Patient Safety: A Quality System Approach to POCT QC

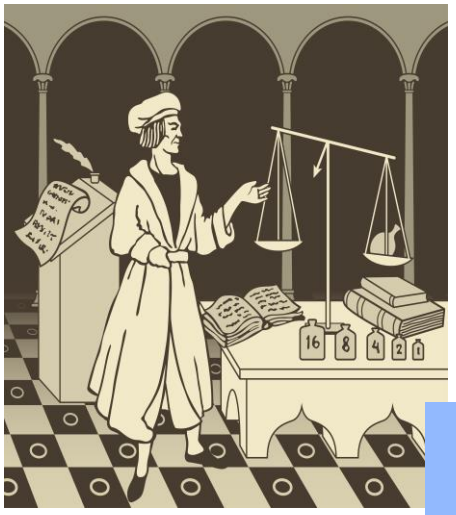
Ellis Jacobs, Ph.D., DABCC, FAACC
Principal, EJ Clinical Consulting, LLC
Adjunct Associate Professor of Pathology,
Mount Sinai School of Medicine

Agenda

1. Review the characteristics of Point of Care Testing
2. Define Quality and Quality Systems
3. Discuss the sources of error in POCT and how they are managed
4. Overview the evolution of POCT technology and types of internal and external quality control processes
5. How to Develop a QC Plan based on risk assessment

Point-of-Care Testing Characteristics

- A broad based process
- Unrestricted to location, personnel or test menu.
- A collective, multi-disciplinary effort.
- Simple to use technology
- Potentially low volume testing



The Truth about POCT

POCT introduces an additional technology

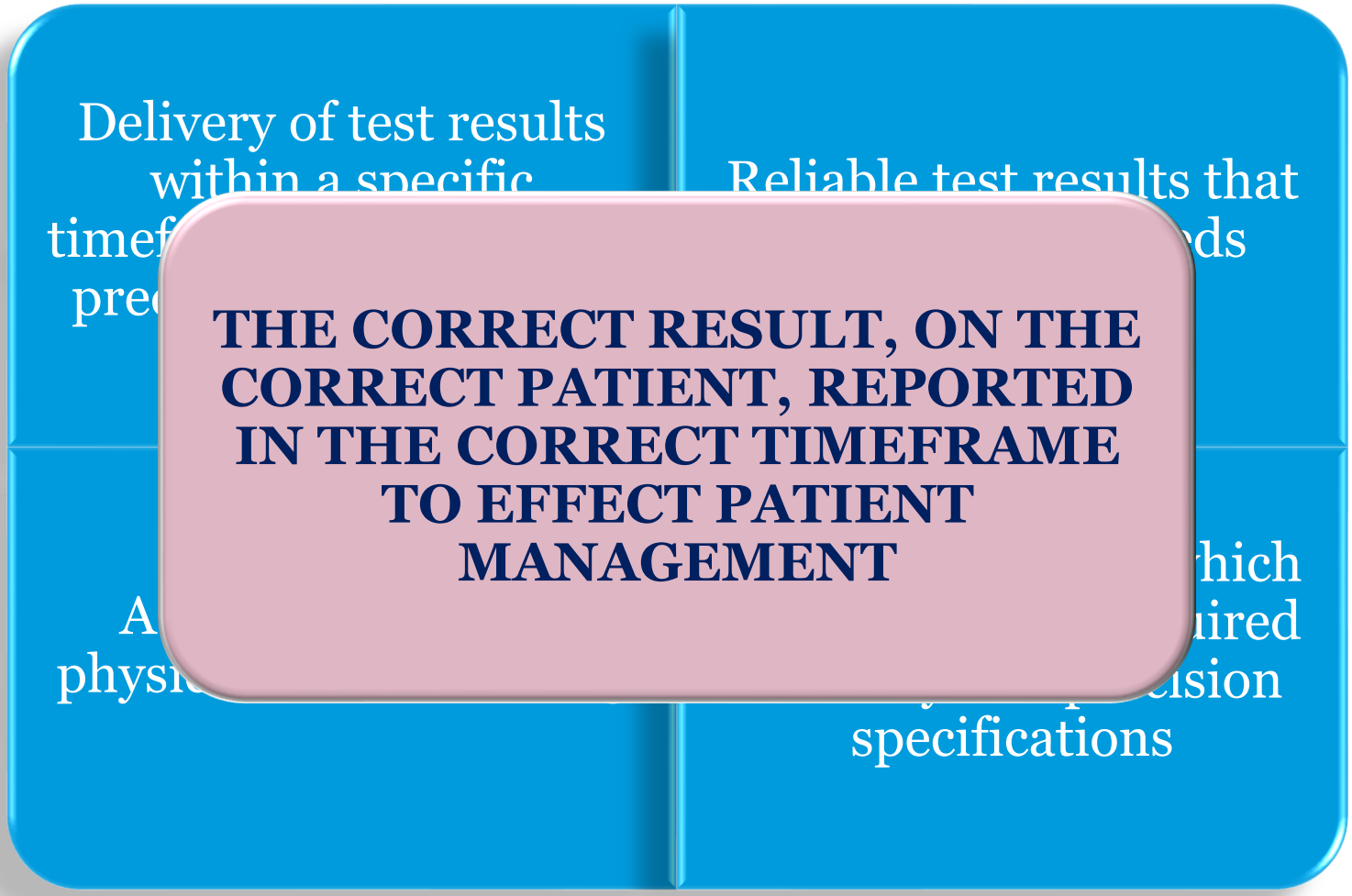
- Different precision
- Biases
- Unique Interferences

POCT results do not necessarily agree with core laboratory results

Quality concerns if manufacturers instructions and controls are not performed as required

Additional testing is ordered when POCT results do not match core lab results or questions about the quality of results present

What is Quality



POCT & Patient Safety: Quality Testing Criteria

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation of POCT result(s)
- Correct and timely clinical response

Quality Issues

There is no “perfect” device, otherwise we would all be using it.

Any device can and will fail under the right conditions.

Any discussion of risk must start with what can go wrong with a test (errors).

Laboratory tests are not foolproof.

Quality System

Organizational structure, resources, policies, processes and procedures needed to implement quality management

(ISO, CLSI)

In other words… all activities which contribute to quality of testing, directly or indirectly.

What is a Quality System?

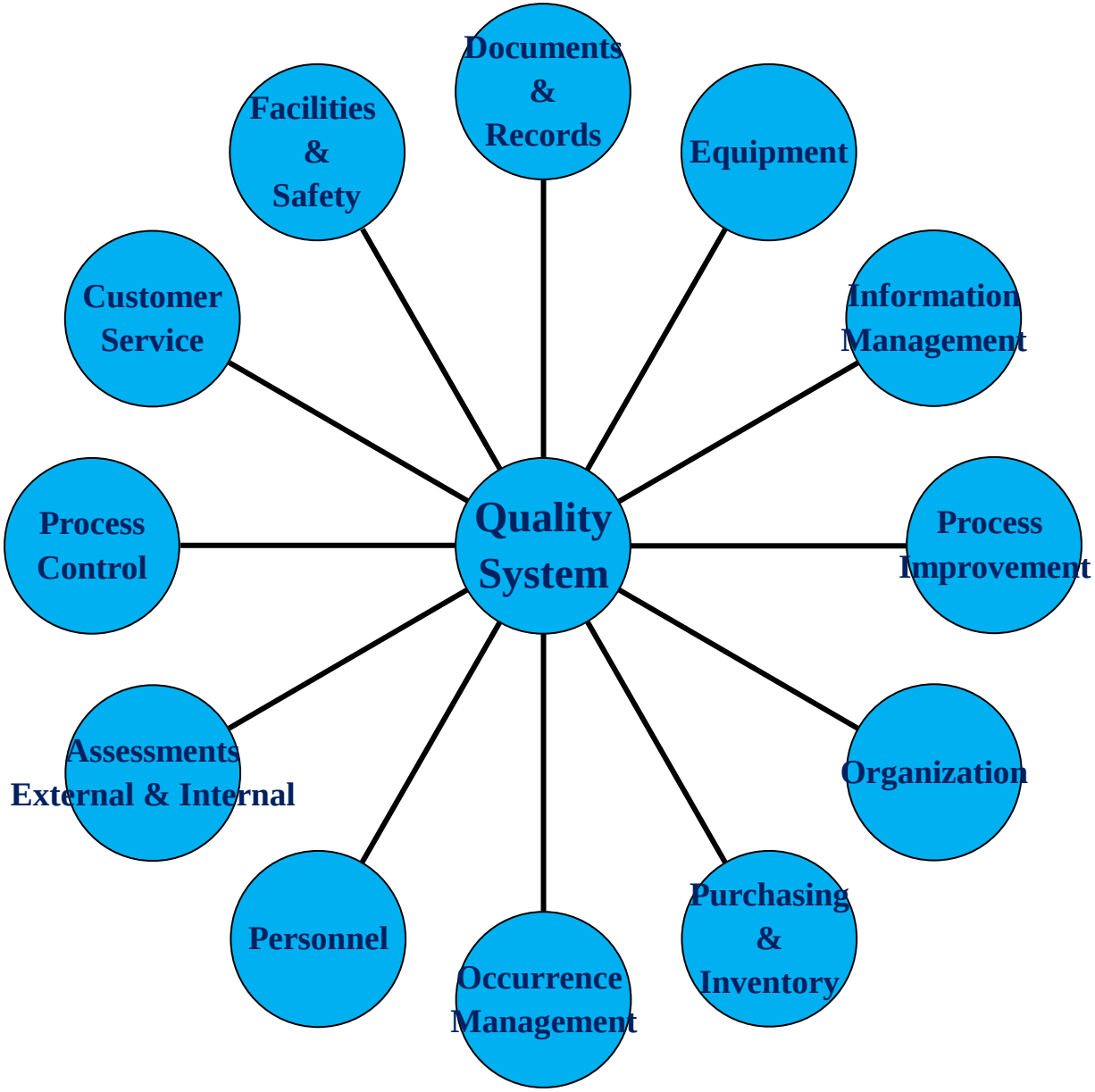
The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided).

