POCT

The Path to Painless Point-of-Care Implementation

POINT OF CARE TESTING UNIVERSITY

Statement of Need

- Point-of-care testing (POCT) is defined as "testing at or near the site of patient care." A point-of-care system includes technology such as bedside terminals, hand-held tablets, PCs, and software used by healthcare professionals to capture medical information from patients where the patient receives care. This allows medical professionals to make informed decisions quicker than traditional methods. Miniaturization and improved instrumentation have accelerated the development of increasingly smaller and more accurate POCT devices.
- POCT has been shown to have an immediate impact on patient care and workflow which can result in operational and economic benefits and increased satisfaction for patients. The benefits of implementing POCT have been well established, but challenges remain.
- Technical issues may prevent new technologies from delivering the required clinical performance in the intended setting. Even when clinical performance standards have been met, challenges with adoption, implementation, and quality control can limit the impact of POCT.
- As POCT increases in popularity, more and more tests will be performed by non-laboratorians, and guidance provided may not be written in language understood by all operators. Understanding local, state, and/or federal laboratory regulations can present as another barrier, especially for healthcare professionals whose background and training is strictly focused on patient care.
- To combat these barriers, it is important that all involved in POCT invest in the necessary support and training to ensure high clinical standards and continued reliability and adoption. This webinar will provide information on the benefits, implementation, maintenance, and future of POCT.

Continuing Medical Education

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Disclosures

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Learning Objectives

1. Identify benefits of POCT.
2. Review currently available POCT methodologies.
3. Evaluate challenges associated with POCT implementation.
4. Determine how to maintain POCT usage in your facility.

Obtain Your Continuing Education Credits

To obtain credit for this program, please listen to the webinar in full
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Dr. Zucker has no disclosures for this program.

Agenda

1. Benefits of Point-of-Care Testing
2. Current Point-of-Care Testing Methodologies
3. Selection and Implementation of New Point-of-Care Testing Platforms
4. Maintaining a Point-of-Care Testing Program
5. Future of Point-of-Care Testing

Benefits of Point-of-Care Testing

Benefits of Point-of-Care Testing

Enhances patient satisfaction and experience

- Enhances patient workflow
- Eliminates the need for sample transport
- Decreases turnaround time
- Avoids delay in procedures

Impacts and enhances continuity of care for the patient

- Allows for patient counseling during the visit
- Avoids unnecessary escalation of treatment

Test-specific benefits

- Finger sticks vs. venipuncture
- Improve antibiotic stewardship

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Cost Benefit Analysis

- POCT can be more expensive than central laboratory testing on a per test basis.
- Savings in other areas of care can justify the cost.
- Patient satisfaction increases when results are shared during the appointment and the care plan is immediately outlined.
- For urgent care centers, primary care clinics, or emergency departments, laboratory results available on-site potentially decreases patient wait time.
  - Improves timeliness of care

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Location, Location, Location… Hospitals

Inpatient Settings

- Triage
- Trauma center/ICU
- Operating rooms
- Extracorporeal membrane oxygenation (ECMO) center
- Catheterization lab/cardiology
- Stroke center
- Cardiac rehab
- Radiology/imaging center
- Coumadin clinic/coagulation clinic

Clinic/Outpatient Settings

- Triage
- Antenatal (Ob-Gyn)
- Oncology
- Urgent care and rapid care centers
- Geriatric
- Pediatric
- Diabetes/endocrinology
- Infectious disease
- General practitioner
- Ambulatory surgical settings
- Congestive heart failure (cardiac rehab)
- Radiology/imaging center
- Coumadin/coagulation
- Mobile health
- Helicopter, ambulance, airplanes
- Executive health

Laboratory

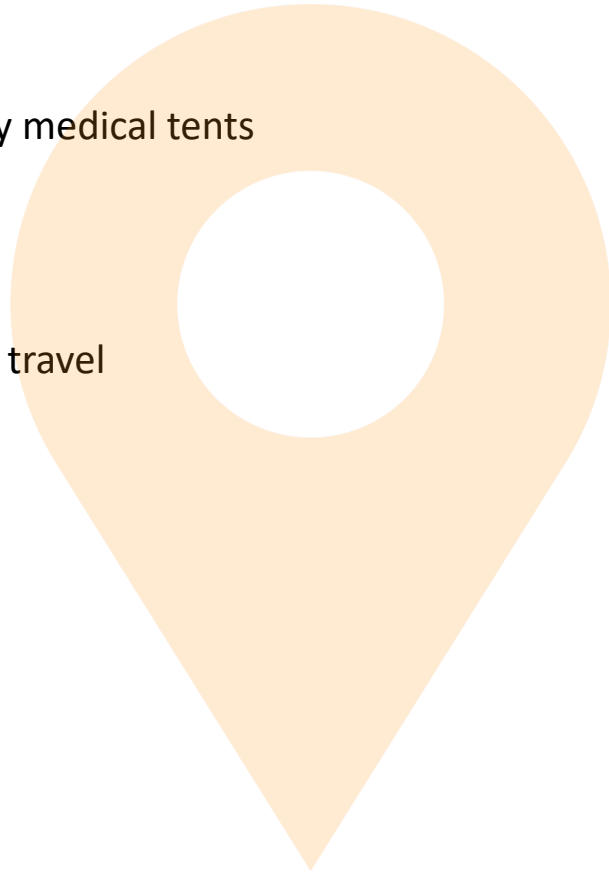
- Rapid response laboratory
- Deployed laboratory services (ER stat labs)
- Emerging infectious disease laboratory/biohazard/disaster planning lab

Abel G, et al. Point-of-care testing: A “how-to” guide for The non-laboratorian. *AACC*. 2022.

