Clinical and Laboratory Standards Institute

David Sterry, MT(ASCP)
Director, Standards, CLSI

KEYPOCC Meeting
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June 15, 2012

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Our Common Goal: Quality Health Care

Today's Presentation

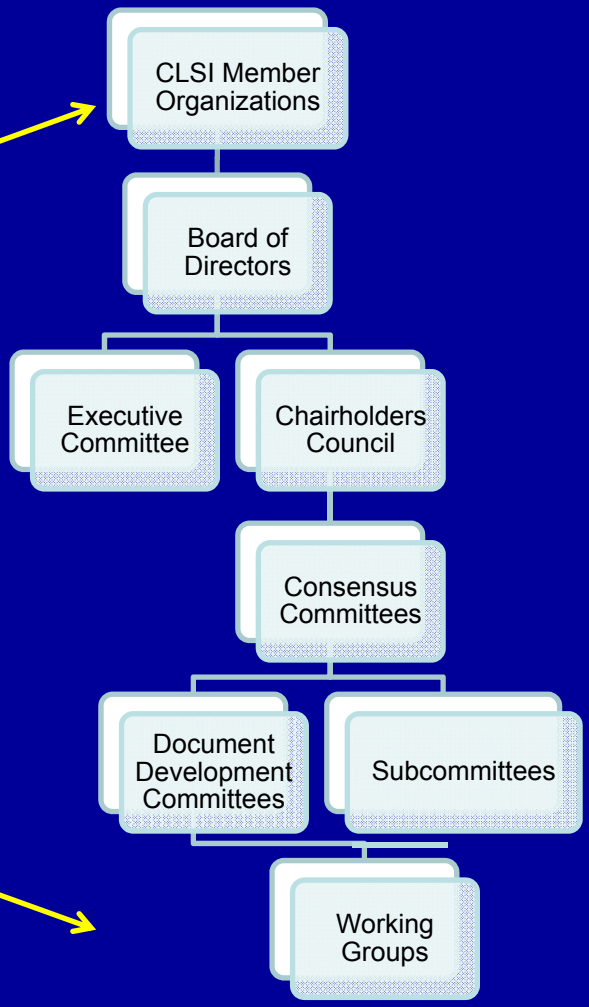
- CLSI background information
- Membership and volunteers
- Document development process
- Crosswalks with the College of American Pathologists (CAP) and The Joint Commission
- Quality management systems
- Point-of-care testing (POCT) documents and companion products
- POCT10-A2—Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition

CLSI Background

- Established in 1968
- Nonprofit corporation based in the United States
- Accredited standards-developing organization
- An organization of organizations
  - (no individual memberships)

CLSI Organizational Chart

2000 member organizations; no individual memberships



70 active projects at a time

ANSI* accredited

2300 active volunteers

75 000 documents distributed per year

CLSI staff (45 employees)

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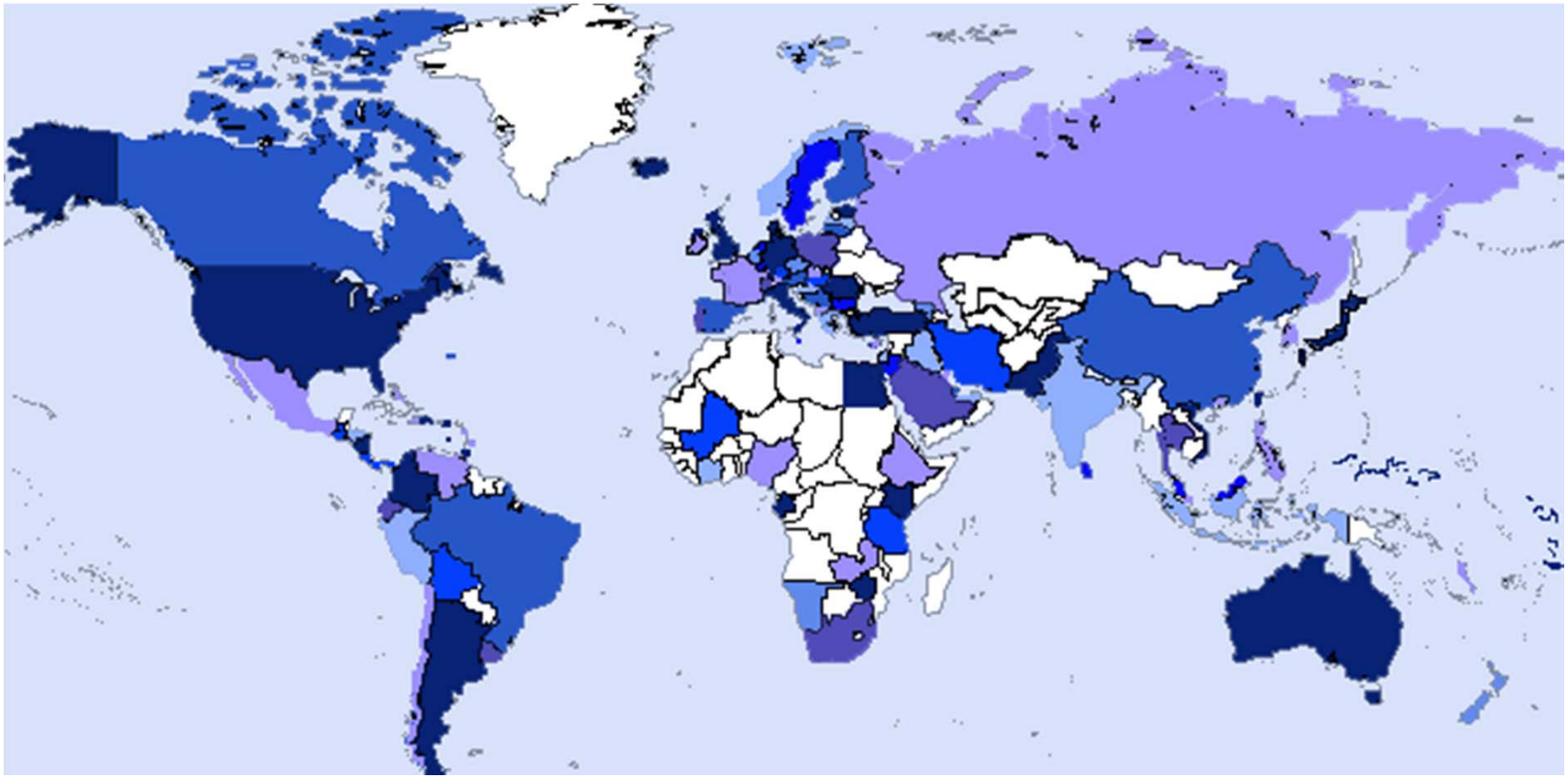
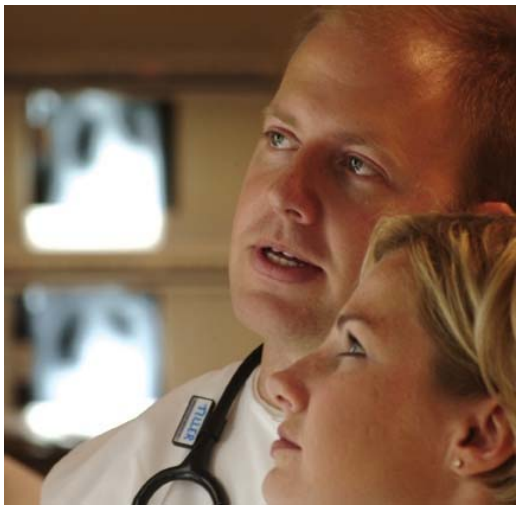
*American National Standards Institute

