Clinical and Laboratory Standards Institute: Addressing POCT Needs; The Good, The Bad, and The Risky

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3 Rivers POCT Network
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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Today's Presentation

- Discuss who CLSI is by providing background, membership, and document information.
- Define the relationship CLSI has with the ISO, the College of American Pathologists, and The Joint Commission.
- Outline POCT growth for the past 20 years, and provide insight on POCT futures.
- Detail CLSI POCT documents and products how they can meet the many POCT needs.
- Discuss the new EP23 document on risk management

CLSI Background

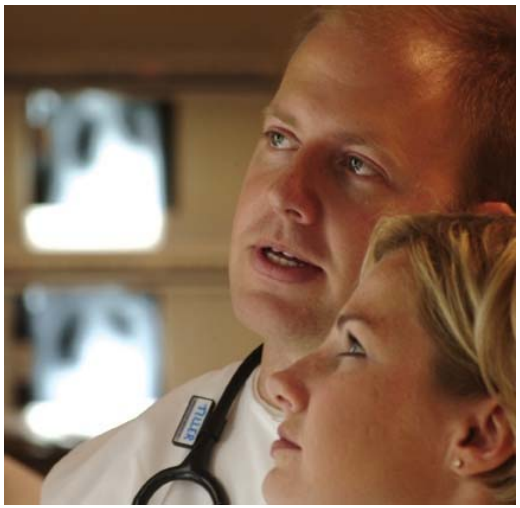
- Established in 1968
- Nonprofit corporation based in the United States
- Accredited standards developing organization
- Volunteer-driven through our governance
  - Structure and technical operations
- An organization of organizations
  - No individual memberships

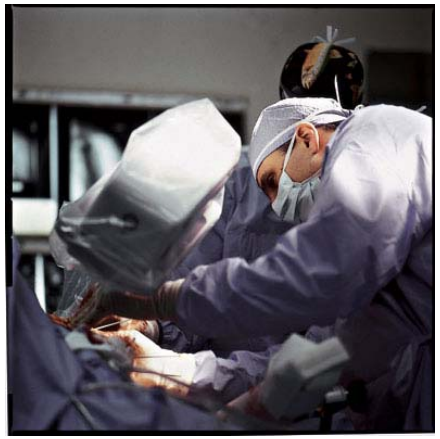
CLSI Today

- 45 employees
- 2000 member organizations
- Nearly 2300 active volunteers
- Consensus standards and guidelines
- > 75 000 documents each year distributed

Vision

To be the leader in clinical and laboratory standards to improve the **quality of medical care.**





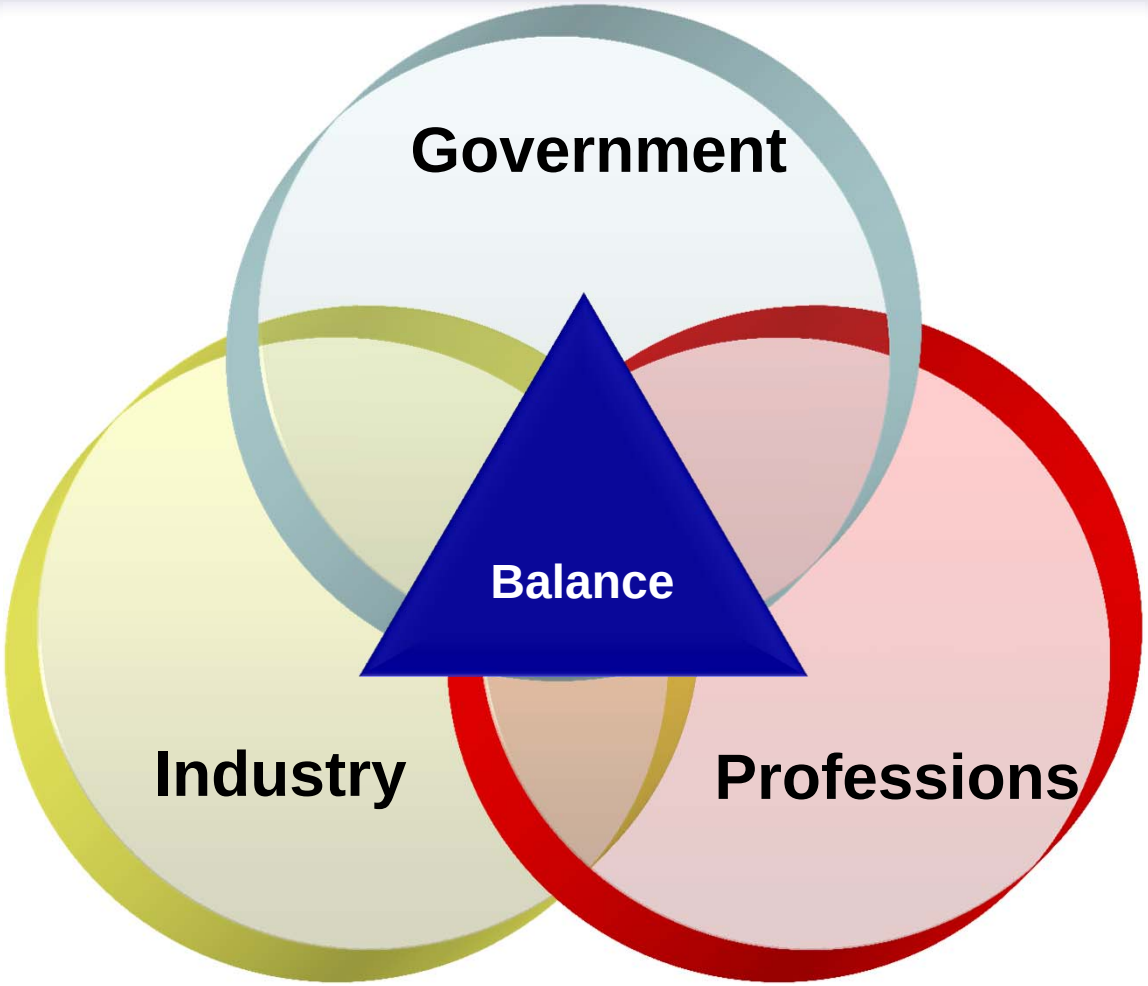
Mission

To develop best practices in clinical and laboratory testing and promote their use throughout the world, using a consensus-driven process that balances the viewpoints of industry, government, and the health care professions.