Location, Location, Location… Non-traditional Settings

Other Testing Sites/Locations

- Airlines, airports
- Cruise ships and shipping ports
- Mobile health clinics
- Pharmacies
- Public events
- Nursing homes
- Long-term acute care and skilled care
- Rehabilitation centers
- Public school and university/student healthcare centers
- Employee health centers
- Disaster relief post/military medical tents
- Expeditions
- Home health
- Hospital at home
- Travel clinics/screening for travel
- Community testing
- Indian Health Services
- Health fairs
- Blood collection centers



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POCT

Current Point-of-Care Testing Methodologies

Common POCT Features

- Usually small and handheld, or somewhat portable
- Usually allow input of patient and operator ID
- Usually include some level of built-in QC processes
- May or may not have connectivity and a means to interface with electronic records
- May ‘lock out’ operators unless they meet required compliance qualifications or ‘lock out’ testing if quality control requirements have not been met
- May include specimen integrity checks
- May include ability to track or document cleaning and/or maintenance

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POCT Methodologies Exist for Several Conditions and Specialties

- Hematology
- Coagulation
- Infectious disease
- Cardiovascular disease
- Diabetes
- Kidney disease
- Pregnancy
- Critical care
- Blood gas
- Chemistry

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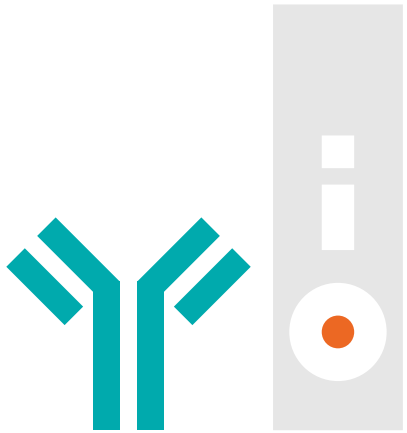
Multiple Laboratory Areas

Immunoassays

- Antibody/antigen
- Small molecular proteins, hormones, fatty acids, drugs and other substances

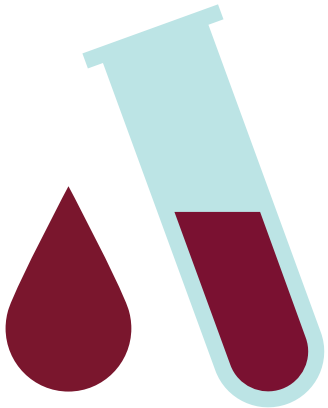


Molecular assays

- DNA or RNA
- Pathogens, biomarkers, genes

Chemical analyzers

- Biochemical reactions
- Enzymes, carbohydrates, lipids, protein and non-protein nitrogen, inorganic elements, liver function and other indicators



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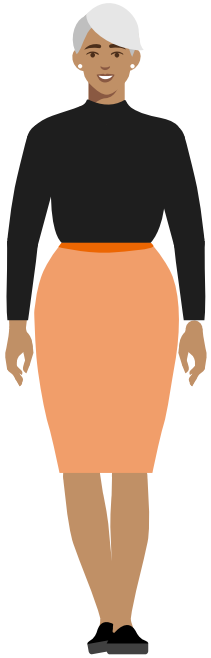
POCT Implementation Is a Team Effort

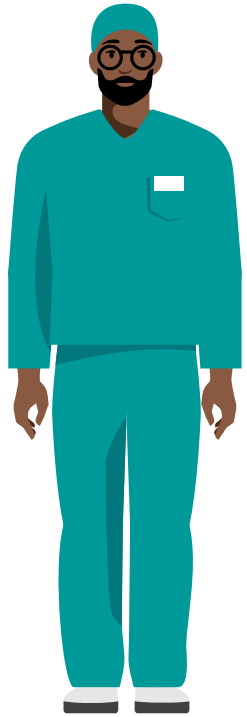
Sales representative

- Provides information from manufacturer on sensitivity, specificity, use, implementation, and QC



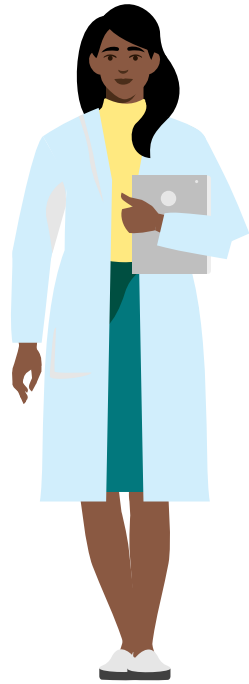
Provider/end user

- Determines clinical need
- Uses results for patient care



Point-of-care coordinator (POCC)

