

# CDC and the Changing Landscape of Clinical Laboratory Medicine

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Division of Laboratory Systems  
October 15, 2019



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

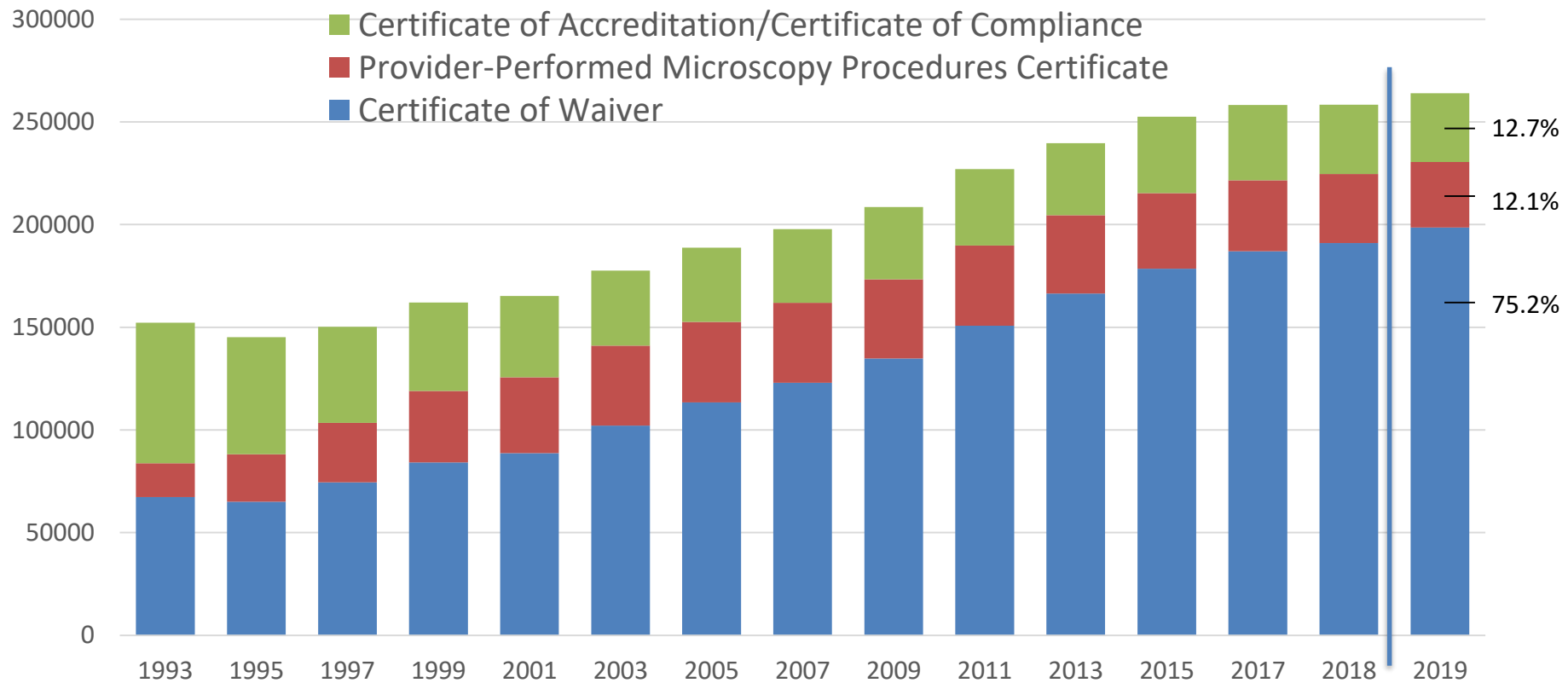
# Clinical Laboratory Community

260,000