CLSI Consensus Process



CLSI Consensus Process

- Meetings are open to everyone.
- Meeting materials are fully available.
- Consensus committees contain a balance of interests.
- Conflicts of interest are fully disclosed
- An appeals process is open to any individual or organization.

Standards Development Consensus

A **consensus** standard or guideline is a document developed to promote uniform products, materials, methods, or practices.

Member Organizations

- 1615 Hospitals and Laboratories
- 121 Industry Organizations
- 106 Educational Institutions
- 43 Start-up Companies and Consultants
- 49 Government Agencies
- 35 Professional Societies

TOTAL = 1969 Organizations

CLSI Members and Volunteers

Diverse representation from three constituencies

Industry	Government	Professions
IVD Manufacturers	Public Health Agencies	Hospitals and Laboratories
LIS Vendors	Regulatory Bodies	Health care Delivery Systems
Start-up Companies	Accrediting Organizations	Educational Institutions
Suppliers	Others	Professional Societies
Trade Organizations		

Abbreviations: IVD, in vitro diagnostics; LIS, laboratory information system.

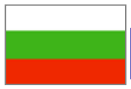
Members and Volunteers


Argentina


Australia


Belgium


Brazil


Bulgaria


Canada


France


Germany


Hong Kong


India


Iran


Israel


Italy


Japan


South Korea


Mexico


Netherlands


PR China


Saudi Arabia


South Africa


Spain


Sweden


Taiwan


Trinidad/Tobago


Turkey


United Kingdom


United States

CLSI Consensus Committees

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- Hematology
- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing
- Quality Systems and Laboratory Practices

Committee Structure

- Chairholder
- Vice-Chairholder
- Members
- Advisors
- Contributors
- Reviewers
- Staff liaison (Executive Office staff)

The Document Development Process

Project Idea → Published Document

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Two Timeline Tracks

Track 1 – 15-month timeline

Track 2 – 25-month timeline

Timeline determined by:

- Scope
- Complexity
- Comprehensiveness and depth
- Degree of controversy

CLSI Publications

Automation and Informatics	20
Clinical Chemistry and Toxicology	25
Evaluation Protocols	17
Hematology	29
Immunology and Ligand Assay	22
Microbiology	33
Point-of-Care Testing	10
Quality Systems &Laboratory Practices	31
Molecular Methods	17
Total	204

Improving the Quality of Medical Care

CLSI's Key Global Activities

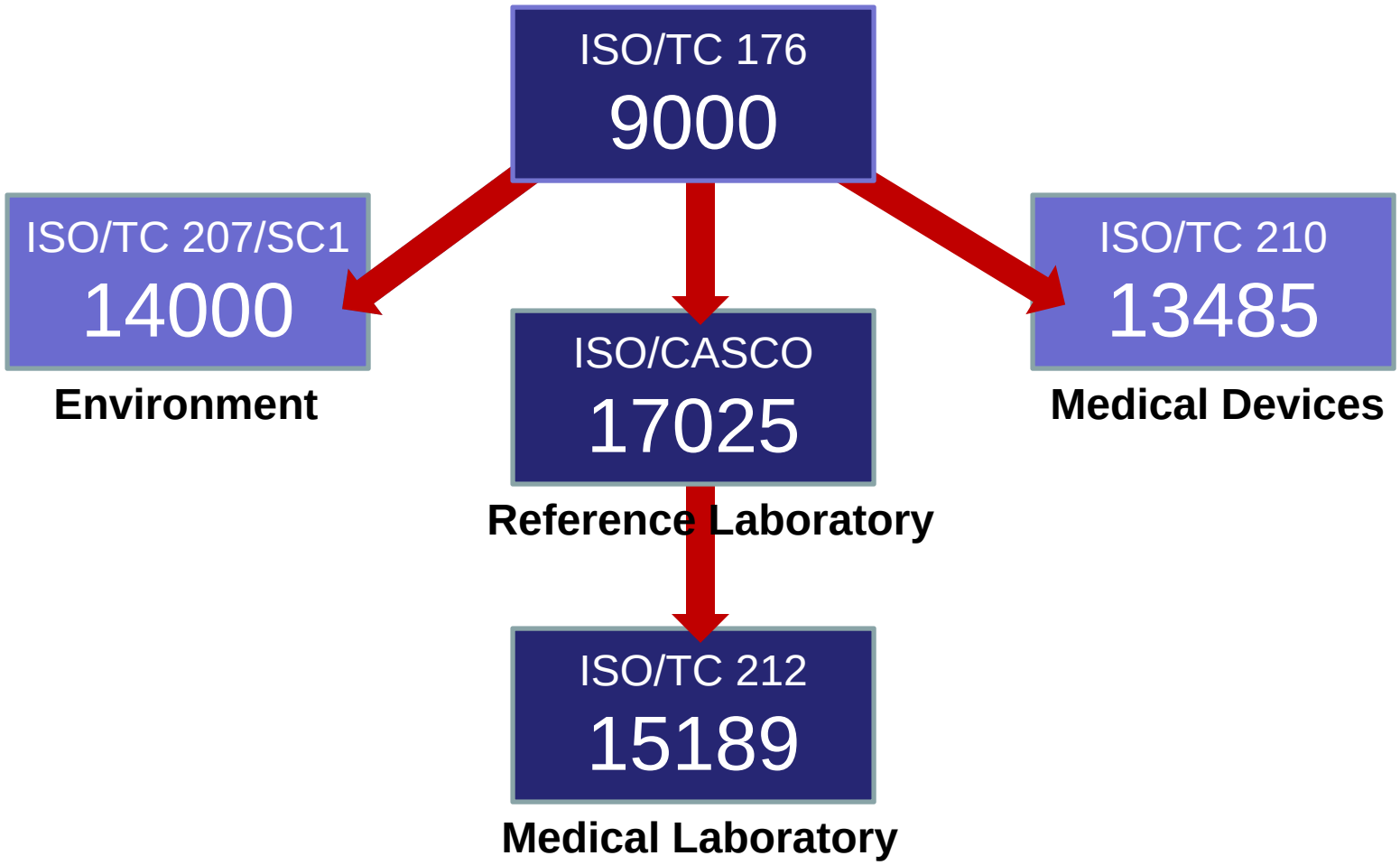
International Organization for Standardization (ISO)

- CLSI is Secretariat for ISO Technical Committee (TC) 212
  "Clinical laboratory testing and *in vitro* diagnostic test systems" and its working groups (WGs):

WG 1: Quality and competence in the medical laboratory
WG 2: Reference systems
WG 3: *In vitro* diagnostic products
WG 4: Antimicrobial susceptibility testing

- CLSI is administrator of the ANSI-Accredited US Technical Advisory Group to ISO/TC 212.