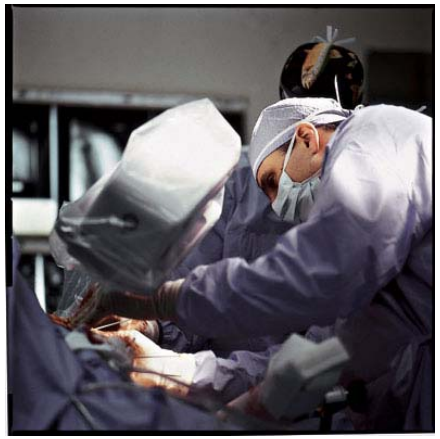
CLSI Recognized Worldwide



Vision

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





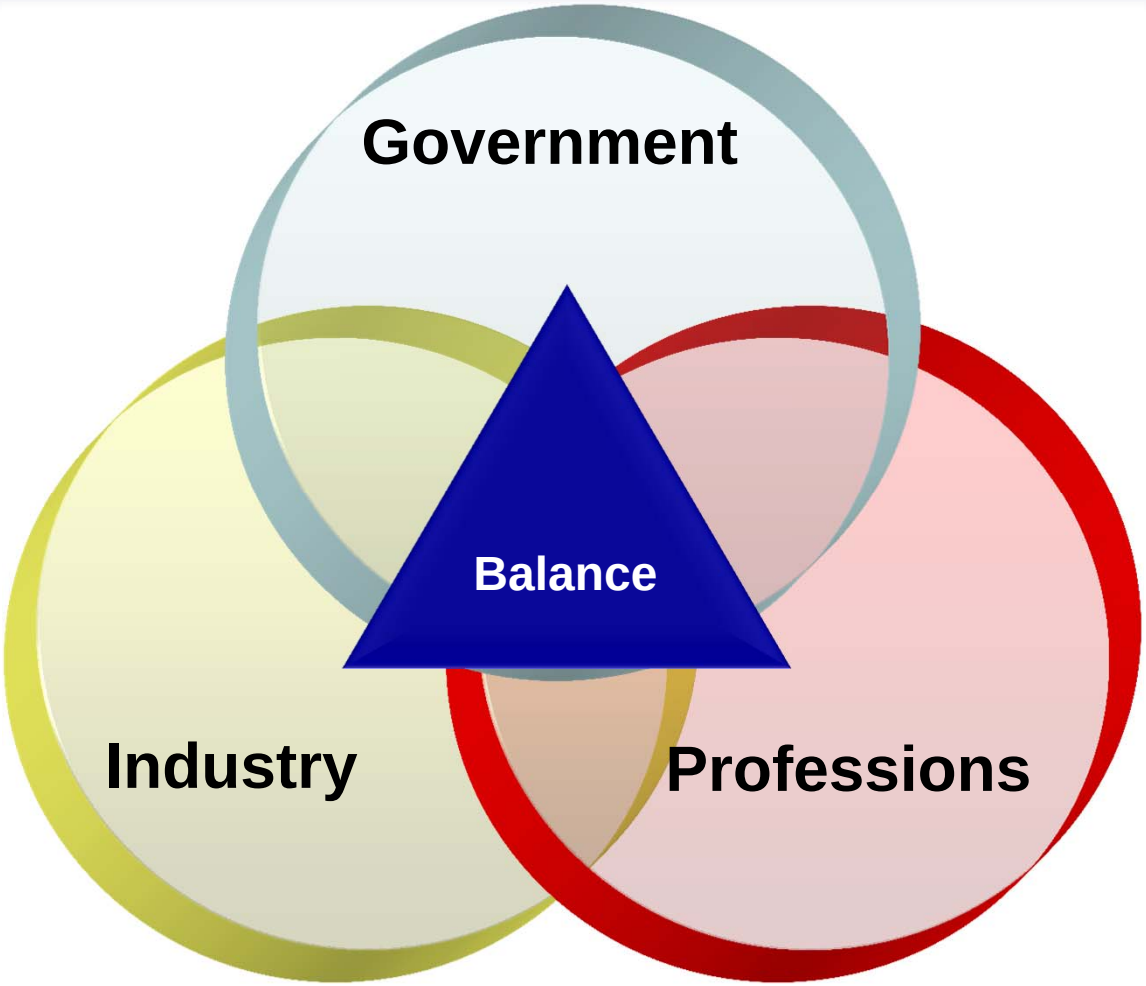
Mission

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

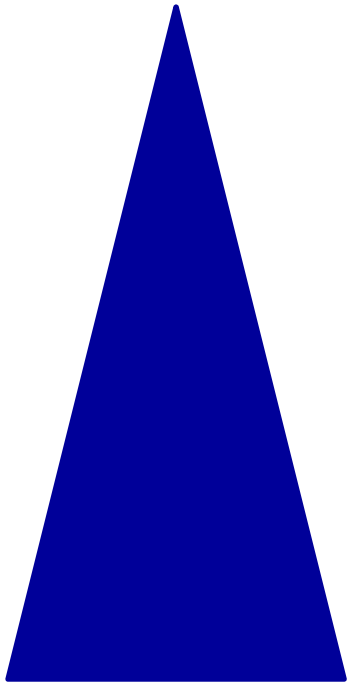


CLSI Consensus Process

- Meetings are open to everyone.
- Meeting materials are available to participants and interested parties.
- A balance of interests is maintained.
- Conflicts of interest are fully disclosed.
- An appeals process exists to address issues or concerns.

Standardization in the Medical Laboratory

the right laboratory test
at the right time with
the right result leads to
quality diagnostics,
improved patient care, and
improved public health
around the world



Standardized test

↓

Standardized procedure

↓

Standardized reporting

↓

Improved outcomes

CLSI Products

- Standards
- Guidelines
- Reports
- Companion Products
  - –Quick Guides
  - –Toolkits
  - –Specialty Collections
  - –DVDs
  - –Software

Standards and the Laboratory

- Most medical laboratory errors are caused by systems and process issues, not people.

- These are the areas where standards can help the most.

Standards Development Consensus

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

Membership and Volunteers

Over 600 non–North American members and volunteers from over 70 countries, and growing

CLSI Members and Volunteers

Diverse representation from three constituencies

Industry	Government	Professions
*In vitro d*iagnostics manufacturers	Public health agencies	Hospitals and laboratories
Laboratory information systems vendors	Regulatory bodies	Health care delivery systems
Startup companies	Accrediting organizations	Educational institutions
Suppliers		Professional societies
Trade organizations		

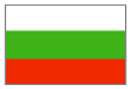
Members and Volunteers


Argentina


Australia


Belgium


Brazil


Bulgaria


Canada


France


Germany


Hong Kong


India


Iran


Israel


Italy


Japan


Korea


Mexico


Netherlands


PR China


Russia


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
- Project Manager/Staff Liaison (Executive Offices' staff)

The Document Development Process

Project Idea → Published Document

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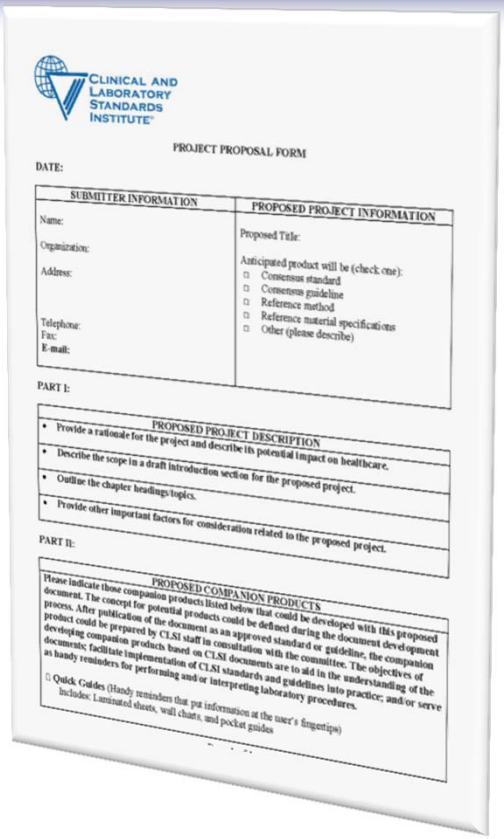
Idea → Document Project