Quality Management System Model

Laboratory's Path of Workflow

QSEs encompass the entire path

Quality Service Essentials (QSEs)



Quality Assurance

All planned and systematic actions necessary to provide adequate confidence that goods or services will satisfy the customer's needs.

QA Issues With POC Testing

- Who performs testing and their training
- Pre-analytical variables and the ability to recognize them
- Reagent Testing
- Instrument verification
- Maintenance requirements
- Result reporting & charting

Sources of Errors in POCT

deviation from truth, accuracy, or correctness; a mistake

Key Processes in Laboratory Workflow Path

Preexamination (Preanalytical) Processes	Examination (Analytical) Processes	Postexamination (Postanalytical) Processes
• Examination ordering • Sample collection and labeling • Sample transport • Sample receipt and accessioning • Preexamination sample processing	• Examination • Results review and follow-up • Medical review	• Results reporting • Results archiving • Sample archiving • Charging for examinations, where applicable

CLSI. *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*. QMS02-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

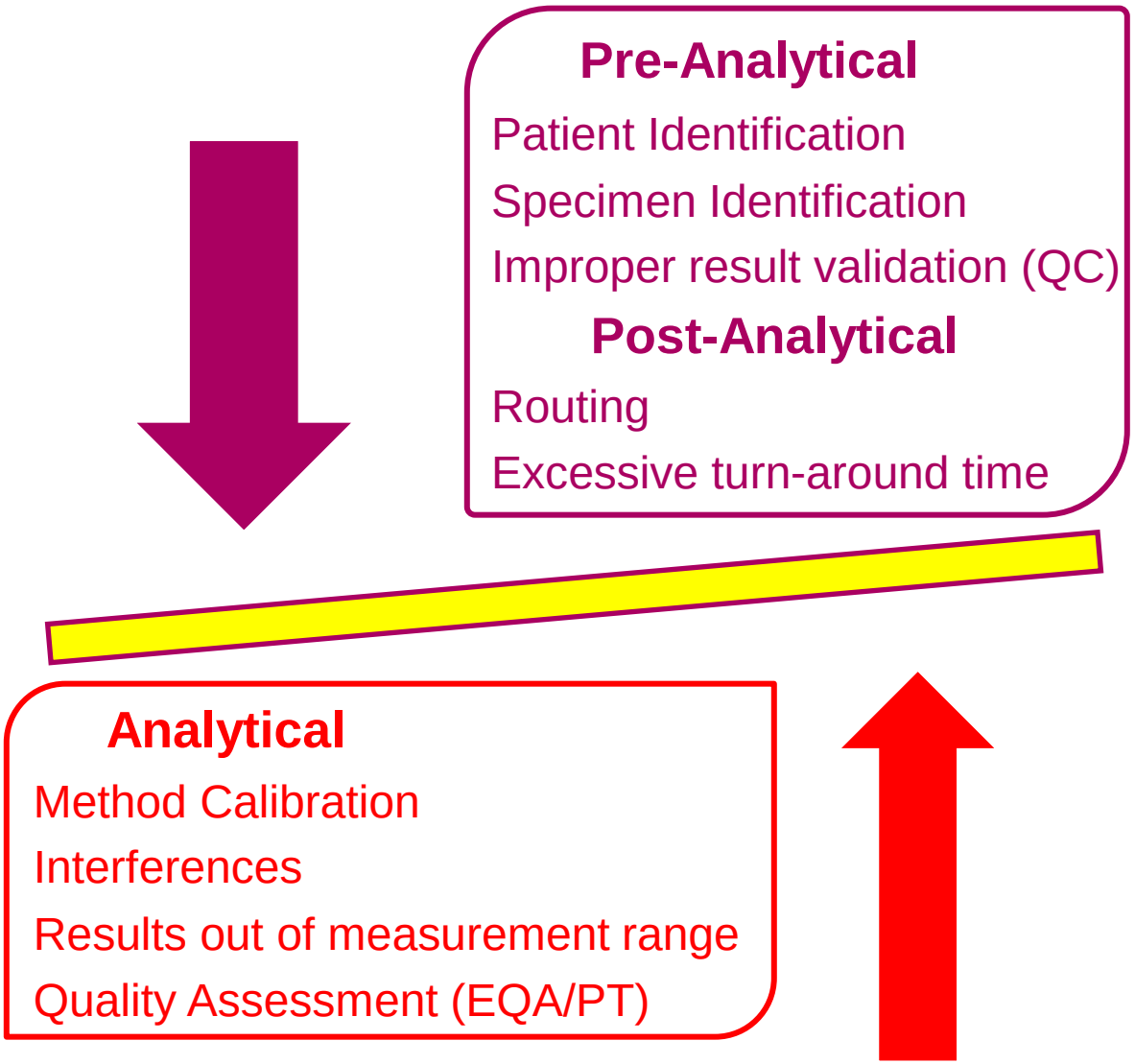
Sources of Testing Error

	1997	2007
Preanalytical	68%	62%
Analytical	13%	15%
Post-analytical	19%	23%

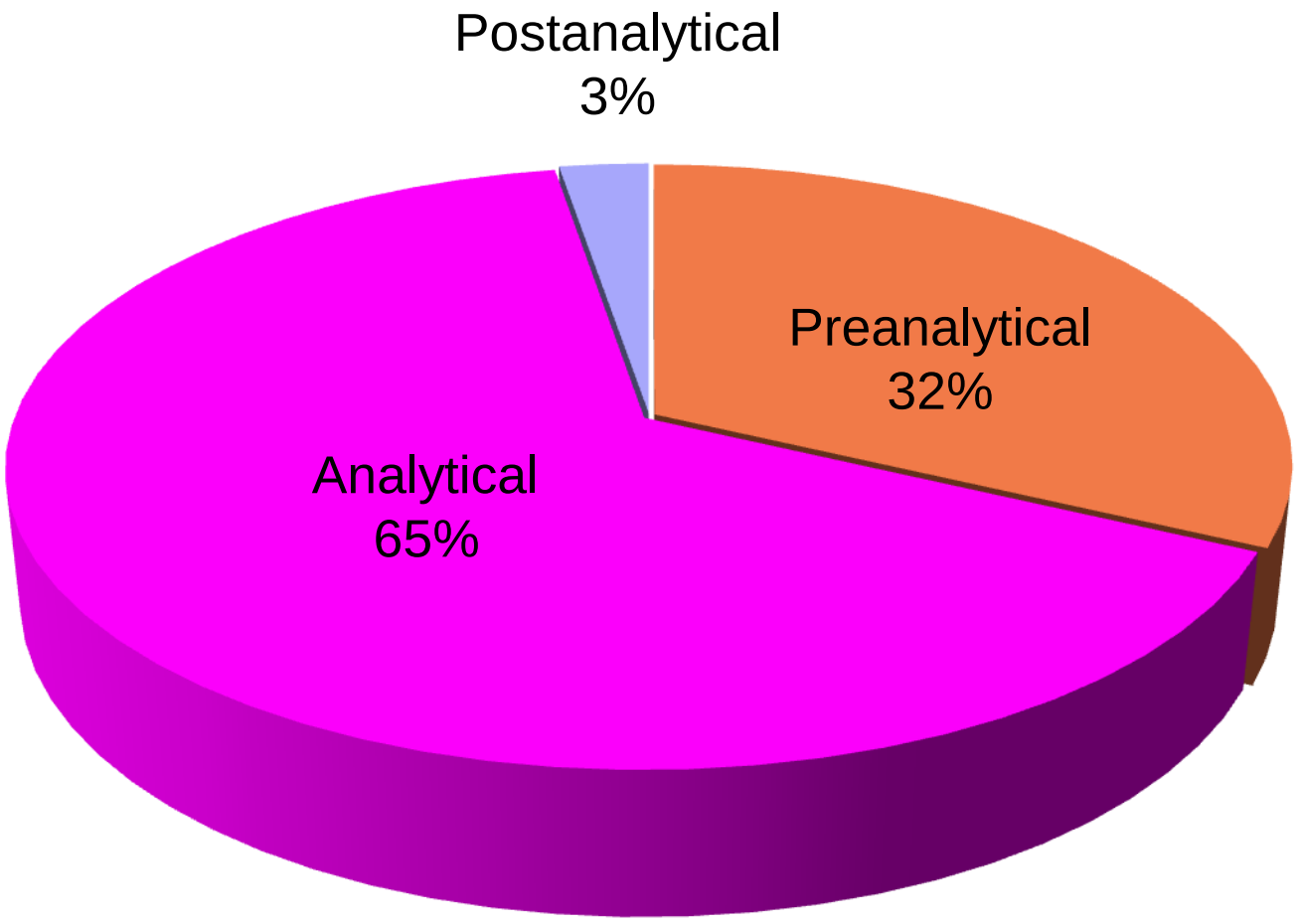
Plebani M, Carraro P, Clin Chem 1997;43:1348-1351