- Coordinates needs for implementation, training, and monitoring



POCT

Selection and Implementation of New Point-of-Care Testing Platforms

Correct Implementation Starts With the End User

End user identifies need

End user confers with POCC

Team develops justification for new POCT

Multiple systems analyzed

Optimal system selected and implemented

Observation of clinical, operational, and financial outcomes

Institutional Implementation Process

Institutional implementation and selection processes should be established

- CLSI POCT09A
- Selection criteria for point-of-care testing devices

Process should include a formal request policy

- Not every test needs to be POC

Formal justification

- Improved outcomes
- Medical, resource, operational, financial

Process change to implement POCT

CLSI. Selection Criteria for Point-of Care Testing Devices; Approved Guideline. CLSI document POCT09-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
Point-of-Care Testing Guideline Published by CLSI. *Lab Med*. 2010;41(8):499-500.

Requests Require Justification

New or replacement?

If new:

- Which analyte(s)?
- For which patient population?
- Why POC?
  - Safety
  - Cost savings
  - Product innovation
  - User complaints
  - Standardization
  - Other

Justification is requester/ end user responsibility

Requester answer the questions:

- Anticipated impact on cost of patient care and treatment
- Personnel expected to perform testing
- Procedures to be changed before implementation
  - Personnel to create new procedures and participate in IQCP development
- Personnel to be responsible for implementation and training

Assess Need, Locations, and Required Features

Need

- Clinical:
  - Why would POCT be of benefit to current processes?
  - Are accuracy and precision claims sufficient for targeted use?
- Operational:
  - Can current processes be changed to meet the clinical need instead?

Locations

- Where, who, how many?
- New connectivity required?

Features

- CLIA complexity
- QC assessment (Built-in; External; Lock-outs)
- Operator oversight (Training; Competency; Lock-out)
- Risk Assessment: IQCP requirements
- Test Menu (current and future needs)
- Test Volume
  - How many tests will be run in a given timeframe?
  - How many instruments are required to handle the expected volume?

Personnel and Training Requirements

- **Operators**
- **Supervisors**
- **Compliance oversight (Lab?)**
- **Providers/ Clinicians**

- **Support Personnel**
  - IT, purchasing, materials management, etc.
  - Who will provide training?
  - Who will perform the ongoing inventory management?

Device Evaluation and Selection

Resources for device identification

- Clinicians
- Other POCC
- Laboratory periodicals and buyer's guides
- Medical alert websites
- Vendor websites
- Trade shows / Vendor fairs
- Other locations using the device

Compare 2 or 3 devices

- Test with expected operators, not vendor representatives

Evaluations

Performance

- Precision
- Method comparisons
- Verification of reportable range
- Ease of Use
- System Calibration and QC

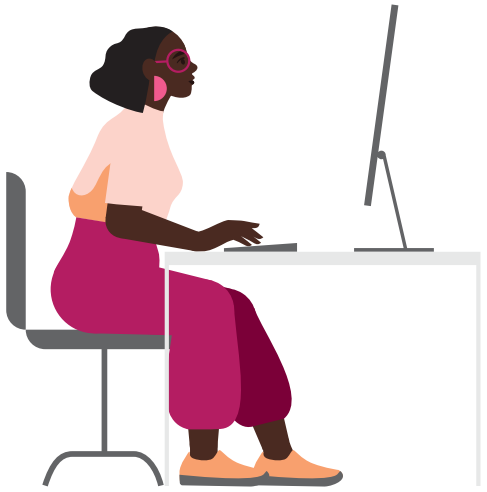
Logistics

- Regulatory and accreditation requirements
- Software/ firmware features
- Reagents / consumables
- Vendor support
- Cost

Implementation and Validation

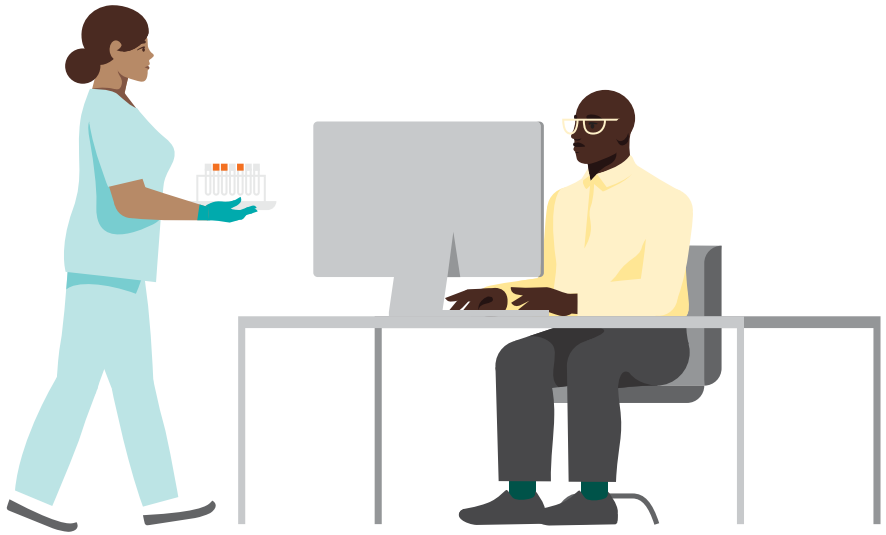
1 Installation

2 System Configuration



3 Device calibration and QC

- CMS Brochure # 3 – Calibration and Calibration Verification[1]
- Implement / Validate IQCP
  - CMS Brochures 11-13[2]



1. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf
2. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

Validation Studies

Validation studies

- CMS Brochure #2 - Verification of Performance Specifications[1]
- CLSI has guidelines for every step of system validation studies
  - Accuracy (quantitative and qualitative)
  - Precision
  - Reportable range
  - Reference interval verification
  - Method comparison studies

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf

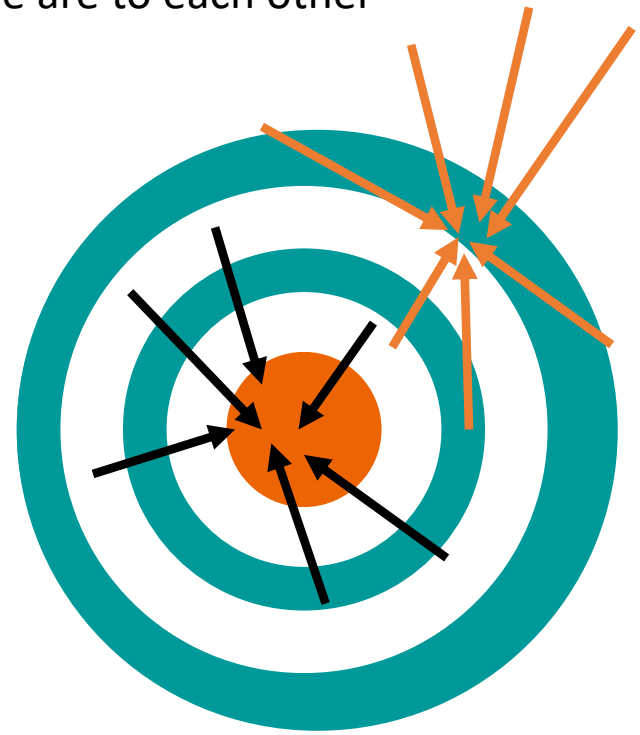
Accuracy and Precision

Accuracy = Measure of how close a measurement is to the "true" result

- How often a measurement is close to the bulls-eye

Precision = Measure of the percent coefficient of variation (CV)