ISO Quality Management Standards



College of American Pathologists Crosswalk

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CLSI REFERENCES IN THE CAP LABORATORY ACCREDITATION PROGRAM CHECKLISTS

CLSI Document Referenced	Updated CLSI Reference	Anatomic Pathology (ANP)	Chemistry & Toxicology (CHM)	Cytogenetics (CYG)	Cytopathology (CYP)	Flow Cytometry (FLO)	Forensic Drug Testing (FDT)	Hematology & Coagulation (HEM)	Histocompatibility (HSC)	Immunology (IMM)	Laboratory General (GEN)	Limited Service Laboratory (LSV)	Microbiology (MIC)	Molecular Pathology (MOL)	Point-of-Care Testing (POC)	Reproductive Laboratory (RLM)	Team Leader Assessment (TLC)	Transfusion Medicine (TRM)	Urinalysis (URN)
Auto02-A2										✔									
Auto03-A										✔									
C03-A4										✔									
C24-A2	C24-A3	✔										✔							
C24-A3			✔				✔		✔	✔	✔	✔	✔	✔	✔	✔			
C28-A2 & P3	C28-A3		✔			✔		✔	✔	✔	✔			✔					✔
C30-A2														✔					
C34-A2			✔																
C43-A			✔			✔													
C46-A	C46-A2													✔					
C49-A										✔†									
C54-A			✔						✔								✔		✔
T/DM01-A*	Withdrawn		✔								✔								
T/DM06 A			✔																
EP05-A	EP05-A2						✔				✔								
EP05-A2			✔						✔		✔								
EP07-A2			✔						✔	✔	✔								✔
EP09-A2							✔			✔	✔								
EP10-A2	EP10-A3		✔							✔	✔	✔							
EP13-R††			✔		✔		✔	✔			✔		✔						

Based on CAP Accreditation Checklist 6/15/2009 Edition.
* Document has been archived.
† Noted, not referenced.
††Electronic only.

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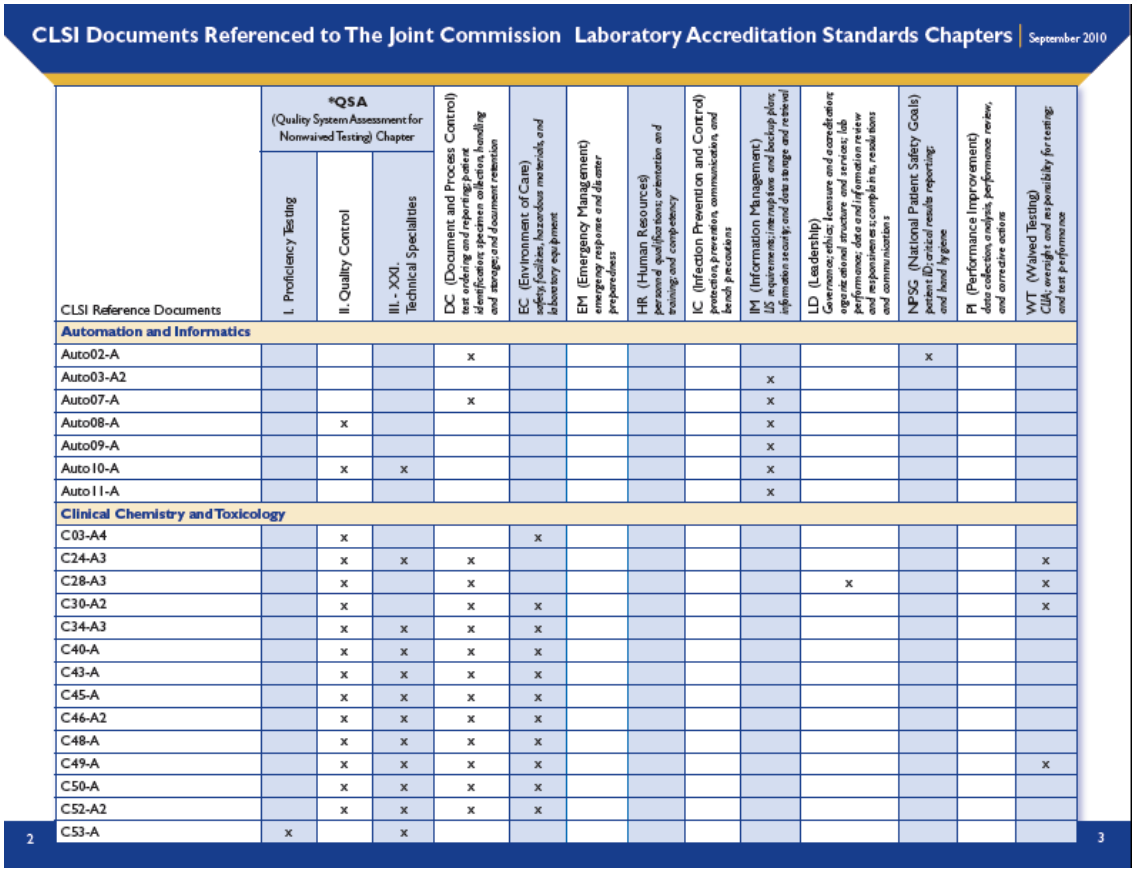
The Joint Commission Crosswalk



CLSI Documents Referenced to The Joint Commission Laboratory Accreditation Standards Chapters | September 2010

