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Reaching Your Point-of-Care Potential

Learn Best Practices for Your POC Process

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Today's Presenter: Dr. Deborah Perry, MD, FCAP

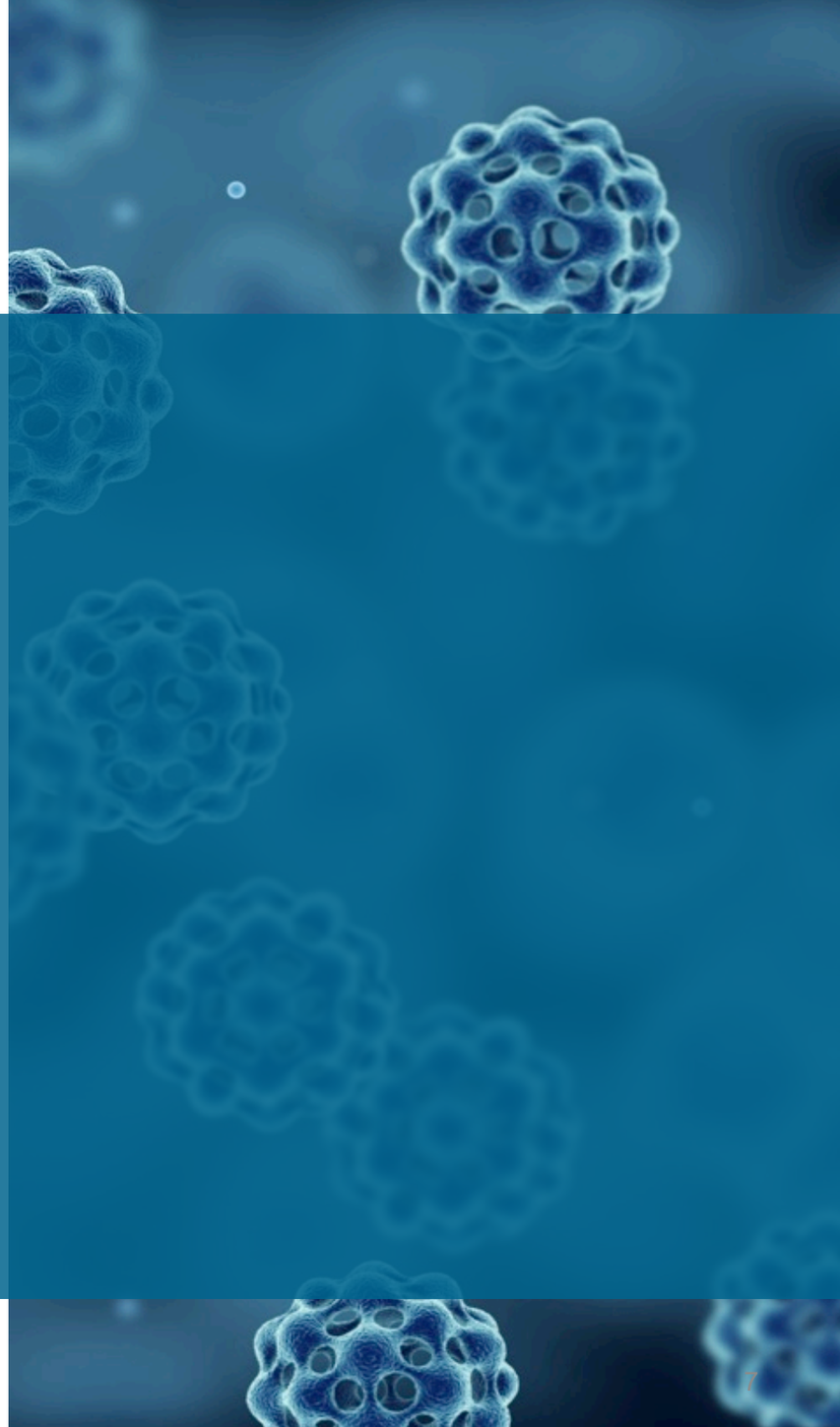
- College of American Pathologists (CAP) Affiliations:
  - Current member of Accreditation Committee
  - International and domestic CAP laboratory inspector
- Pathologist and Medical director for Methodist Hospital and Methodist Women's Hospital Pathology in Omaha, Nebraska (United States)
- Medical Director of Pathology for the following laboratories:
  - Lexington Regional Health Center in Lexington, NE
  - Tri-Valley Health Center in Cambridge, NE
  - Grape Community in Hamburg, IA
- Subspecialty board certification in Hematopathology (blood, bone marrow and lymph node disorders) and Pediatric Pathology

Agenda

- Competency Assessment and Personnel
- Individualized Quality Control Plan (IQCP)
- Proficiency Testing
- Q&A

Objectives

- Gain knowledge of POC testing considerations, including pre-analytical information
- Improve understanding of competency assessments relative to POC
- Utilize IQCP as part of a quality POC program



Competency Assessment and Personnel

Competency Assessment

The competency of each person performing patient testing is assessed at the required frequency at the site where testing is performed.

Competency

- Point-of-Care (POC) Testing Personnel
  - What tests are being performed?
    - What is the test complexity?
  - Who is performing them?
    - Laboratory staff? RN? RT? Medical assistants?
  - Who trains them?
    - Laboratory staff? POC coordinator?
  - Who insures continual test performance competency?
    - Laboratory staff? POC coordinator?

Key Points to Consider

Waived / Low-Complexity	Non-Waived / Moderate or High Complexity

Annual assessments	Assessments
	• At six months and one year (annually thereafter)
	• For each CAP/CLIA testing site
	• Performed by competent personnel:
	  • Moderate complexity: Technical consultant
	  • High Complexity: Section director or general supervisor personnel requirements

Selected elements	All six elements

Six Elements for Nonwaived, Moderate or High Complexity Testing

For nonwaived testing, competency assessment must include **all** six elements for each test system:

1. Direct observations test performance
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results or worksheets
4. Direct observation of instrument maintenance/function checks
5. Employee analysis of proficiency testing (PT) or blind sample
6. Evaluation of problem-solving skills