- Identified need/project idea
- Project proposal developed
- Assessment/endorsement by consensus committee
- Call for volunteers
- Document development committee (DDC) membership established
- Business plan developed
- Presentation to Chairholders Council
- Project authorization



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PROJECT PROPOSAL FORM

DATE:

SUBMITTER INFORMATION	PROPOSED PROJECT INFORMATION
Name: Organization: Address: Telephone: Fax: E-mail:	Proposed Title: Anticipated product will be (check one): ☐ Consensus standard ☐ Consensus guideline ☐ Reference method ☐ Reference material specifications ☐ Other (please describe)

PART I:

PROPOSED PROJECT DESCRIPTION
• Provide a rationale for the project and describe its potential impact on healthcare.
• Describe the scope in a draft introduction section for the proposed project.
• Outline the chapter headings/topics.
• Provide other important factors for consideration related to the proposed project.

PART II:

PROPOSED COMPANION PRODUCTS
Please indicate those companion products listed below that could be developed with this proposed document. The concept for potential products could be defined during the document development process. After publication of the document as an approved standard or guideline, the companion product could be prepared by CLSI staff in consultation with the committee. The objectives of developing companion products based on CLSI documents are to aid in the understanding of the documents; facilitate implementation of CLSI standards and guidelines into practice; and/or serve as handy reminders for performing and/or interpreting laboratory procedures. ☐ Quick Guides (Handy reminders that put information at the user's fingertips) Includes: Laminated sheets, wall charts, and pocket guides

Document Development Process

- The document development process begins with the inaugural webinar for the DDC.
- Refine expanded outline.
- Introduce draft text to support scope and outline points.
- Prepare text for submission as a preliminary draft document.

Five Voting Stages

- **Voting Stage 1:** Draft 1 for document development committee approval

- **Voting Stage 2:** Draft 2 for approval by delegates; review and comment by consensus committee, board of directors, and nonmembers
  - Replaces proposed-level documents, which are no longer published
  - Provided to member organizations at no cost

Five Voting Stages (cont'd)

- **Voting Stage 3:** Draft 3 for document development committee approval
- **Voting Stage 4:** Draft 4 for review and approval by consensus committee
- **Voting Stage 5:** Final Draft for consensus committee approval to publish

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 – Approved Level

Automation	21
Clinical Chemistry	24
Evaluation Protocols	17
Hematology	29
Immunology	26
Microbiology	42
Point-of-Care Testing	8
Quality Systems	38
Molecular Methods	16
Total	221

Document Review Schedule

Within five years after its approval, the appropriate consensus committee(s) initiates a review to determine the necessary action to reaffirm, revise, archive, or withdraw an approved consensus document.

Crosswalks with CAP and The Joint Commission

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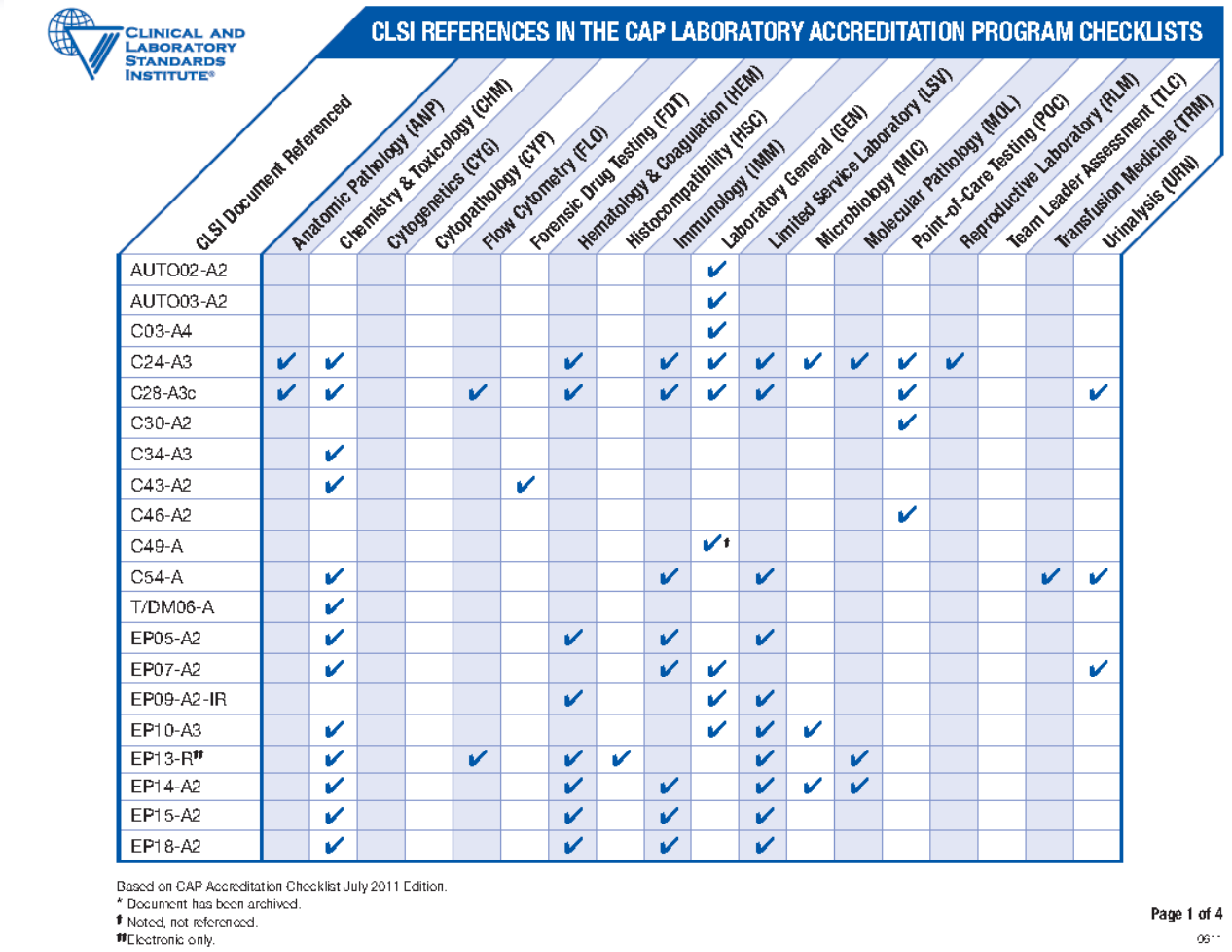
Adoption of Documents Into Accreditation Crosswalk



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CLSI REFERENCES IN THE CAP LABORATORY ACCREDITATION PROGRAM CHECKLISTS

CLSI Document Referenced	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-A2										✔								
C03-A4										✔								
C24-A3	✔	✔					✔		✔	✔	✔	✔	✔	✔	✔			
C28-A3c	✔	✔			✔		✔		✔	✔	✔			✔				✔
C30-A2														✔				
C34-A3		✔																
C43-A2		✔				✔												
C46-A2														✔				
C49-A										✔†								
C54-A		✔							✔		✔						✔	✔
T/DM06-A		✔																
EP05-A2		✔					✔		✔		✔							
EP07-A2		✔							✔	✔								✔
EP09-A2-IR							✔			✔	✔							
EP10-A3		✔								✔	✔	✔						
EP13-R††		✔			✔		✔	✔			✔		✔					
EP14-A2		✔					✔		✔		✔	✔	✔					
EP15-A2		✔					✔		✔		✔							
EP18-A2		✔					✔		✔		✔							

Based on CAP Accreditation Checklist July 2011 Edition.
* Document has been archived.
† Noted, not referenced.
†† Electronic only.