- How close repeated measurements of the same sample are to each other



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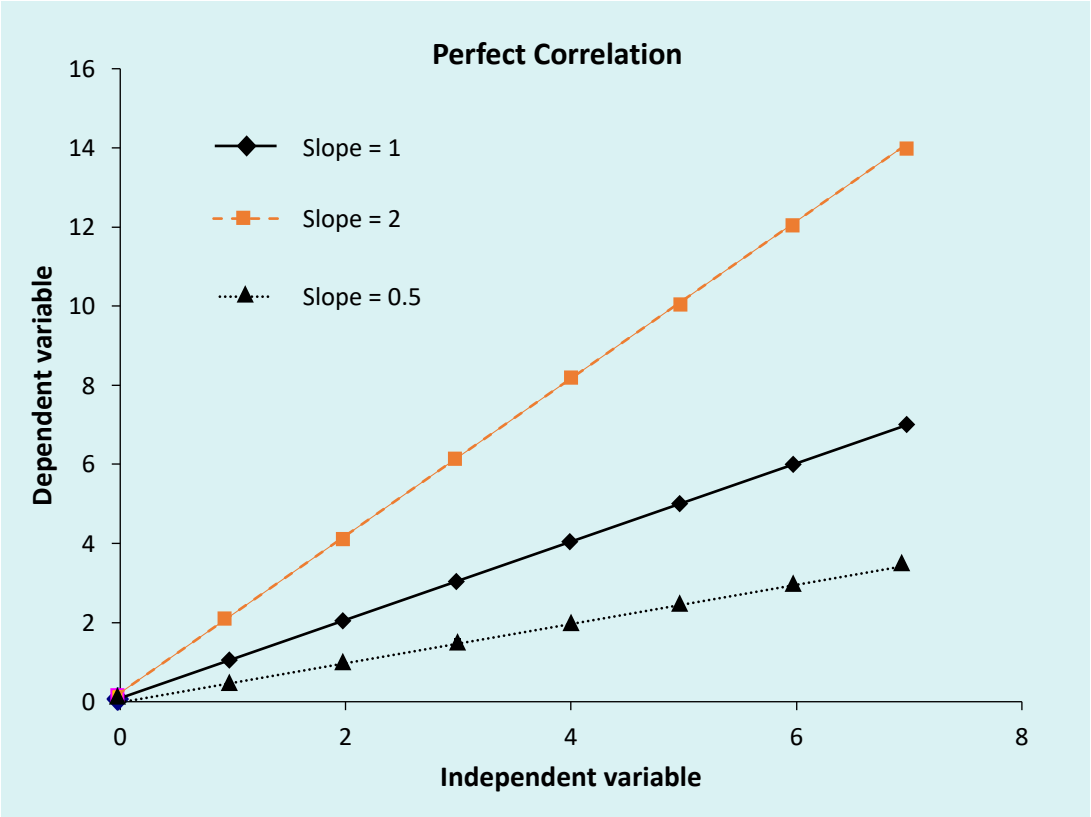
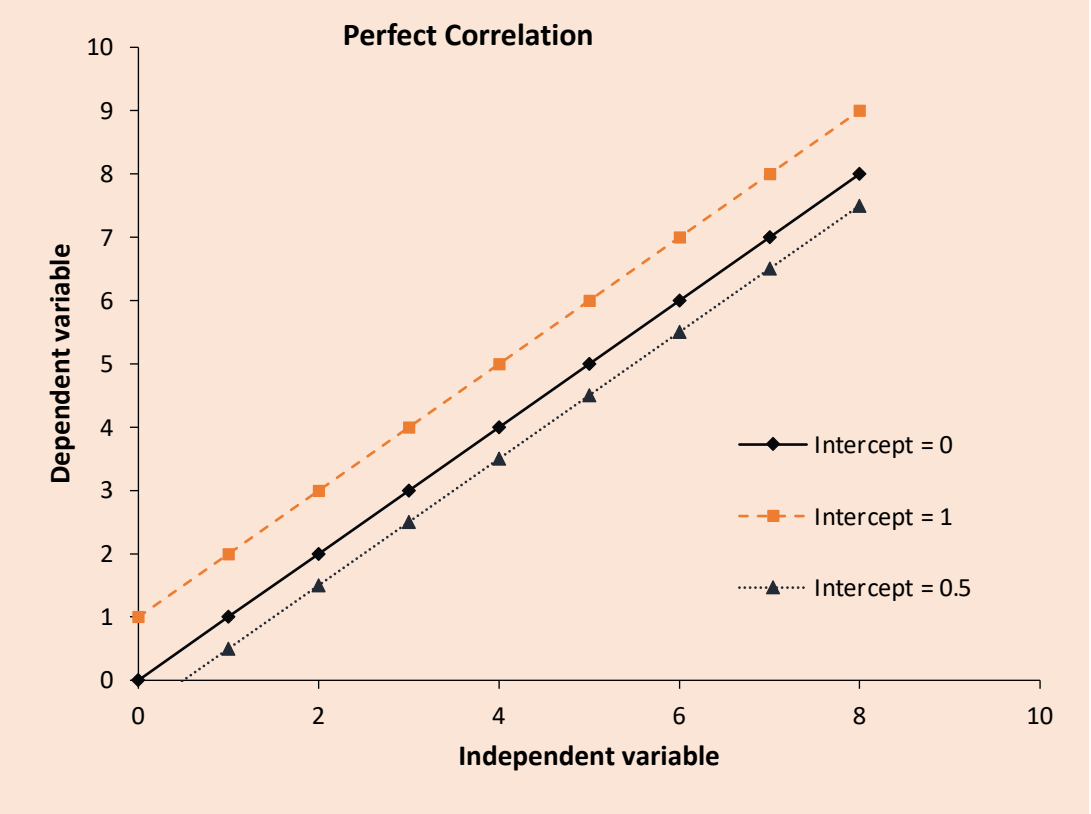
Hazra A, Gogtay N. *IJD*. 2017;62(1):18-24.

Accuracy and Correlation

Determined by correlation to local standard - Correlate does not mean match





Clinical Equivalence

Non-Standardized Assay Correlations

System	POC 1	POC 2
Slope	0.456	0.718
Intercept	0.011	-0.138
R	0.988	0.974

Slope of POC 2 is closer to 1.0

Is it more accurate?

Clinical Evaluation

Reference	POC 1	POC 2
0	0.01	-0.14
0.2	0.10	0.01
0.5	0.24	0.22
1.0	0.47	0.58
5.0	2.29	3.45

Two systems equivalent across critical range (0 – 0.5)

Adapted from Wu, et. al. *Clinica Chimica Acta* 346: (2004) 211-219.