Most Commonly-Cited Deficiencies

CAP Wide – 2020	Description	CAP Checklist
1	Activity Menu	COM.01200
2	Competency Assessment – Non-waived Testing	GEN.55500
3	Procedure Manual	COM.10000
4	Maintenance and Function Checks	COM.30600
5	Comparisons of Instruments and Methods	COM.04250
6	PT/Alternative Assessment Result Evaluation	COM.01700
7	PT Attestation Statements	COM.01400
8	Instrument/Equipment Monthly Record Review	COM.04200
9	Reagent Labeling	COM.30300
10	Procedure Manual Review	COM.10100

Most Commonly-Cited POCT Deficiencies

CAP Wide – 2020	Description	CAP Checklist
1	Competency Assessments – Non-waived Testing	GEN.55500
2	Qualifications of Individuals Assessing Competency	GEN.55510
3	PT/Alternative Assessment Result Evaluation	COM.01700
4	PT Attestation Statements	COM.01400
5	Temperature Checks	COM.30750
6	Comparisons of Instruments and Methods	COM.04250
7	Procedure Manual	COM.10000
8	Reagent Handling/Storage – Waived Testing	COM.30250
9	QM Program Implementation and Review	GEN.16902
10	Correction of Laboratory Records	GEN.20450

Ensuring Competency for All Personnel

1. Assessments do not exceed one year
2. New staff performing non-waived testing are assessed semiannually the first year of testing.
3. Your POC Test Systems are defined and all six elements of competency are used for each non-waived test system.
4. For waived testing document which competency element was assessed.
5. Qualified individuals are assessing competency.

Point of Care Checklist

Competency assessment
- Throughout the year or skills fair
- Don’t limit to one assessor

Test system definition

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Checklist Requirement – POC.06910	
Question -	**Answer -**
How can we accomplish all six elements of competency assessment for 200 users?	Some options that may help you with performing competency assessment of larger numbers of staff include: • Evaluating and recording different elements of competency as part of the routine review of personnel throughout the year. • Having additional qualified staff assist with performing competency assessments. For moderately complex tests, those individuals must be qualified as a technical consultant and for high complexity tests, those individuals must be qualified as a general supervisor and have those duties delegated to them in writing by the laboratory director. • Performing competency assessment at a skills fair if your facility has this type of event. Please note that for nonwaived testing competency, this may be done at a skills fair if it is performed at the corresponding CAP/CLIA site.
Can we share competency records with our sister lab?	No, competency of nonwaived testing personnel must be assessed at the laboratory where testing is performed (CAP/CLIA number).
Is a signature required by both the employee and person assessing competency?	The person who assesses the employee’s competency must sign or initial the competency form. It is a great idea to have an employee also sign, but it is not required.
Does competency have to be assessed for each type of cartridge utilized on an instrument?	The answer depends on whether the use of different cartridges on the instrument can still be defined as one test system. A test system is defined as the process that includes pre-analytic, analytic and post-analytic steps used to produce a test result or set of results. The laboratory is responsible for identifying the different test systems used to generate patient results. Often, tests performed on the same instrument may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform, competency must be assessed as a separate test system to ensure staff are performing those aspects correctly.

Source: CAP ELSS
(https://elss.cap.org/elss/ShowProperty?nodePath=/UCMCON/Contribution%20Folders/WebApplications/pdf/POC.06910.pdf)

Scenario

300-bed community hospital with 20 operating rooms currently has:

- One Hemochron for ACT in 2 OR's
- One EPOC
- Six glucose meters

New cardiovascular surgeon arrives and requests for immediate availability:

- One additional Hemochron
- Two additional EPOCs for PACU & cardiac care unit

What are your next steps?

A. Order new POC devices and immediately place in OR/PACU/CCU

B. Meet with OR and cardiac team leaders to develop an implementation plan

C. Remove the POC devices from their current locations and place where the surgeon directs

Recommended Plan of Action

- Meet with OR and cardiac team leaders
- Determine:
  - Number of cardiac cases requiring POC?
  - Who will be performing the POC testing?
  - When is the surgeon starting practice/timeline?
  - Which department will purchase the devices?
- POCT coordinator will:
  - Provide training
  - Draft a procedure
  - Work on IT interface
  - Verify billing

Ensure POCT Personnel are Trained and Assessed for Competency

Pre-analytic	Analytic	Post-analytic
• Appropriate sample, right patient	• Analytic procedural steps • Proper material handling, control and PT performance • Correct test/properly performed	• Results charting • Interface to EMR • Verification of unusual results and appropriate steps to ensure correctness • Notification of responsible individuals • Billing

Training

- Training is **not the same as Competency**.
- **Each individual** that performs testing **must have training** and **be evaluated** for proper performance.
- Training occurs prior to:
  - Starting patient testing
  - Reporting patient results for new methods and instruments
- The records must cover all testing performed by each individual.

Competency

- The first assessment takes place after training is complete and the individual has begun testing on their own.
- Retraining and competency reassessment must occur when problems are identified with an individual's performance.
- The laboratory director must ensure that the **individuals performing competency assessments are qualified** through education and experience to meet the defined regulatory requirements.

Managing a Successful POCT Program Requires

- Networking with peers
- Using available resources
- Standardization across system
- Encompassing all steps:
  - Pre-analytical
  - Analytical
  - Post-analytical
- Documenting procedures:
  - Make sure they work
  - Train staff
  - Monitor performance
- Encouraging testing personnel self-management
- Monitoring quality consistent with the central laboratory
- Using PT as a quality monitoring tool to identify errors and disclose potential quality risks as soon as possible
- Embracing change and being creative

Individualized Quality Control Plan (IQCP)

Scenario

400-bed community hospital

- Offers POC testing in the ED and ICU
- EPOC and bedside glucose testing is performed
- Testing performed by nursing staff

CAP on-site inspection cited two deficiencies related to POC testing:

1. The technical consultant performing the competency assessment was not qualified
2. Risk Assessment portion of the IQCP was incomplete

IQCP Risk Assessment

- EPOC is a non-waived test and thus an IQCP was written.
- CAP Concerns:
  1. One IQCP was written for both testing locations – ED and ICU.
  2. There was a QC failure in the ED in the past year, and this was not addressed in either the monthly or annual reviews.

