POCT

The Path to Painless Point-of-Care Implementation: Training, Competency, & Quality Control

POINT OF CARE TESTING UNIVERSITY

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Respiratory Therapists – This program has been approved for up to 1.5 total contact hours of Continuing Respiratory Care Education (CRCE) credit by the American Association for Respiratory Care, 9425 N MacArthur Blvd., Suite 100, Irving, TX, 75063.

Disclosures

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Learning Objectives

1. Identify training requirements for POCT.
2. Review competency assessment elements and implementation.
3. Evaluate methods of quality control.
4. Determine how to develop and incorporate and individualized quality control plan (IQCP).

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

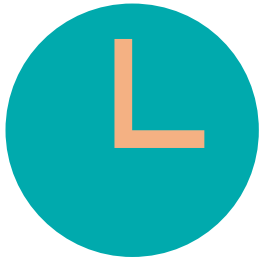
1. POCT & CLIA
2. Training
3. Competency Assessment
5. Quality Control & IQCP

POCT & CLIA

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

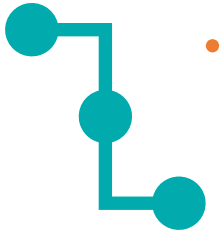
- Finger sticks vs. venipuncture
- Improve antibiotic stewardship

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

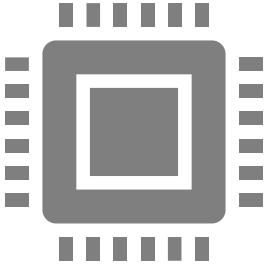
Features Expected in POCT

- Quality Control
  - Built-in
  - External
  - Lock-outs

- Operator control
  - Lock-out



- Connectivity
  - Electronic transfer of data to LIS / HIS
  - Usually through middleware vendors



- Memory
  - QC and Patient records
    - Include date/time stamp
    - Operator ID
    - Reagent lot numbers

CLIA Regulations [42CFR493]

- All laboratories
  - A **facility** that examines materials derived from the human body for the purpose of providing information for the:
    - Diagnosis,
    - Prevention,
    - Or treatment of
  - Any disease or impairment of, or the assessment of the health of, human beings

- All tests
  - Any examination using materials derived from the human body for the purpose of providing information for the:
    - Diagnosis,
    - Prevention,
    - Or treatment of
  - Any disease or impairment of, or the assessment of the health of, human beings

CLIA Complexity

Three levels defined by CLIA

1 **WAIVED**
Least regulated

2 **MODERATE**
Most POC diagnostic tests

3 **HIGH**
More complicated laboratory analysis

- Assigned by FDA following clearance
  - 510(k) or PMA
  - Or following request for CLIA classification

CLIA Licensure

- Required for any site running diagnostic tests
  - Type of license determines testing that can be performed

Four Certificate Types

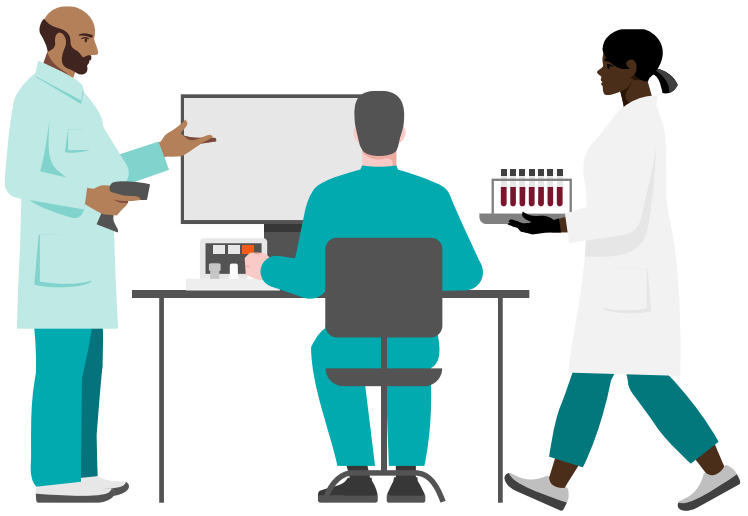
Waiver	Provider Performed Microscopy Procedures	Compliance	Accreditation
(only CLIA-waived tests)	(plus CLIA-waived tests)	(all complexities)	(all complexities)

Training

Who Needs Training to Use POCT Assays?

Operators / Supervisors

Compliance Oversight (Lab)



Providers / Clinicians

POCT Assays Are Simple…Why Do We Need Training?

A majority of the staff who perform POCT are not trained laboratory staff.

