CLSI COVID-19 Resources for Validation, Implementation, and Management of New Tests

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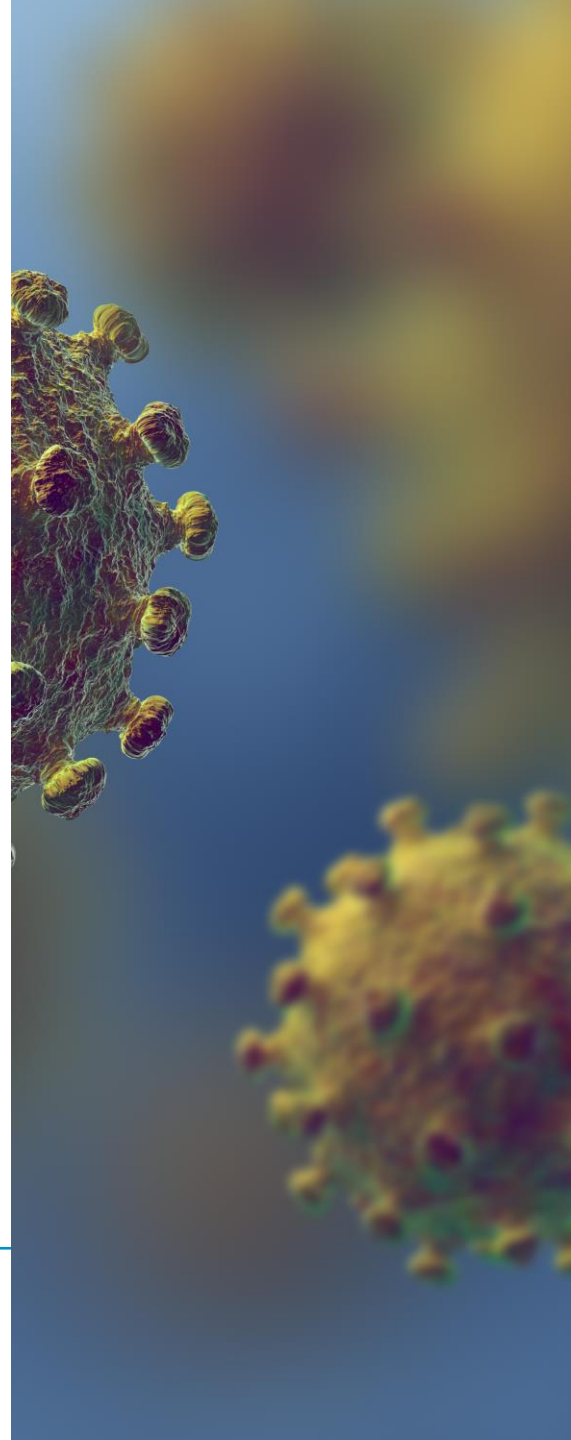
CLSI brings together the worldwide laboratory community to advance a common cause: **Fostering excellence in laboratory medicine.**

Vision: Setting the standard in laboratory medicine for a healthier world.

Mission: Develop clinical and laboratory practices and promote their use worldwide.

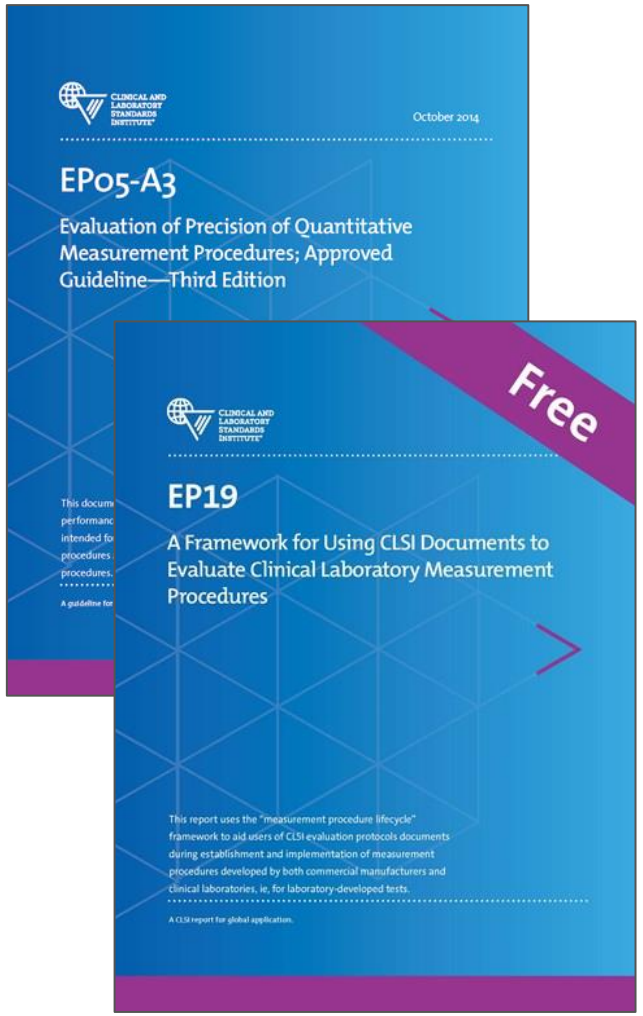
Values: inclusiveness, excellence, responsiveness, integrity, and teamwork.



CLSI

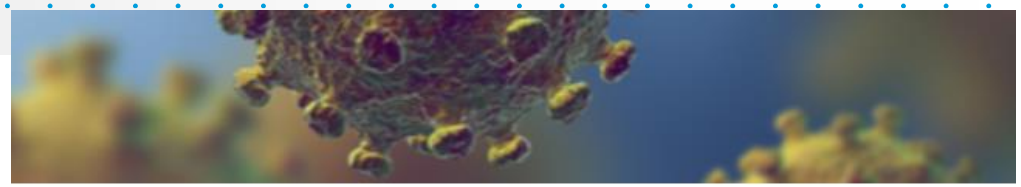
CLSI's Response to COVID-19

- Identified 30 CLSI standards most needed by laboratories to implement COVID-19 testing.
  - Created a dedicated webpage for these and linked it from their homepage (www.clsi.org).
  - Several of the documents are free of charge.



CLSI's Response to COVID-19

- Provided a consolidated listing of helpful links for available resources from government and other sources.