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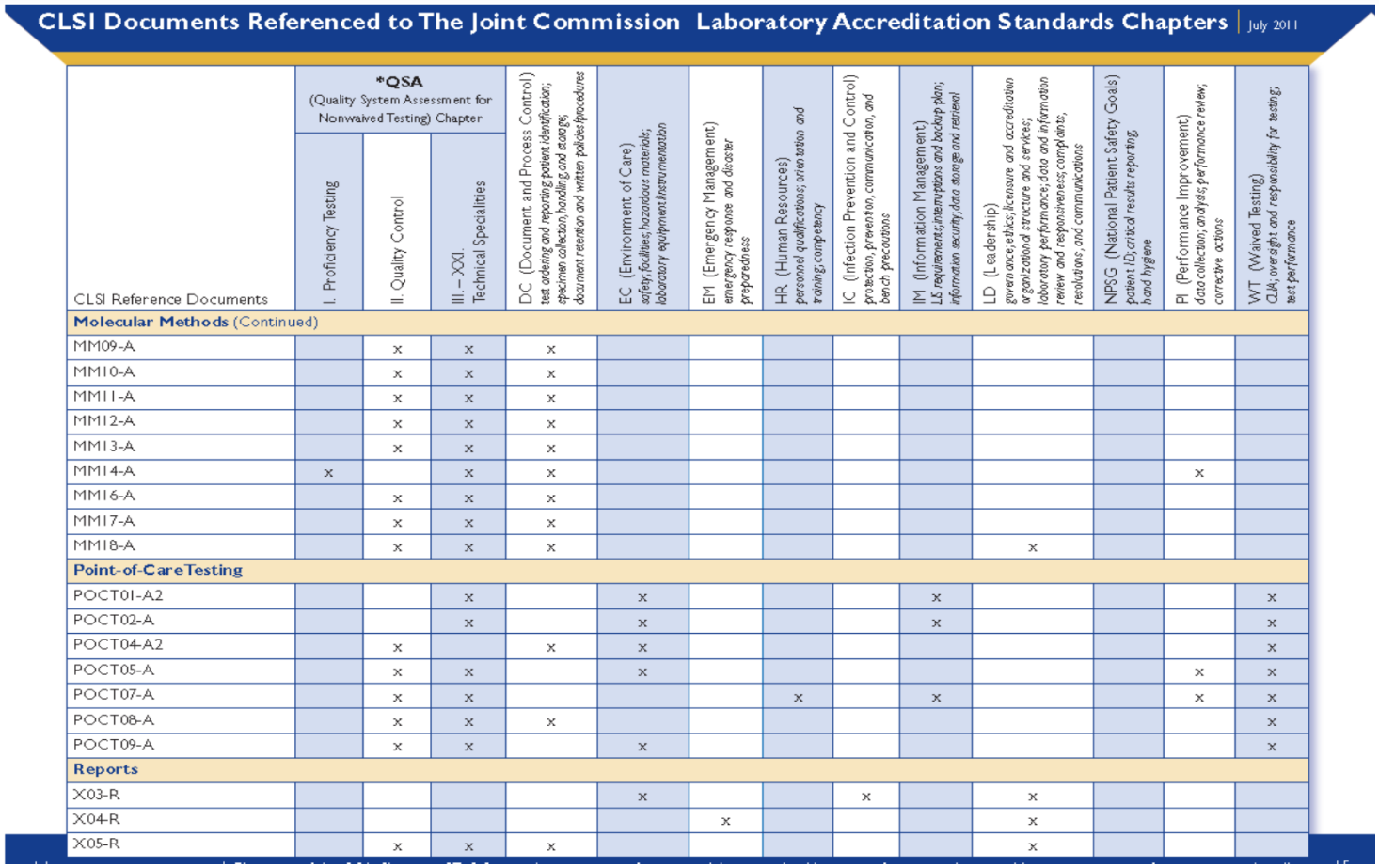
CLSI Documents Referenced to The Joint Commission



CLSI Documents Referenced to The Joint Commission Laboratory Accreditation Standards Chapters | July 2011

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; document retention and written policies/procedures*	EC (Environment of Care) *safety; facilities; hazardous materials; laboratory equipment/instrumentation*	EM (Emergency Management) *emergency response and disaster preparedness*	HR (Human Resources) *personnel qualifications; orientation and training; competency*	IC (Infection Prevention and Control) *protection, prevention, communication, and bench precautions*	IM (Information Management) *LIS requirements; interruptions and backup plan; information security; data storage and retrieval*	LD (Leadership) *governance; ethics; licensure and accreditation organizational structure and services; laboratory performance; data and information review and responsiveness; complaints, resolutions; and communications*	NPSG (National Patient Safety Goals) *patient ID; critical results reporting; hand hygiene*	PI (Performance Improvement) *data collection; analysis; performance review; corrective actions*	WT (Waived Testing) *CLIA; oversight and responsibility for testing; test performance*
	I. Proficiency Testing	II. Quality Control	III. – XXI. Technical Specialties										
Molecular Methods (Continued)													
MM09-A		x	x	x									
MM10-A		x	x	x									
MM11-A		x	x	x									
MM12-A		x	x	x									
MM13-A		x	x	x									
MM14-A	x		x	x								x	
MM16-A		x	x	x									
MM17-A		x	x	x									
MM18-A		x	x	x						x			
Point-of-Care Testing													
POCT01-A2			x		x				x				x
POCT02-A			x		x				x				x
POCT04-A2		x		x	x								x
POCT05-A		x	x		x							x	x
POCT07-A		x	x				x		x			x	x
POCT08-A		x	x	x									x
POCT09-A		x	x		x								x
Reports													
X03-R					x			x		x			
X04-R						x				x			
X05-R		x	x	x						x			

Quality Management Systems

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Quality Management System

The Quality Management System (QMS) provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.

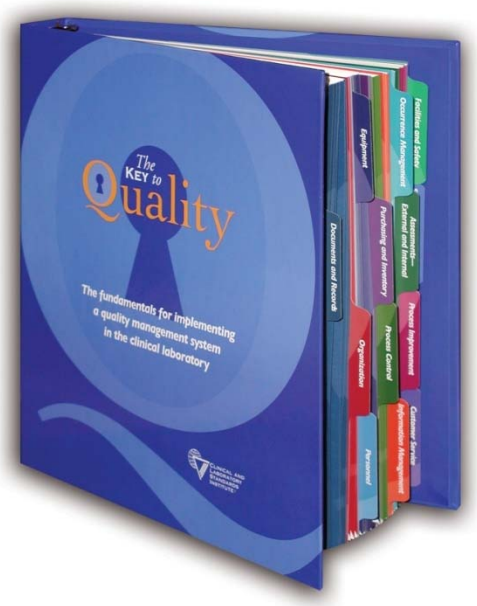
Quality Systems and the Laboratory

Principles of high-quality laboratory testing are the same anywhere in the world.

It is one area of health care that can be, and should be, highly standardized.

CLSI and the Quality Management System

CLSI produces globally recognized QMS guidelines.