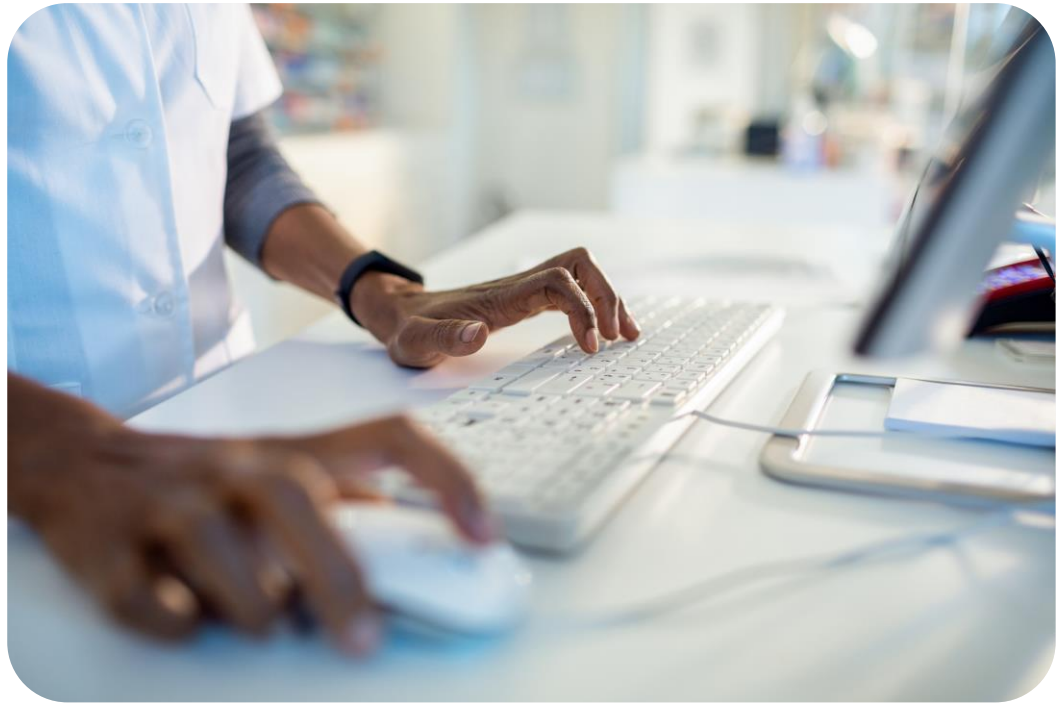
Staff performing POCT must have the proper training and experience to ensure test results are accurate and reliable.

Reduce risk from untrained personnel performing laboratory testing.

Yenice S. *EJIFCC.* 2021;32(2):167–178.

Qualifications for Training

- CLIA regulations require specific education level by test complexity.
  - For moderate complexity a high school diploma or equivalency.
- Some state agencies require a license and/or a specific level of professional qualifications.
- Each qualified POCT user must complete initial training and orientation on each test method.



Before training, qualifications must be verified with state or national authority requirements and accreditation agencies, if appropriate.

Yenice S. *EJIFCC.* 2021;32(2):167–178.

Training for Waived Testing Methodologies

Personnel must be able to…

1. Read
2. Understand
3. Follow manufacturer’s directions

Ehrmeyer SS. https://acutecaretesting.org/en/articles/the-role-of-training-competency-assessment-and-continuing-education. Accessed February 2, 2024.

Training for Moderate Complexity Testing Methodologies

Personnel must be

1. Qualified
2. Competent

Personnel are found to be qualified and competent through

1. Education
2. Training
3. Experience

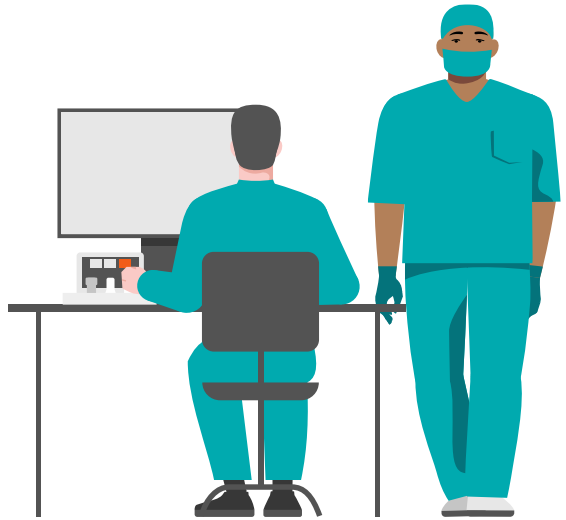
Documented training in all methods must be performed
and competency assessed twice in the first year and once every year after.

Ehrmeyer SS. https://acutecaretesting.org/en/articles/the-role-of-training-competency-assessment-and-continuing-education. Accessed February 2, 2024.

Assessment for Moderate Complexity Testing Methodologies

Personnel must

1. Adhere to policies and procedures for entire testing process
2. Perform and document quality control, proficiency testing, and maintenance
3. Follow established correction policies
4. Identify, correct, and document problems that may adversely affect test results



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Who Performs Training?