Carraro P, Plebani M, Clin Chem 2007;53;1338-1342

Potential Impact of POCT on Laboratory Errors



Sources of Quality Errors in POCT



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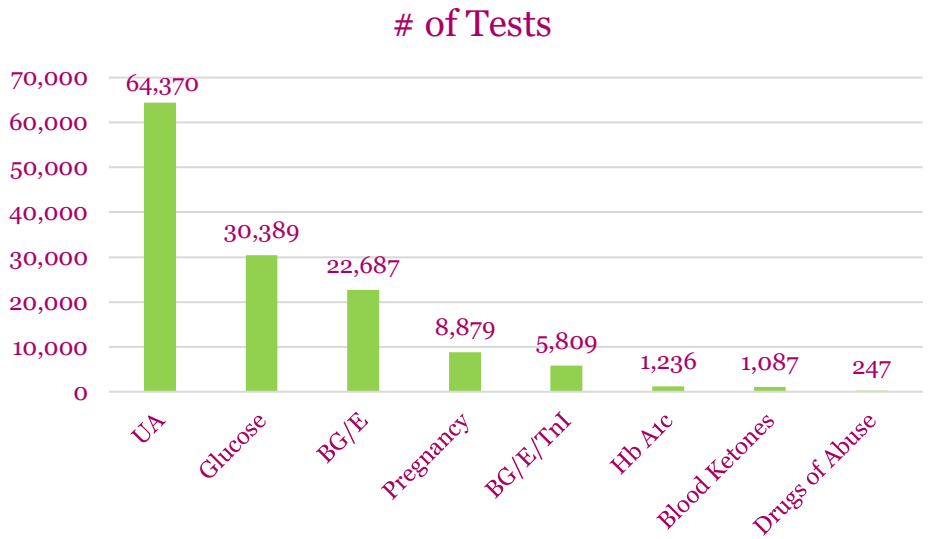
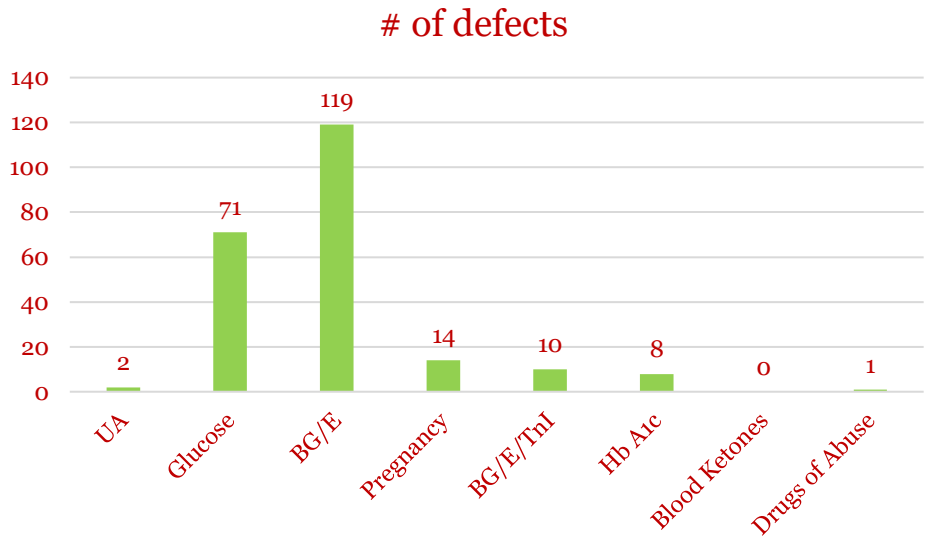
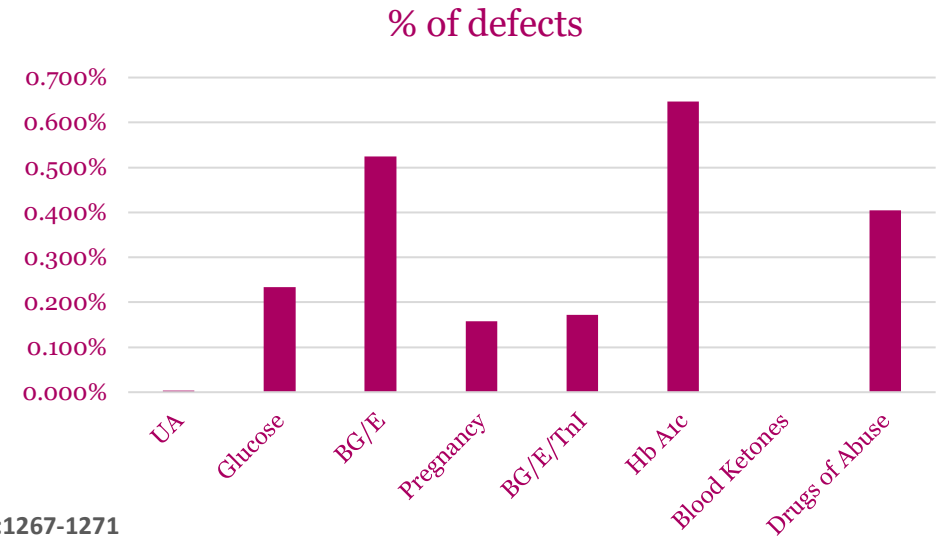
O'Kane M, et al, Clin Chem 2011;57:1267-1271