CLSI Reference Documents	*QSA (Quality System Assessment for Nonwaived Testing) Chapter			DC (Document and Process Control) *test ordering and reporting; patient identification; specimen collection, handling and storage; and document retention*	EC (Environment of Care) *safety; facilities, hazardous materials, and laboratory equipment*	EM (Emergency Management) *emergency response and disaster preparedness*	HR (Human Resources) *personnel qualifications; orientation and training; and competency*	IC (Infection Prevention and Control) *protection, prevention, communication, and bench precautions*	IM (Information Management) *LIS requirements; interruptions and backup plans; information security; and data storage and retrieval*	LD (Leadership) *Governance; ethics; licensure and accreditation; organizational structure and services; lab performance; data and information review and responsiveness; complaints, resolutions and communication*	NPSG (National Patient Safety Goals) *patient ID; critical results reporting; and hand hygiene*	PI (Performance Improvement) *data collection, analysis, performance review, and corrective actions*	WT (Waived Testing) *CLIA; oversight and responsibility for testing; and test performance*
	I. Proficiency Testing	II. Quality Control	III. - XXI. Technical Specialties										
Automation and Informatics													
Auto02-A				x							x		
Auto03-A2									x				
Auto07-A				x					x				
Auto08-A		x							x				
Auto09-A									x				
Auto10-A		x	x						x				
Auto11-A									x				
Clinical Chemistry and Toxicology													
C03-A4		x			x								
C24-A3		x	x	x									x
C28-A3		x		x						x			x
C30-A2		x		x	x								x
C34-A3		x	x	x	x								
C40-A		x	x	x	x								
C43-A		x	x	x	x								
C45-A		x	x	x	x								
C46-A2		x	x	x	x								
C48-A		x	x	x	x								
C49-A		x	x	x	x								x
C50-A		x	x	x	x								
C52-A2		x	x	x	x								
C53-A	x		x										

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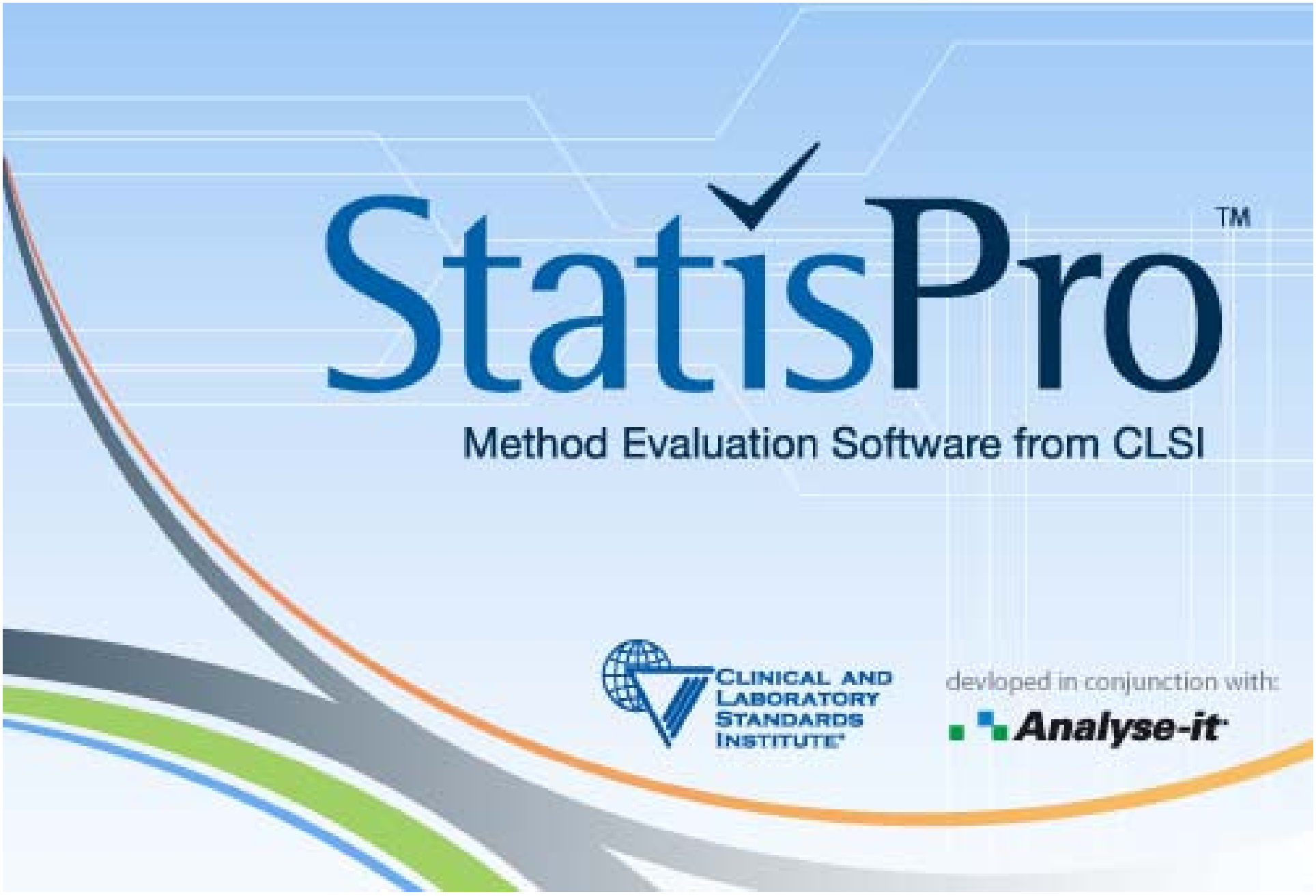

StatisPro™
Method Evaluation Software from CLSI
Clinical and Laboratory Standards Institute®
developed in conjunction with:
Analyse-it®

CLSI Guidelines in StatisPro

- **EP05** – Evaluation of Precision
- **EP06** – Evaluation of Linearity
- **EP09** – Evaluation of Bias and Comparability Using Patient Samples
- **EP10** – Preliminary Evaluation
- **EP15** – Verification of Precision and Trueness
- **EP17** – Limits of Detection and Limits of Quantitation
- **C28** – Establishment or Verification of Reference Intervals

Point-of-Care Testing

The consensus committee did not form until 2001 when the Connectivity Industry Consortium document was presented to CLSI.

