



# Division of Laboratory Systems

## CLIA Regulations Assessment Workgroup

### Introduction

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Division of Laboratory Systems



# Background and Workgroup Charge

- CLIAC April 2019 Recommendations:
  - HHS should update CLIA regulations to address new technology
  - Create a new workgroup for input on how CLIA might be updated
- Workgroup Charge:
  - ...provide input to CLIAC for deliberation on how CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups....

# Discussion Topics

Total Testing Process Review

Data as a Specimen

Histopathology

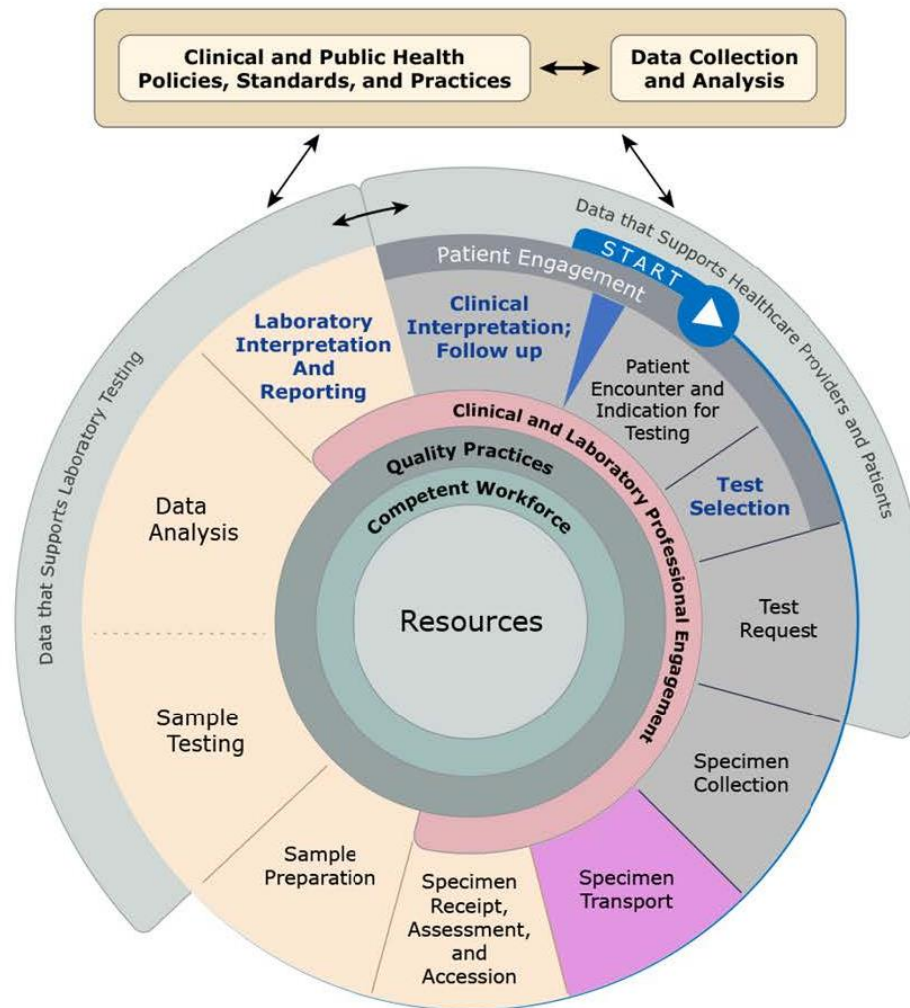
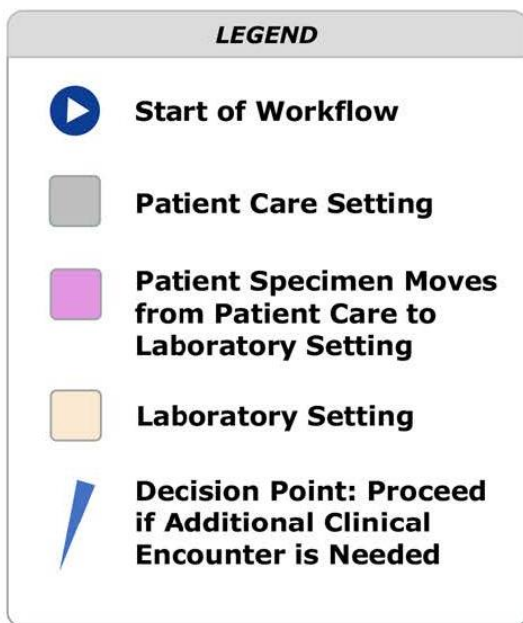
Analytical Testing Specifications

Digital Pathology

# Workgroup Members

- Kimberle C. Chapin, MD, ABMM, FCAP – Workgroup Co-Chair
- Gregory N. Sossaman, MD – Workgroup Co-Chair
- Tariq S. Adwan, PhD
- Erica F. Andersen, PhD, FACMG
- Jonathan B. Bakst, MBA, MHS, PA(ASCP)<sup>CM</sup>
- Michael Black, MBA, MT(ASCP), DLM
- Alexis B. Carter, MD
- Qing Jackie Cao, MD, PhD
- David Chhieng, MD, MBA, MSHI, MSEM, MLS
- Sugganth Daniel, MD, FCAP
- Denise K. Driscoll, MS, MT(ASCP)SBB
- Birgit Funke, PhD, FACMG
- John E. Gibson MA, MT(ASCP), DLM
- William A. Glover II, Ph.D., D(ABMM), MT(ASCP)
- Lee Hilborne, MD
- Karen Kaul, MD, PhD, FASCP
- Eric Klee, PhD
- Robert Klees, PhD
- Jordan Laser, MD
- Christina Lockwood, PhD, DABCC, DABMGG
- Valerie Ng, MD, PhD
- Liron Pantanowitz, MD
- Elizabeth L. Palavecino, MD
- Beverly Rauch, MS
- Owatha Loye Tatum, PhD, HCLD/CC (ABB), MBA
- Erika Tyburski
- Kevin Wickware MLS(ASCP), MBA
- Sarah Bennett, MT(ASCP) – CMS Ex Officio
- Víctor R. De Jesús, PhD – CDC Ex Officio
- Peter Tobin, PhD – FDA Ex Officio
- Nancy Anderson, MMSc - Executive Secretary
- Heather Stang, MS, MT(AMT) – Workgroup DFO

# The Total Testing Process (TTP): An Expanded Representation



# April 1, 2022 Meeting

- **At what point in the total testing process should CLIA regulations begin to apply and where does CLIA coverage of the process end?**
  - How should the CLIA requirements be revised to clarify the laboratory's role and responsibilities for providing consultation for test selection, especially considering emerging technologies?
  - How should the CLIA requirements be revised to clarify the laboratory's role and responsibilities with respect to result interpretation and reporting, especially considering emerging technologies?
- **Workgroup discussion on definitions**

# Division of Laboratory Systems

For more information, contact CDC  
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TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

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