- GP26-A4—*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*
- "The Key to Quality"

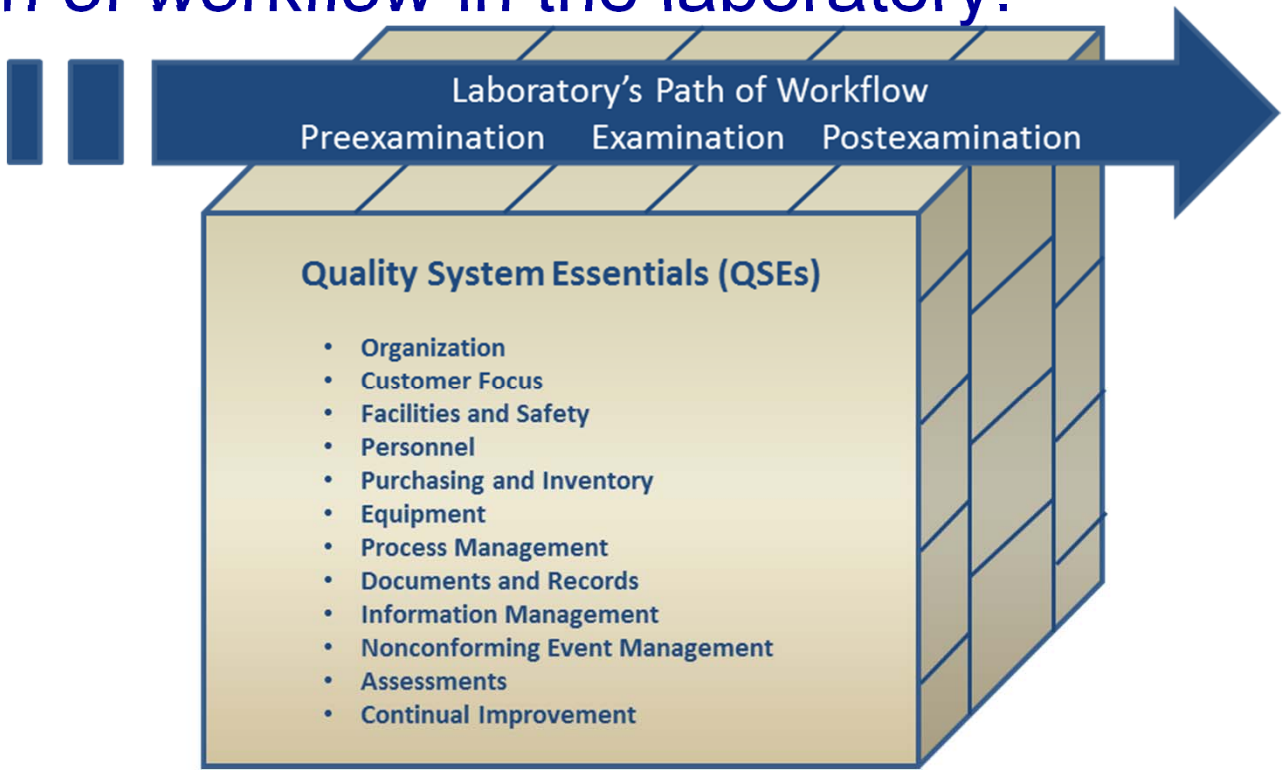
Quality Systems Models

There are two major models for QMS used globally.

ISO: 15189	CLSI: GP26-A4
• Broad-based • Overarching standards • 15 management requirements • Eight technical requirements	• Specific • Practical implementation guidelines • 12 quality systems essentials
Both are built on the same concepts, but differ in the amount of specificity described. ISO is broader and CLSI is more specific. ISO = what to do; CLSI = how to do it	

Quality Management System

QMS is a simple, systematic approach of organizing all key work processes around the path of workflow in the laboratory.



Global Momentum Toward QMS Adoption

40+ countries have implemented, or are in some stages of national adoption, of the QMS model approach to their laboratory services.

The World Health Organization has fully adopted the QMS approach on a global basis and is in the process of education and training.

In the United States, the Centers for Medicare & Medicaid Services is encouraging laboratories to adopt a QMS approach to laboratory licensure and accreditation.

POCT Documents and Companion Products

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Why is Point-of-Care Testing Important?

- Point-of-care testing (POCT) includes patient self testing, physician office laboratories, and hospital-based testing.
- Estimated revenues of approximately $3 billion (USD), excluding non-IVD applications and whole blood glucose testing
- Overall IVD market growth 6 to 7% per year
- POCT market growth 10 to12% per year
- Numerous new technologies and applications entering POCT (eg, molecular methods, MRSA)

IVD Market R. Sutherland, Jan 2010

Point-of-Care Testing Guidelines

- AST04-A2—*Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition* (under revision; will be published as POCT13)
- C30-A2—*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition* (under revision; will be published as POCT12)
- H49-A—*Point-of-Care Monitoring of Anticoagulation Therapy; 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 Testing; Approved Guideline—Second Edition* (under revision)

Point-of-Care Testing Guidelines

- 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-A2—*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*

Guidelines in Development

- POCT06—*Guidelines on the Impact on Glucose Measurement When Different Sample Types Are Used*
- POCT14—*Point-of-Care Testing for Infectious Disease*
- POCT15—*Emergency and Disaster Point-of-Care Testing*

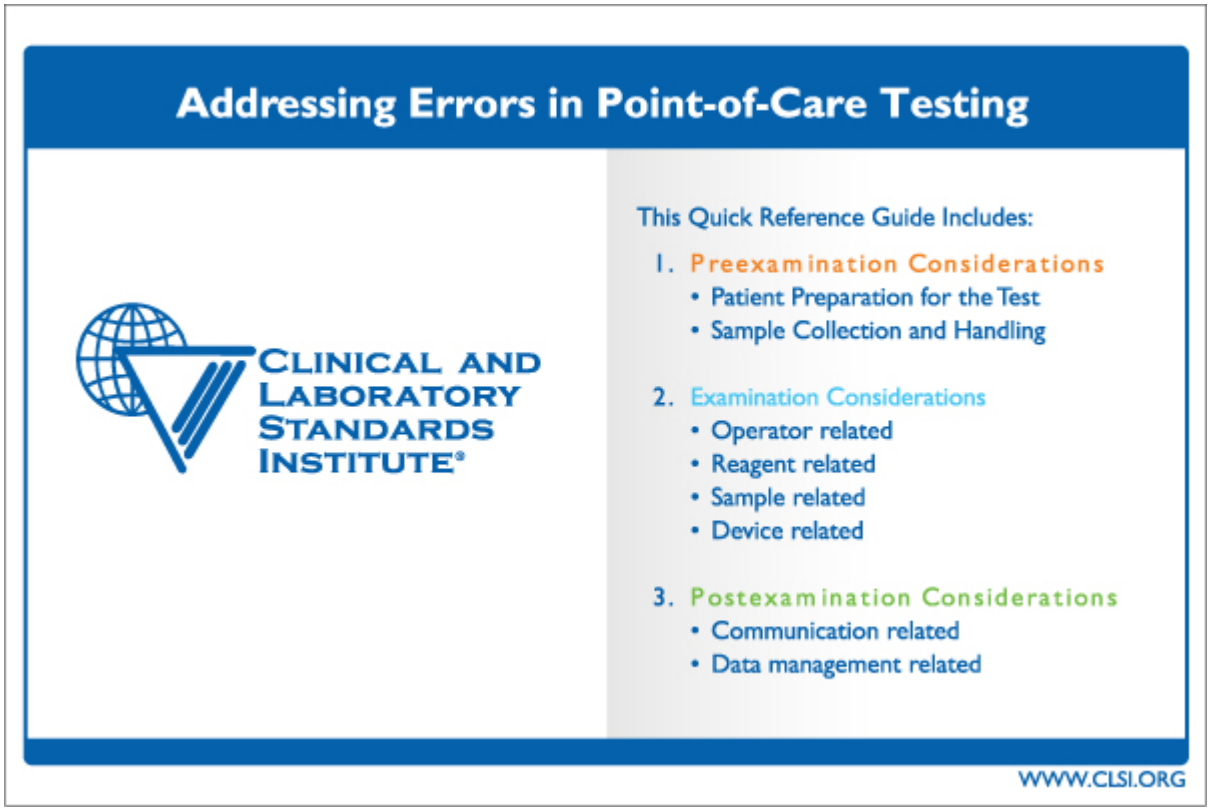
Potential Projects

- Noninvasive monitoring
- Oral POCT
- Cost and advantages of POCT vs testing in main laboratory (a report)