Coronavirus (COVID-19) Update From CLSI

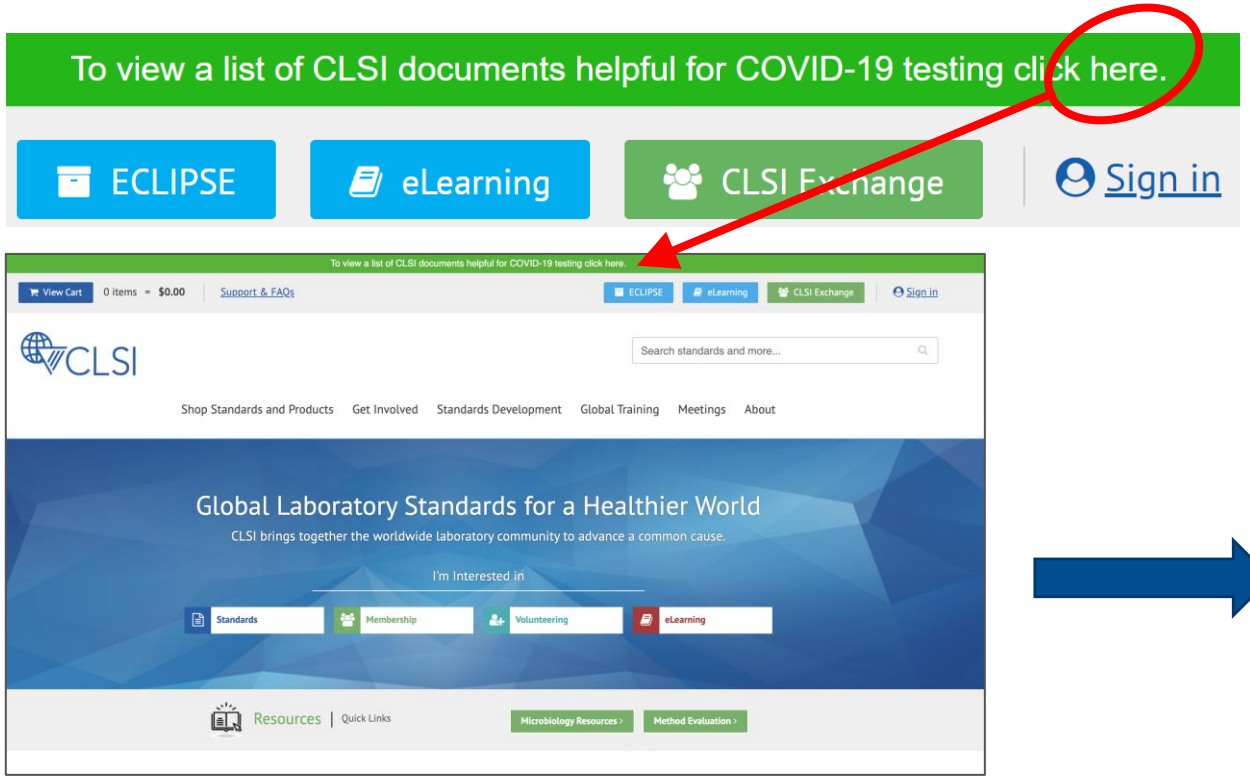
With a global pandemic underway, CLSI's mission to "develop clinical and laboratory practices and promote their u
before. CLSI recognizes the important contributions of laboratory professionals and the health care community an
against COVID-19.

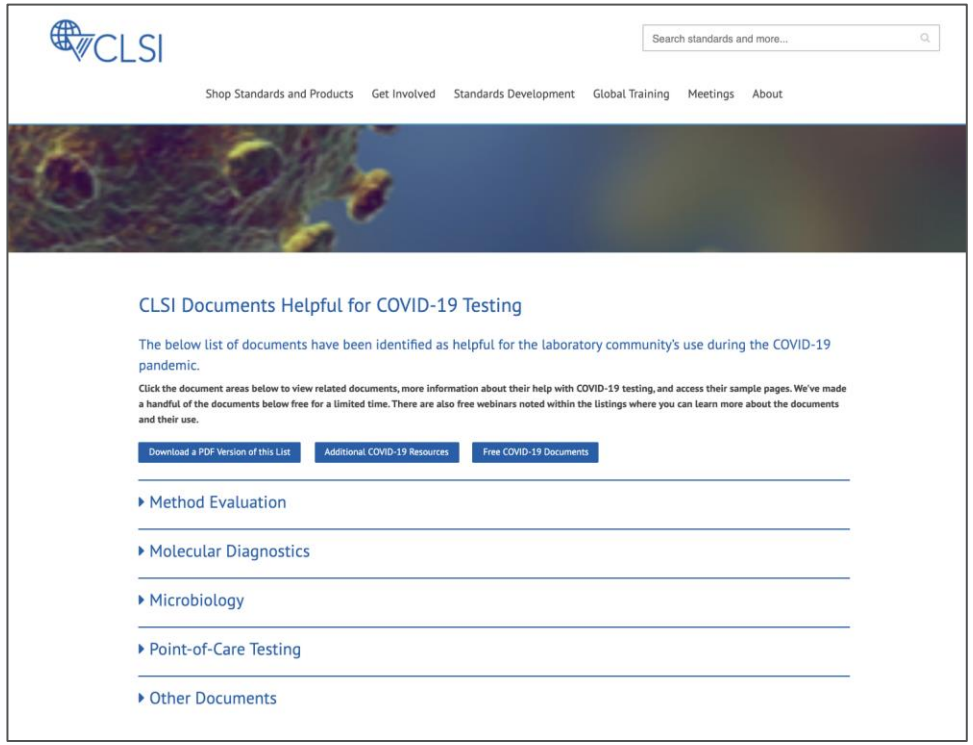
Meeting Cancellation Notice
CLSI's in-person September Committees Week has been cancelled. This decision was made to ensure the safety an
staff and the community at large. Leadership and staff are working on options for standards development to conti
September. These committees will be contacted directly about virtual meeting options.