Point-of-Care Testing Documents

- **AST04-A2** Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
- **C30-A2** Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition
- **C52-A2** Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline—Second Edition
- **H49-A** Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
- **HS02-A** Provider-Performed Microscopy Testing; Approved Guideline
- **HS03-A** Pulse Oximetry; Approved Guideline
- **POCT01-A2** Point-of-Care Connectivity; Approved Standard—Second Edition
- **POCT02-A** Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
- **POCT04-A2** Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline—Second Edition
- **POCT05-A** Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline
- **POCT07-A** Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline
- **POCT08-A** Quality Practices in Noninstrumented point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
- **POCT09-A** Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
- **POCT10-A** Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline – Second Edition
- **POCT11-A2** Pulse Oximetry; Approved Guideline - Second Edition

Growth 1990-2000

- Clinical Laboratory Improvement Ammendments of 1988 (CLIA ’88)
- CLSI document C30-A2: *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition*
- Reduction in turnaround times (TAT), errors, and paper
- Smaller sample size

Growth 2000-mid 2008

- Creation of more waived testing
- Handheld devices with more choices
- Data management
- Connectivity and getting results into the Electronic Medical Record
- 2007 National Academy of Clinical Biochemistry Guideline: Evidence-based Practice for POCT
- Greater acceptance of POCT

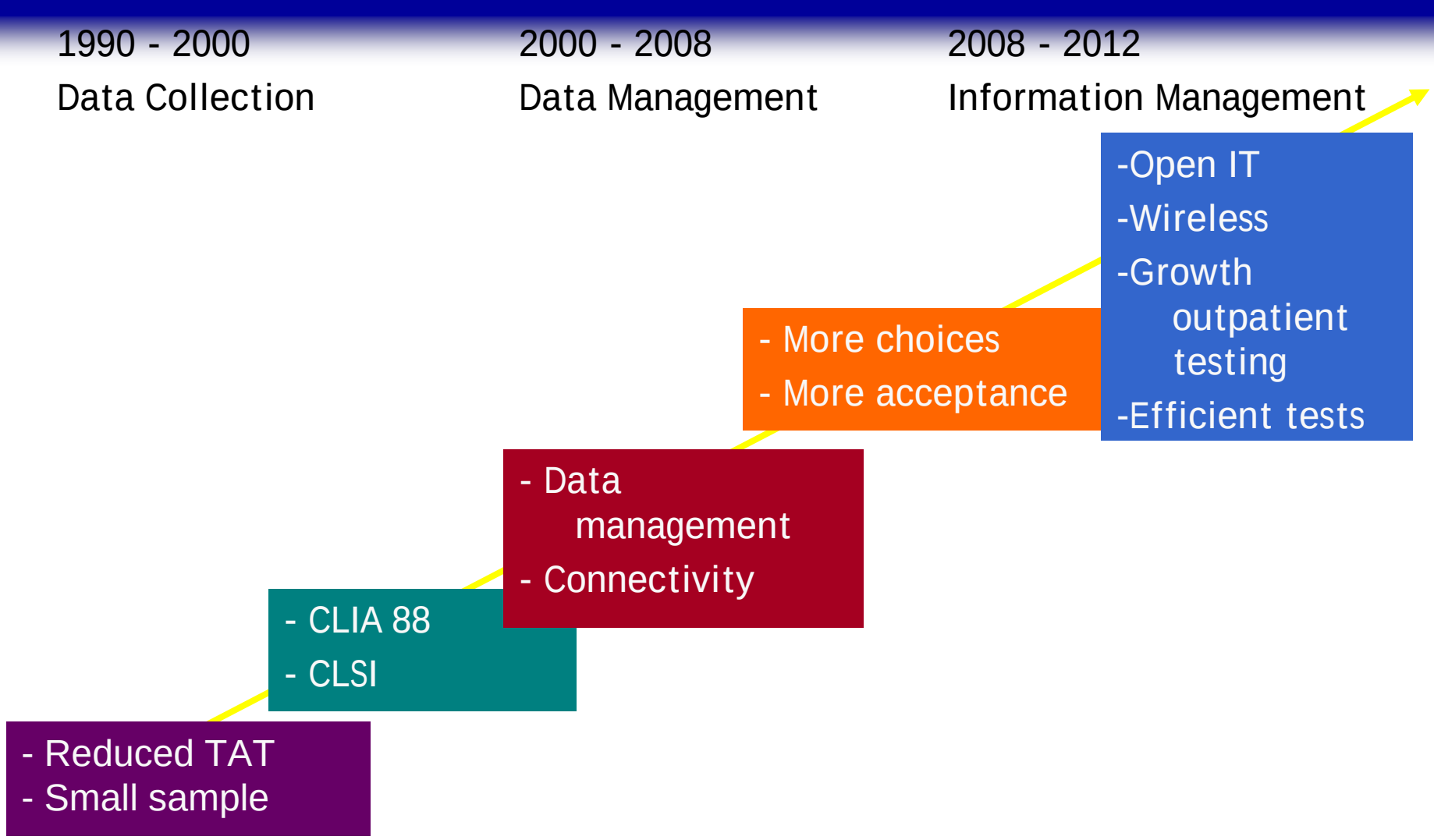
Growth mid-2008-2011

- Information technology (IT) done instantly (wirelessly)
- Open IT platforms with security systems in place
- Hospitals and vendors under extreme pressure
- Decrease in inpatient numbers

Growth for the Future

- Increase in outpatient care/Physician office laboratory (POL) market
- Growth of self care through the Internet and drug store accessibility
- Focus on efficient and cost-effective tests
- Information management as opposed to data management

Timeline


1990 - 2000
Data Collection
2000 - 2008
Data Management
2008 - 2012
Information Management
- Reduced TAT
- Small sample
- CLIA 88
- CLSI
- Data management
- Connectivity
- More choices
- More acceptance
-Open IT
-Wireless
-Growth outpatient testing
-Efficient tests

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Internal Factors

- Hospitals are more focused on critical care (eg, increase in patient age, increase in heart disease)
- Intensive insulin therapy initiatives
- Clinical effectiveness
- Workforce issues: technologist shortage
  - **12 200 new technologists needed/year but only 4000 – 6000 new graduates/year**
  - **Projected need for 710 000 technologists by 2013**

External Factors

- Significant growth in number of waived tests
- Significant growth in number of nonglucose POC tests in hospital setting
- Clarity on reimbursement (Centers for Medicare and Medicaid Services is committed to this)