Manufacturers

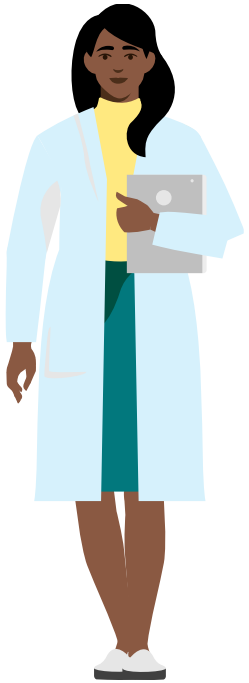
Designated instructors

Self-instructional materials

Vendors often prefer to train operators, trainers, and coordinators

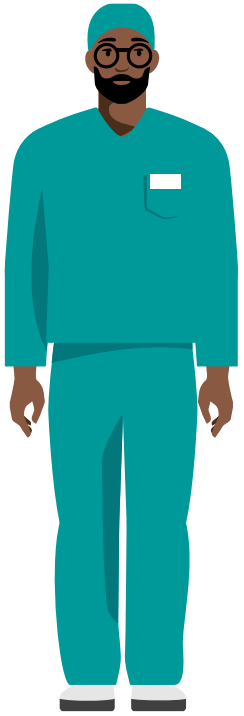
Ehrmeyer SS. https://acutecaretesting.org/en/articles/the-role-of-training-competency-assessment-and-continuing-education. Accessed February 2, 2024.

Who is the Right Person to Perform Training in Different Settings?



Laboratory personnel can maintain accreditation

May not be the best to train non-laboratory staff



Nurse trainers

Respiratory therapists

Ehrmeyer SS. https://acutecaretesting.org/en/articles/the-role-of-training-competency-assessment-and-continuing-education. Accessed February 2, 2024.

Initial Training and Competency Timeline

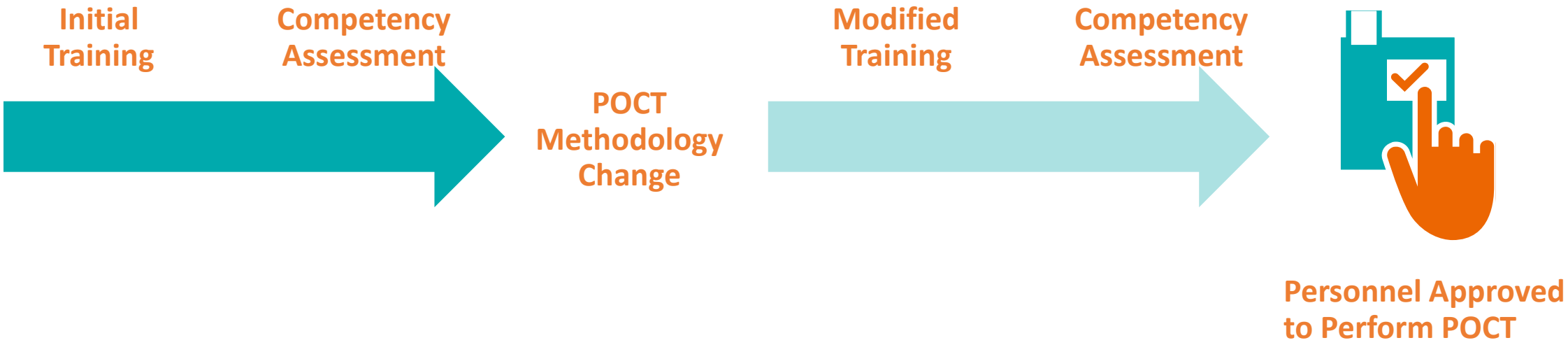
Initial Training → Competency Assessment → Personnel Approved to Perform POCT

- Must be completed before any patient testing
- Include training needs identified in IQCP development
- Documentation retained

Yenice S. *EJIFCC.* 2021;32(2):167–178.

Methodology Changes Require Additional Training

- Additional training must occur and be documented following any changes or updates in POCT methodology before any patient testing.
- Training must be performed by a qualified individual and the competency of the tester verified before performing patient testing.



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POCT

Competency Assessment

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.

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 2024.

Who Can Assess Competency?

Moderately complex testing

- 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.