Quality Control Options

Default CLIA QC

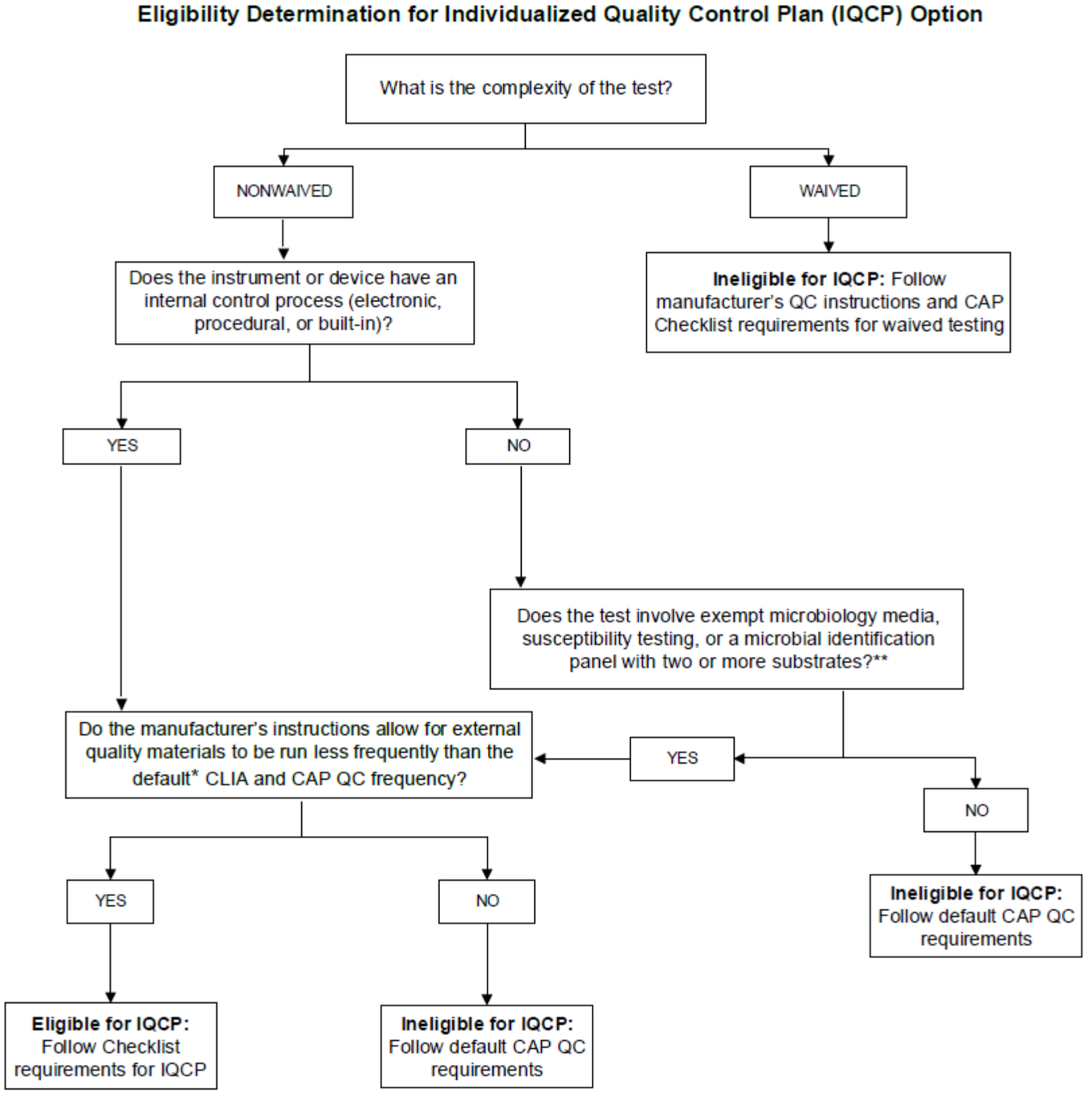
Two levels of QC per day

IQCP

IQCP Eligibility for POCT

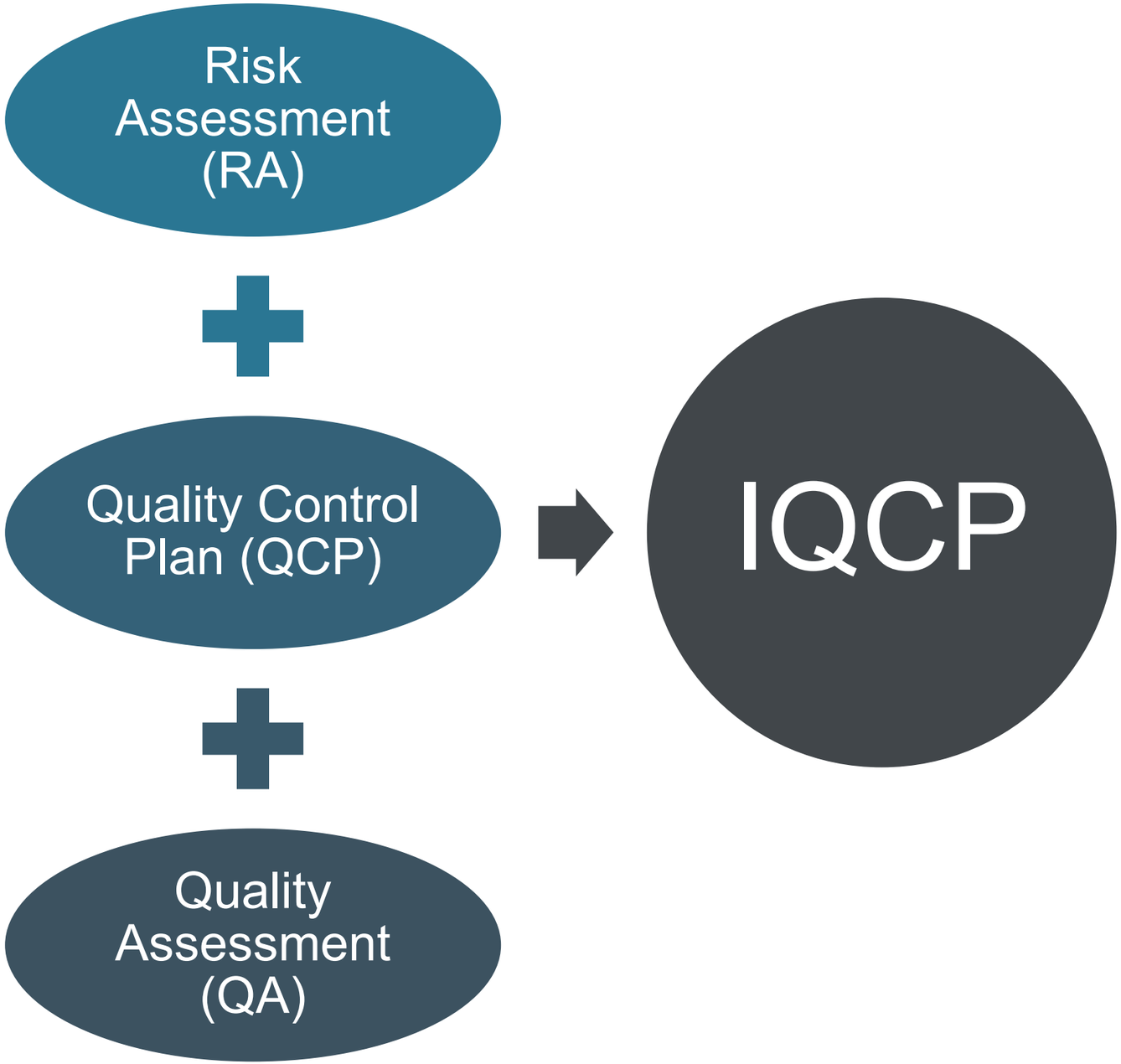
- Nonwaived testing that employs an internal (electronic/procedural/built-in) QC system
  - Exception: Microbiology media and reagent used for microbial identification and susceptibility testing may implement an IQCP.
- Number and frequency of controls tested cannot be less than indicated by the manufacturer's instructions.
- Eligibility algorithm to help determine eligibility

