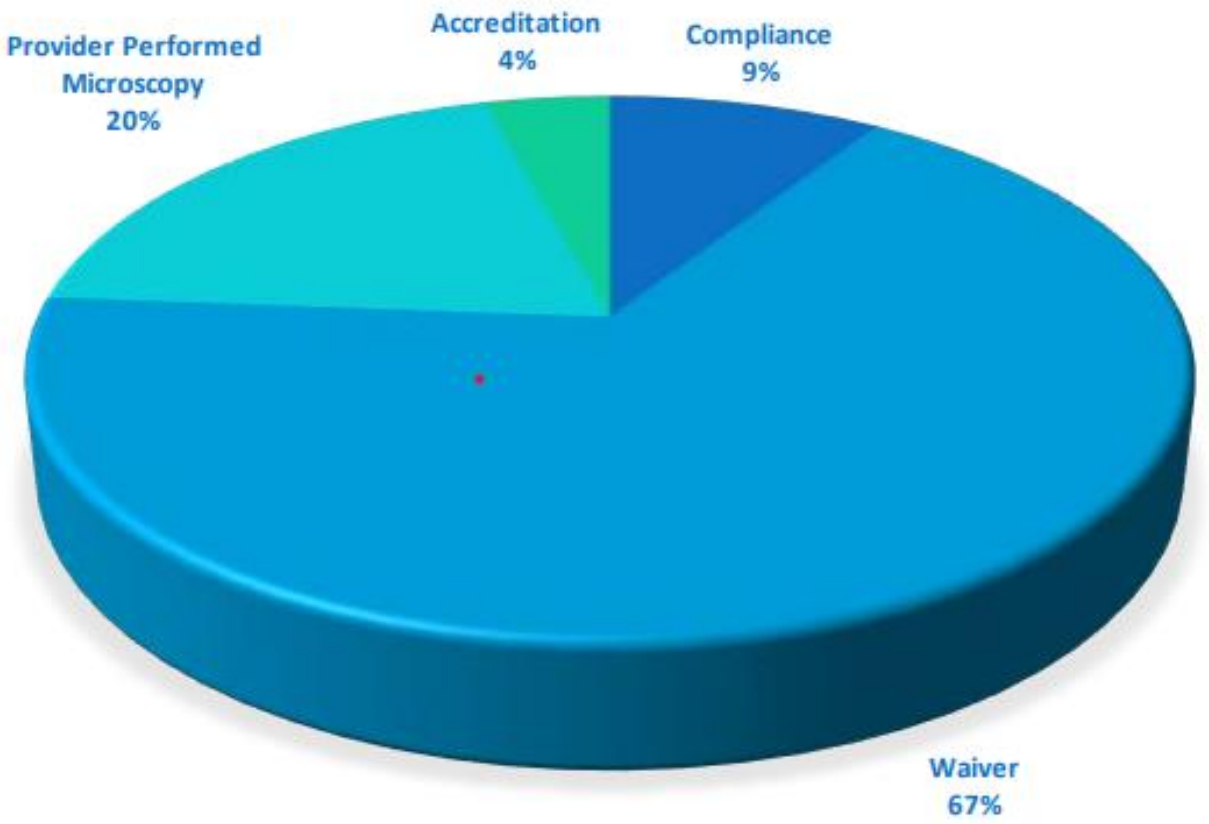
CLIA Laboratory Certification (Non-Exempt)



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

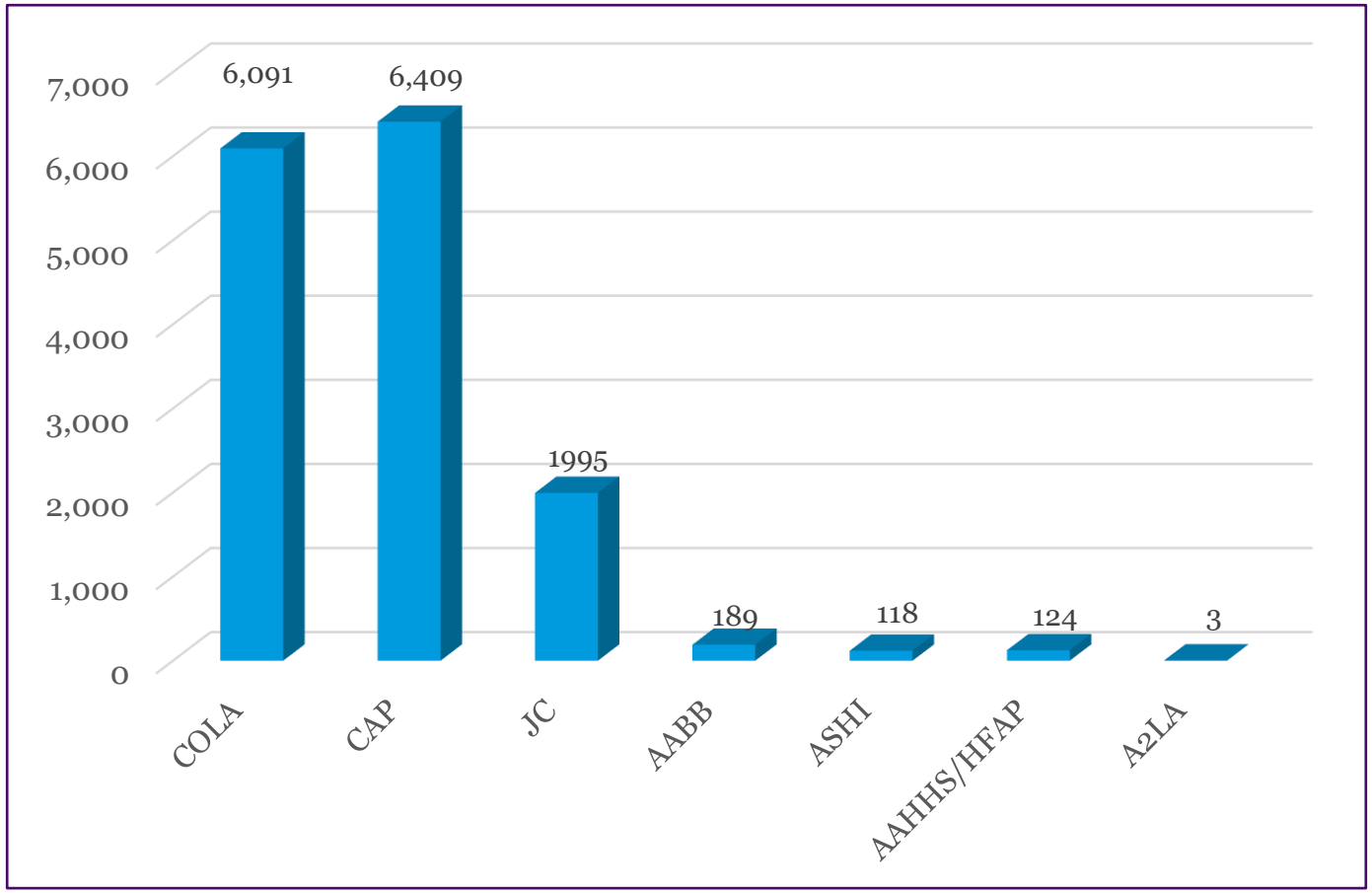
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html Accessed 07/14/2020