POCT Quality Errors by Test

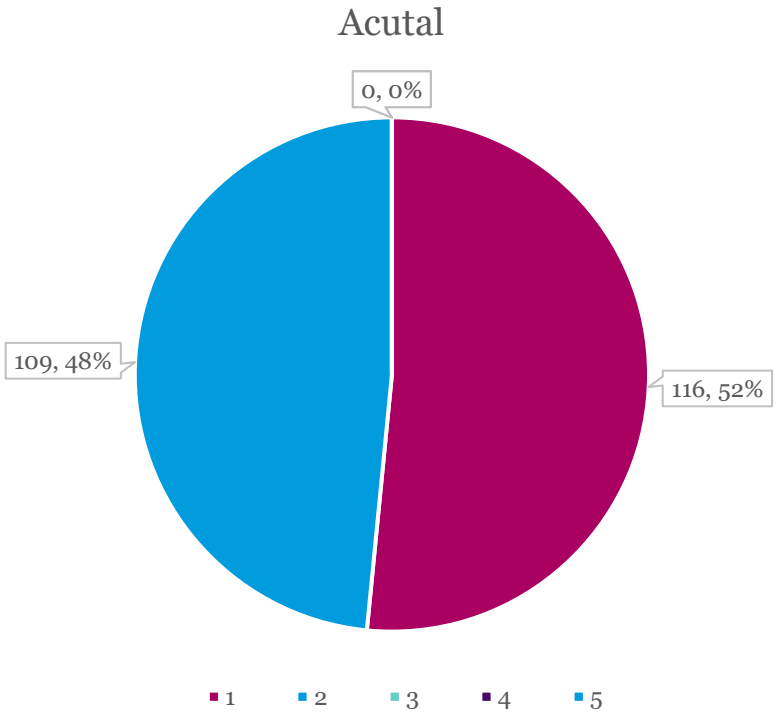


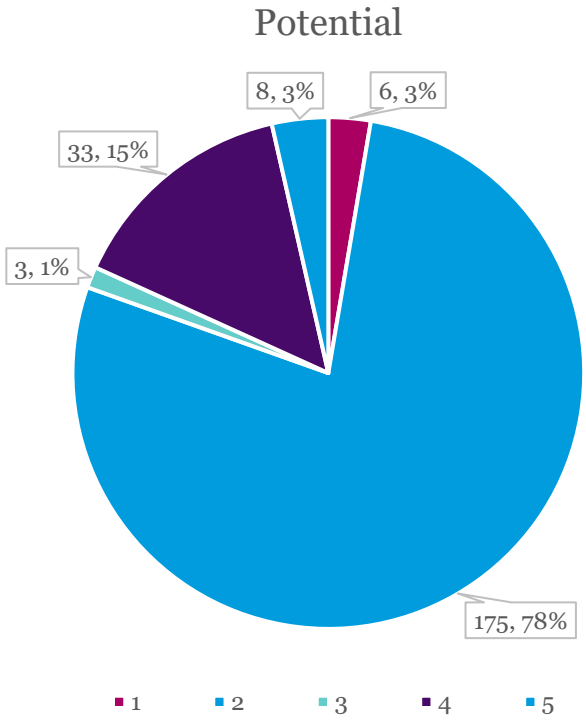




O'Kane M, et al, Clin Chem 2011;57:1267-1271

Impact of POCT Errors





O'Kane M, et al, Clin Chem 2011;57:1267-1271

Managing Errors in POCT

Managing Sources of POCT Errors

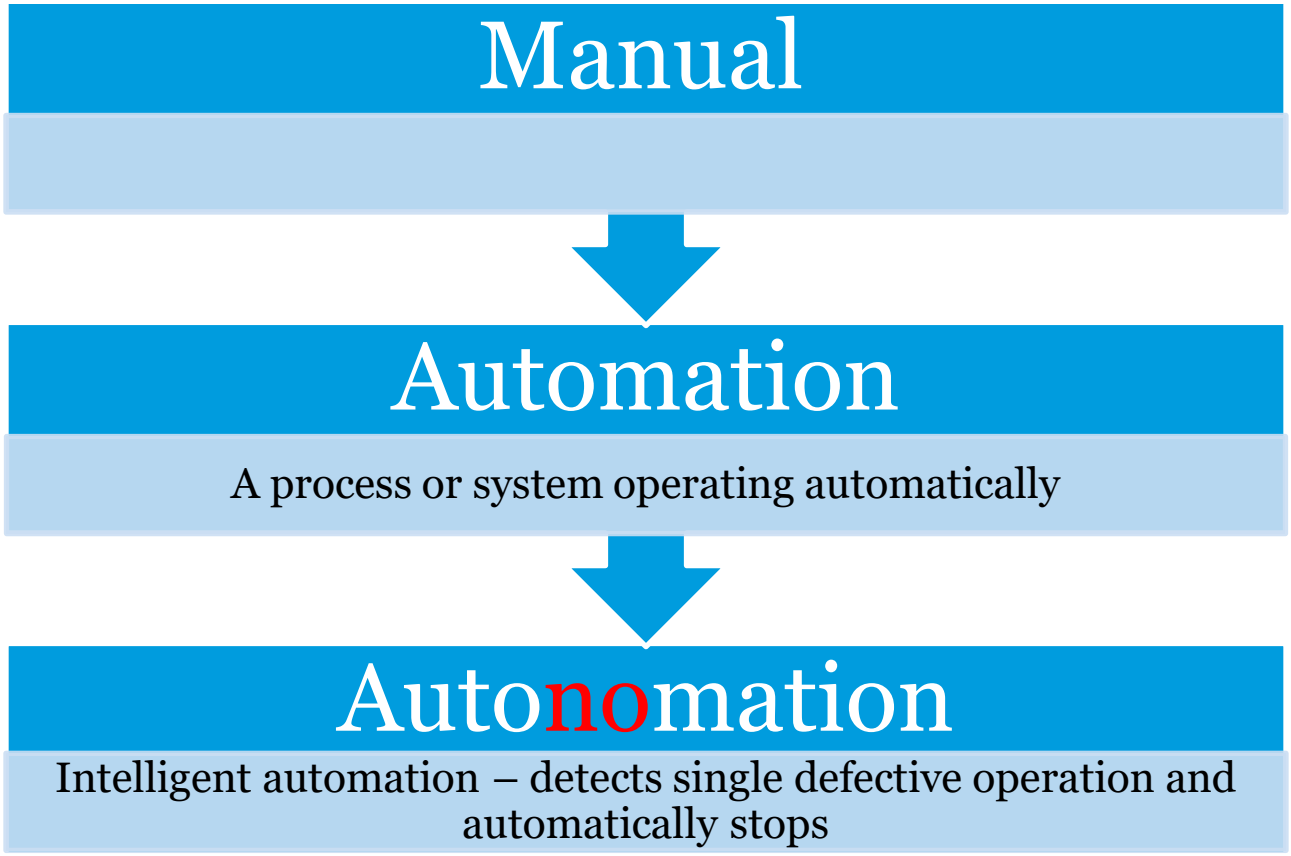
Designed out of the product

Tested for

Warned about

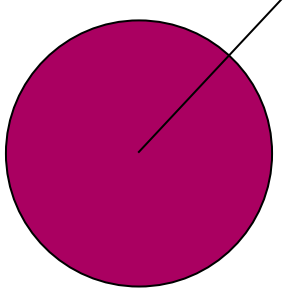
- monitored

Evolution of POCT



Ehrmeyer S, Lassig R. Clin Chem Lab Med 2007;45(6):766-773

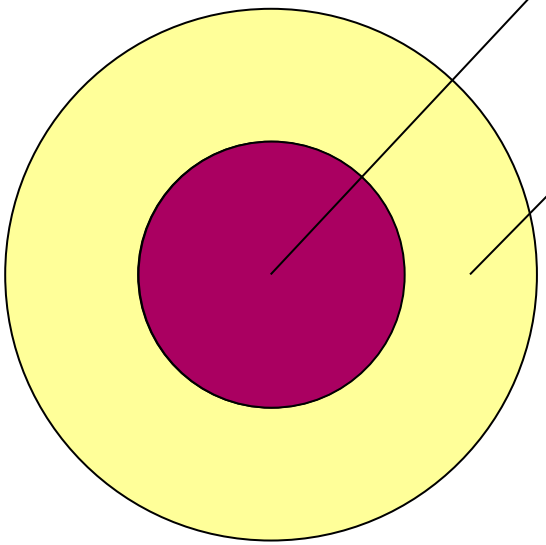
Evolution of Glucose POCT Technology



Manual Testing

- Incorrect sample amount
- Incorrect reagent amount
- Incorrect mixing
- Wrong position of testing device
- Wrong wait time
- Color blindness

Evolution of Glucose POCT Technology

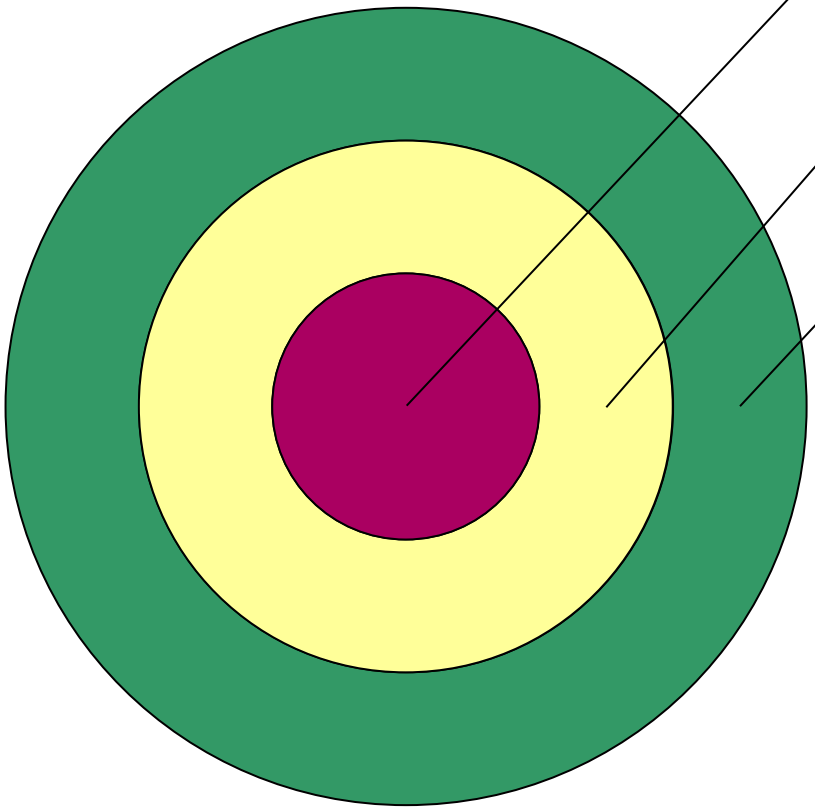


Manual Methods

1st/2nd Generation Instruments

- Wipe/Wipeless technology
- Operator ID / Patient ID
- Reduced operator intervention
- Operator prompts
- Check on reagent viability
- QC lock-outs
- Rudimentary Data Management

Evolution of Glucose POCT Technology



Manual Tests

1st/2nd Generation Instruments

Current Technology

- Electrochemical Technology
- Ability to use universal specimen types
- Extended linearity
- Minimally Invasive Technology (<3 uL Sample Size)
- Consolidated Testing Platforms
- Real Time Data Management and Connectivity

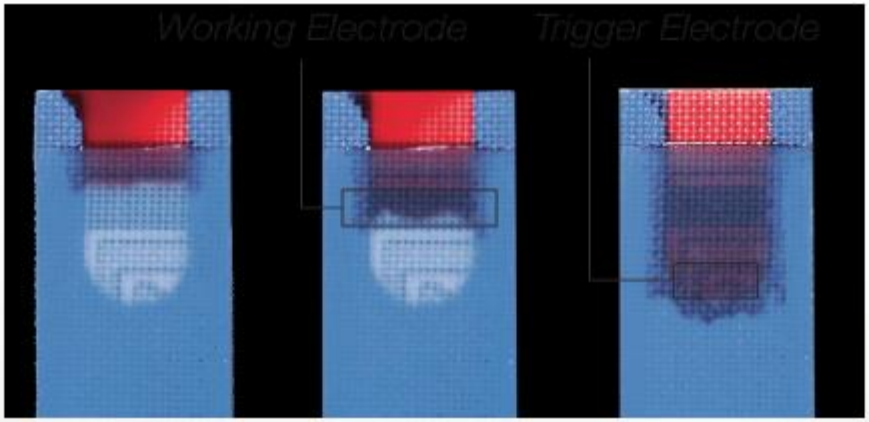
Patient/Sample Identification

Pre-barcoded arterial syringe for positive patient identification

Establishes and maintains sample ID throughout testing process

Analytical Error Reduction – Specimen Volume

- Some glucose meters recommend that operators visually inspect strips for uniform color development after each test (detects underfilling and bubbles)
- Other meters have automate sample detection. (Fill-trigger is designed to prevent short-sampling.)
- Test starts only when enough blood has been applied.



Unit use and POCT devices

It is often suggested that QC has no role in a unit use device because…

- QC of a single unit (good or bad result) does not inform about other units [same argument would apply to non POCT analyzers in main lab that use discrete (unit use) reagent packs]
- IMS fulfills QC role in unit use devices

Unit use and continuous flow systems are not that different

Quality Control

Operational techniques and activities used to fulfill requirements for quality (ISO 9000)

Part of quality management focused on fulfilling quality requirements (ISO 9000).