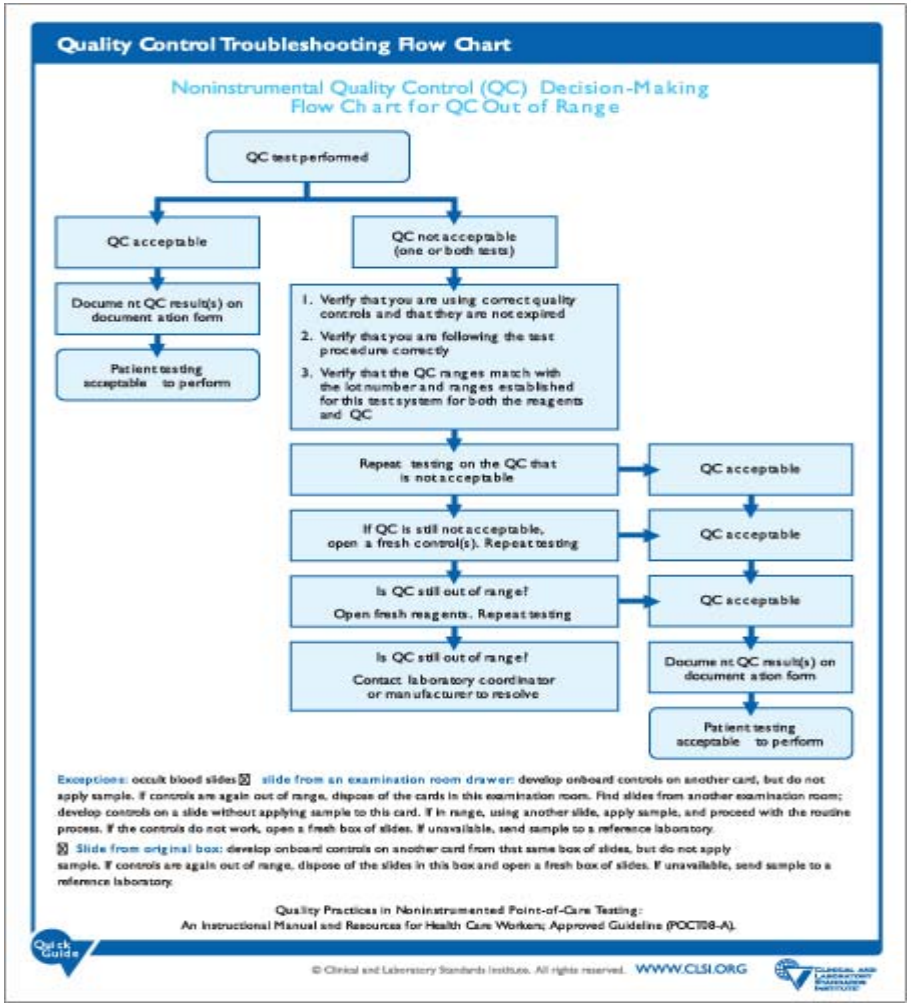
Companion Products for POCT Documents

- POCT07—Addressing errors in point-of-care testing (reference guide)
- POCT08—Quality control troubleshooting (flow chart)
- POCT08—Corrective action report (quick guide)
- POCT08—Quality control log sheet (quick guide)
- POCT09—Instrument selection (worksheet)
  - Clinical needs assessment
  - Testing system specifications

POCT07 Companion Product



POCT08 Companion Product



Quality Control Troubleshooting Flow Chart

Noninstrumental Quality Control (QC) Decision-Making Flow Chart for QC Out of Range

QC test performed

QC acceptable

Document QC result(s) on documentation form

Patient testing acceptable to perform

QC not acceptable (one or both tests)

1. Verify that you are using correct quality controls and that they are not expired
2. Verify that you are following the test procedure correctly
3. Verify that the QC ranges match with the lot number and ranges established for this test system for both the reagents and QC

Repeat testing on the QC that is not acceptable → QC acceptable

If QC is still not acceptable, open a fresh control(s). Repeat testing → QC acceptable

Is QC still out of range? Open fresh reagents. Repeat testing → QC acceptable

Is QC still out of range? Contact laboratory coordinator or manufacturer to resolve

Document QC result(s) on documentation form

Patient testing acceptable to perform

Exceptions: occult blood slides ☒ slide from an examination room drawer: develop onboard controls on another card, but do not apply sample. If controls are again out of range, dispose of the cards in this examination room. Find slides from another examination room; develop controls on a slide without applying sample to this card. If in range, using another slide, apply sample, and proceed with the routine process. If the controls do not work, open a fresh box of slides. If unavailable, send sample to a reference laboratory.

☒ Slide from original box: develop onboard controls on another card from that same box of slides, but do not apply sample. If controls are again out of range, dispose of the slides in this box and open a fresh box of slides. If unavailable, send sample to a reference laboratory.

Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline (POCT08-A).

Quick Guide

 WWW.CLSI.ORG

POCT10-A2, *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*

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General Information

- Safety – personal protective equipment, hand hygiene, workspace disinfection, medical waste, and chemical safety
- Microscope – operation and maintenance
- Quality assurance – training and competency of the provider, procedure manual, QC, proficiency testing, and accreditation

Procedures Included in POCT10-A2

- Fecal leukocyte examination
- Fern test
- Nasal smears for inflammatory cells
- Pinworm examinations
- Postcoital, direct, qualitative examinations of cervical mucus
- Qualitative semen analysis
- Urine sediment examination
- Wet mount preparations and potassium hydroxide (KOH) preparations

Consistent Layout of Procedures

- Principle
- Materials
- Specimen collection
- Testing procedure
- Quality control
- Reporting results
- Limitations of the procedure

Appendixes in POCT10-A2

- Microscopic components of urine sediment
- Microscopic components in vaginal fluid and KOH preparations
- Ectoparasites
- List of figures and tables

Updates to POCT10-A2

- A reorganized and more comprehensive section (Section 14) for wet preparations, identifying differences between wet preparation for vaginal and nonvaginal procedures
- Representative pictures (or images) for as many procedures as possible, to facilitate training programs using this document as a teaching tool
- To complement the inclusion of so many images, the creation of Appendix C to help the reader identify and locate the images within the document