Added resources relevant to COVID-19 and laboratory standards:

- **CLSI Documents Helpful for COVID-19 Testing**
  This list includes documents that have been identified as helpful for the laboratory community's use during
  - Interactive Webpage
  - Downloadable PDF
  - Free Interactive CLSI Document Portal for documents helpful for COVID-19 testing
- What you need to know from The Centers for Disease Control and Prevention
- Resources from the World Health Organization
- Information from the Association of Public Health Laboratories
- Mapping the virus from Johns Hopkins
- Novel Coronavirus (COVID-19) Resources from American Society for Microbiology
- What's new information and what's happening now podcast from Infectious Disease Society of America
- COVID-19 Testing Directory from AACC

Access to COVID-19–Related Documents and Resources



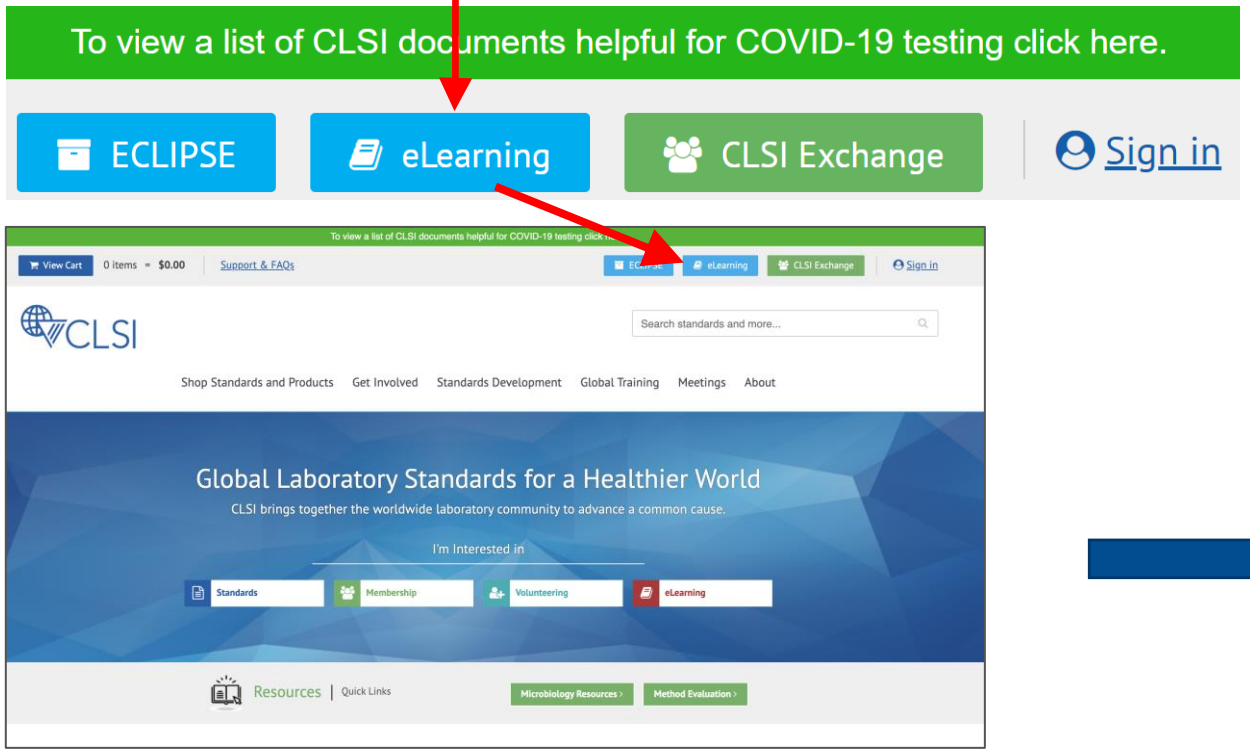


www.clsi.org

CLSI's Response to COVID-19

- Ensured that each of the identified standards has an associated free webinar available.
  - Webinars describe the contents of the standards.
  - Many were developed by CLSI technical staff.

Access to Webinars



From CLSI's homepage, you can also click on "eLearning" to access **free webinars** for each of the COVID-19 related documents. These webinars present overviews of the contents of the documents, so that you can decide which are helpful for you.

www.clsi.org

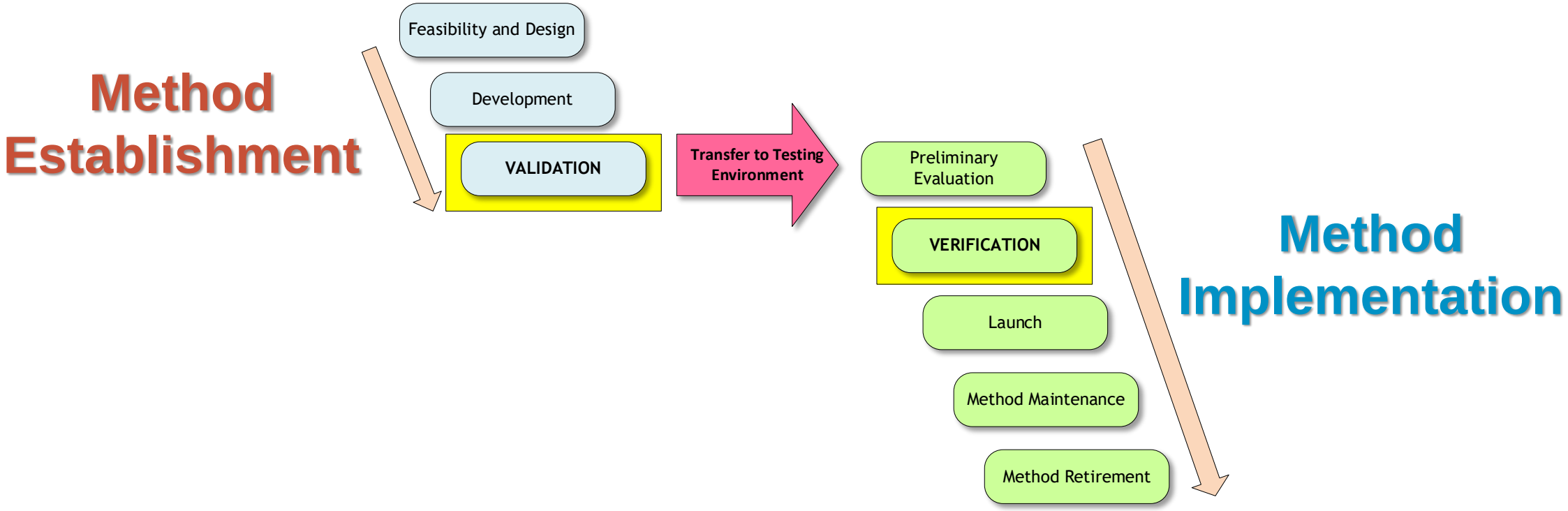
COVID-19 Response Results

Since March:

- Over 3,400+ copies of the free COVID documents downloaded
- 1,500+ views for the free webinars
- Positive impact on global pandemic testing