External Factors

- Shifts in the IVD sector. Growth in POCT market of 10% to15%. Traditional IVD is flat.
- Disasters:
  - Emergency preparedness
  - Epidemics/pandemics
- POCT is more entrepreneurial-Big players such as Alere, Roche, and Siemens, but also many of the little players

Data Management

- Each device has its own data management capabilities.
- New devices communicate more information to existing applications.
- Wireless connectivity
- Paperless patient charts

Informatics and Middleware

- Outside vendor choices have grown.
- Large databases contain information of which other hospital areas may not be aware.
- Information sharing, Computers on Wheels
- On-demand patient outcomes and information to connect various department data

Technologies

- Minimal to noninvasive sampling
  - Transcutaneous bilirubin
  - Pulse oximetry
  - Continuous glucose monitoring
- Broader range of immunoassay tests, hematology testing, and nucleic acid-based tests (DNA/RNA) and tests for infectious diseases
- Sepsis disease markers and stroke markers
- Lab-on-a-chip

Outpatient Areas-Physician Office Laboratories

- Increase in:
  - Number of CLIA-waived licenses
  - Use of POCT devices
  - Patient satisfaction
  - Therapy adjustments
  - Time and money saved by POLs
- Health care cost controls (fewer hospital admissions by using POCT to triage patients)

Outpatient Areas-Clinics

- Disease management clinics
- Sexually transmitted disease clinics
- Coagulation clinics help with patient compliance
  - ➢Clinical efficiencies through frequent and timely laboratory measurements (eg, INR)
  - ➢Continuum of care

Outpatient Areas- Patient Self Testing

- Internet access and number of sites has increased.
  - Labtestsonline.org
  - Physician laboratories,privatemdlabs.com
- More over-the-counter drugs
  - Number of choices and information about these choices grows.
- Simpler health care solutions to the growing cost of care
  - Lack of health care insurance
  - Increasing insurance co-pays

Outpatient Areas- Patient Self-Testing (cont'd)

- Direct Access Testing
  - Certain states allow this type of testing.
  - Online laboratory kit ordering sites have grown.
  - Typically a lab draw site is within 10 miles of one's home.
  - Walgreens, Walmart, and other are taking part of this testing.

Limitations

- Cost of testing
- Analytical accuracy of POCT solutions
- Data management and the lack thereof in manual testing.
- Evidence for improved patient care outcomes

How Can You Help

- Be a champion for laboratory medicine in general.
  - http://www.clsi.org view Committees and Volunteer areas
- Get involved with a number of laboratory and legislative organizations (eg, American Society for Clinical Laboratory Science or Clinical Laboratory Management Association).
  - http://wwwn.cdc.gov/cliac/pdf/CLIAC0209.pdf
- American Association of Clinical Chemistry POC specialist certificate program
  - http://www.aacc.org/development/certification
- Get involved with teaching in nursing programs.
- Market and promote the POCT field.
  - http://aacc.org/members/divisions/cpoct/Documents/AllPosters.pdf

Certificate Program

- Regulations
- Policies and Procedures
- Connectivity and IT
- Quality Management
- Administration
- Instrument Selection and Validation
- Education and Training
- Communication

- Courses must be taken within a 12 month period.
- After completing all eight online courses, you must take a multiple choice comprehensive examination to receive your POC Specialist Certificate.

AACC
Improving healthcare through laboratory medicine

Point-of-Care Specialist Certificate

Betsy Garman

Has successfully completed the AACC Point-of-Care Specialist Certificate Program, an online education program which covers administration, communication, connectivity and information technology, education and training, instrument selection and validation, policies and procedures, quality management, and regulations associated with the practice of point-of-care testing.

Given this 29th day of October, 2008

Larry Broussard, PhD
President
AACC

Kent Lewandrowski, MD
Chair, Critical and Point-of-Care Testing
A Division of AACC

American Association of Clinical Chemistry, 1850 K Street NW Suite 625, Washington DC 20006, (202) 857-0717

Point-of-Care Testing Documents

- **POCT07-A** Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline
- **POCT08-A** Quality Practices in Noninstrumented point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
- **POCT09-A** Selection Criteria for Point-of-Care Testing Devices; Approved Guideline

Future Documents

- **POCT06-A** Guidelines on the Impact on Glucose Measurements When Different Sample Types are Used; Approved Guideline
- **POCT12-A3** Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline - Third Edition
- **POCT13-A3** Point-of-Care Glucose without Laboratory Support; Approved Guideline - Third Edition