Physician Office Laboratories
CLIA Laboratory Certification



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

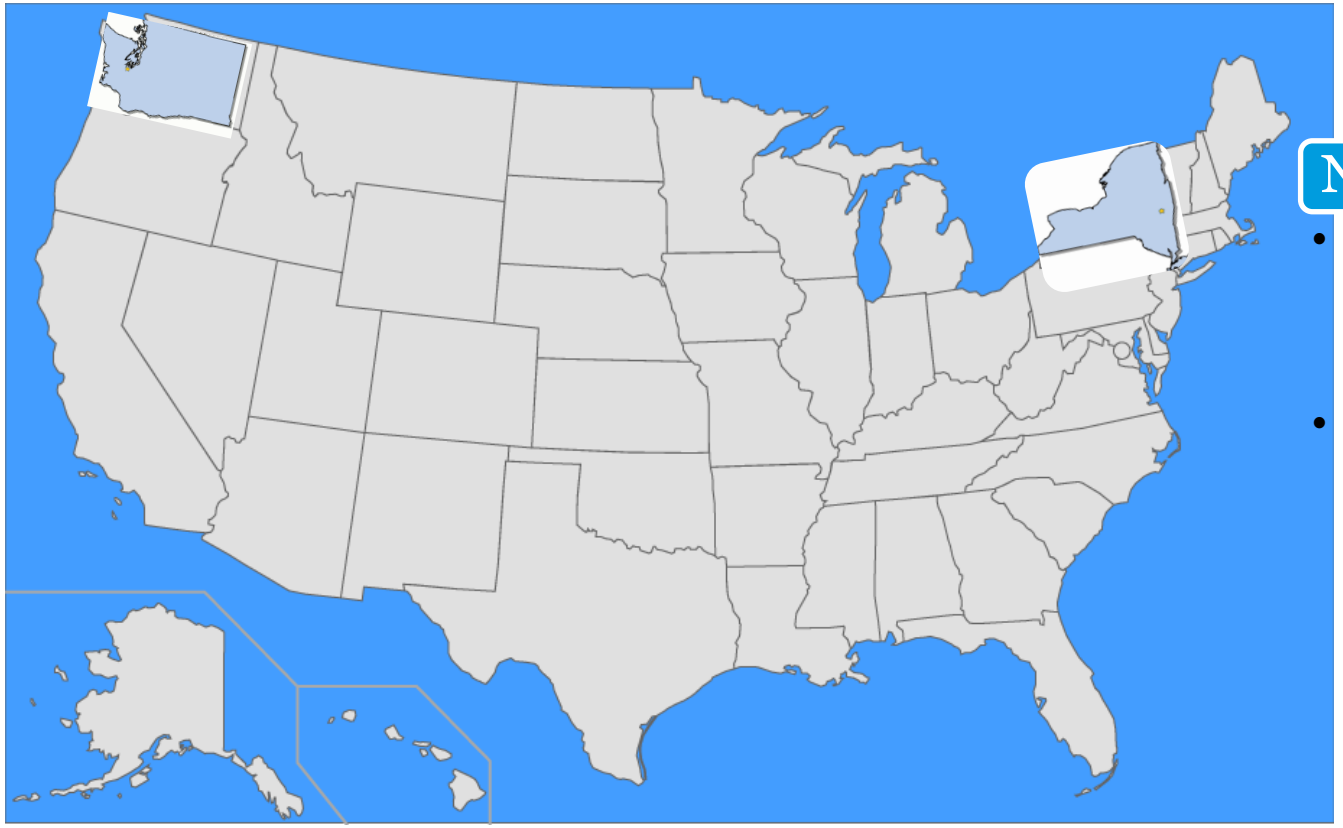


https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html Accessed 07/14/2020

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 Accessed 07/14/2020

Waived Tests Definition

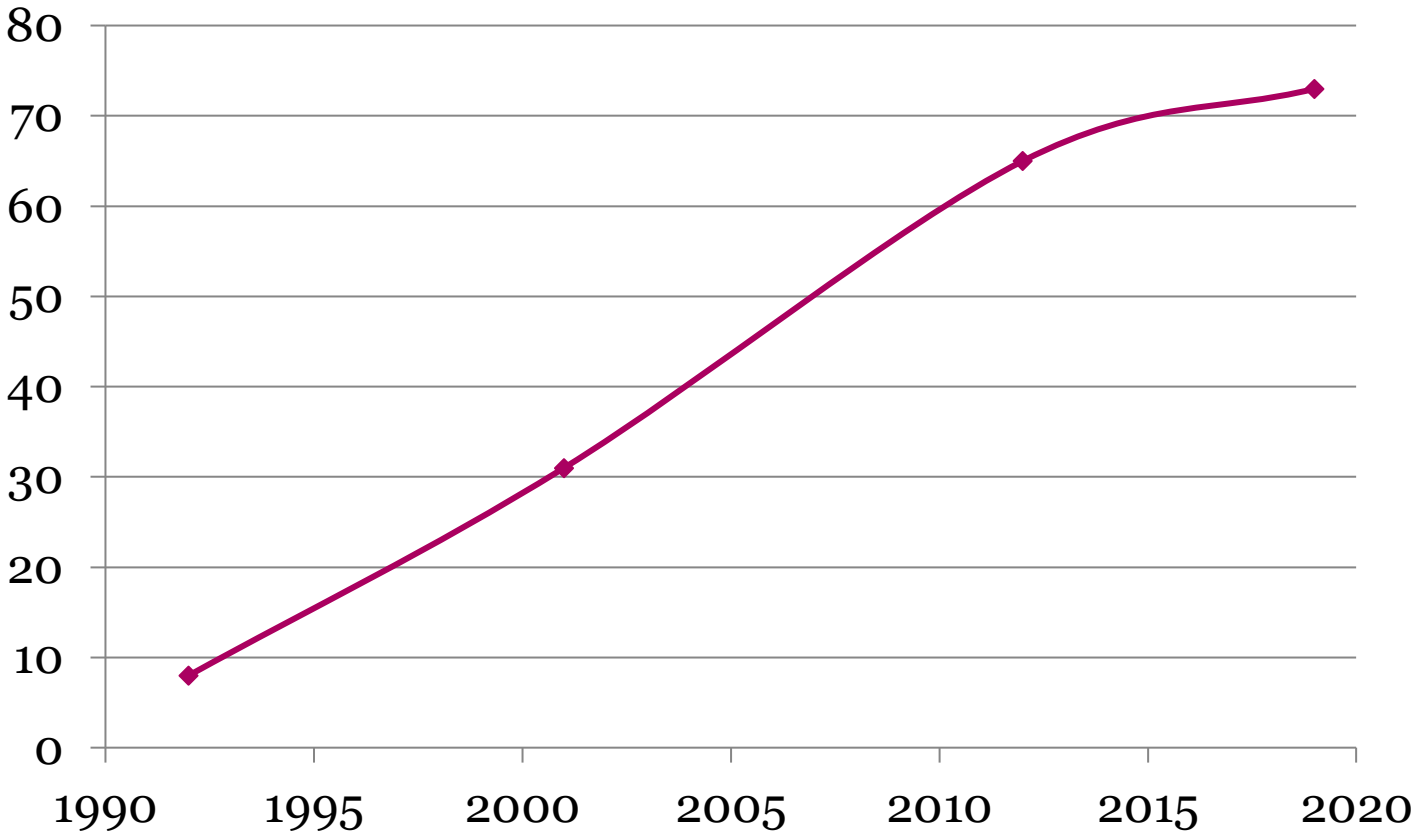
Simple laboratory examinations and procedures that are:

- 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

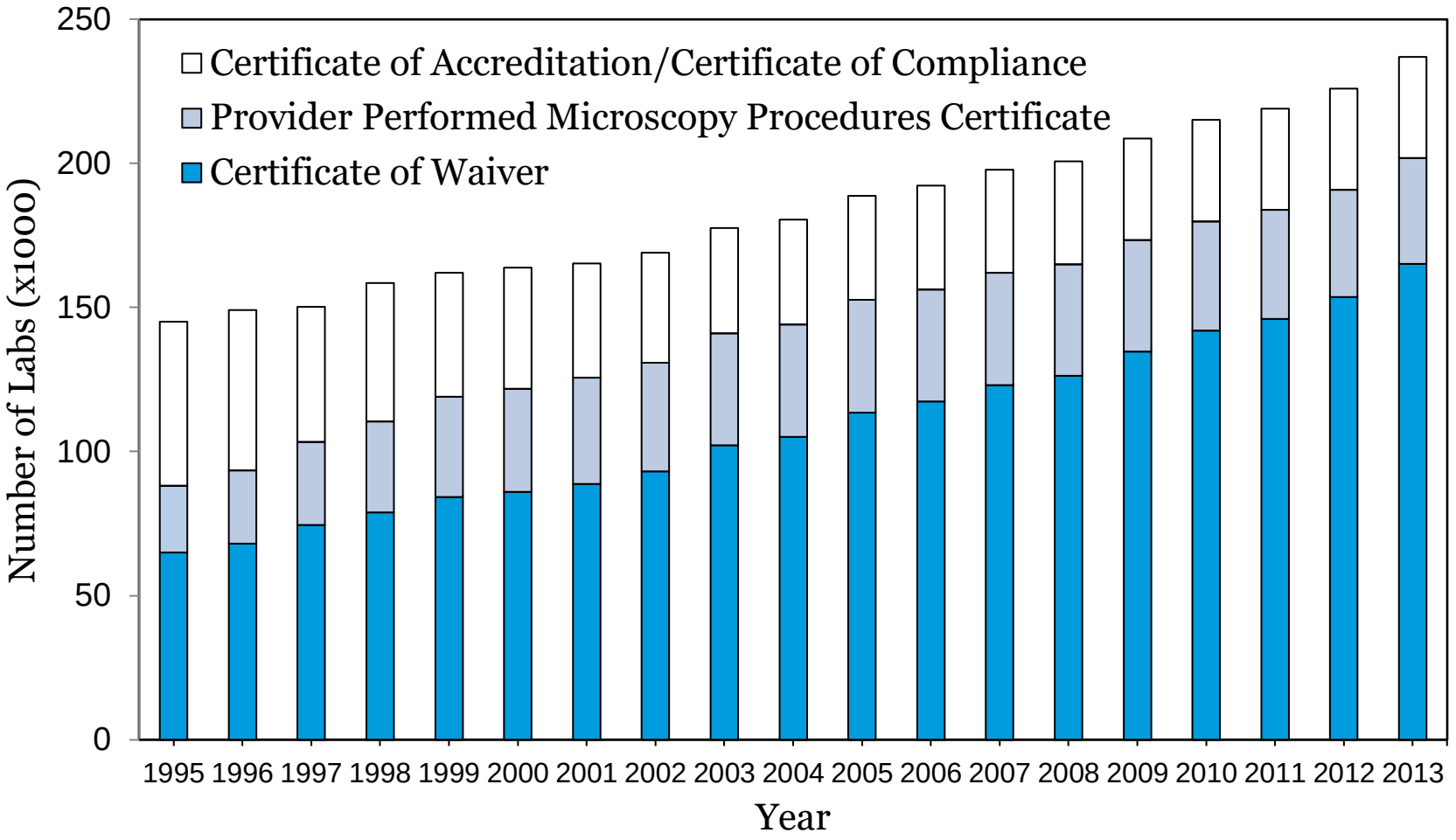


Current CLIA Waived Tests

- 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^{++}, Cl, CO_2
- 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

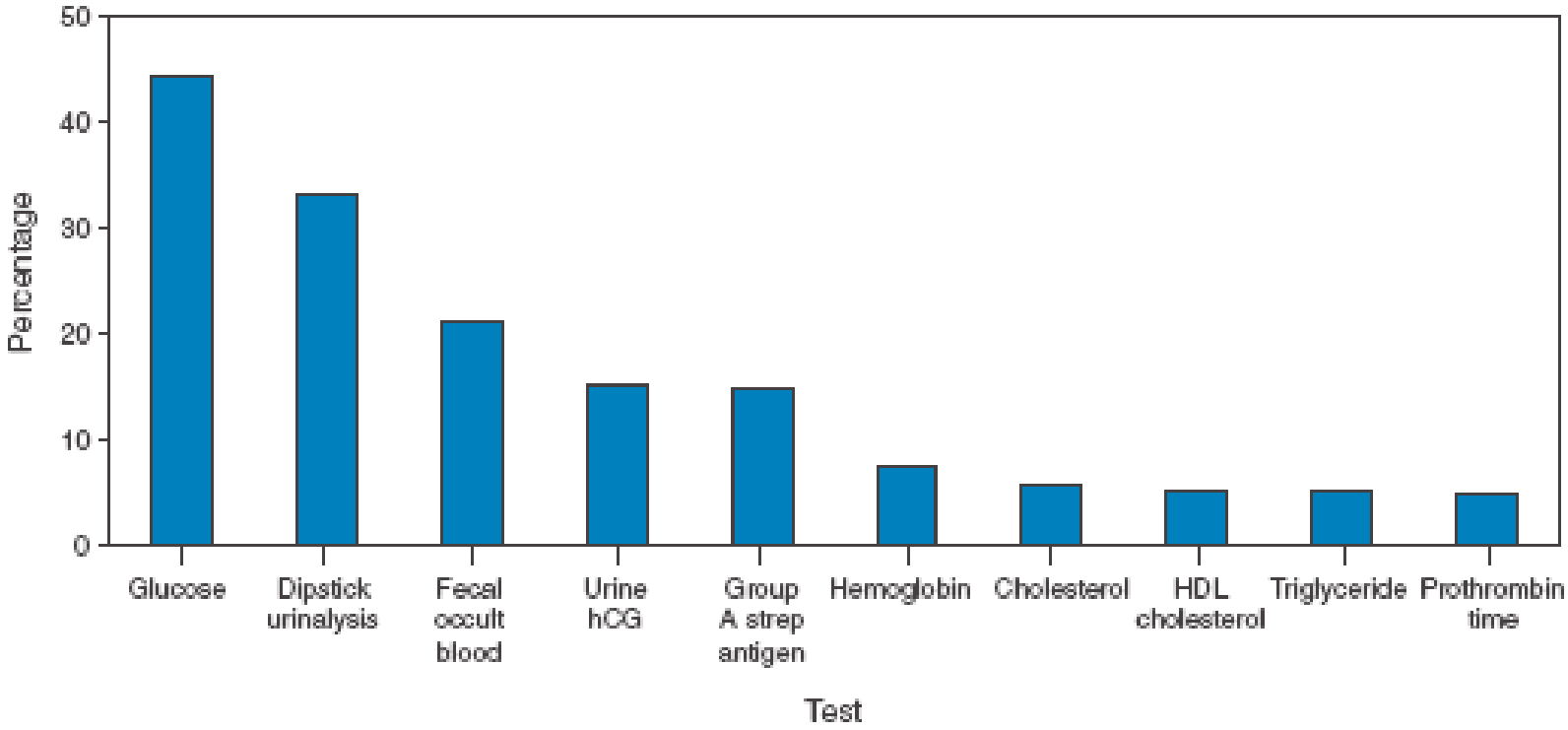
www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html, last accessed 7/20/20

CLIA Certified Laboratories



https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html Accessed 07/14/2020