IQCP Eligibility Document



Modified Source: CAP ELSS
(https://elss.cap.org/elss/ShowProperty?nodePath=/UCMCON/Contribution%20Folders/WebApplications/pdf/IQCP-eligibility-determination.pdf)

IQCP Components



IQCP Overview

Risk Assessment

- Identifies and evaluates potential failures and sources of errors in the testing process, includes:
  - Three phases of testing
  - Five components of the tests

Individualized Quality Control Plan (IQCP)

- Written document describing the practices and procedures to reduce the chance of possible failures and errors in the test processes
- Ensures accurate, reliable test results

Quality Assessment

- The continuous process of monitoring the effectiveness of the IQCP
- QC reviews, PT performance, complaints

IQCP Risk Assessment – Potential Sources for Errors

- Evaluate potential sources of errors including:
  - Three phases of the testing process
    - Pre-analytic
    - Analytic
    - Post-analytic
  - Five components of the test
    - Reagents
    - Environment
    - Specimen
    - Testing personnel
    - Test system

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IQCP Risk Assessment – Additional Potential Sources of Errors

- Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)
- Providers' expectations of testing
- Variations in the components based on use of test
  - Use in different environments
  - Used by different personnel

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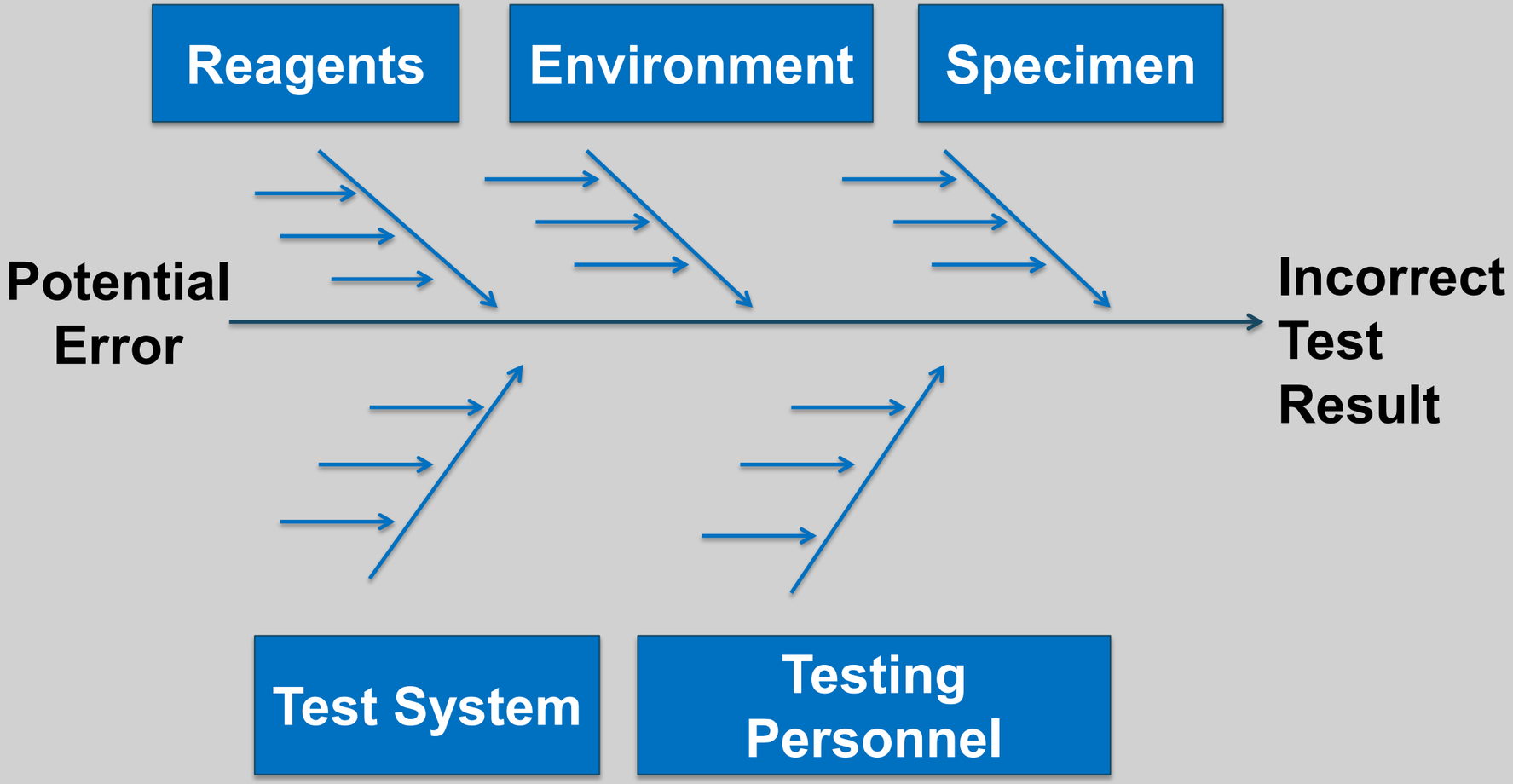
IQCP Risk Assessment Lab Data & Verification