Lab Personnel 800,000

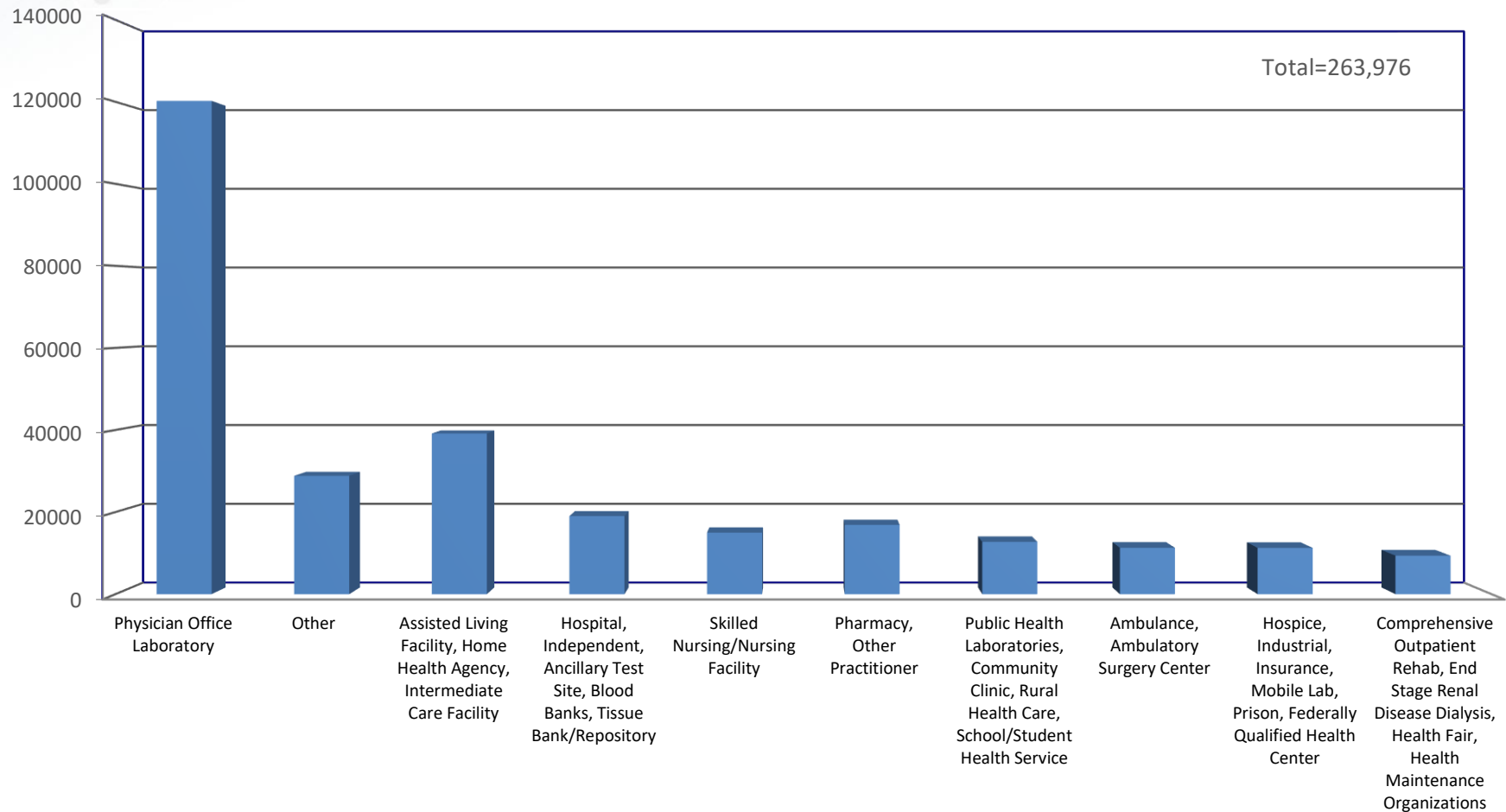
# Number of CLIA Certified Laboratories: 1993-2019



Data obtained from CMS QIES database, 09/10/2019. Lab types in QIES data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA. Data does not include CLIA Certificate of Registration laboratories.