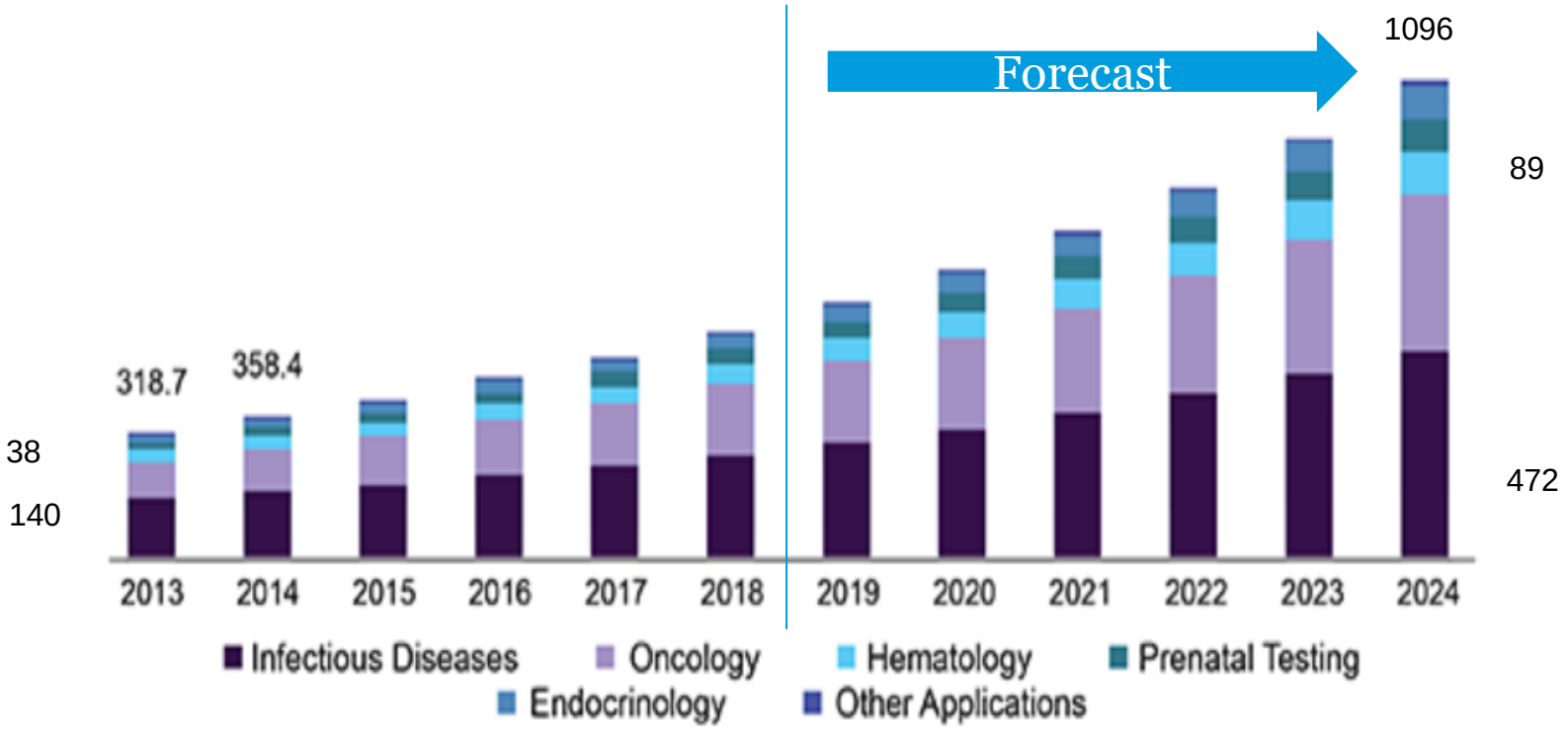
Top Waived Tests 2003-04



n = 3,317 sites surveyed by CMS

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

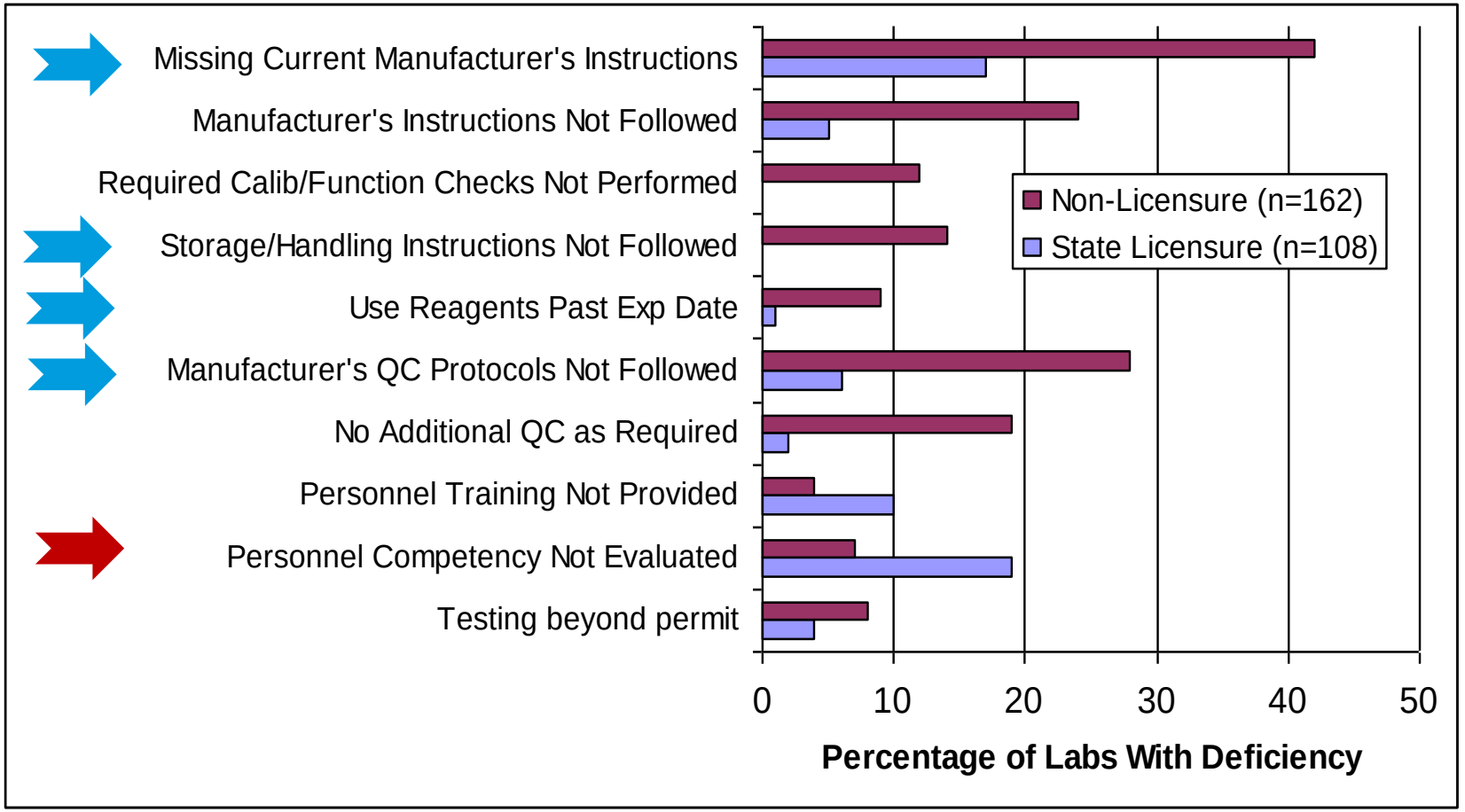
U.S. Point-of-Care Molecular Dx Market 2013-2024