Internal quality control (IQC) – set of procedures for continuously assessing laboratory work and the emergent results; immediate effect, should actually control release of results (WHO, 1981)

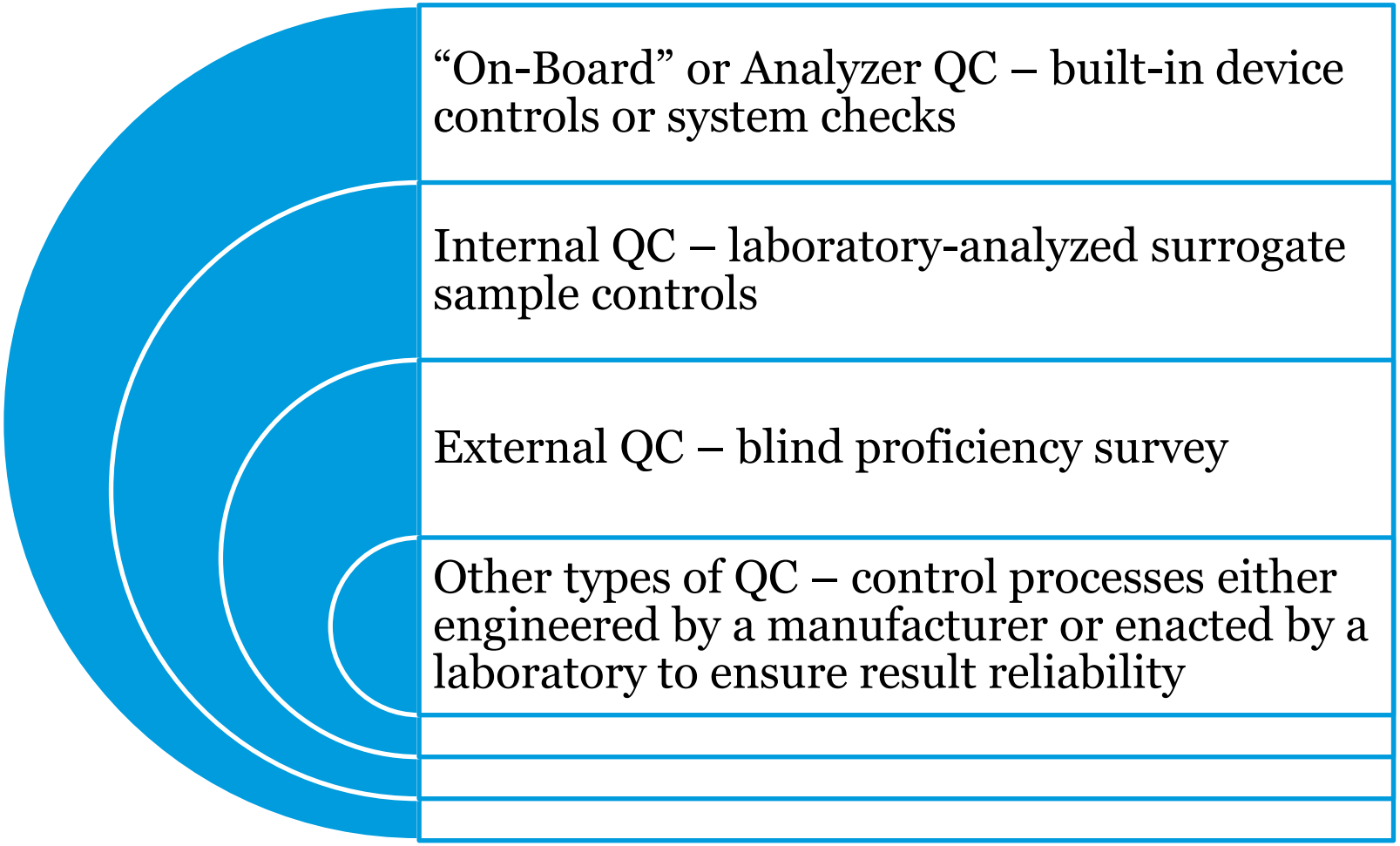
493.1256 – QC procedures

For each test system, the laboratory mustt est, at a minimum, two levels of external QC materials each day it performs a nonwaived test.

However, the regulations now allow the laboratory to reduce the frequency of testing external QC materials for certain test systems.

CMS: Equivalent Quality Control Procedures Brochure #4

Types of Quality Control

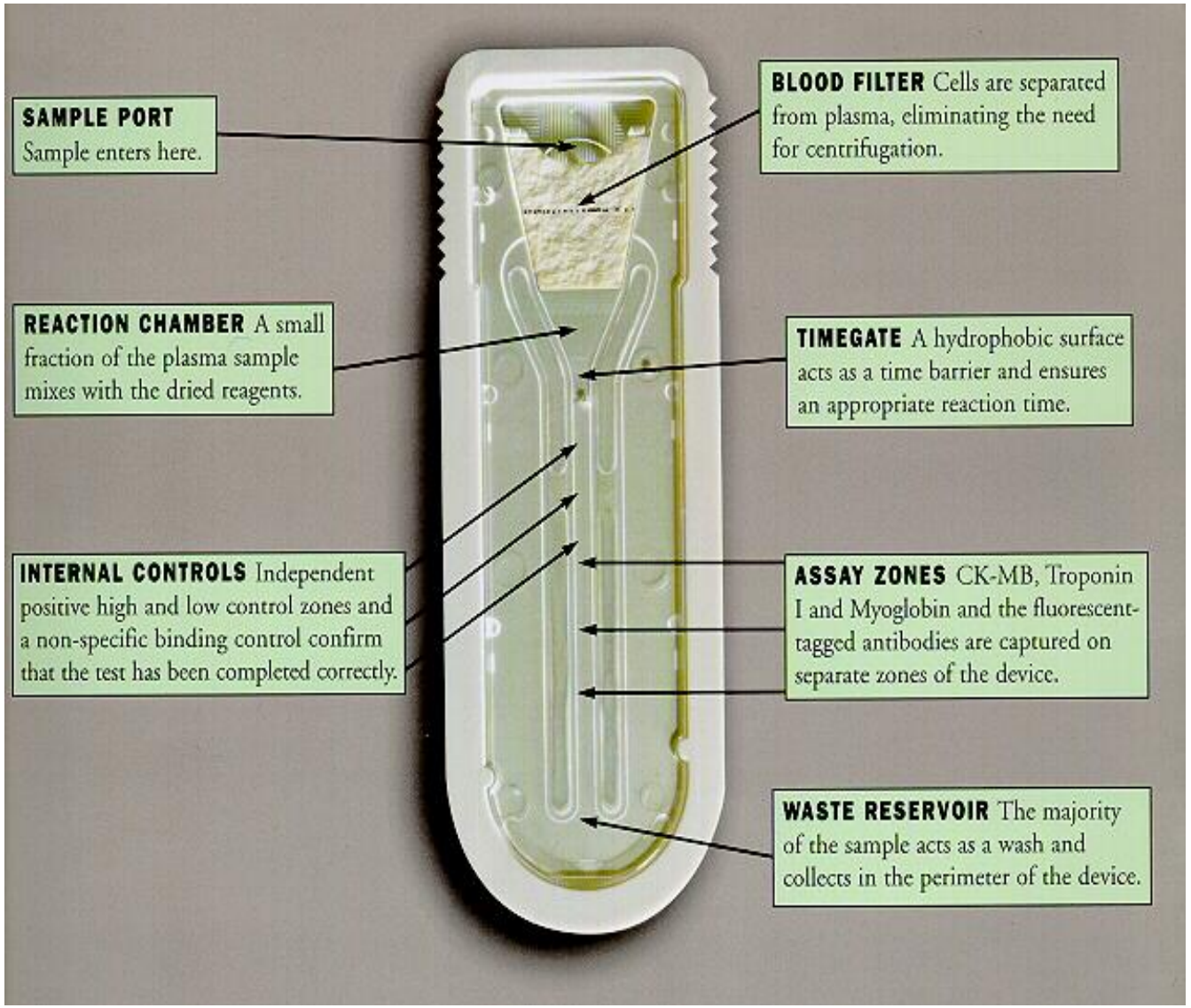


Nature of QC Procedures

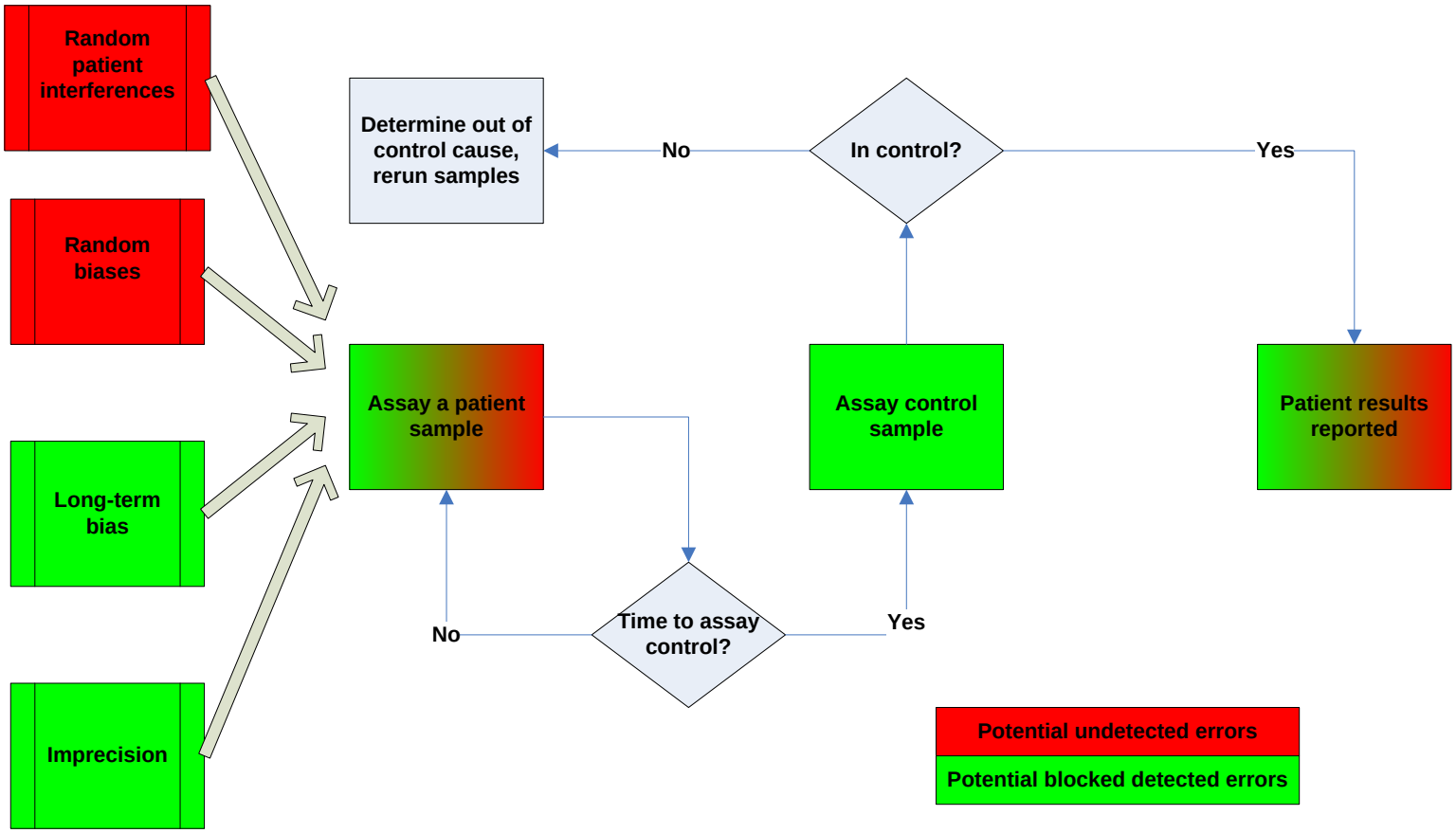
- Use of electronic checks, including any instrument software features that serve as error detection or prevention mechanisms
- Use and number of surrogate samples, where appropriate, to be included as part of the QC procedure
- Testing of controls that are engineered into the test system