- Data from:
  - Laboratory's own environment
  - Instrument/equipment performance
  - Testing personnel
- Can use:
  - Historical data, if available
  - Data gathered during test method verification process
  - Manufacturer data – supplement in-house data
- May use default QC until sufficient data can be collected to perform a risk assessment
  - Number of days/data points determined by medical director

CLSI Guideline – Risk Assessment Using a Fishbone Diagram



Risk Acceptability Matrix – Based on ISO 14971

	Severity of Harm				
Probability of Harm	**Negligible**	**Minor**	**Serious**	**Critical**	**Catastrophic**
Frequent	**unacceptable**	**unacceptable**	**unacceptable**	**unacceptable**	**unacceptable**
Probable	acceptable	**unacceptable**	**unacceptable**	**unacceptable**	**unacceptable**
Occasional	acceptable	acceptable	acceptable	**unacceptable**	**unacceptable**
Remote	acceptable	acceptable	acceptable	acceptable	**unacceptable**
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable

IQCP Risk Assessment

- Each laboratory with a separate CAP number must conduct its own Risk Assessment (RA).
- If there are multiple sites utilizing the same instrument/device/test within one CAP number, the laboratory has an option.
- If a single Risk Assessment is performed:
  - All variations in the required components must be taken into account when conducting the RA (differences in sites, environments, personnel, etc)
  - A laboratory can then develop one IQCP that accounts for all the differences in the RA or can develop individual IQCPs to address differences by site.
  - Each device must be monitored in some way, as well as each location.

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IQCP Quality Control Plan

Quality Control Plan Elements

- Defines all aspects monitored based on risk assessment
  - Follow manufacturer's instructions and recommendations for QC at minimum

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Quality Control Plan Elements

- The number, type (external and internal quality control systems), and frequency of quality control
- Criteria for acceptable performance
- Monitoring of the testing environment and reagents
- Specimen quality
- Instrument calibration, maintenance, and function checks
- Training and competency of testing personnel
- Provisions for multiple identical devices and variation for uses covered under one IQCP

Example Quality Control Plan

Individualized Quality Control Plan (QCP)
Test System: Cepheid GeneXpert
Assay: C. difficile/Epi, Norovirus
Location(s): Microbiology/Serology Methodist Hospital

Type of Quality Control	Criteria for Acceptability	Frequency	Documentation
External Quality Control			
Positive (C. difficile ATCC 9689)	Toxigenic C. diff Positive /027 Presumptive Negative	New lot/new shipment of kits. Once every 31 days for current lot.	External QC is recorded in LIS
Negative (C. difficile ATCC 700057)	Toxigenic C. diff Negative /027 Presumptive Negative		
NATtrol GI/GII Norovirus Positive (NATNOV-6MC)	NORO GI/NORO GII Detected		
NATtrol GI/GII Norovirus Negative (NATROTA-6MC)	NORO GI/NORO GII Not Detected		
Internal Quality Control			
Sample Processing Control (SPC)	Pass	Every Test	Internal QC is recorded in LIS, GeneXpert Archive data and Result Reports
Probe Check Control (PCC)	Pass		
Environmental/Maintenance Checks			
Instrument maintenance	All elements performed	Daily, Weekly, Monthly	GeneXpert Maintenance Sheet
Module Calibration	Pass	Yearly	PDF file on Desktop and M Drive
Temperature	68-72° F	Recorded daily	QC records (Manual Temp/QC sheet)
Personnel Training and Competency Assessment			
Competency Assessment	Pass	Initial training, after 6 months, and yearly thereafter	Training and CA sheets in employee files
Proficiency Testing			
CAP Stool Pathogen (SP)	Satisfactory	2 specimens twice yearly	CAP Binders
CAP Stool Pathogen (SP1)		1 specimen twice yearly	

Prepared by: Kathryn Parsons, MT(ASCP) **Date: March 2021**
Title: Technical Coordinator Microbiology/Serology

Laboratory Director Review/Approval:
The Risk Assessment and Individual Quality Control Plan for this test system and identified locations has been reviewed and is determined to be acceptable for on-going quality patient testing.

Reviewed and Approved by: _____ **Date:** _____
Title: Microbiology Medical Director

Source: Perry, D. Unpublished, Nebraska Methodist Health System.

IQCP Quality Assessment

Quality Assessment Monitoring requires **ongoing** monitoring of the effectiveness of the IQCP.

- Review of **quality control** and instrument/equipment **maintenance** and function check data at least **monthly**
- Review of **complaints** from clinicians and other healthcare providers regarding the quality of testing
- **Re-evaluation** of the quality control plan **if changes** to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur

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Ongoing Monitoring for IQCP Effectiveness

- Evaluation of **errors relating to all phases** of the testing process
- Evaluation of **corrective actions** taken if problems are identified
- **Re-approval** of the quality control plan by the laboratory director **at least annually**
  - NOTE: if ongoing assessments identify failures in one or more components of the QC plan, the laboratory must investigate the cause and consider if modifications are needed to the QC plan to mitigate potential risk.
- IQCP quality plan should be a **part of the laboratory quality management** program

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IQCP Quality Assessment Tool Example

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IQCP Quality Assessment (example)

Laboratory Section/Department:		Instrument/Device/Tests:	Date:
	QA Process/Monitor	**Issues Identified**	**Actions Taken (eg, retraining, patient lookback, investigation of cause)**
☐	Quality Control performed appropriately and reviewed monthly	QC issues resolved?	
☐	Temperature log sheets completed and reviewed monthly	Out of range or missing temperatures resolved?	
☐	Maintenance logs completed and reviewed monthly	Incomplete data? Corrective actions recorded?	
☐	Instrument issues resolved and recorded	Instrument failures or downtime?	
☐	Proficiency testing performed and reviewed	Unsuccessful PT performance?	
☐	Sampling of personnel training/competency reviewed	Retraining needed?	
☐	Sampling of patient results reviewed	Reporting errors corrected?	
☐	Relevant quality indicators reviewed	Turnaround time, corrected reports, specimen rejection, etc.?	
☐	Laboratory occurrence reports	Corrective actions completed?	
☐	Complaint reports	Physician or care giver concerns?	
☐	IQCP reapproval by laboratory director or designee, as required	Does the IQCP need to be modified based on any issues identified?	
☐			
☐			

Please note this is a sample form only.
Use is not required and will not guarantee that your facility is compliant.