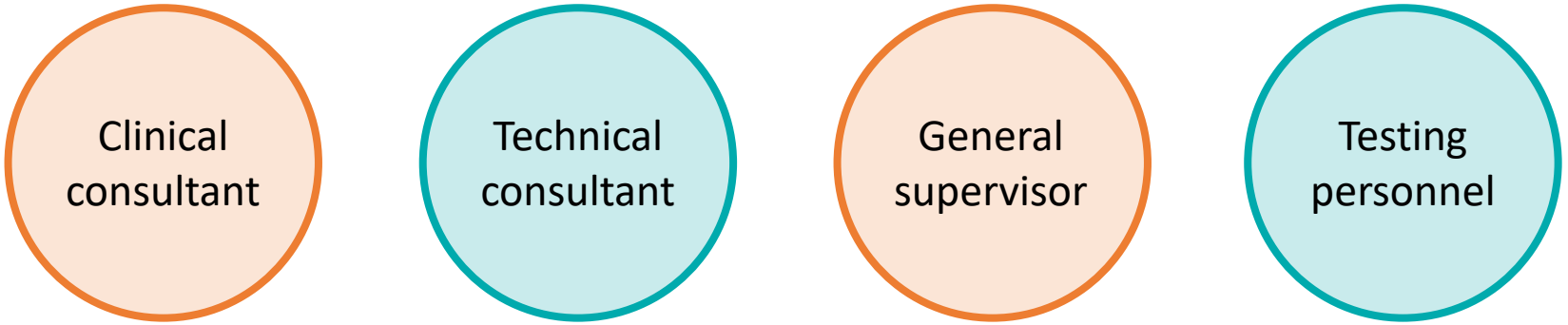
Who Assesses the Assessor?

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

Who Is Required to Have a Competency Assessment?

- Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations:



When Is Competency Assessment Required?

Following initial training

Semiannually in first year of testing

Annually thereafter

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 2024.

How Is Competency Assessed?

Six competency elements defined by CLIA

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

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 2024.

Competency Elements 1 & 2

1 Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing

- If there are unique aspects to testing different analytes on a single system, each analyte must be observed.
  - Venous versus fingerstick sampling

2 Monitoring the recording and reporting of test results

- How are data transferred to the EMR?
- Are there critical value reporting requirements?

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 2024.

Competency Elements 3 & 4

3 Review of quality control records, proficiency testing results

- Identifying when QC is out of range

4 Direct observations of performance of instrument maintenance and function checks

- EQC
- Cleaning and Disinfection

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 2024.

Competency Elements 5 & 6

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

- Document when an operator performs PT in their competency file

6 Assessment of problem-solving skills

- When to repeat a test
- When to call POCC

CMS Brochure #10. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf. Accessed January 12, 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

POCT

Quality Control

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.

CLIA QC Subpart K. 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.

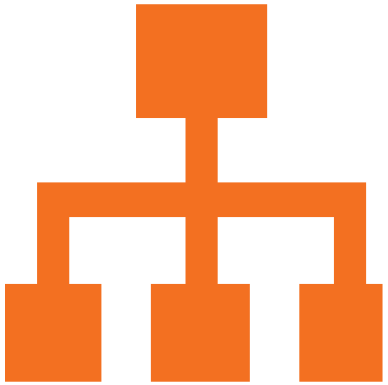
QC & POCT

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

CLIA QC Subpart K. 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.
IQCP Workbook. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/iqcp-workbook.pdf. Accessed January 16, 2024.

Process Issues

- Value of POCT QC varies by location
  - High volume sites recognize potential erroneous results
    - Daily QC does not improve patient care
  - Low volume testing allows operators to forget important steps
    - QC each day of patient testing may mitigate operator error

Optimization

Frequency

- Risk assessment process can define QC frequency
  - Manufacturer fail-safes understood
    - Improved clinician buy-in with participation
  - QC frequency based on risk mitigation
    - Reduced operator grumbling

Risk

- Risk defined QC procedures
  - Patient care
  - Safety optimization

CLIA Default Frequency

EACH Test System

Unless IQCP Created, QC required

- At least once each day that patient specimens are assayed.
  - Hematology and blood gas should run controls at least once per eight-hour shift.
- Quantitative procedures
  - Include two control materials of different concentrations.
- Qualitative procedures
  - Include a negative and positive control material.

CLIA QC Subpart K. 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.

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

CLIA QC Subpart K. 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.
IQCP Workbook. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/iqcp-workbook.pdf. Accessed January 16, 2024.

Roles of Manufacturer & Lab

Manufacturer

- Manufacturer is a key resource
  - Likely has an IQCP template
  - Has specific QC recommendations (usually)
  - Can answer questions about built-in mitigations
    - Often has suggested mitigations for known residual risks

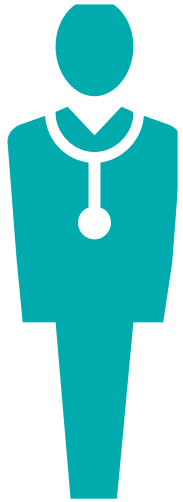
Lab

- According to CLIA
  - **Lab** must establish the number, type, and frequency of testing control materials
    - Cannot just implement from manufacturer template