CLSI Test Validation Resources

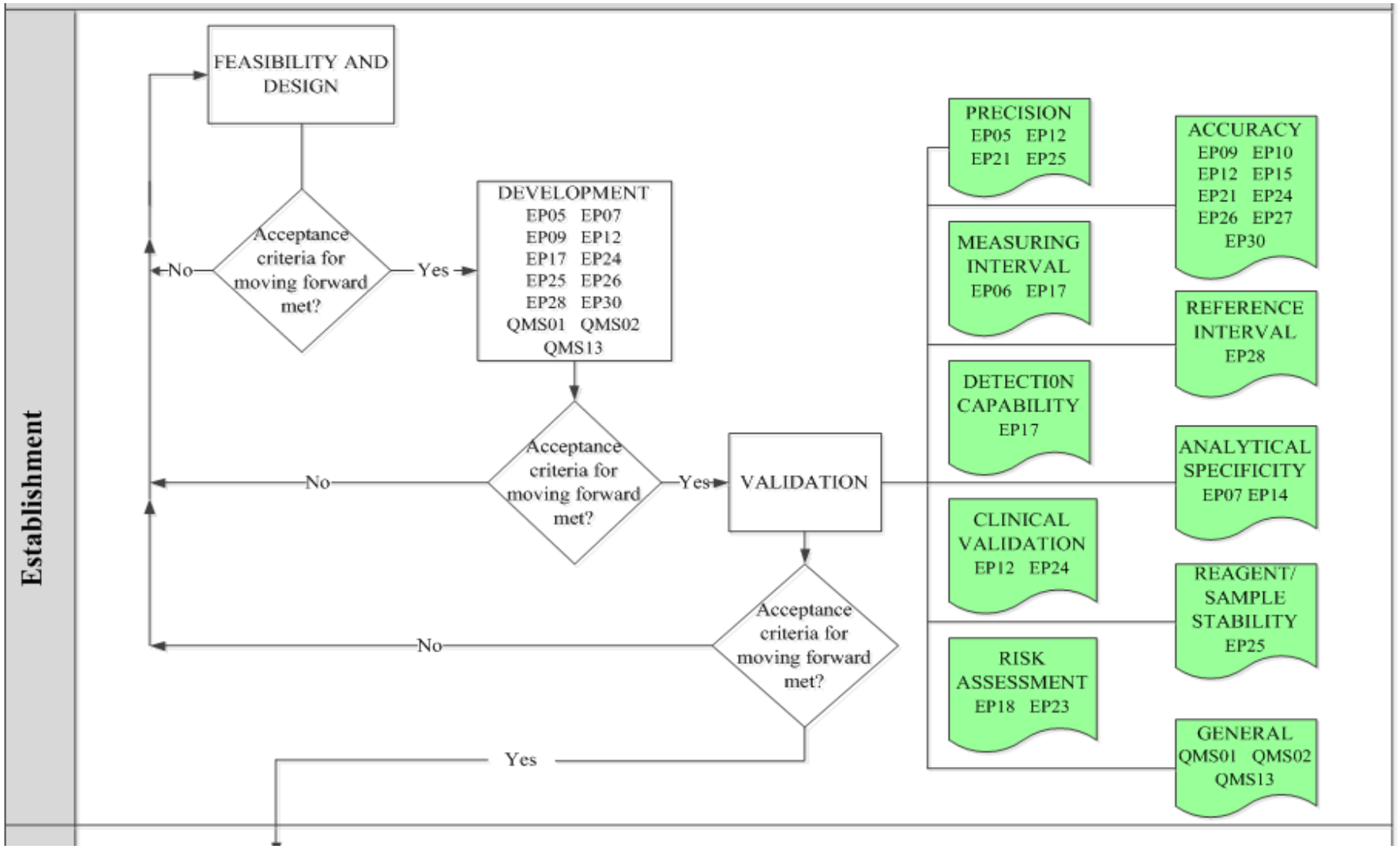
Measurement Process Life Cycle Phases



CLSI Document EP19

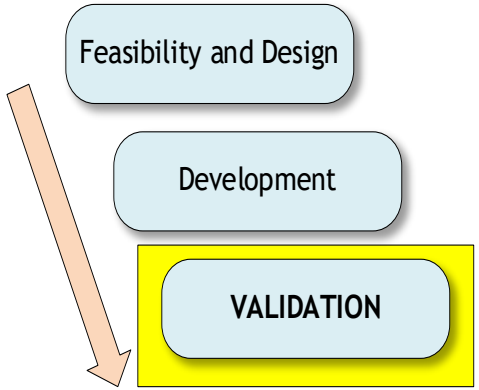
- *A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 2nd Ed.*
  - Free resource from CLSI available on CLSI's website
- Defines the measurement process life cycle.
  - Establishment
  - Implementation
- Provides guidance for manufacturer (test developer) and laboratory user.
- Provides a list of CLSI resources for each phase of a test.

Establishment



Feasibility and Design

- Consider the demand and requirements for a particular type of testing.
- Make an approximate, preliminary appraisal about whether demands and requirements can be satisfied.
- CLSI does not offer guidelines specific to this phase of development.
- This development phase generally includes:
  - Literature review.
  - Clinical usefulness/intended use.
  - Feasibility assessment.
  - Marketing assessment.
- Ends with a decision to move forward with development.

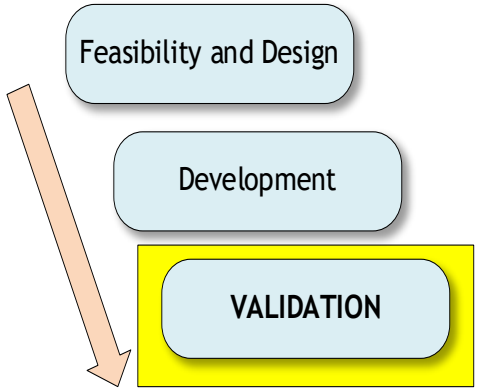


Method Establishment

Development

- Concept to reality through systematic, iterative improvements
  - Technical aspects determined
  - Testing against requirements
    - CLSI Method Evaluation standards (EP)
  - Creation of manufacturing procedures

- At the end, the developer has a test that "works."
  - Can be evaluated to determine if requirements have been met.

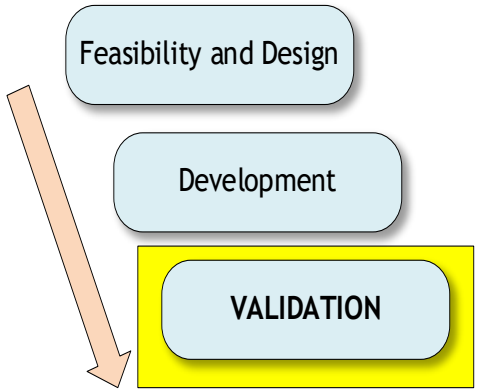


Method Establishment

Validation Defined

- Validation is the confirmation, through the provision of objective evidence, that **the requirements for a specific intended use or application** have been fulfilled.