POCT10-A2 Companion Products

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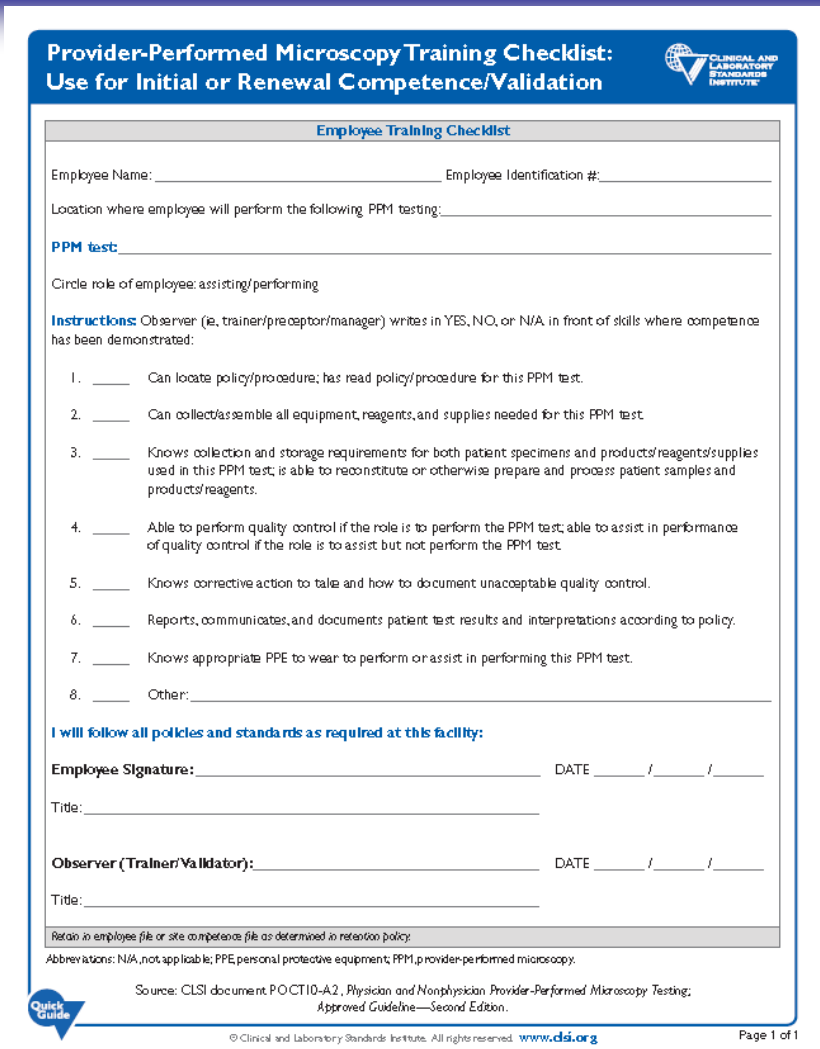
Checklists

- Cumulative training
- Employee training



Provider-Performed Microscopy Training Checklist: Use for Initial or Renewal Competence/Validation

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Employee Training Checklist

Employee Name: _____ Employee Identification #: _____

Location where employee will perform the following PPM testing: _____

PPM test: _____

Circle role of employee: assisting/performing

Instructions: Observer (ie, trainer/preceptor/manager) writes in YES, NO, or N/A in front of skills where competence has been demonstrated:

1. _____ Can locate policy/procedure; has read policy/procedure for this PPM test.
2. _____ Can collect/assemble all equipment, reagents, and supplies needed for this PPM test.
3. _____ Knows collection and storage requirements for both patient specimens and products/reagents/supplies used in this PPM test; is able to reconstitute or otherwise prepare and process patient samples and products/reagents.
4. _____ Able to perform quality control if the role is to perform the PPM test; able to assist in performance of quality control if the role is to assist but not perform the PPM test.
5. _____ Knows corrective action to take and how to document unacceptable quality control.
6. _____ Reports, communicates, and documents patient test results and interpretations according to policy.
7. _____ Knows appropriate PPE to wear to perform or assist in performing this PPM test.
8. _____ Other: _____

I will follow all policies and standards as required at this facility:

Employee Signature: _____ DATE _____/_____/_____

Title: _____

Observer (Trainer/Validator): _____ DATE _____/_____/_____

Title: _____

Retain in employee file or site competence file as determined in retention policy.

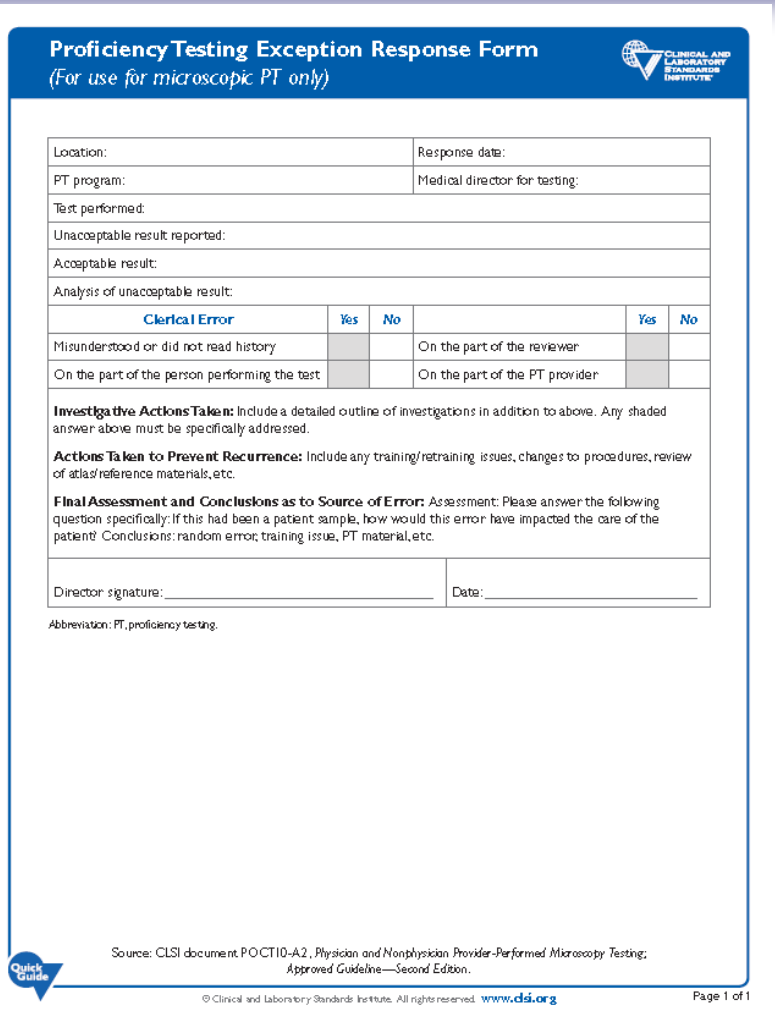
Abbreviations: N/A, not applicable; PPE, personal protective equipment; PPM, provider-performed microscopy.

Source: CLSI document POCT10-A2, *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*.

Quick Guide

Forms

- Proficiency testing exception response form
- Microscope maintenance log



Proficiency Testing Exception Response Form
(For use for microscopic PT only)

Location:			Response date:		
PT program:			Medical director for testing:		
Test performed:					
Unacceptable result reported:					
Acceptable result:					
Analysis of unacceptable result:					
Clerical Error	*Yes*	*No*		*Yes*	*No*
Misunderstood or did not read history			On the part of the reviewer		
On the part of the person performing the test			On the part of the PT provider		

Investigative Actions Taken: Include a detailed outline of investigations in addition to above. Any shaded answer above must be specifically addressed.

Actions Taken to Prevent Recurrence: Include any training/retraining issues, changes to procedures, review of atlas/reference materials, etc.

Final Assessment and Conclusions as to Source of Error: Assessment: Please answer the following question specifically: If this had been a patient sample, how would this error have impacted the care of the patient? Conclusions: random error, training issue, PT material, etc.