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

Analytic Risk Mitigation

- CLIA requires that QC of the test system do two things to mitigate risk…

1 Detects Immediate Errors

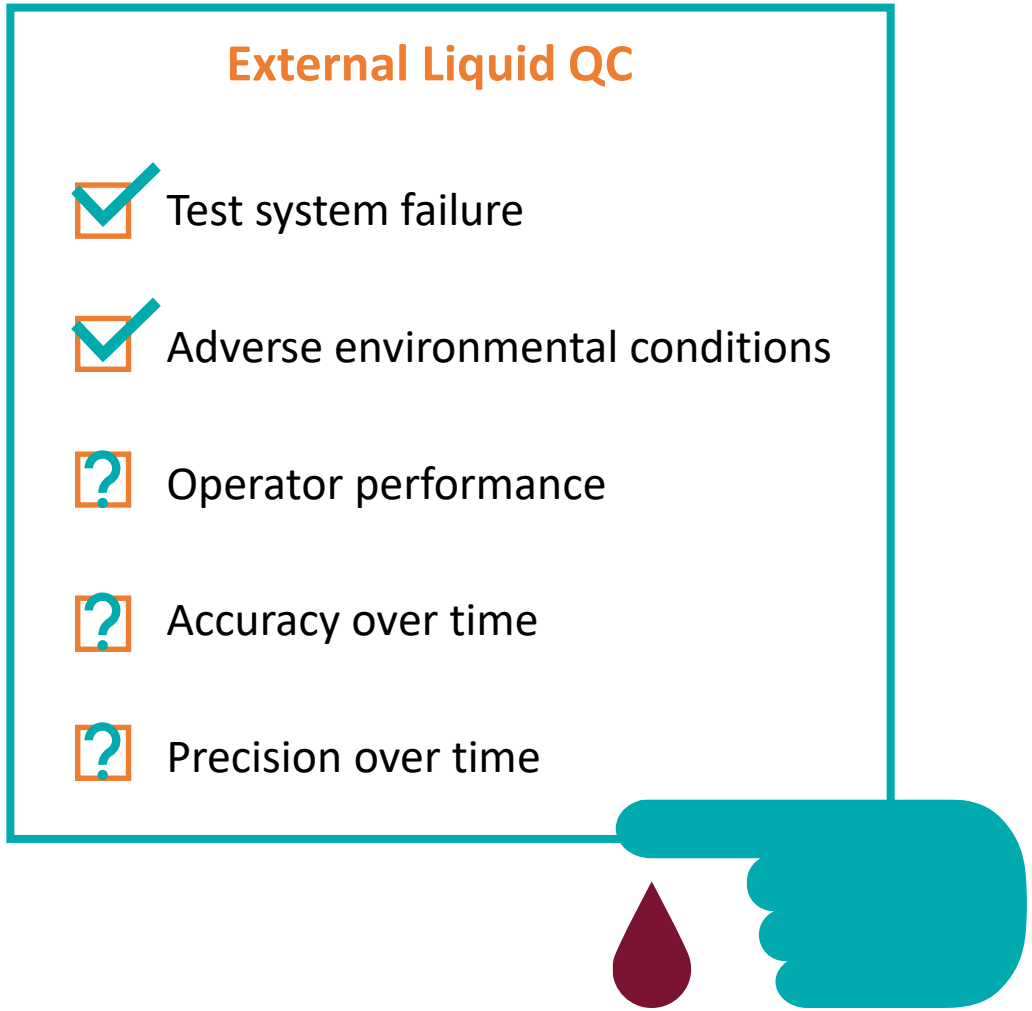
- Test system failure
- Adverse environmental conditions
- Operator performance

