

# The Role of Artificial Intelligence and Machine Learning in the Clinical Laboratory

## Introduction

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# CLIAC Regulations Assessment Workgroup

## Chairs

Dr. Kimberle C. Chapin

Dr. Gregory N. Sossaman

## Workgroup Charge

The CLIA Regulations Assessment Workgroup provides input to CLIAC for deliberation on how the CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups. The workgroup is charged with providing advice to CLIAC for consideration in making recommendations to HHS on revising the CLIA regulations.

<https://www.cdc.gov/cliac/workgroups/regulations-assessments.html>

# CLIA Regulations Assessment Workgroup: Total Testing Process Evaluation

## Workgroup Questions

- How do technologies that utilize artificial intelligence play a role in the total testing process?
  - How does CLIA apply to the use of these technologies?
  - What requirements should be added or revised in CLIA to ensure the quality of testing when artificial intelligence is part of the total testing process?

# Presentation

## The Basics of Artificial Intelligence and Machine Learning

**Alexis B. Carter, MD**

Physician Informaticist and Molecular Pathologist

Pathology and Laboratory Medicine

Children's Healthcare of Atlanta

## Questions to CLIAC

- 1) What are the challenges to applying the CLIA regulations to technologies utilizing artificial intelligence and machine learning?
- 2) Should a CLIAC workgroup be formed to discuss the requirements that should be added or revised in CLIA to ensure the quality of testing when artificial intelligence and machine learning are part of the total testing process?



For more information, contact CDC  
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