Companion Products

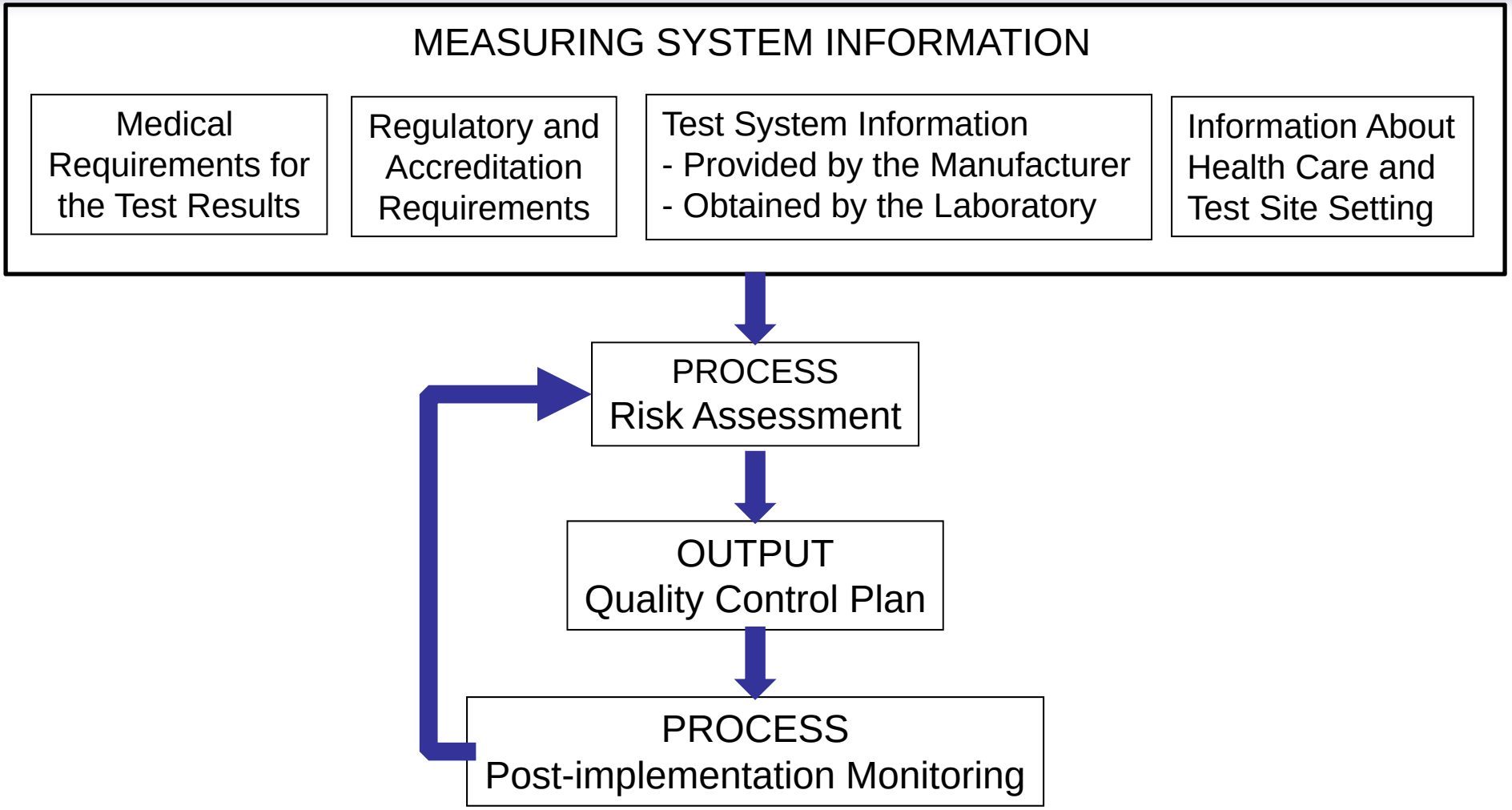
- Addressing Errors in Point-of-Care Testing Reference Guide
- Instrument Selection Worksheet
- Quality Control Troubleshooting Flow Chart
- Corrective Action Report Quick Guide
- Quality Control Log Sheet Quick Guide
- Nasal Smears for Inflammatory Cells Quick Guide
- Proficiency Testing Exception Response Form Quick Guide
- Urine Sediment Examinations Quick Guide
- Wet Mount Preparations and KOH Preparations Quick Guide

EP23

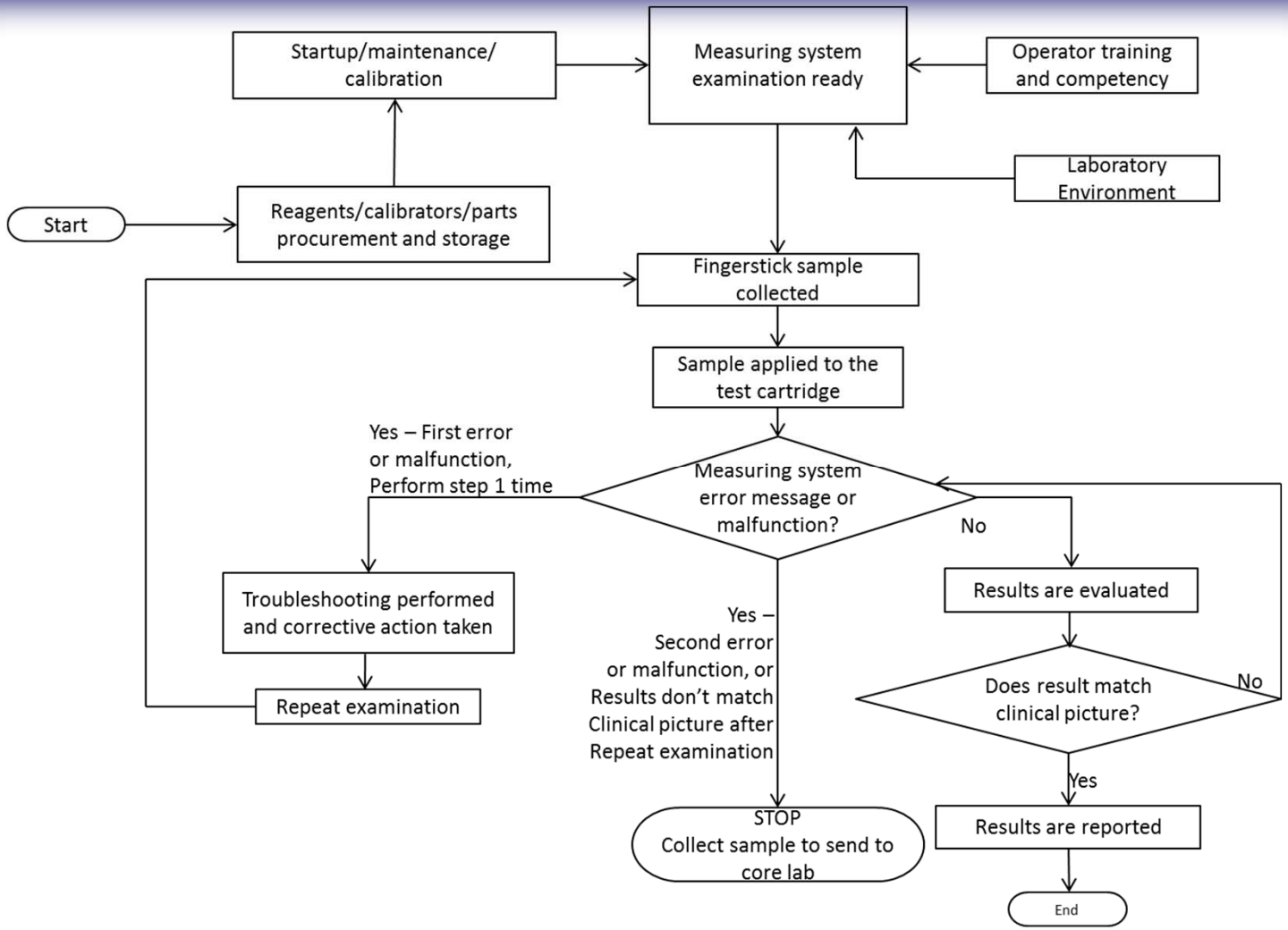
Laboratory Quality Control Based on Risk Management; Approved Guideline

- Provides guidance for laboratories to develop a customized quality control (QC) plan based on risk management.
- Assists laboratories by describing the multiple factors that must be considered when developing laboratory-specific QC protocols.