- When validation testing is successful, the test is proven to be appropriate for:
  - Measuring a specific measurand.
  - Use with an intended population.
  - Providing useful information for a target condition.



Method Establishment

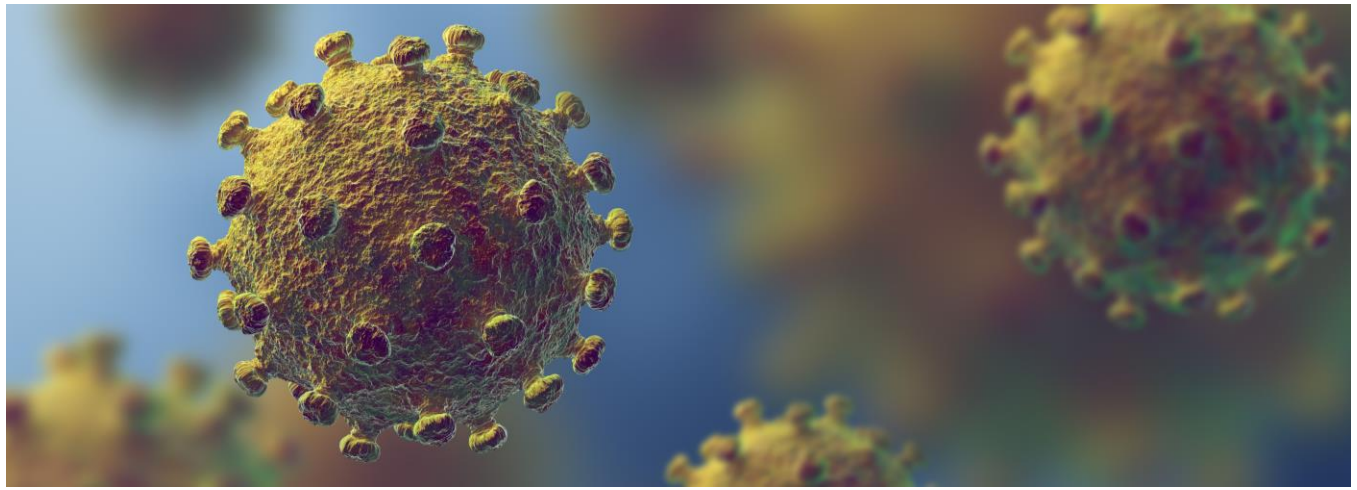
Validation Testing

- Precision (EP05)
- Accuracy (EP09)
- Linearity (EP06)
- Measuring Interval (EP17, EP34)
- Reference Interval (EP28)
- Detection Capability (EP17)
- Analytical Specificity (EP07)
- Clinical Validation (EP12, EP24)
- Reagent & Sample Stability (EP25)
- Risk Assessment (EP18)

Once validation testing is completed, the test developer's claims have been established.

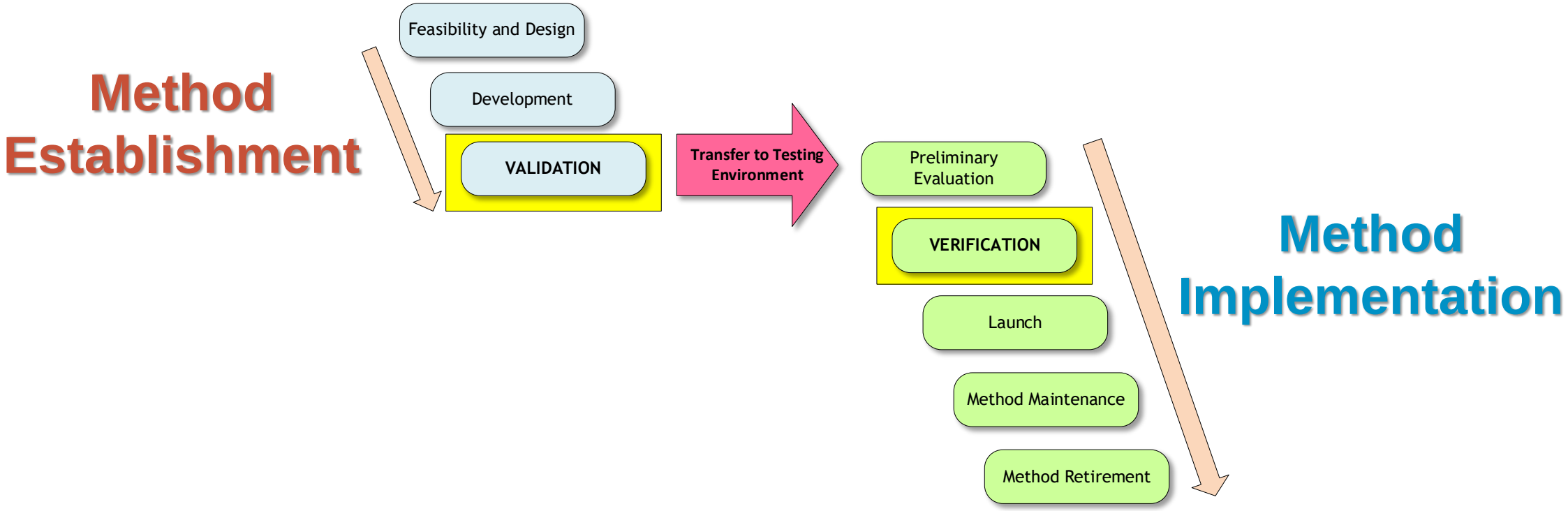
COVID-19 Test Validation - What's Different?

- Validations may be limited with fewer samples included.
  - Especially during the beginning of the pandemic when specimens were difficult to acquire
- Some testing could be based on contrived samples.