Integrated Surrogate Controls Centrifugal Analyzer

Integrated Surrogate Control
Quantitative Immunochromatography



Surrogate QC doesn't detect all errors



Non-Surrogate Sample QC

Includes all forms of quality control other than the measurement of a surrogate sample, usually integrated into the device

- electronic QC (which simulates signals electronically)
- automated procedural controls (which ensure that certain steps of the procedure occur appropriately), ex. Immunochromatography test kits
- automated internal quality controls (which may, for example, ensure the quality of a raw signal)
- diagnostic pattern recognition systems

Procedural Control
Immunochromatography – Urine Dip

Internal Monitoring Systems

IMS are a collection of hardware and software that detect errors and prevent the effect of the error from occurring

- Example: Noise in the signal of a patient sample is detected, the result is flagged and not reported

IMS are not new – although improved, they have been in systems for over 30 years

Internal Monitoring Systems

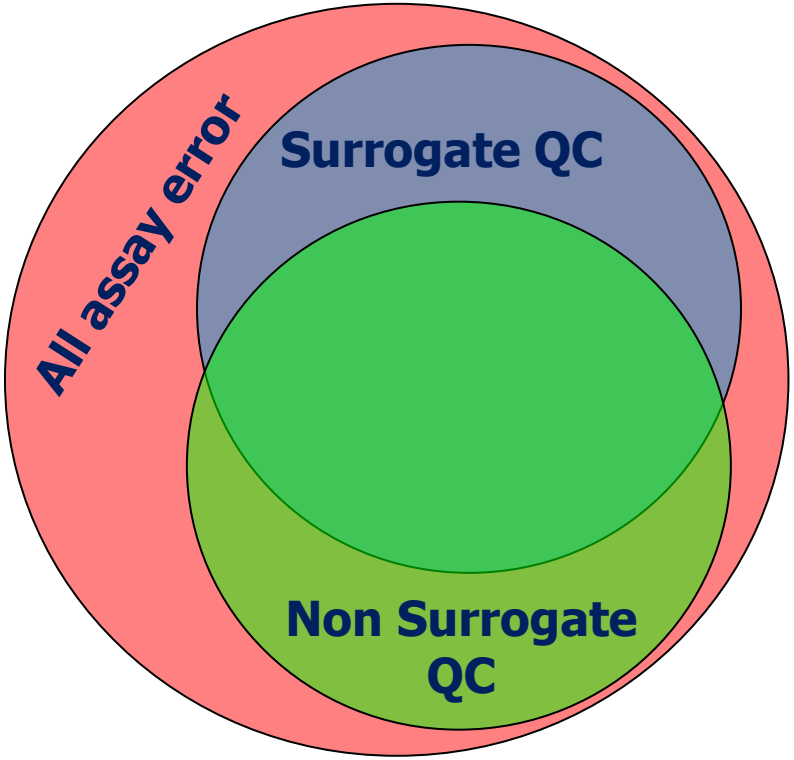
Internal monitoring systems don't detect all errors, because:

- Complexity of instrument systems prevents perfect failure mode models
- There is management pressure to release new products quickly
- There is insufficient knowledge to "design things right the first time"

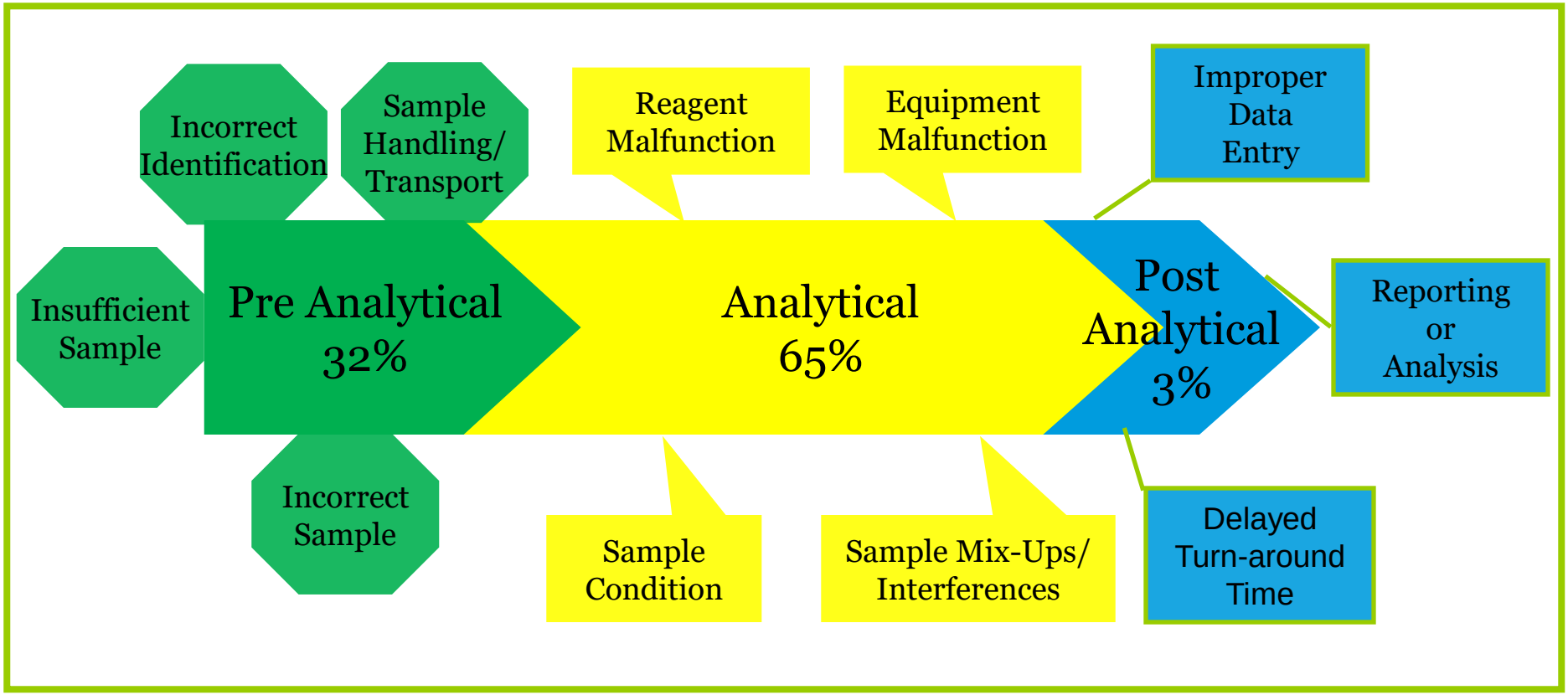
Non-Surrogate QC and QC

Are not completely redundant

Do not detect all errors



Thinking in the POCT Box



As autonomation reduces errors in the box, further reductions must occur outside the box

Thinking Outside the POCT Box

Pre-pre: Physician must consider:

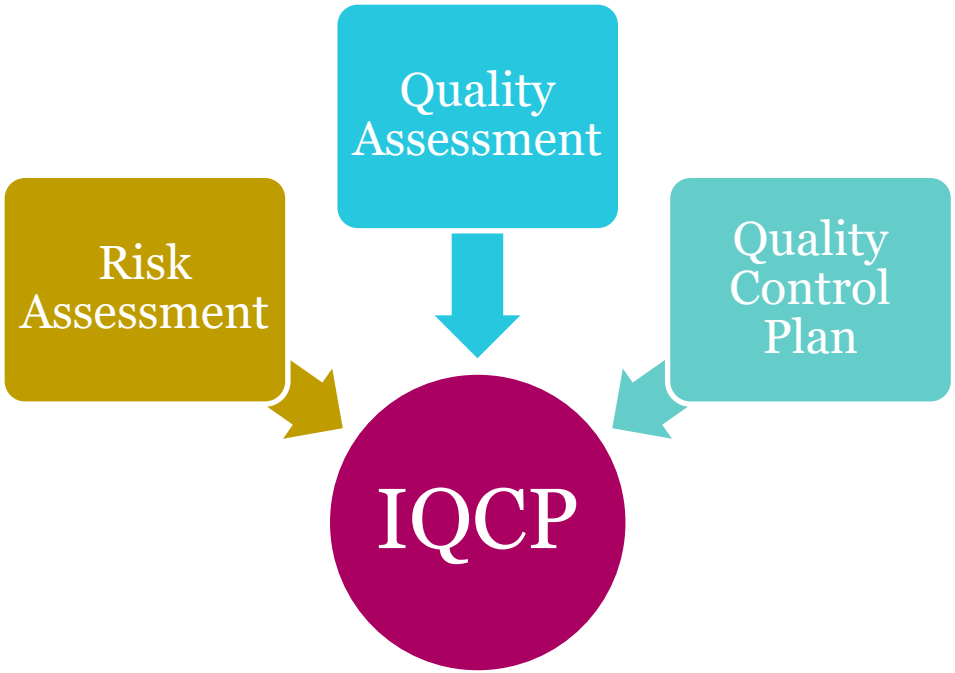
- What POCT is available?
- What POCT will best serve the patient?
- Will an immediate answer improve the patient's outcome?