Qualitative Accuracy

		"True" Result: Positive	"True" Result: Negative	
Result being evaluated	**Positive**	True positive (TP)	False Positive (FP)	*(PPV) - Positive Predictive Value*
	Negative	False Negative (FN)	True Negative (TN)	*(NPV) - Negative Predictive Value*
		Sensitivity	*Specificity*	*Concordance*

$$\textbf{Sensitivity} = \frac{TP}{TP + FN} \qquad \textbf{Specificity} = \frac{TN}{TN + FP}$$

$$\textbf{PPV} = \frac{TP}{TP + FP} \qquad \textbf{NPV} = \frac{TN}{TN + FPN}$$

$$\textbf{Concordance} = \frac{TP + TN}{\text{Total Number of Samples}}$$

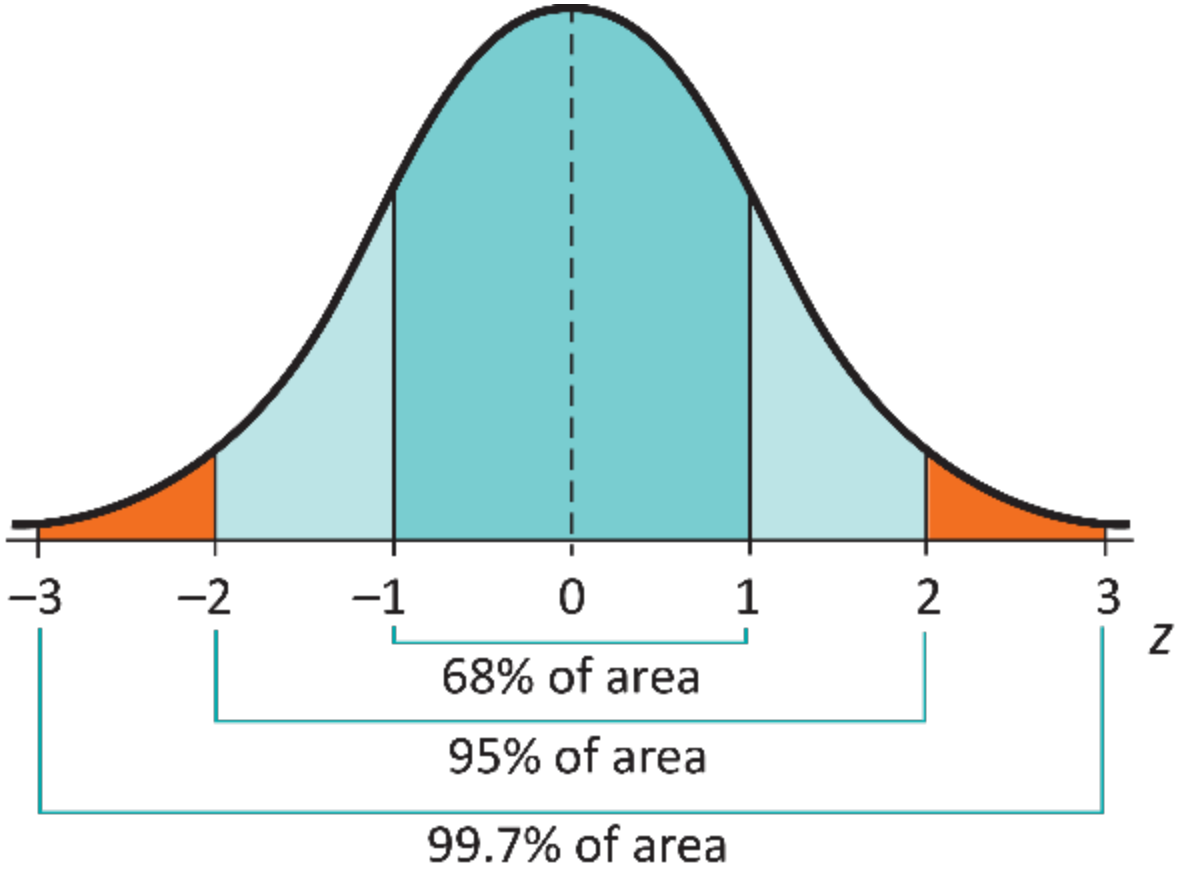
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf
Hazra A, Gogtay N. *IJD*. 2017;62(1):18-24.

Validation - Reference Interval and Reportable Range

Reference Range

- Usually, 99th percentile
  - If determined using a 100-patient study, values listed in increasing order, 99th value is 99th percentile
  - Approximated as the mean value of the normal reference group plus three standard deviations.

- **Reportable Range**
  - Use controls, calibrators, patient samples
  - Only samples within the validated range should be used for patient assessment / treatment



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POCT

Maintaining a Point-of-Care Testing Program

What Is Competency and When Is It Required?

Competency **com·pe·ten·cy (ˈkäm-pə-tən(t)-sē) noun:**
ability of personnel to apply skill, knowledge, and experience to perform their duties correctly.

Competency assessment
com·pe·ten·cy as·sess·ment (ˈkäm-pə-tən(t)-sē ə-ˈses-mənt) noun:
process used to ensure laboratory personnel are fulfilling duties as required by federal regulation.

Competency is required for all personnel performing non-waived testing:

- Following initial training
- Semiannually in first year of testing
- Annually thereafter

CMS Brochure #10: What do I need to do to assess personnel competency
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

How Is Competency Assessed?

Six competency elements defined by CLIA

1. Direct observations of routine patient test performance
2. Monitoring the recording and reporting of test results
3. Review of quality control records, proficiency testing results
4. Direct observations of performance of instrument maintenance and function checks
5. Assessment of test performance
6. Assessment of personnel problem-solving skills

CMS Brochure #10: What do I need to do to assess personnel competency
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

Who Can Assess Competency?