0919

IQCPQA 3.0

Source: CAP ELSS
(https://elss.cap.org/elss/ShowProperty?nodePath=/UCMCON/Contribution%20Folders/WebApplications/doc/IQCP%20Annual%20Assessment%20example%20form.docx)

IQCP Quality Assessment Tool Example

- Have test process failures been identified?
  - Assess the use (eg, timely, effective) of the monthly review process of quality control, temperature, and maintenance logs to identify problems.
  - Record any corrective action for patient results affected by the testing process failure.
  - Evaluate the effectiveness of the corrective action taken.
- Have any changes been made to the five elements of the Risk Assessment (ie, reagents, environment, specimen, testing personnel, or test system) requiring reevaluation of the Quality Control Plan?

IQCP Quality Assessment Tool Example (continued)

- Have any changes been made to the Quality Control Plan?
  - Specify any updates/modifications
- Have revisions to the Quality Control Plan been signed by the laboratory director (including signature and date)?
- Is the IQCP sufficient to mitigate risk in this laboratory? If no, explain actions to be taken.
- Reviewed, signed and dated by laboratory director/designee

IQCP QC Plan Approval

Individualized Quality Control Plan (IQCP) Approval

- IQCP signed and dated by the laboratory director prior to implementation
- No delegation allowed
- Separate approved IQCP for each laboratory with a separate CAP/CLIA number

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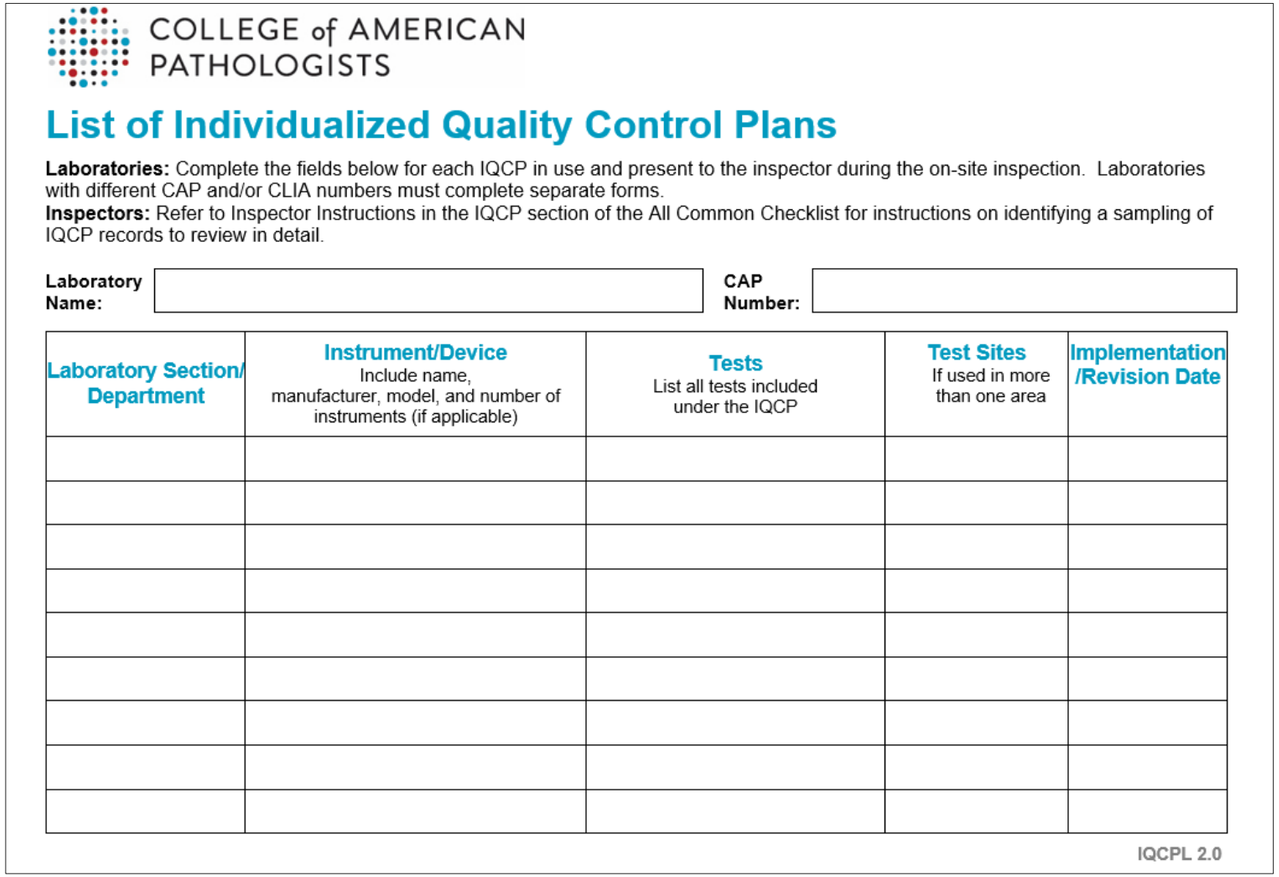
List of Individualized IQCPs

- Form details all tests that have an IQCP
- Required for CAP accredited laboratories to provide to inspection team



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List of Individualized Quality Control Plans

Laboratories: Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Laboratories with different CAP and/or CLIA numbers must complete separate forms.
Inspectors: Refer to Inspector Instructions in the IQCP section of the All Common Checklist for instructions on identifying a sampling of IQCP records to review in detail.