Post-post: Is the Physician?

- Receptive to using an immediate POCT result
- Able to interpret result in the patient's context
- Amenable to initiating an immediate response

Developing the Quality Control Plan

Individualized Quality Control Plan



Risk Assessment

- Process to identify risks

Quality Control Plan

- List of errors and actions to mitigage the risks

Quality Assessment

- Monitoring of that plan

Where is the Risk Here?

What is Risk

The chance of suffering or encountering harm or loss (*Webster's Dictionary and Thesaurus*. Ashland, OH: Landall, Inc.; 1993).

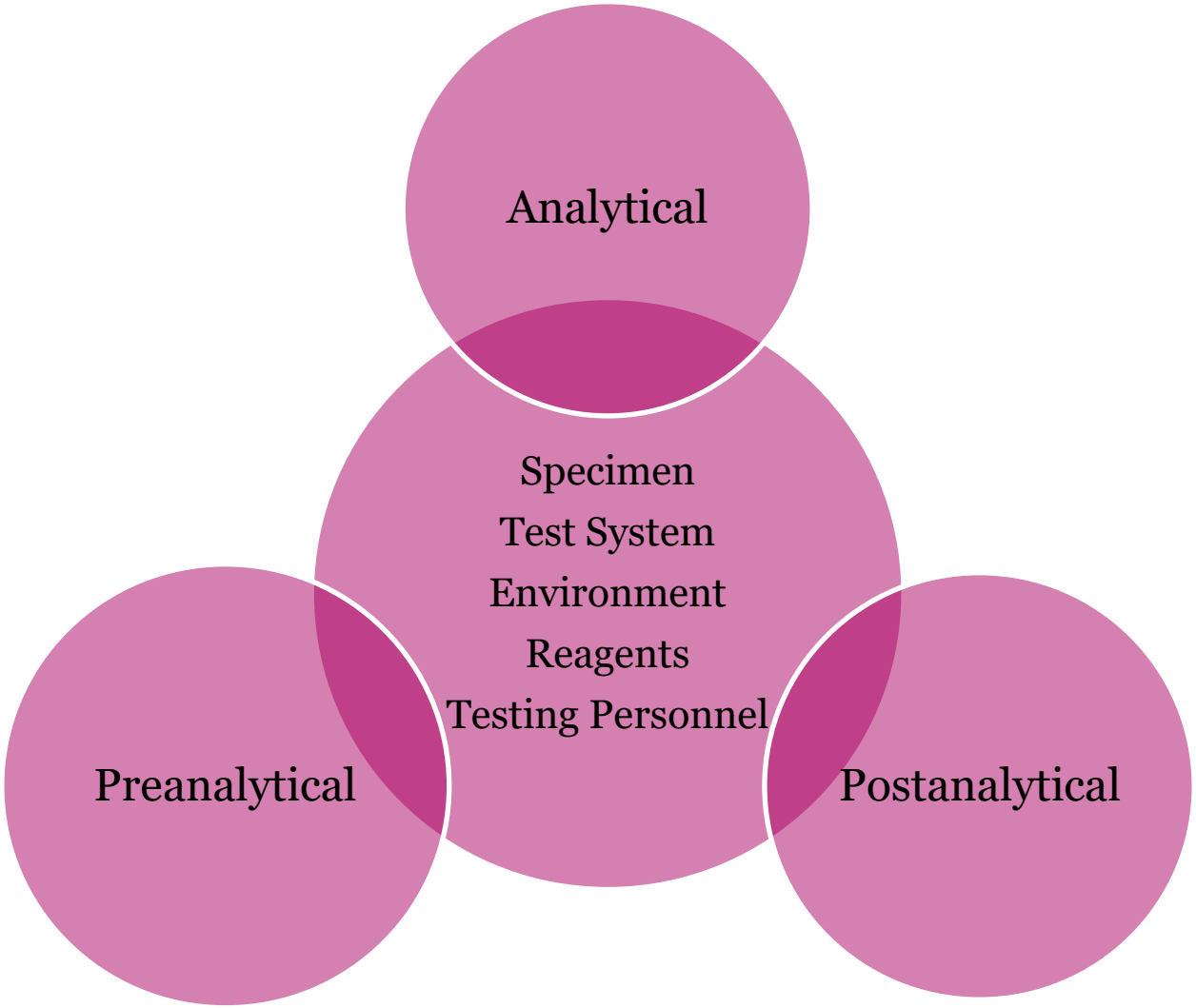
Risk can be estimated through a combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).

The potential for an error to occur that could lead to patient/staff harm

Risk Management Definition

Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)

What is Risk Assessment in IQCP



Resources for Identifying Potential Errors

Manufacturer's package insert including but not limited to:

- Intended use
- Limitations
- Environmental requirements
- QC frequency
- Specimen requirements
- Reagent storage
- Maintenance
- Calibration
- Interfering substances

Resources for Identifying Potential Errors

- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Training manuals

Resources for Identifying Potential Errors

- Testing personnel qualifications, training, and competency records
- QC/Proficiency testing data
- QA information including corrective actions taken
- Scientific publications/journals
- Internet/database searches
- Laboratory community/specialty forums

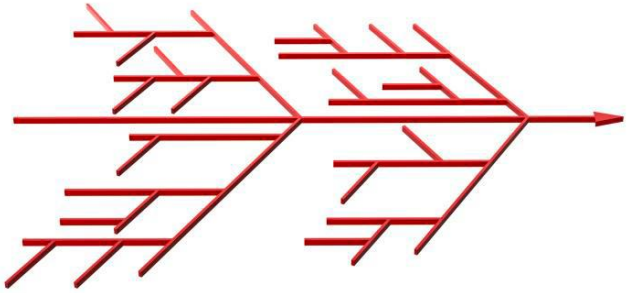
Risk Assessment/Occurrence Management Tools