www.grandviewresearch.com, last accessed 8/4/20

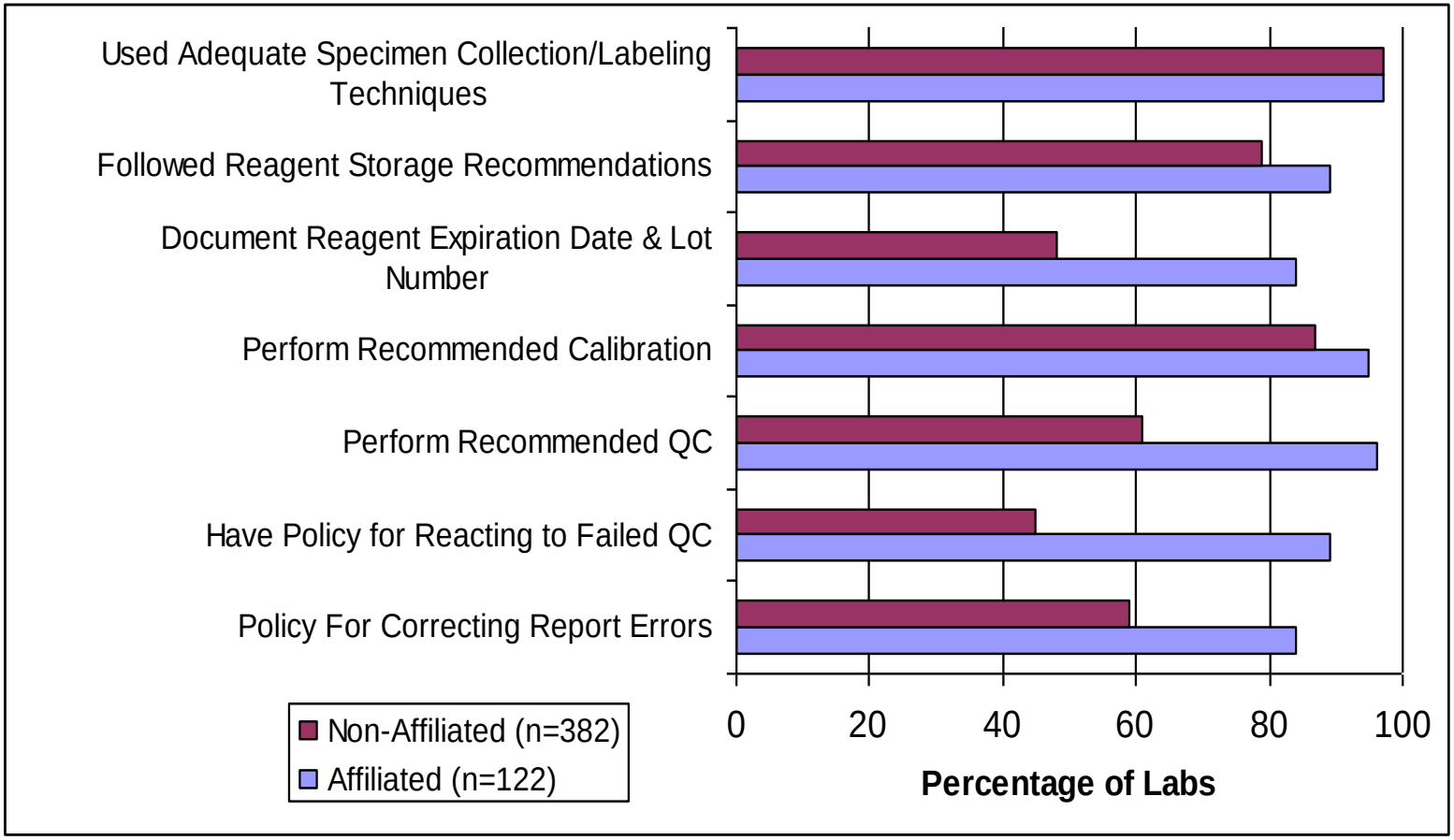
POCT Deficiencies

Common Survey Deficiencies in COW Laboratories



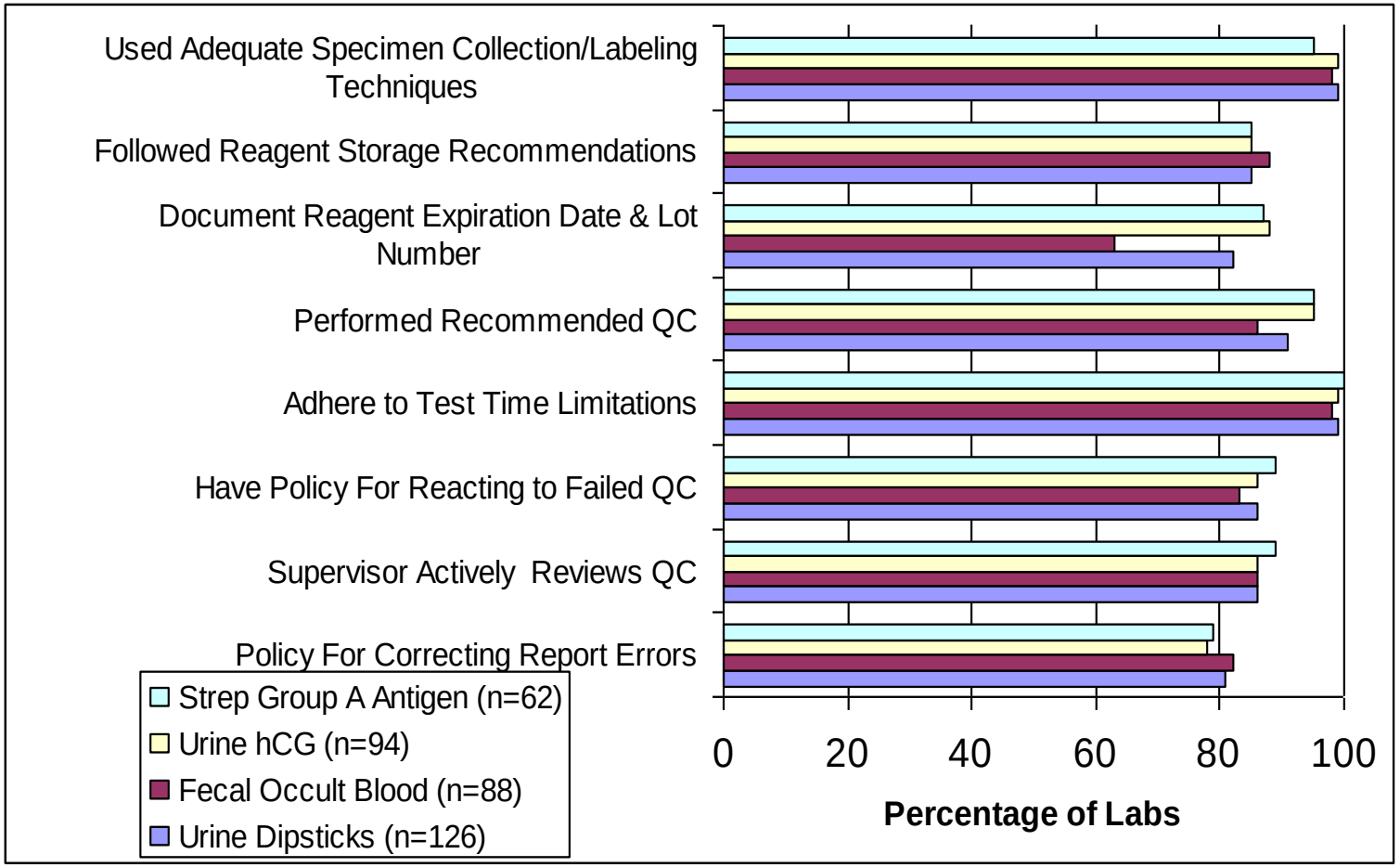
Source: CMS Certificate of Waiver Procedures Pilot Project, 2002