Laboratory Name: _____ **CAP Number:** _____

Laboratory Section/ Department	Instrument/Device Include name, manufacturer, model, and number of instruments (if applicable)	Tests List all tests included under the IQCP	Test Sites If used in more than one area	Implementation /Revision Date

IQCPL 2.0

Source: CAP ELSS
(https://elss.cap.org/elss/ShowProperty?nodePath=/UCMCON/Contribution%20Folders/WebApplications/doc/List%20of%20IQCP%20form.docx)

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Proficiency Testing (PT)

Scenario

You are a laboratory director for a STAT lab and POC

- STAT lab & POC perform plasma PT/INR
- Supporting several dozen non-waived POC meters performing whole blood INR
- Operating under same CAP #

For best practice, you should:

A. Order separate plasma and whole blood PT kits

B. Order a plasma INR PT survey and do crosschecks against one or more POC meters

C. Order a plasma INR PT survey and quality crosscheck product to test each meter

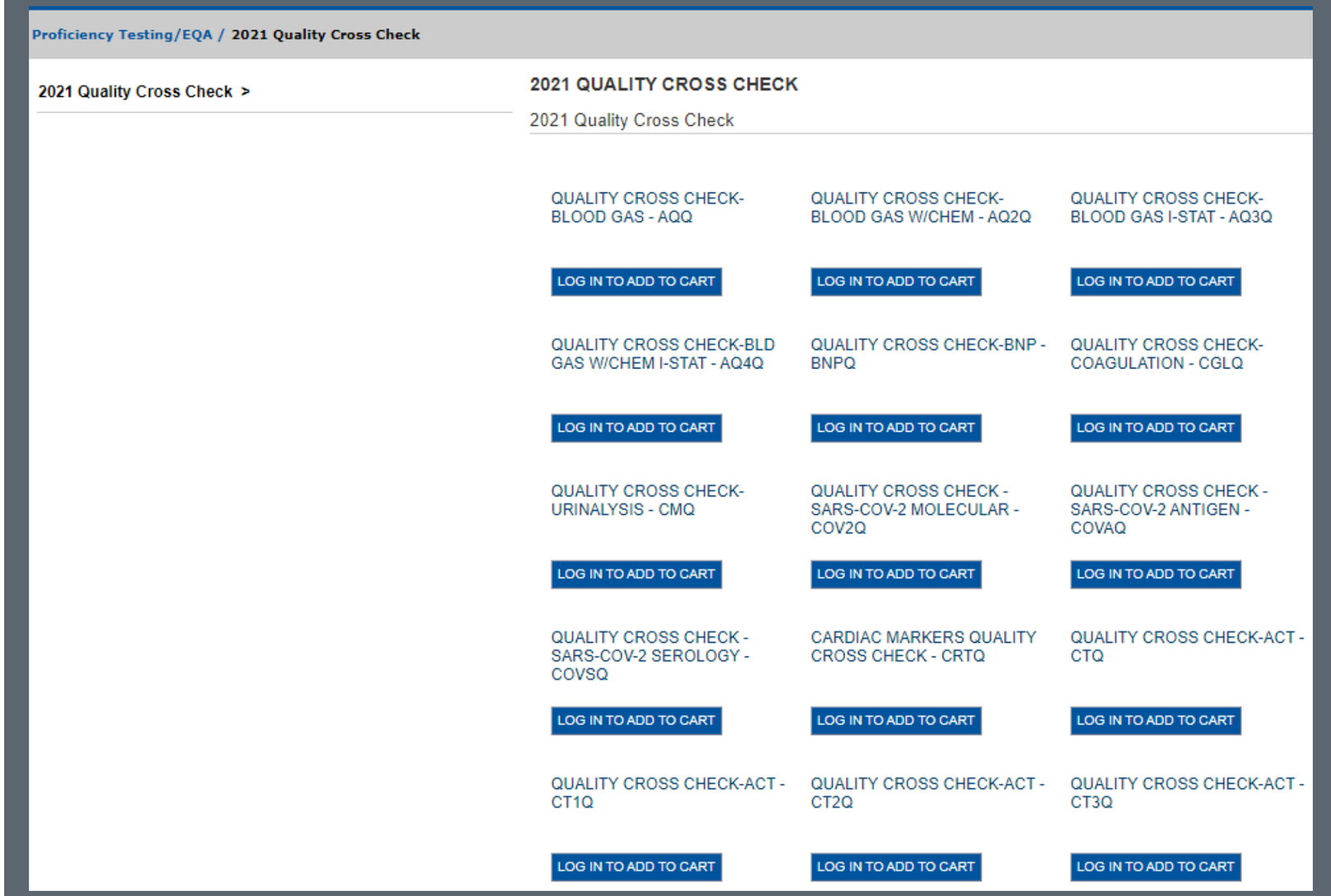
How to Handle Multiple Matrices

- Primary instrument should be used for PT survey (generally highest volume but labs can ultimately determine).
- If a laboratory routinely uses more than one primary method or instrument to report the same analyte, PT can be rotated among the primary methods or instruments during different PT events.
- CAP offers Quality Crosscheck products to monitor performance across multiple instruments (not subject to regulation as PT).
  - Evaluation of results and comparative data