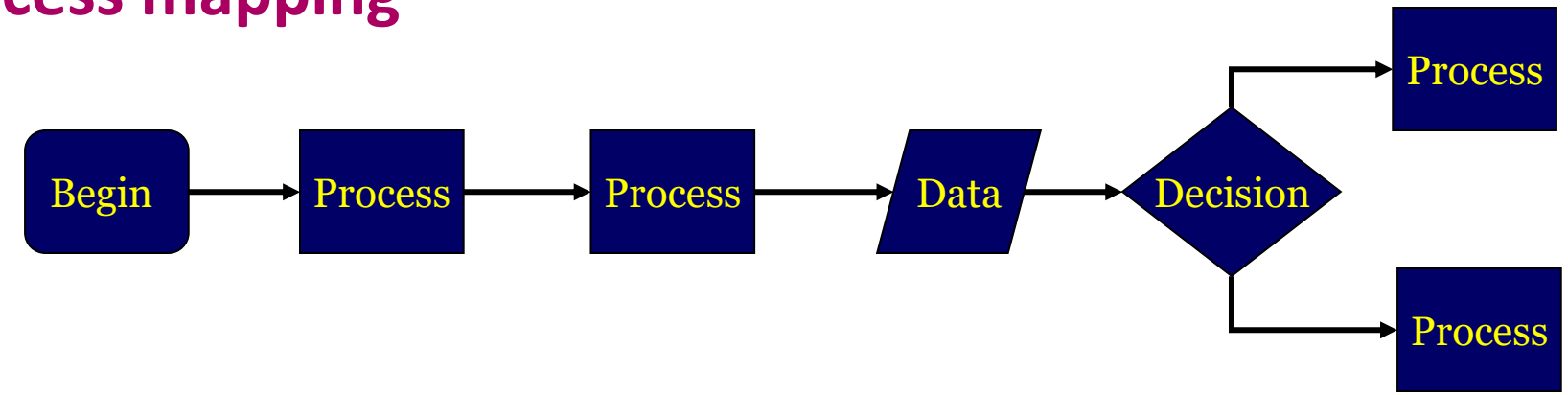
Brainstorming

5 Whys

Fishbone diagrams

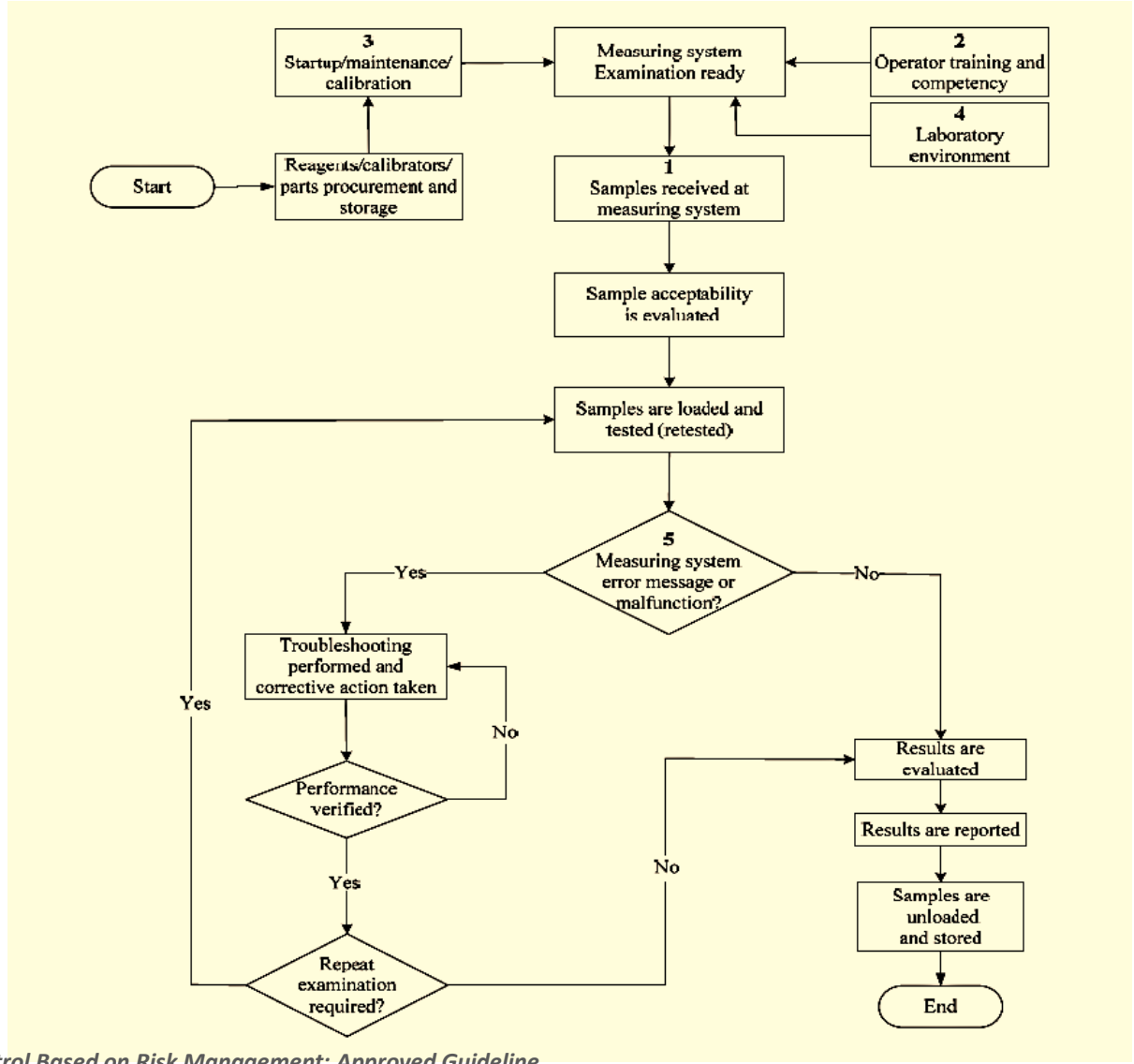
Process mapping





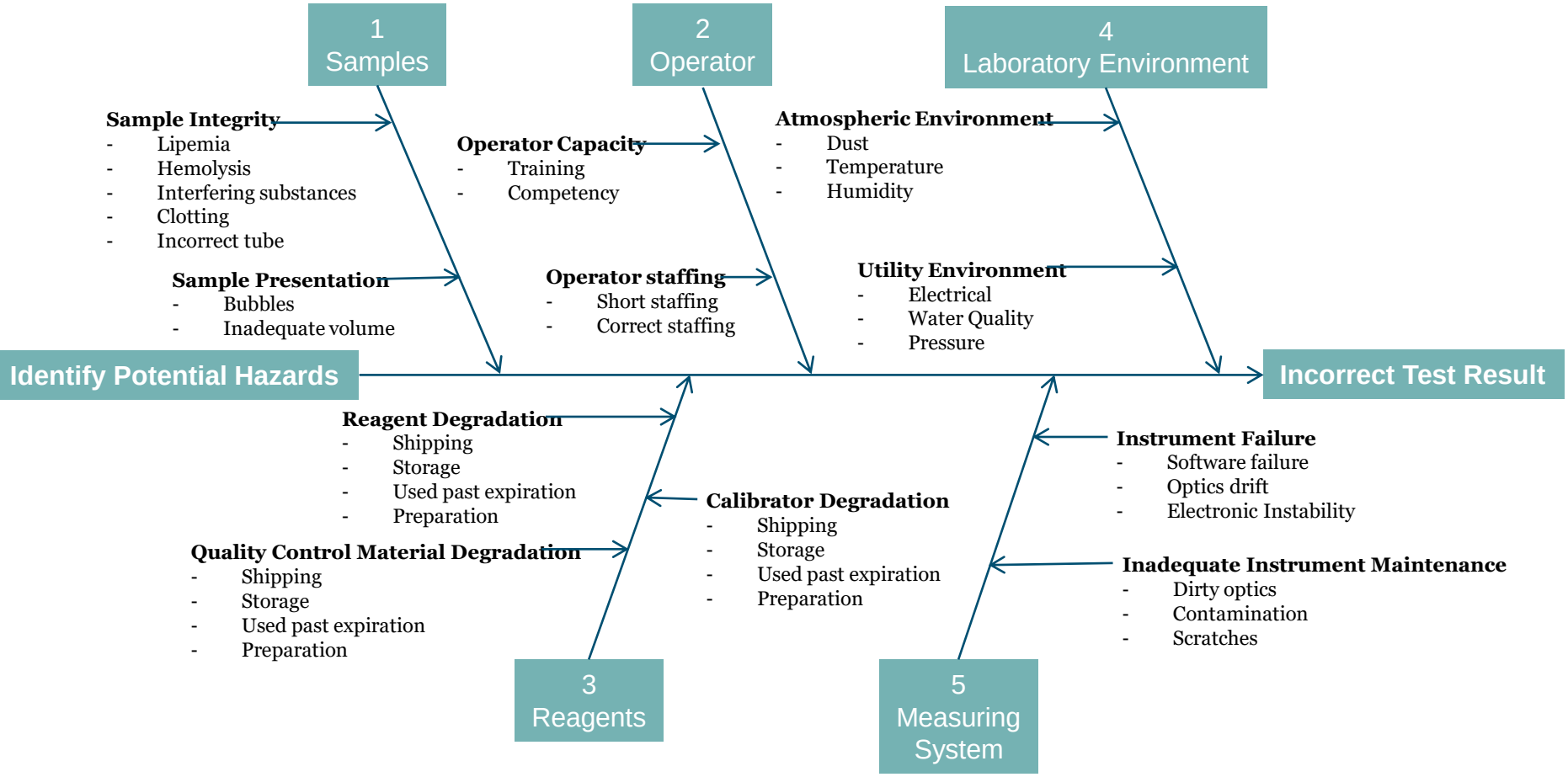
Use the right root cause analysis tool for the situation

Process Map –High Level



CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A*. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Fishbone Diagram of Potential Failure Modes



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Risk Acceptability

	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

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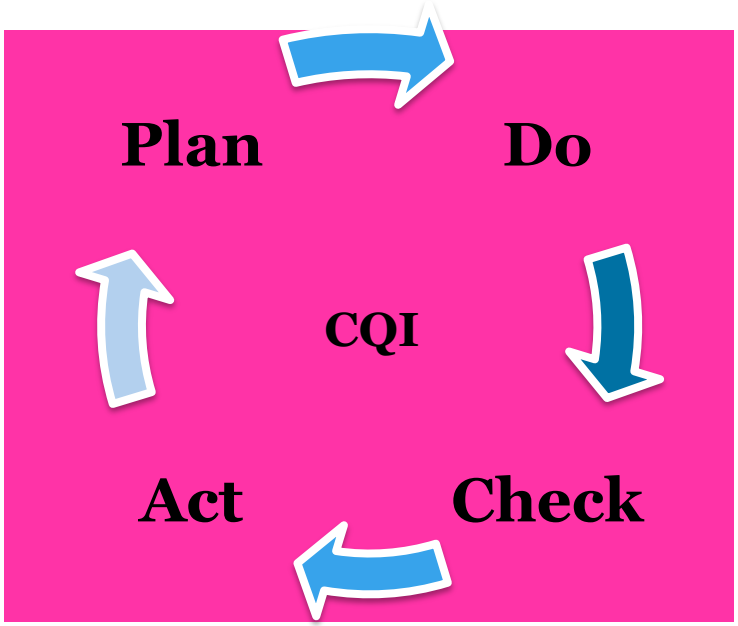
Is the IQCP effective?

- **Implement** the PLAN
- **Monitor, verify** and **improve** the PLAN, when needed
- **QA step is nothing new –** the process is required for all testing processes
  - Include in lab's overall QA plan



Plan-Do-Check-Act for Continuous Quality Improvement (CQI)

Critical Factors in QC Decisions

QC must be able to detect mistakes to enable immediate correction

Risks and costs must be weighed

QC is only one part of the quality control plan / quality management system

Not all laboratories have the same competencies and organization

Science and common sense must converge

Individualized QC Plan

Summarizes the potential errors for a device and how the lab will address them.

Can be high level or very detailed - depends on the device, the laboratory, and the clinical application and can vary from lab to lab.

Is scientifically based. It depends on the extent to which the device's features or actions achieve their intended purpose and the laboratory's expectations for ensuring quality test results.

Summary

Risk management is something laboratories are already doing..

An IQCP assesses the medical need for test, performance requirements, and weaknesses in the testing process as well as actions to address those risks.

Each IQCP is unique because the combination of device, setting, medical requirements and operators may differ between laboratories.

An IQCP is the industry standard. It depends upon the extent to which the device's features achieve their intended purpose in union with the laboratory's expectation for ensuring quality results.

Once implemented, the IQCP is monitored for effectiveness and modified as needed to maintain risk at a clinically acceptable level.

Questions?

ellisjacobs1@gmail.com