Blood Glucose



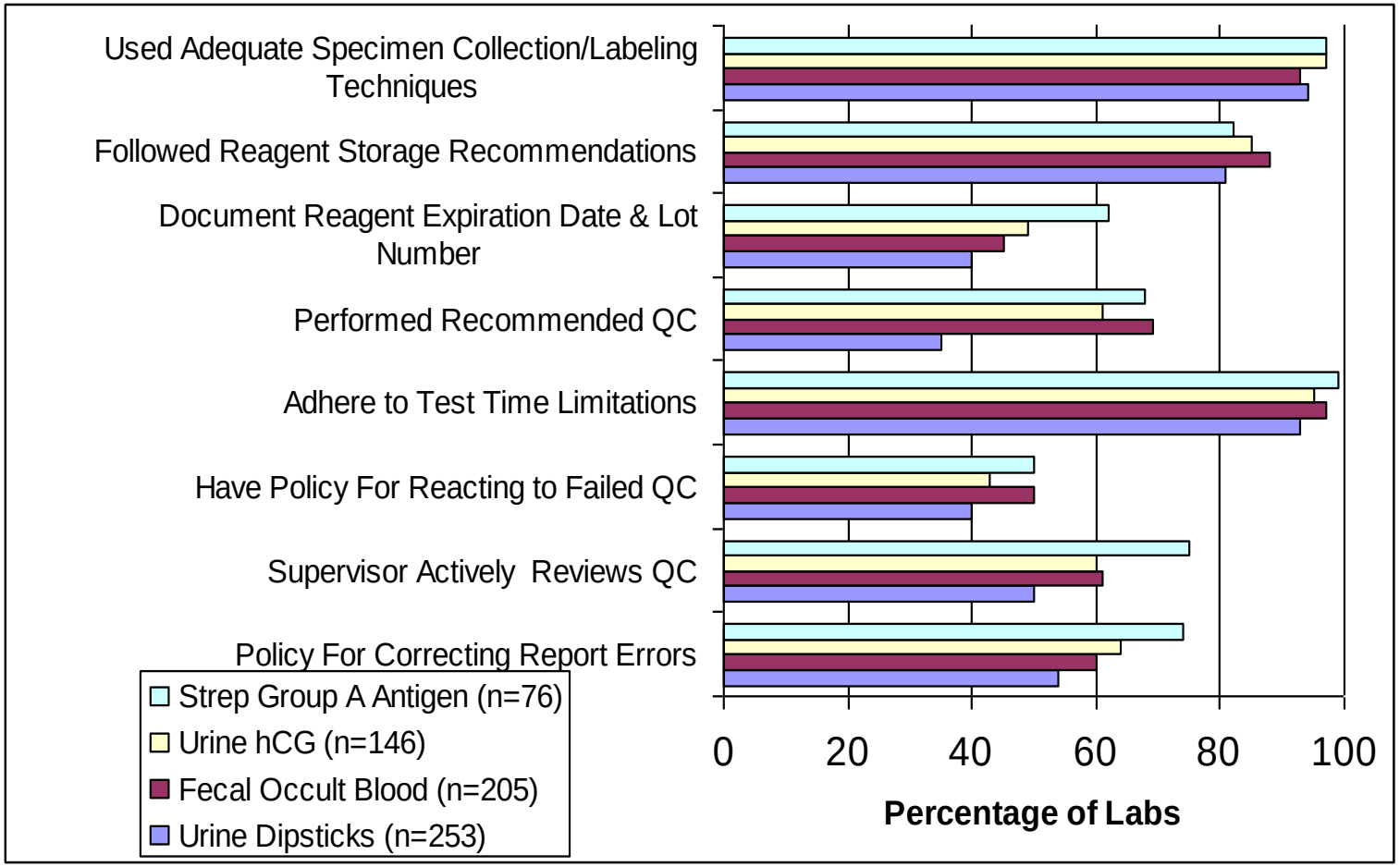
Source: CMS Certificate of Waiver Procedures Pilot Project, 2002

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 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.

CLSI POCT4-A3

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

CLSI POCT4-A3

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.

CLSI POCT4-A3

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.

CLSI POCT4-A3

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…

ISO 22870 – 5.1.5

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.

ISO 22870 – 5.1

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
Preanalytical

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

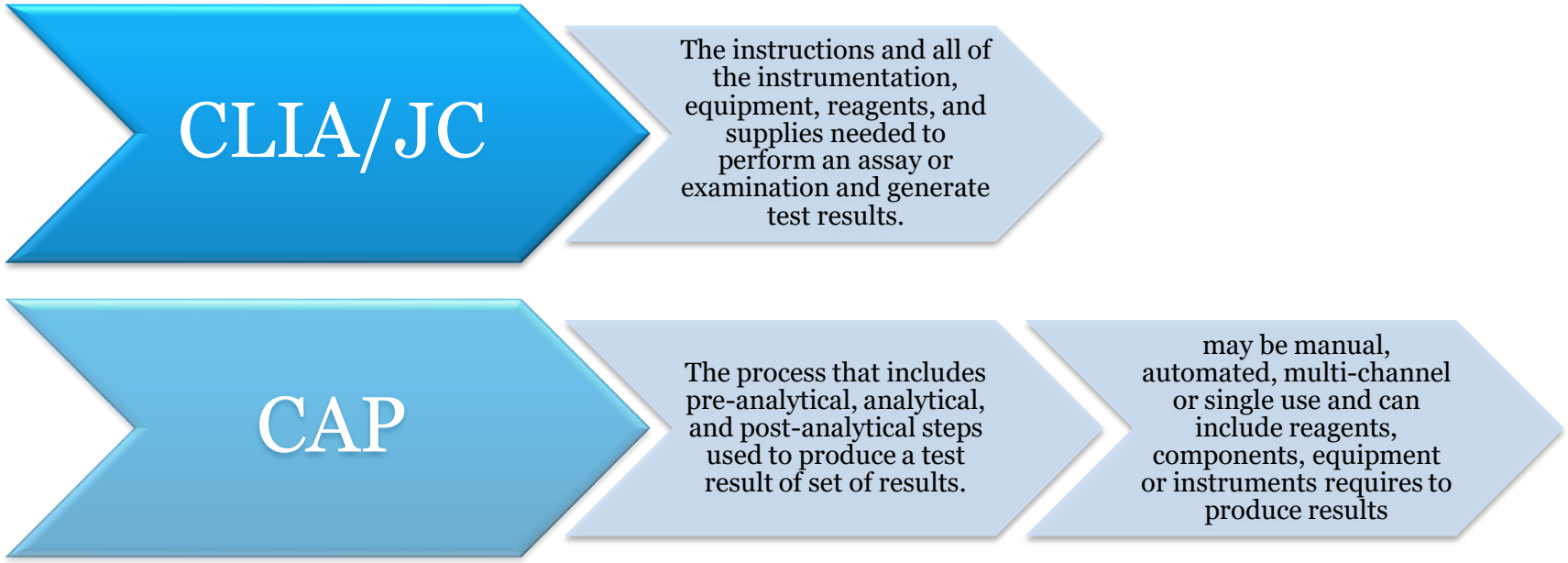
COLA includes an initial training, 6 month competency first year, and every year.

Why are Competency Requirements Confusing?