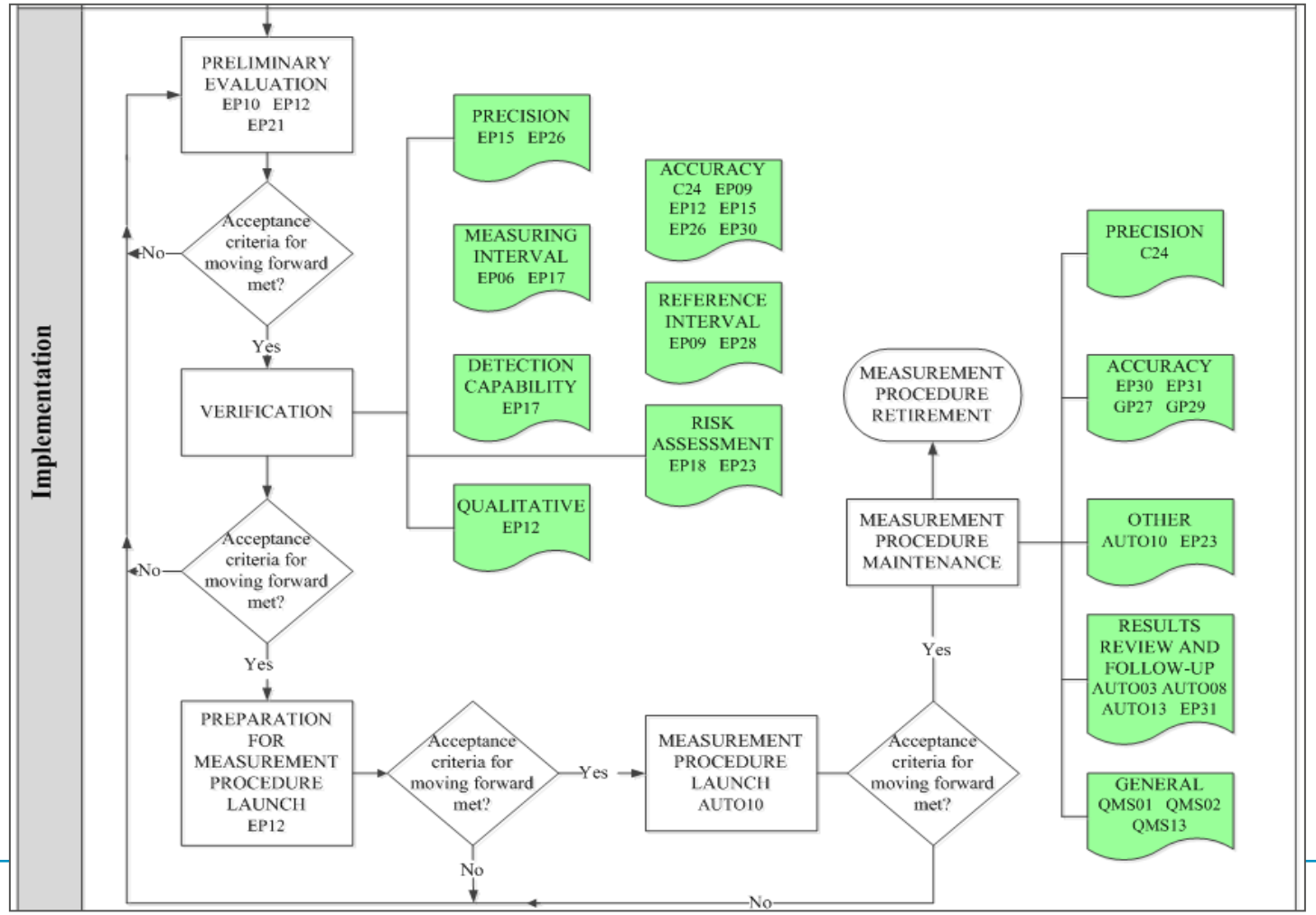


CLSI Test Implementation and Management Resources

Measurement Process Life Cycle Phases

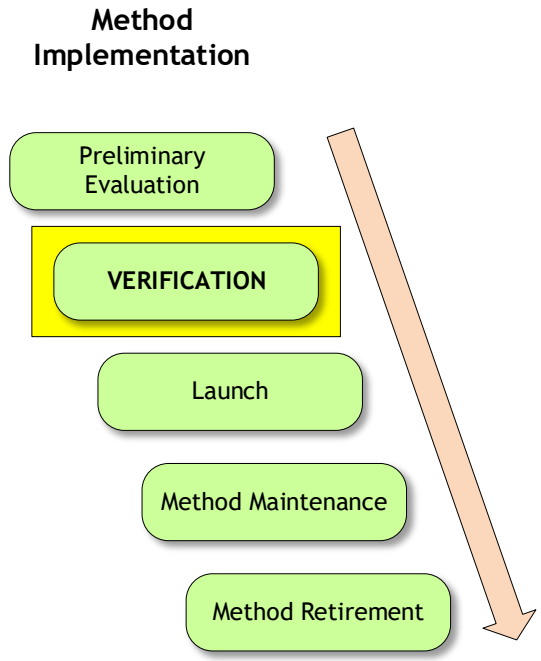


Implementation



Preliminary Evaluation by End User

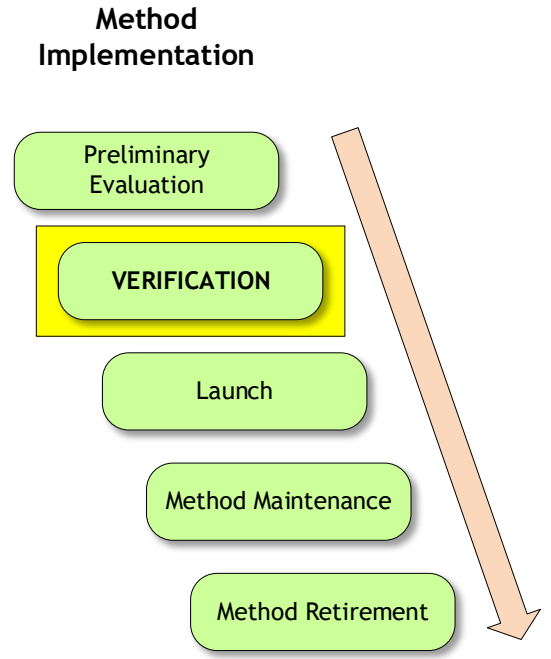
- Establish instrumentation in working order
- Calibration
- Initial QC
- Initial performance testing
- Verify performance appears to be acceptable



Verification Defined

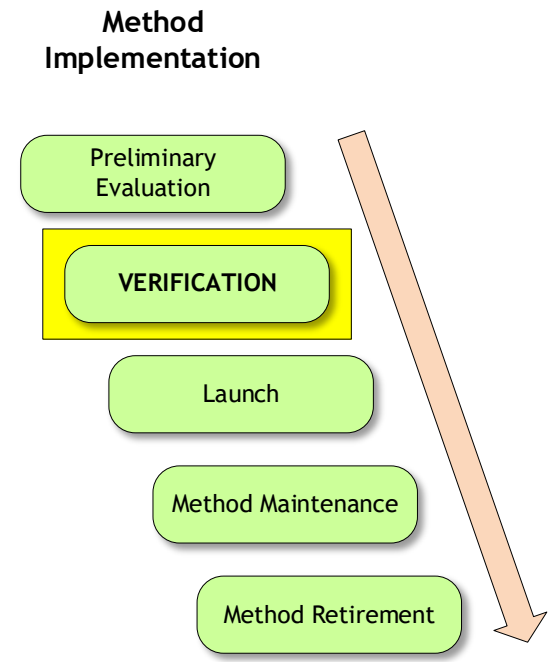
- Confirmation, through the provision of objective evidence, that **specified requirements** have been fulfilled.