2 Monitors

- Accuracy and precision of test performance over time

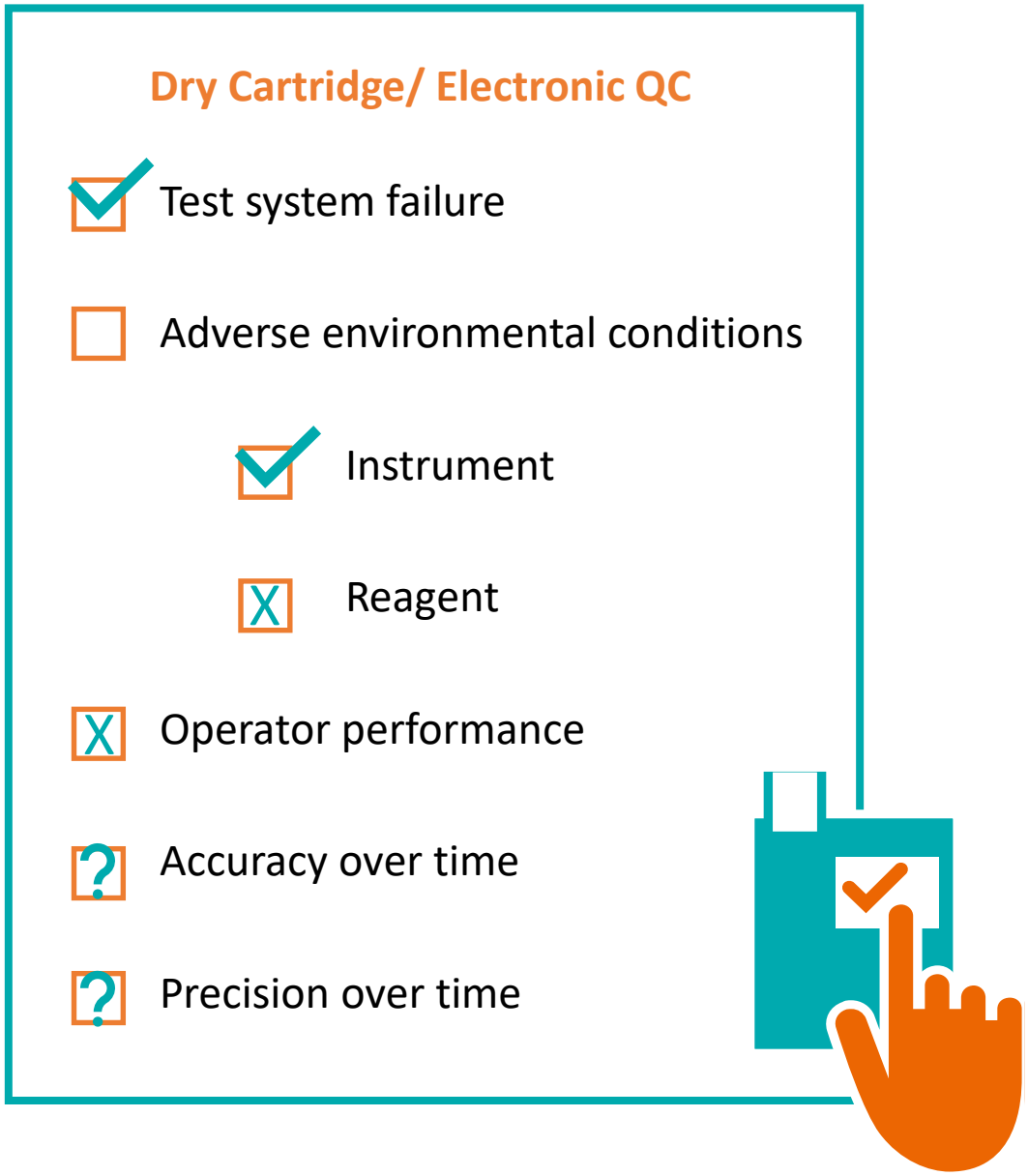
QC for POCT – Liquid QC

- External liquid QC
  - Surrogate sample testing
  - Evaluates instrument, reagent and operator
    - Presumably