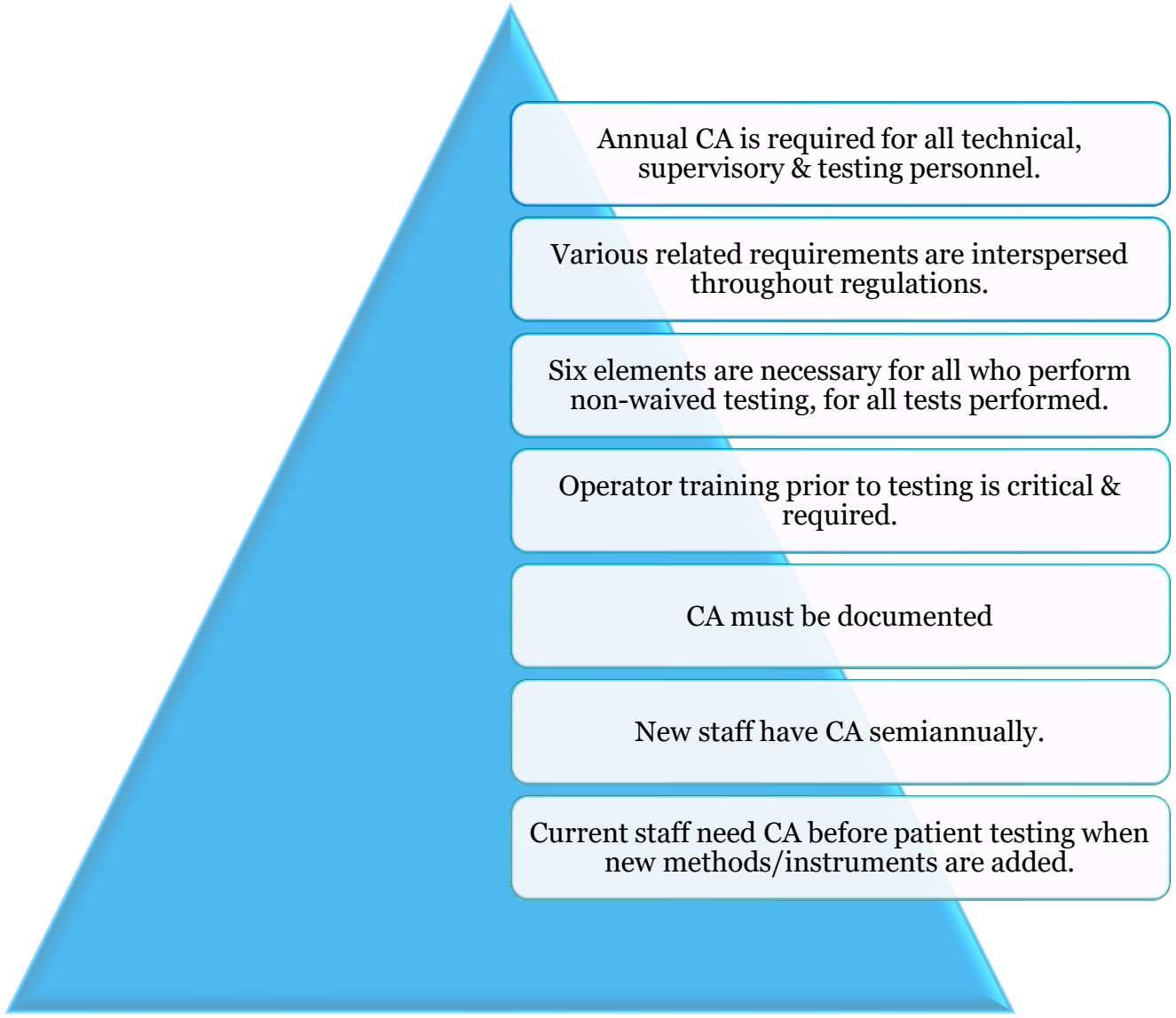
CLIA regulations for competency assessment have not changed

- 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 Competency Assessment Policy



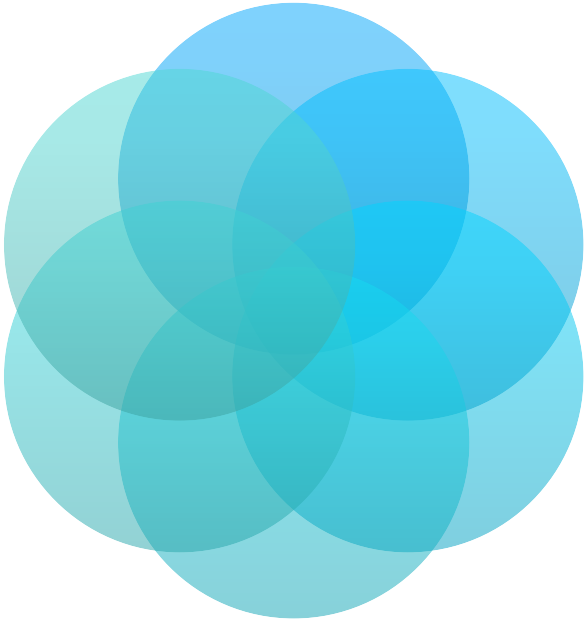
- Annual CA is required for all technical, supervisory & testing personnel.
- Various related requirements are interspersed throughout regulations.
- Six elements are necessary for all who perform non-waived testing, for all tests performed.
- Operator training prior to testing is critical & required.
- CA must be documented
- New staff have CA semiannually.
- Current staff need CA before patient testing when new methods/instruments are added.

Six Elements for Non-Waived Testing

Direct observation of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing

Review of intermediate test results or worksheets, QC records, PT results, and preventative maintenance records

Evaluation of problem solving skills



Assessment of test performance through testing previously analyzed specimens, internal blind specimens, or external proficiency testing specimens

Monitoring the recording and reporting of test results, including, as applicable, reporting critical results

Direct observation of performance of instrument maintenance and function checks, as appropriate.

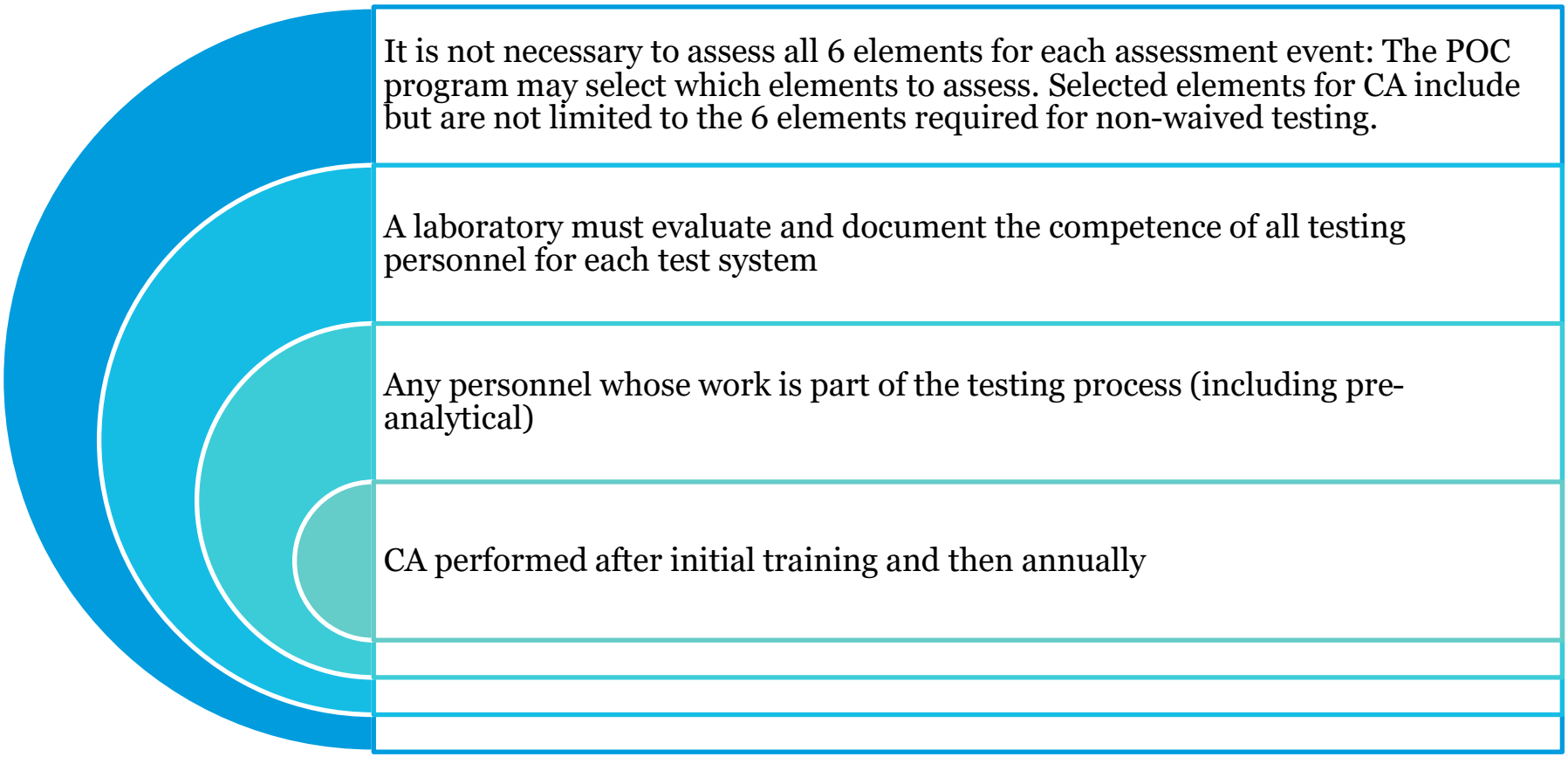
Does CLIA Require Competency for Waived Testing ?