- Critical developer's performance claims are evaluated by the laboratory to ensure that it can achieve performance in alignment with the claims.



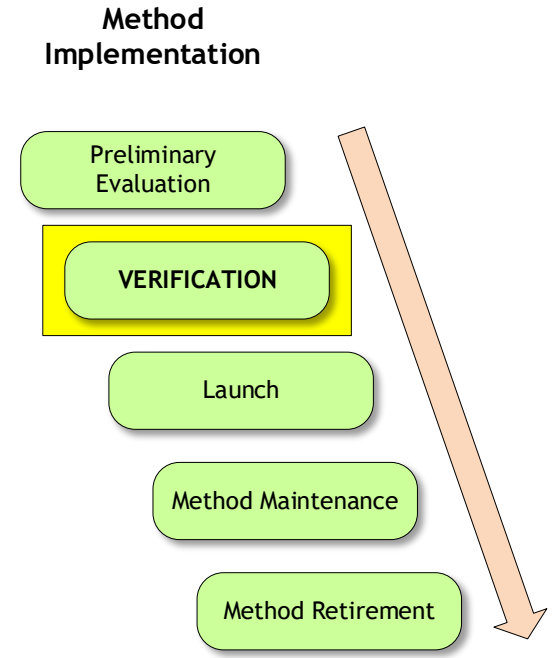
Test Verification

- Verify performance for different:
  - Operators.
  - Storage space.
  - Equipment.
  - Room.
  - Patient population.
- Final performance verification before clinical use



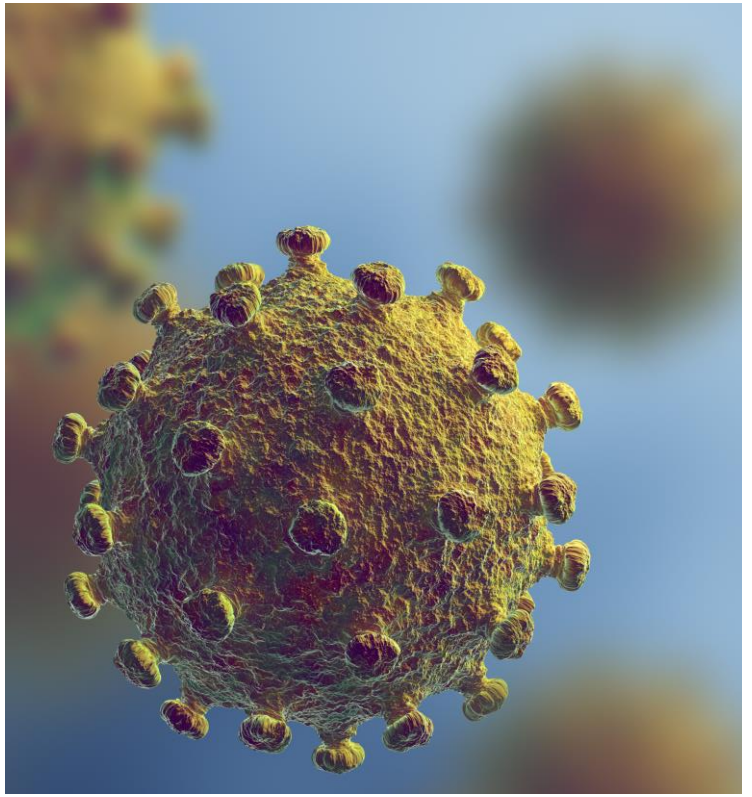
Some CLSI Documents for Test Verification

- Precision (EP15)
- Measuring Interval (EP06)
- Detection Capability (EP17)
- Accuracy (EP09)
- Reference Interval (EP28)
- Risk Assessment (EP18)
- Qualitative Tests (EP12)



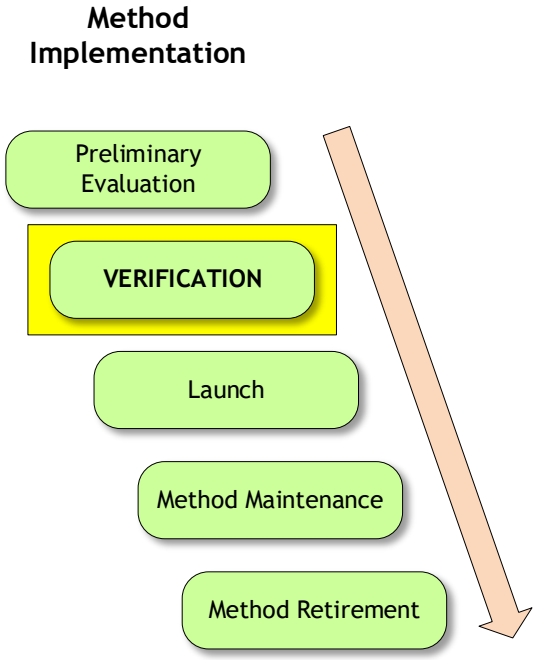
COVID-19 Test Verification – What's Different?

- Laboratories need to pay special attention to the testing performed by the developer, as it could have been limited, especially in number of samples used for each performance claim.
- For example, confidence limits for accuracy testing could be wide due to fewer samples tested.
- Laboratories don't need to "fill the gaps" but should be aware of possible variability around the developer's claims.



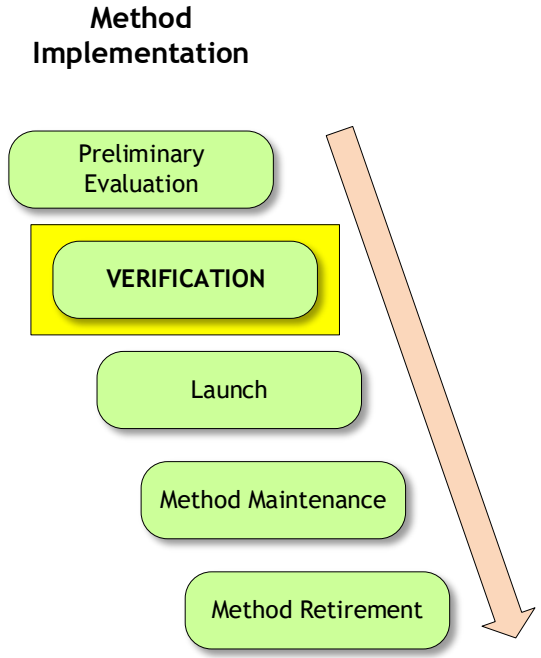
Test Launch

- Train operators.
- Verify Informatics.
  - LIS
  - HIS
- Troubleshoot any Issues.
- Place into clinical service.