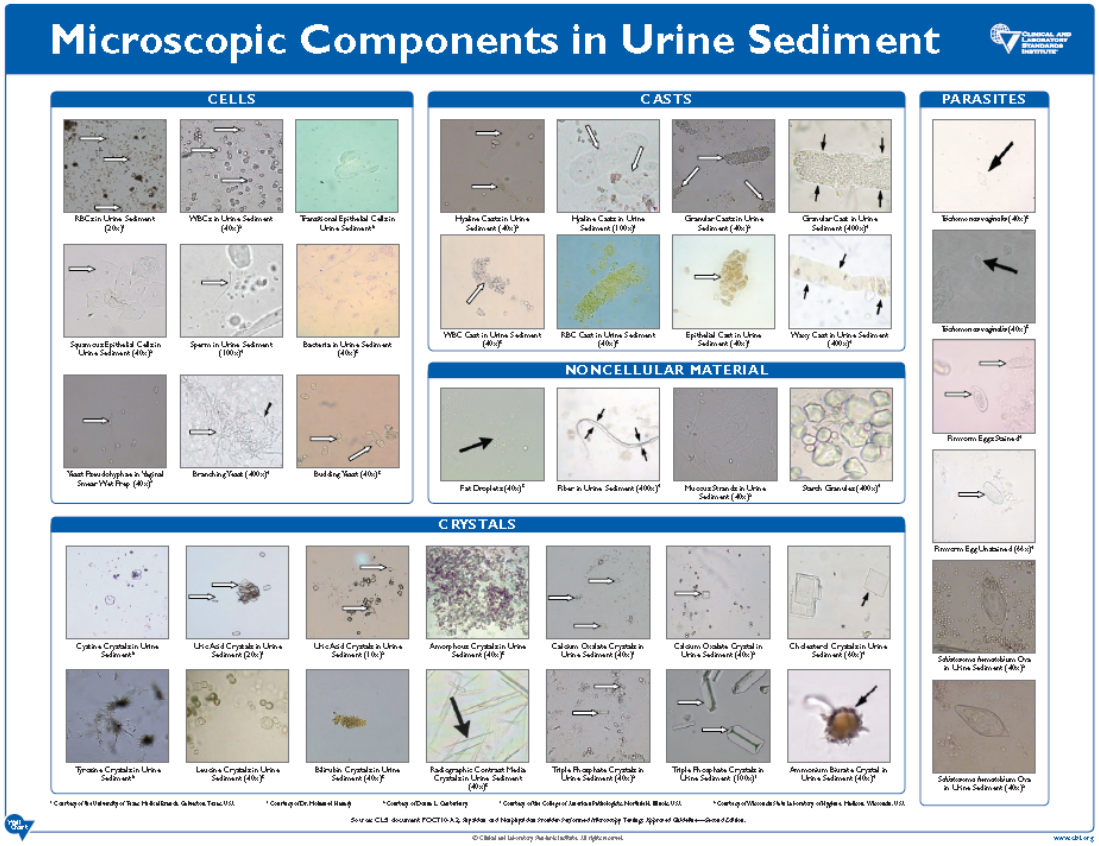
Director signature:_____ Date:_____

Abbreviation: PT, proficiency testing.

Source: CLSI document POCT10-A2, *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition.*

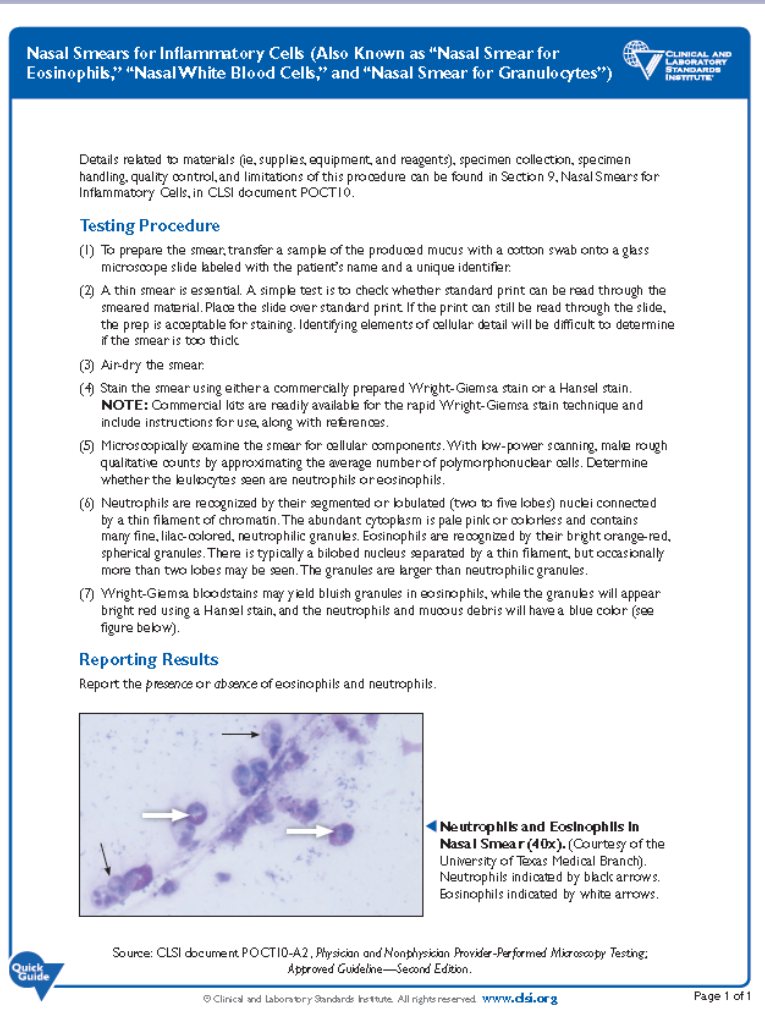
Wall Charts

- Microscopic components in urine sediment
- Microscopic components in vaginal fluid and KOH preparations
- Ectoparasites



Procedures

- Fecal leukocyte examination
- Nasal smears for inflammatory cells
- Urine sediment examinations
- Wet mount and KOH preparations



Nasal Smears for Inflammatory Cells (Also Known as "Nasal Smear for Eosinophils," "Nasal White Blood Cells," and "Nasal Smear for Granulocytes")

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Details related to materials (ie, supplies, equipment, and reagents), specimen collection, specimen handling, quality control, and limitations of this procedure can be found in Section 9, Nasal Smears for Inflammatory Cells, in CLSI document POCT10.

Testing Procedure

(1) To prepare the smear, transfer a sample of the produced mucus with a cotton swab onto a glass microscope slide labeled with the patient's name and a unique identifier.

(2) A thin smear is essential. A simple test is to check whether standard print can be read through the smeared material. Place the slide over standard print. If the print can still be read through the slide, the prep is acceptable for staining. Identifying elements of cellular detail will be difficult to determine if the smear is too thick.

(3) Air-dry the smear.

(4) Stain the smear using either a commercially prepared Wright-Giemsa stain or a Hansel stain. **NOTE:** Commercial kits are readily available for the rapid Wright-Giemsa stain technique and include instructions for use, along with references.

(5) Microscopically examine the smear for cellular components. With low-power scanning, make rough qualitative counts by approximating the average number of polymorphonuclear cells. Determine whether the leukocytes seen are neutrophils or eosinophils.

(6) Neutrophils are recognized by their segmented or lobulated (two to five lobes) nuclei connected by a thin filament of chromatin. The abundant cytoplasm is pale pink or colorless and contains many fine, lilac-colored, neutrophilic granules. Eosinophils are recognized by their bright orange-red, spherical granules. There is typically a bilobed nucleus separated by a thin filament, but occasionally more than two lobes may be seen. The granules are larger than neutrophilic granules.

(7) Wright-Giemsa bloodstains may yield bluish granules in eosinophils, while the granules will appear bright red using a Hansel stain, and the neutrophils and mucous debris will have a blue color (see figure below).

Reporting Results

Report the *presence* or *absence* of eosinophils and neutrophils.

Neutrophils and Eosinophils in Nasal Smear (40x). (Courtesy of the University of Texas Medical Branch). Neutrophils indicated by black arrows. Eosinophils indicated by white arrows.

Source: CLSI document POCT10-A2, *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition.*

Quick Guide

Summary

- CLSI is an internationally recognized, consensus-based standards organization that produces a large number of documents and related materials.
- Document development is a highly organized, systematic process involving a balanced approach by all stakeholders.
- QMS improve laboratory practice.
- Documents are applicable in laboratory standardization, preparation for inspection and accreditation, and in improving the quality of results and patient care.
- POCT documents can provide guidance as well as tools to help create and maintain a comprehensive program.

How to Contact CLSI

- Web: www.CLSI.org
- E-mail: customerservice@clsi.org
- Customer Service: 1.610.688.0100

- David Sterry
- dsterry@clsi.org
- Phone: 484.588.5942

Thank you.

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