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

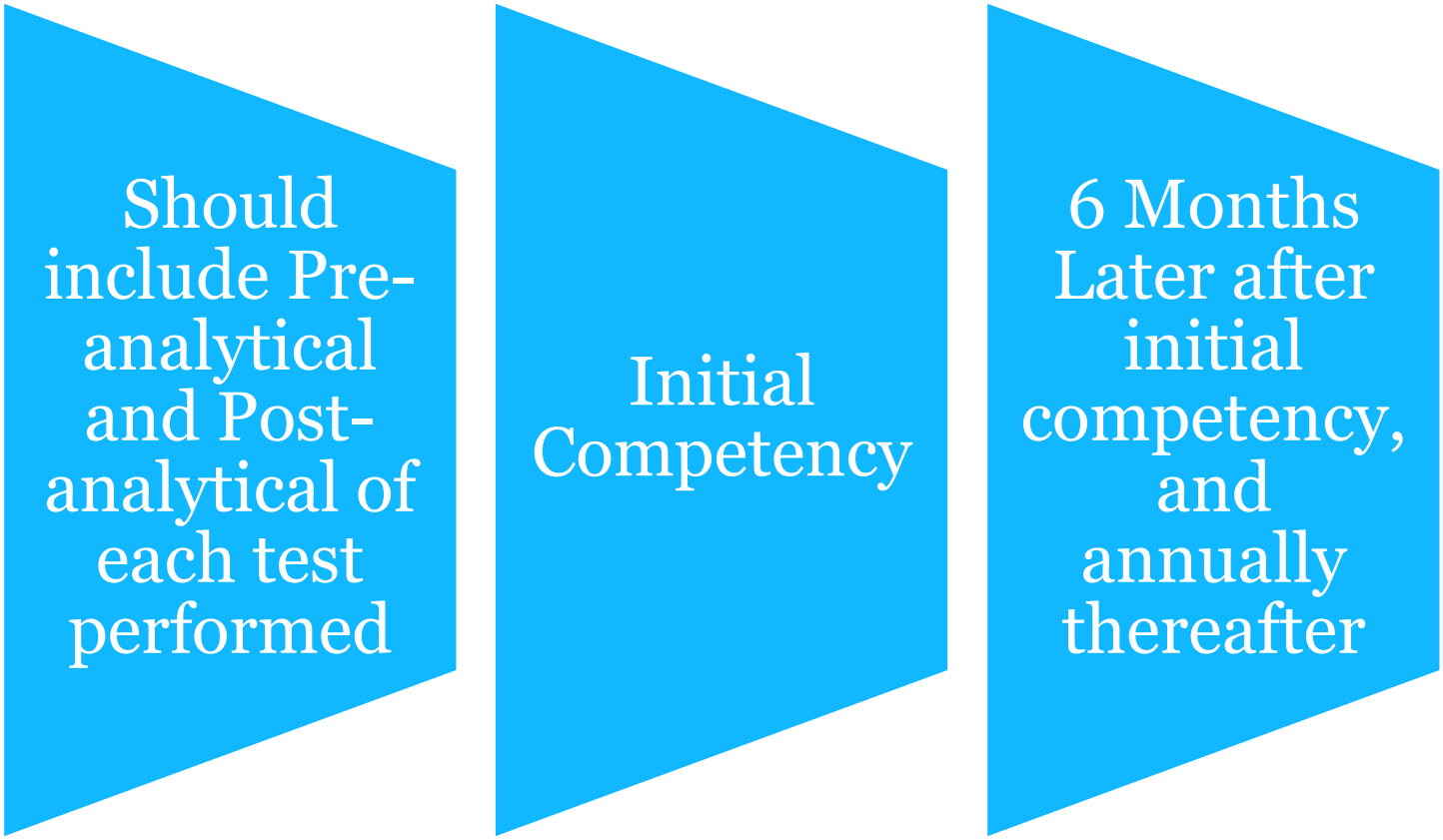
Personnel involved in pre- or post-analytical processes are not required to undergo CA.

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

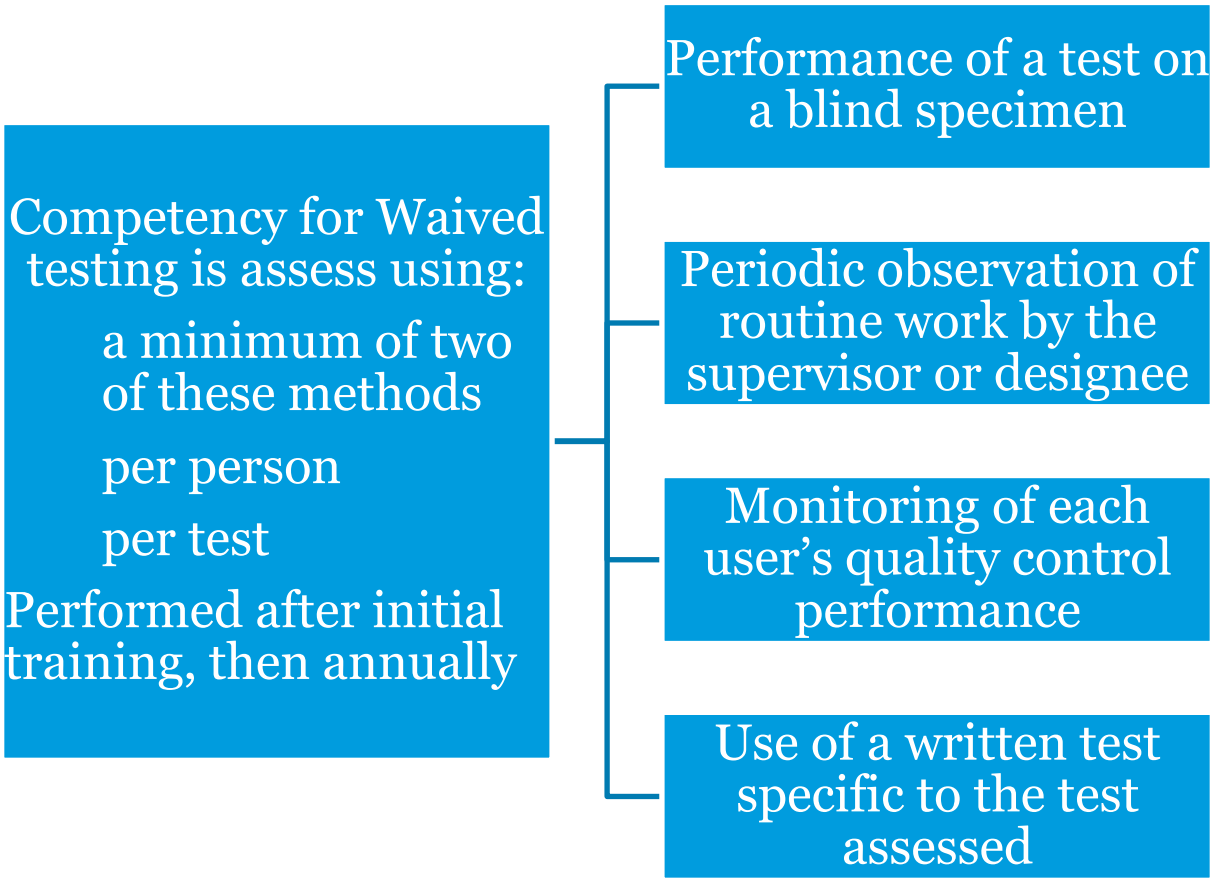
CAP Waived Testing Competency



COLA Waived Competency Assessment



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.

ISO 22870 – 5.3.2

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.

ISO 22870 – 5.6.8

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.

Questions?

ellisjacobs1@gmail.com