Developing a Quality Control Plan



Process Map

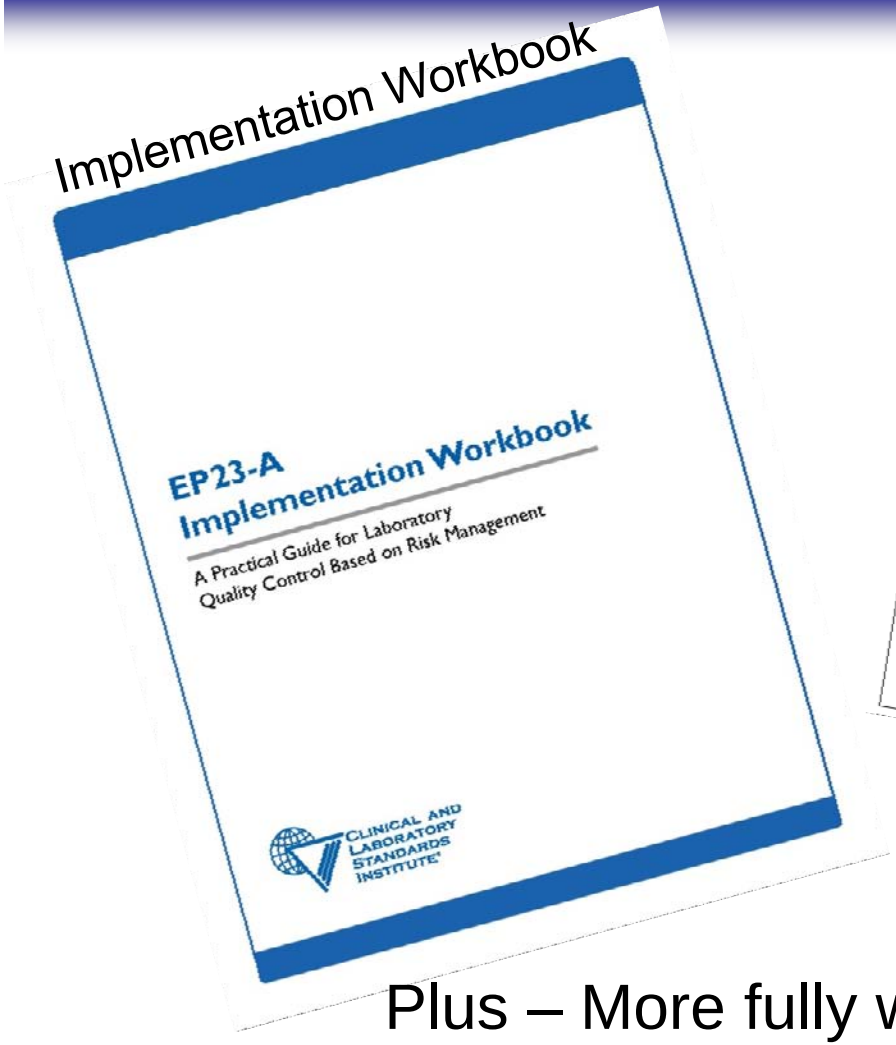

Startup/maintenance/ calibration
Measuring system examination ready
Operator training and competency
Laboratory Environment
Start
Reagents/calibrators/parts procurement and storage
Fingerstick sample collected
Sample applied to the test cartridge
Yes – First error or malfunction, Perform step 1 time
Measuring system error message or malfunction?
No
Troubleshooting performed and corrective action taken
Repeat examination
Yes – Second error or malfunction, or Results don't match Clinical picture after Repeat examination
Results are evaluated
Does result match clinical picture?
No
Yes
STOP Collect sample to send to core lab
Results are reported
End

Risk Acceptability Matrix

	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	Unacceptable	Unacceptable	Unacceptable
Remote	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Unacceptable

EP23 Companion Products

Implementation Workbook



Risk Assessment Worksheet

Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Frequency (1 - 5 scale)	Severity (1 - 5 scale)	Detectability (1 - 5 scale)	Criticality (Frequency X severity X detectability)	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
Manner in which the test system could fail or error could occur.	*Are there manufacturer control processes, checks or recommended actions to reduce or detect failure?*	*What are the known limitations to the control processes or recommended actions?*	*What is the frequency of failure?*	*How severe is impact of failure on patient?*	*Does the control process detect or prevent the failure? Low = 1 control can detect failure High = 5 control ineffective*	*A measure of laboratory risk and priority for laboratory to address failure mode Low <10 Mid= 10 - 20 High >20*	*The laboratory's assessment of residual risk with all manufacturer, external, and other control processes implemented.*	*The action required to address residual risk to include as an element of the QCP.*	*The laboratory's assessment of clinical acceptability of residual risk.*
Lipemia	No internal, manufacturer, or other control process available	Manufacturer verbally states that there is no interference from lipemia. Measurement system is not optical Not stated in operator's manual or test cartridge package insert	5 Lipemic samples occur more than one a week	1 Measurement system not affected by lipemia	1 Measurement system not affected by lipemia	5 Low risk and priority	If laboratory agrees with manufacturer- no further action If laboratory concerned or doubts information, can conduct own lipemia studies	No action required Conduct lipemia study	Yes Yes after lipemia study
Reagent degradation during shipping	No internal or manufacturer control process available	Use external QC to detect cartridge deterioration during shipping	4 New shipments arrive every 2 months	5 Compromised reagent can impact patient, wrong PT/INR results can lead to coumadin overdosing or underdosing	1 External QC will detect compromised reagent before patient testing	20 Moderate risk and priority for laboratory to address	External QC will detect compromised reagent before patient testing Laboratory should ensure QC visibility and appropriate ranges set before use	Evaluate each shipment of reagent before use for patient testing	Yes

Plus – More fully worked examples coming soon