Moderately complex testing

- To qualify as Technical Consultant (TC)
  - Bachelor's degree
  - 2 years of laboratory training or experience with non-waived testing
- Nurses can qualify
- Laboratory director must delegate this task in writing beforehand.

Peer testing personnel who do not meet the regulatory qualifications of a TC or higher cannot be designated to perform competency assessments.

Who Assesses the Assessor?

Technical Consultant (TC) competency

- Must document that person doing assessment is qualified
  - Demonstrate ability to:
    - Troubleshoot test system
    - Verify compliance with quality policy
    - Assess training needs
    - Ensure competency assessments completed in a timely manner

CMS Brochure #10: What do I need to do to assess personnel competency
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR10813e8157e2976/section-493.1411. Accessed January 16, 2024.

Competency Assessment Implementation

Lots of ways to implement

- All elements must be completed within a year

Documentation is key

- Assessor authorization must be in written form
- Assessor must be qualified

CMS Brochure #10: What do I need to do to assess personnel competency
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

QC: CLIA Definition

Quality control **qual·i·ty con·trol** (ˈkwä-lə-tē kənˈtrōl) **noun:**
Process which monitors the accuracy and precision of the **complete** analytical process.

Control procedures must:

(1) Detect immediate errors that occur due to

- **test system failure**
- **adverse environmental conditions**
- **and operator performance**

(2) Monitor over time the accuracy and precision of test performance

According to CLIA, the lab must establish the number, type, and frequency of testing control materials.

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFRc96daead380f6ed/section-493.1256. Accessed January 16, 2024.

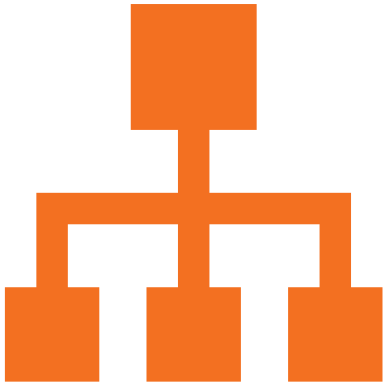
QC & POCT

Reagent issues

- Traditional QC may not be relevant

Process issues

- Value of POCT QC varies by test system



Organization

- Risk assessment process can define QC frequency
- Risk defined QC procedures

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFRc96daead380f6ed/section-493.1256. Accessed January 16, 2024.
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/iqcp-workbook.pdf. Accessed January 16, 2024.

IQCP

Individualized Quality Control Plan

Optional alternative to CLIA requirements

Risk Assessment (RA)

Quality Control Plan (QCP)

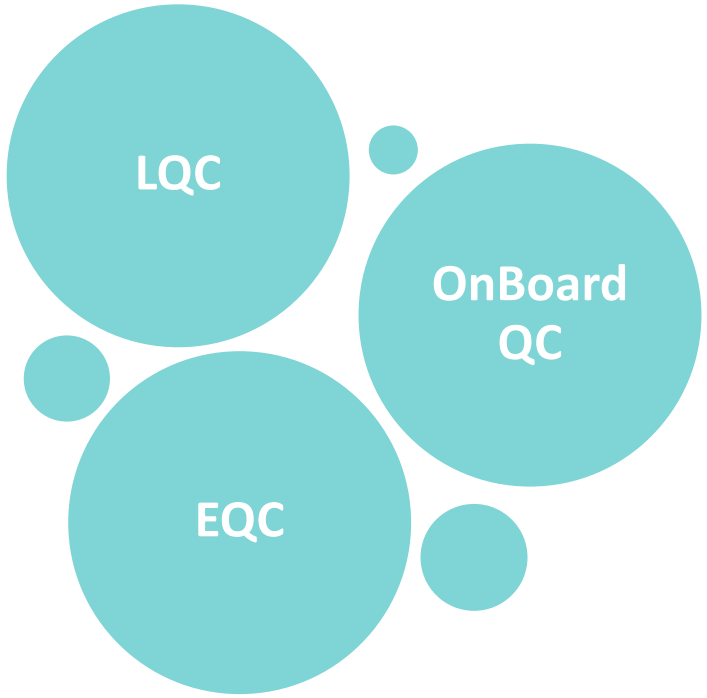
Quality Assessment (QA)

Only CMS approved alternative QC procedure

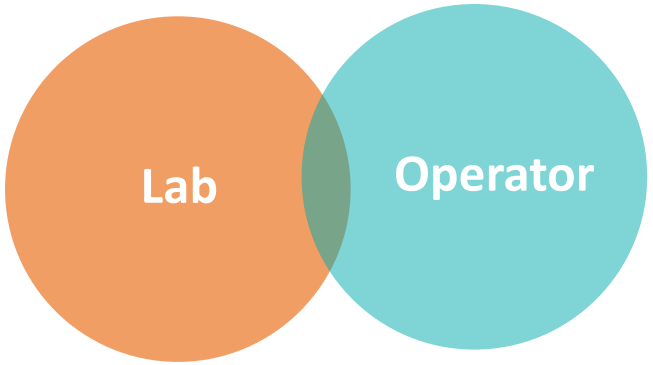
- Required for any test not adhering to CLIA defined QC frequency
  - At least once each day patient specimens are assayed
  - Quantitative procedure: two control materials of different concentrations
  - Qualitative procedure: include a negative and positive control material

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFRc96daead380f6ed/section-493.1256. Accessed January 16, 2024.
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/iqcp-workbook.pdf. Accessed January 16, 2024.