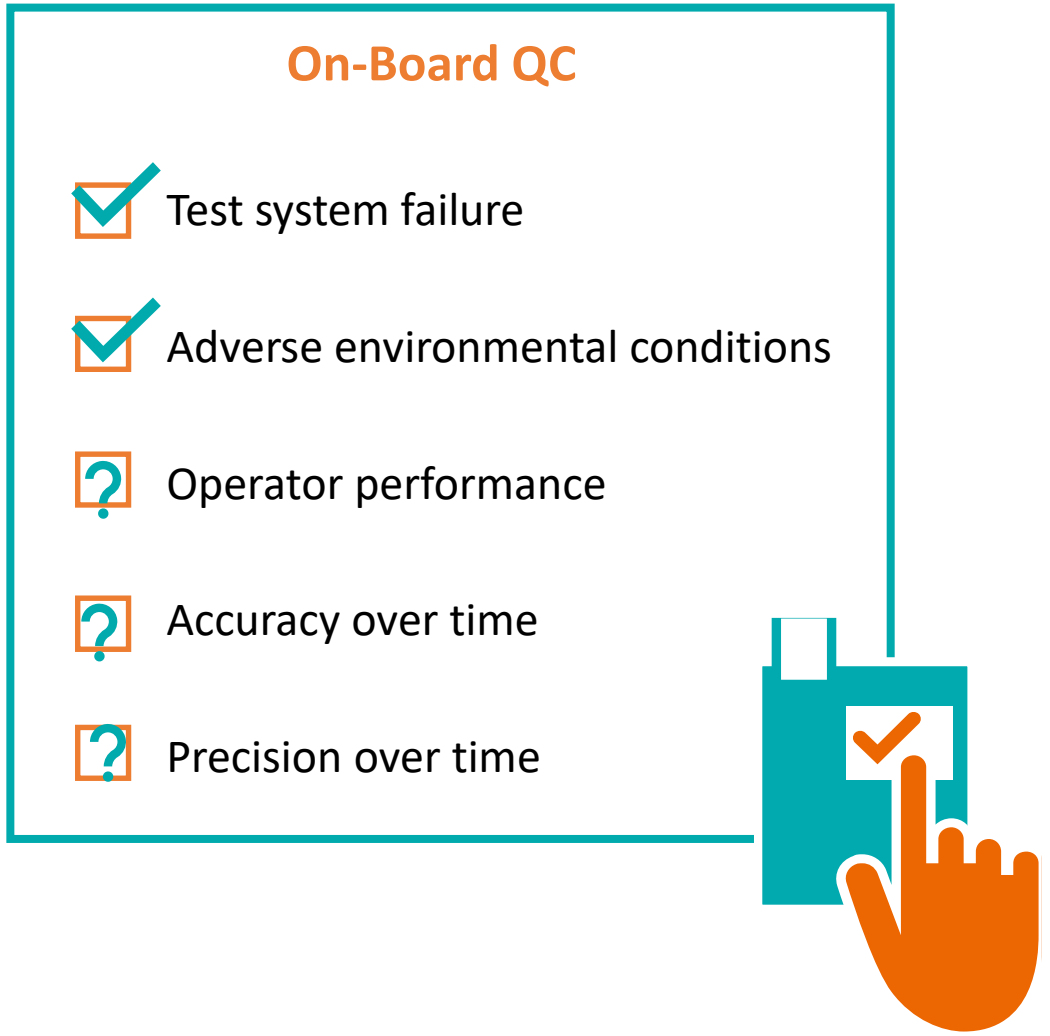
QC for POCT – Electronic QC

- Dry cartridge / Electronic QC
  - Built-in or external disposable “end-point”
  - Simulates result



QC for POCT – On-board QC

- On-board QC
  - Generally, refers to internal reagent controls
  - Manufacturer can verify all functions
    - Some are more complete than others
  - Operator performance, accuracy, and precision may or may not be present



Most Common Manufacturer's Recommendation

Based on reagent stability studies

Electronic: Daily

Liquid: Monthly

- Is it sufficient?
  - Must have some local validation
  - Many options:
    - Liquid daily for 2 weeks / 1 month / 6 months
    - Then Q 2 weeks for 2 months / 6 months / 1 year
    - Then monthly
  - IQCP states procedure verified frequency

Manufacturer's Recommendations

On-Board QC

- Tests
  - System failure
  - Adverse environmental conditions
  - Operator performance
  - Accuracy & precision over time
- Frequency
  - Every sample
  - Preset interval
  - Automatic

No IQCP Needed?

- CMS deems equivalent to CLIA requirement
- Written statement on company letterhead or copy of letter from CMS

No QC Available

- Develop alternative QC

Alternative Quality Control

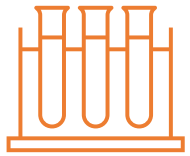
- Can include LQC (but not necessarily)
  - Blind samples
  - Leftover lab samples
  - Delta checks
  - Comparisons with lab
  - Population statistics
  - Scheduled precision studies

- Evaluate if, with built-in mitigations, this will check all boxes and allow performance trending over time
- If yes, appropriate Quality Control

Alternative QC

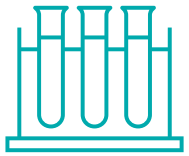
- ☐ Test system failure
- ☐ Adverse environmental conditions
- ☐ Operator performance
- ☐ Accuracy over time
- ☐ Precision over time

Blind Samples



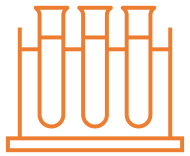
Any sample with known value

- QC
- Proficiency
- Cal/Ver
- De-identified patient samples



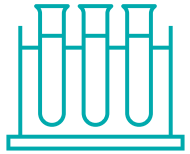
Independently labeled

- Non-operator keeps key



Operators test as per patient sample

- As much as possible

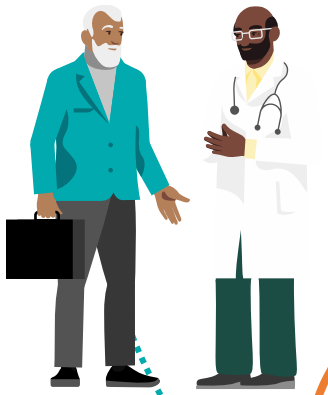


Can be used as QC or alternative proficiency samples

- PT not commercially available
- Investigate PT failure / trending

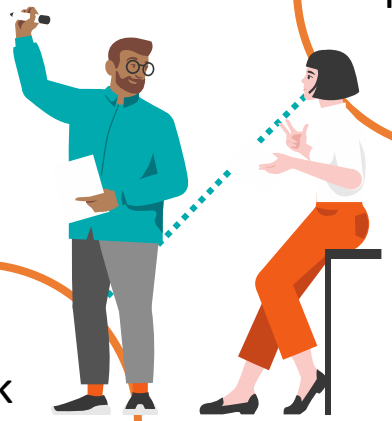
Use Risk Assessment to Demonstrate Risk Reduction Through QC