Test Maintenance

- Testing to ensure that the measurement procedure continues to perform properly:
  - QA and risk assessment (EP23, EP18)
  - QC (EP23, C24)
  - Proficiency (EQAS) testing
  - Routine evaluation of precision, accuracy, linearity, measuring interval (EP15, EP09, EP06, EP17, EP34)
  - Results review and follow-up

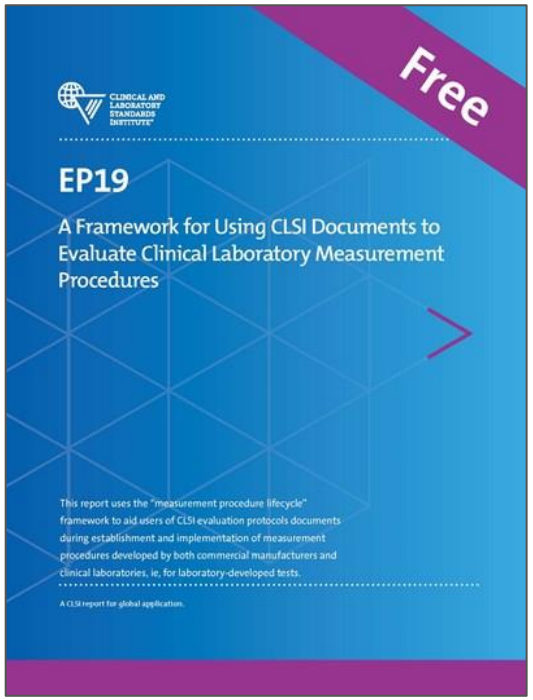


Retirement

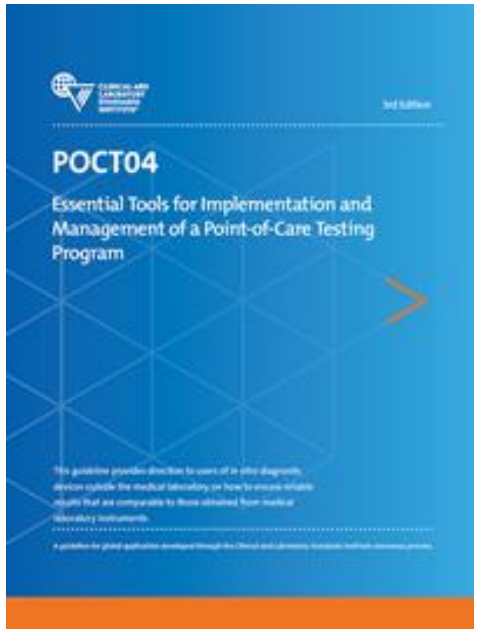
- Document control
- Records retention
- CLSI QMS02, *Quality Management System: Development and Management of Laboratory Documents, 6th Ed.*

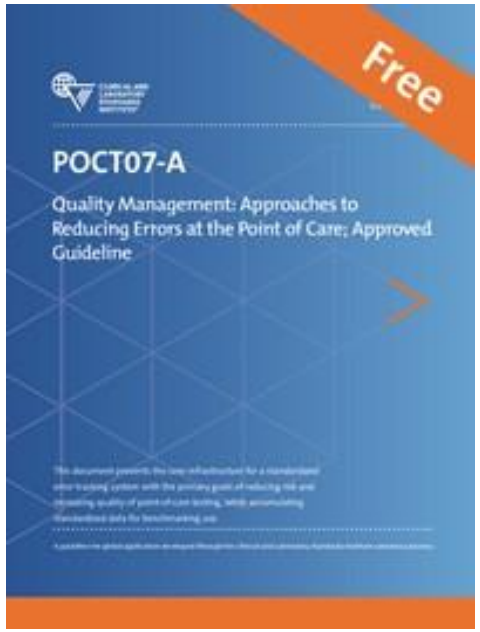
More Help From EP19

- Appendix A. Basic Statistical Concepts in the Evaluation of Measurement Procedure Performance Characteristics
  - High-level description of statistical concepts
  - High-level description of measurement procedure performance characteristics and relevant statistics
  - References appropriate CLSI documents
- Establishment checklist
- Implementation checklist



Point-of-Care Testing Resources

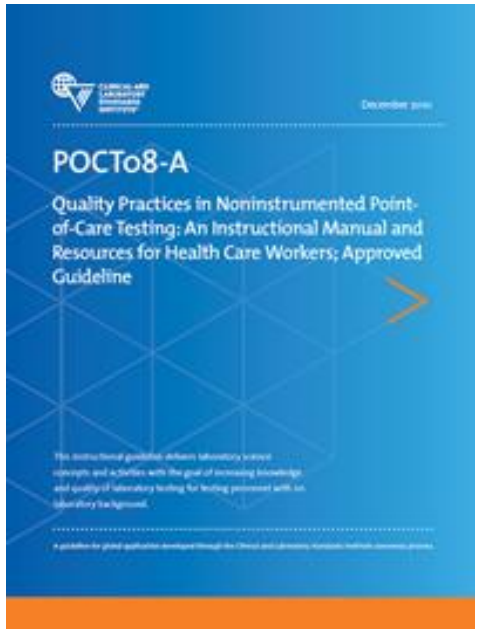




POCT04—*Essential Tools for Implementation and Management of a Point-of-Care Testing Program*, helps laboratories ensure reliable results that are comparable to those obtained from medical laboratory instruments.

POCT07—*Quality Management Approaches to Reducing Errors at the Point-of-Care*, available for free, helps the laboratory implement a standardized error tracking system with the primary goals of reducing risk and increasing quality, while accumulating standardized data for benchmarking use.

Point-of-Care Testing Resources



POCT15—*Point-of-Care Testing for Infectious Diseases*, summarizes the current knowledge of rapid and point-of-care testing practices and methods for infectious diseases.

POCT08—*Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers*. This document includes laboratory science concepts and activities with the goal of increasing knowledge and quality of laboratory testing by personnel who do not have a laboratory background.


STOP
COVID-19
LET'S FIGHT IT TOGETHER!

Thank you!

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