Quality Control in POCT



Options abound



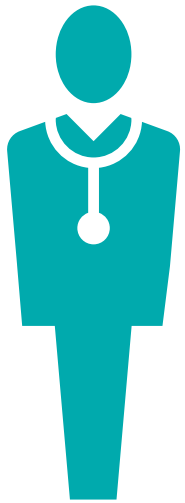
Working together

Compliant program

New Device Risk Assessment and Mitigation

Clinician/end-user involvement

- Pre- and post-analytic risk
- How wrong is clinically wrong?
- What clinical presentation might indicate an erroneous result?
- How can risks be mitigated?



Appreciate clinician expertise

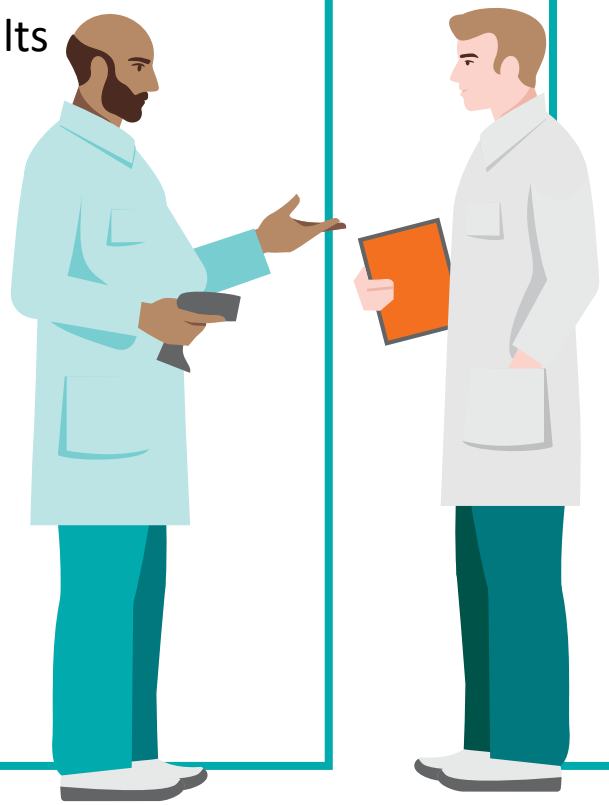
- Input for specific mitigations
- QC may not be the answer

QC of the test system

- CLIA requirements - QC detects immediate errors that occur due to:
  - Test system failure
  - Adverse environmental conditions
  - Operator performance
- Monitors the accuracy and precision of test performance over time

Operators

- Trained in patient care
- Not trained in laboratory testing
- Not trained to question results
- Not trained on importance of QC and PT
- May resent need to run QC and / or PT



Clinician Participation

- Improved recognition of unlikely results
  - Tests repeated
  - Questions asked
  - Process changes suggested
- Improved communication identifies need for changes
- Direct correlation of quality test results and improved patient care

IQCP Is a Continuous Process

Maintenance

- Define routine review frequency
- Identify problems with existing equipment
- Change locations using IQCP

Revision

- Quality Assessment
- Risk Assessment

Each change is documented and signed as per original IQCP[1]

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf. Accessed January 16, 2024.

POCT

Future of Point-of-Care Testing

Future of POCT Involves New Disease States and New Technologies

The future of POCT will likely bring new testing for a wide variety of uses, such as the following:[1]

- Mobile wearable devices
- Transcutaneous monitors
- Breath alcohol testing, breath hydrogen/H. pylori testing
- Continuous glucose monitoring
- Lab-on-a-chip (LOC)
- DNA testing
- Molecular PCR
- Sepsis
- Stroke markers
- Epidemic and pandemic testing

John AS, Price CP. *Clin Biochem Rev*. 2014;35:155.
Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. *AACC*. 2022.

COVID-19 Effects

- Rapid development of POCT due to patient-centered care from SARS-CoV-2 pandemic
- COVID-19 rapid tests balanced rapid testing at home or on-site with large laboratory-level results
- Allowed quicker clinical decision-making, real-time diagnosis, improved outcomes without normal central lab delay.
- Now type of rapid results are expected by patients.

Abel G, et al. Point-of-care testing: A “how-to” guide for The non-laboratorian. *AACC*. 2022.

Summary

1

All stakeholders need to collectively identify what testing is needed, which method or platform best meets the clinical need

2

Stakeholders include clinical laboratorians, physicians, compliance personnel, and end user representatives.

3

The success of future POCT relies on partnering for implementation and maintenance of POCT platforms and programs.

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Thank you.