CAP Quality Cross Check Programs

31 programs

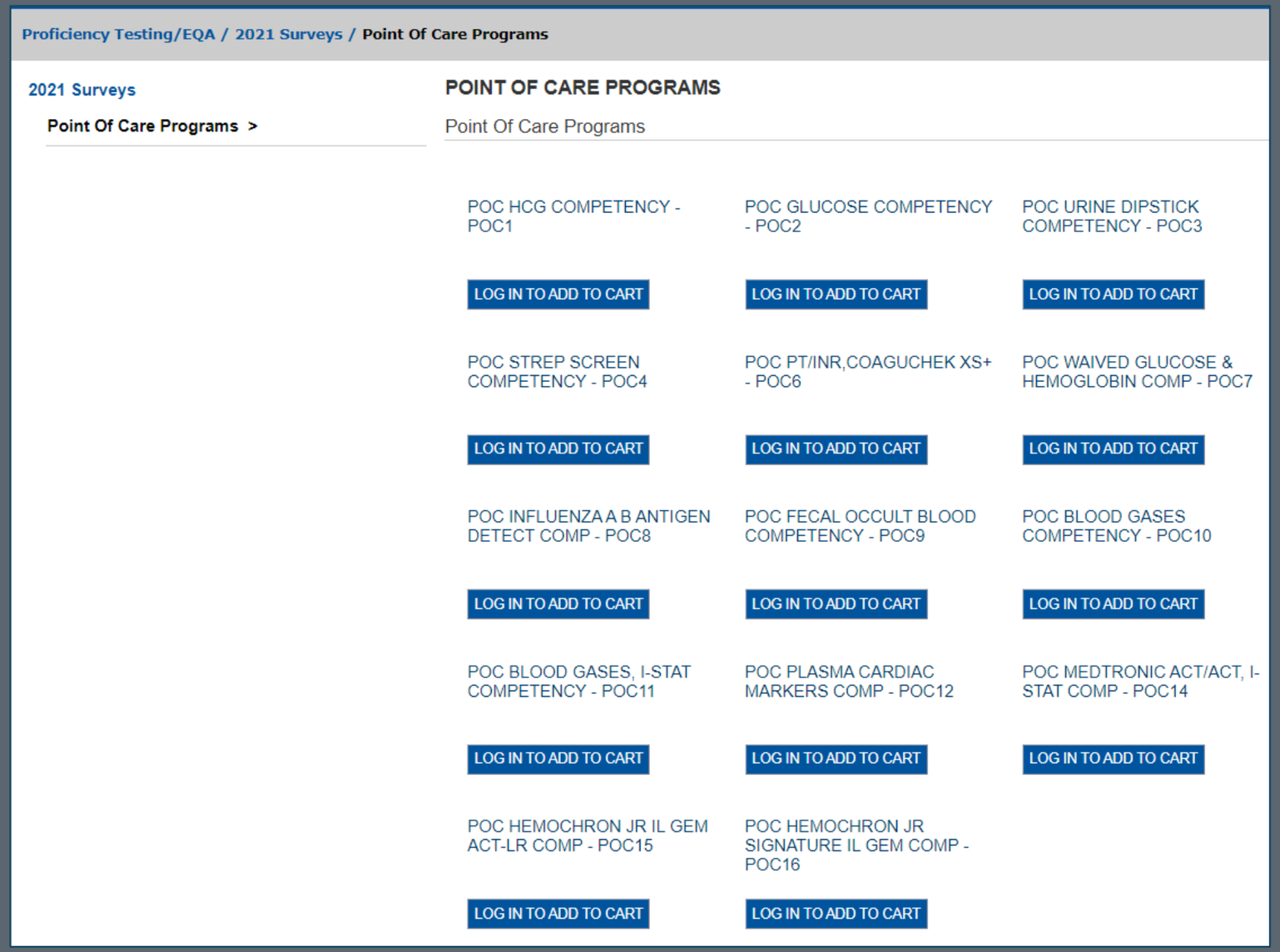
- Monitor instrument performance
- Assess comparability across multiple instruments
- Identify potential issues before they affect patient results



CAP Point Of Care Programs

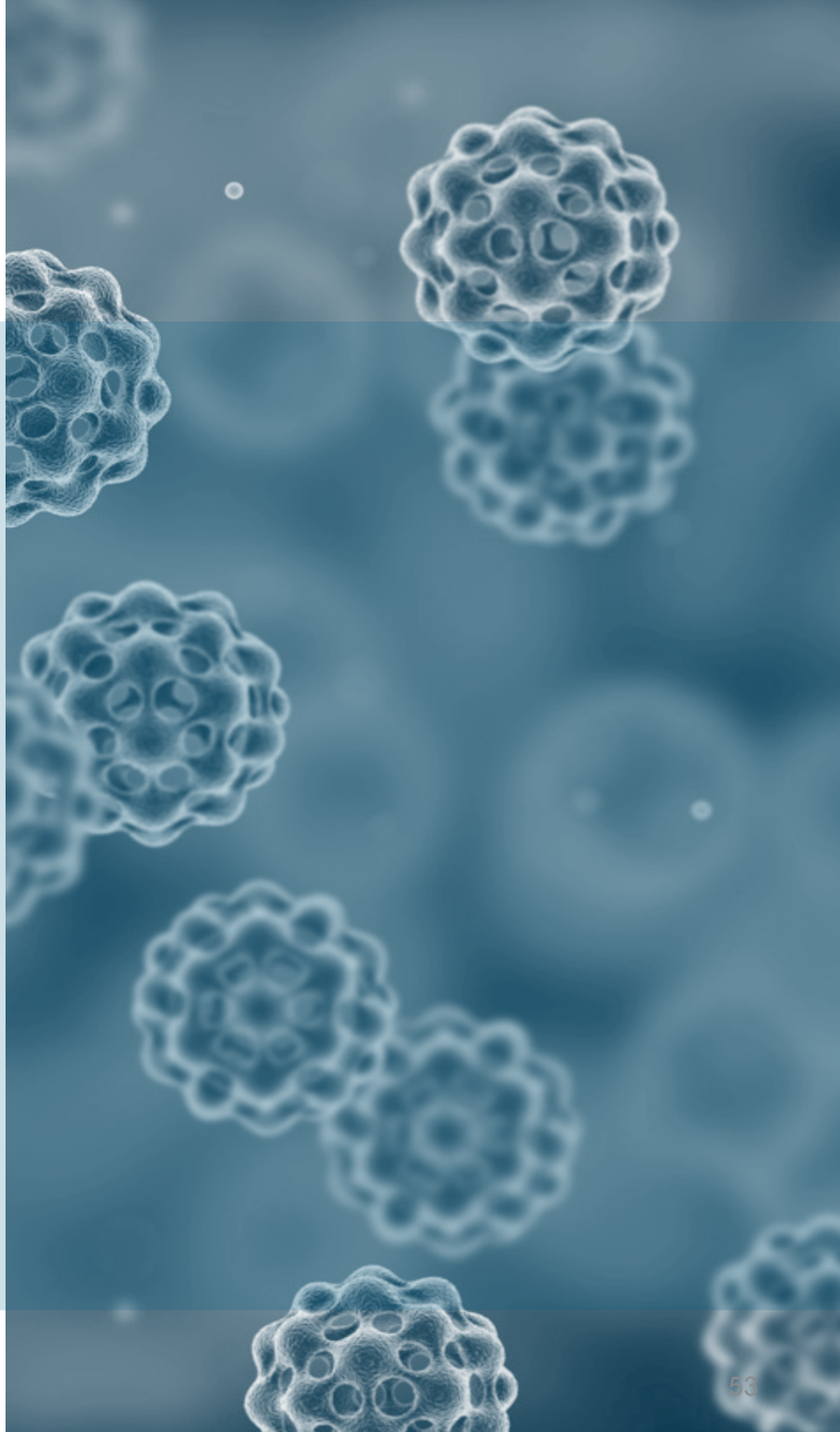
14 **competency** programs

- Evaluate instrument and method performance
- Assess staff competency



Summary

- Ensure your POC team has the right qualifications and requirements.
- A strong IQCP includes quality assessment.
- Don’t forget a good PT program for your POC.
- POC programs include insight from a variety of resources – use them!



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