QC mitigates risk of error



Step by step evaluation

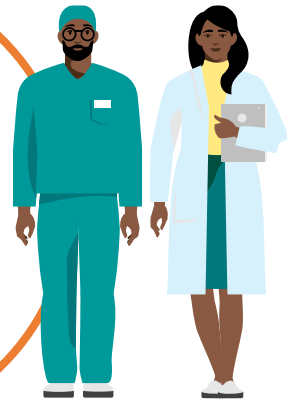
Risk reduction



Training

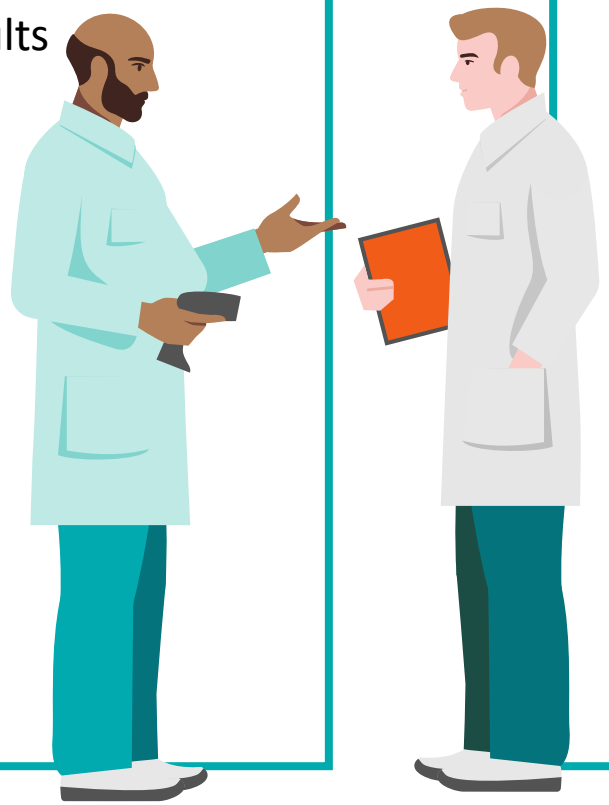
Competency assessment

Alter workflow to minimize disruptions



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]

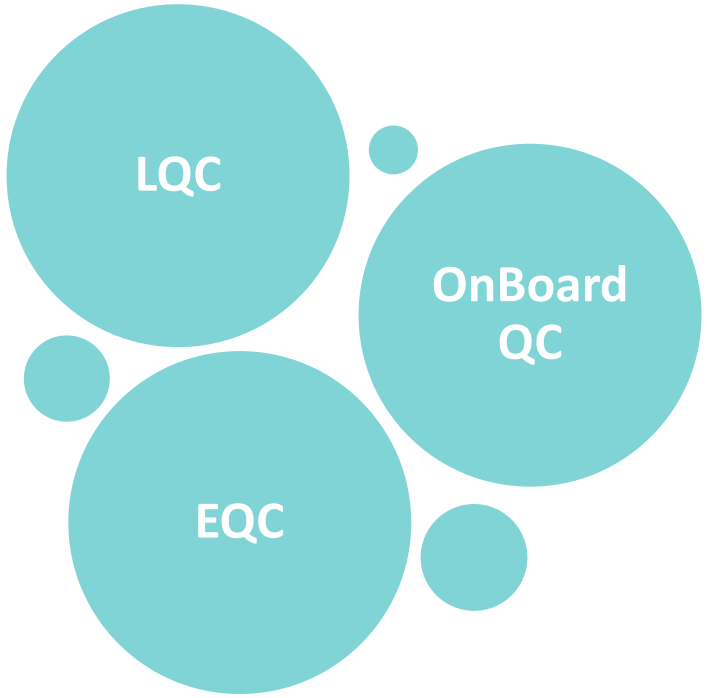
IQCP Workbook. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf. Accessed January 16, 2024.

IQCP Revision

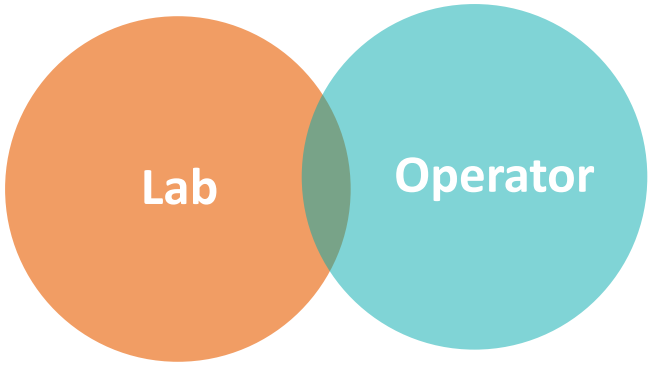
- Quality Assessment
  - Problem indicates a non-mitigated risk
    - Or not sufficiently mitigated
- Risk Assessment
  - Add new risk to assessment
    - Pre-, analytic or post?
  - Why was it missed?
    - Other potential unmitigated risks?

Ask Operators and Clinicians

Quality Control in POCT



Options abound



Working together

Compliant program

Thank you.