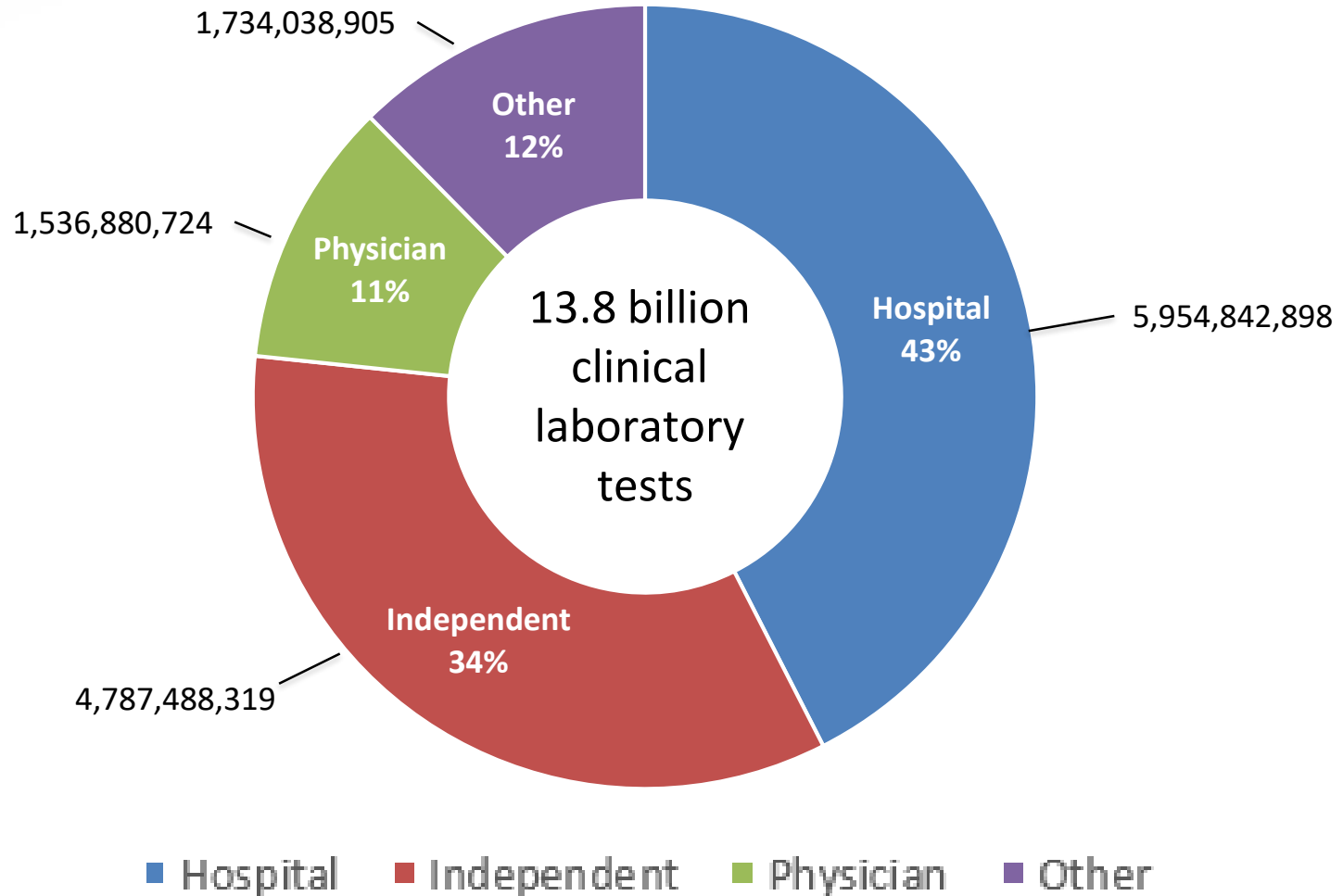
# U.S. Laboratory Demographics, Sept 2019

## All CLIA-Certified Laboratories by Laboratory Type<sup>1</sup>



<sup>1</sup>Data obtained from CMS QIES database, 09/10/2019. Lab types in QIES data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA. Data does not include CLIA Certificate of Registration laboratories.

# 2018 Annual Test Volumes



Data obtained from CMS QIES database, September 2019

# Clinical Laboratory Improvement Amendments of 1988 (CLIA)



# CDC Role in the CLIA Program



**Identifies** critical technical and scientific issues in clinical laboratory medicine



**Develops and distributes** technical information and educational materials



**Manages** the US Clinical Laboratory Improvement Advisory Committee (CLIAAC)



# CDC Division of Laboratory Systems

## Vision

*Exemplary laboratory science and practice drive clinical care and public health.*

## Mission

*Improve public health surveillance and practice as well as patient outcomes by advancing clinical laboratory quality and safety, data and biorepository science, and workforce competency.*





# Four Goal Areas



Quality Laboratory Science



Highly Competent Laboratory Workforce



Safe and Prepared Laboratories



Accessible and Usable Laboratory Data

# Free CDC Resources to Promote Good Laboratory Practices for Waived Testing

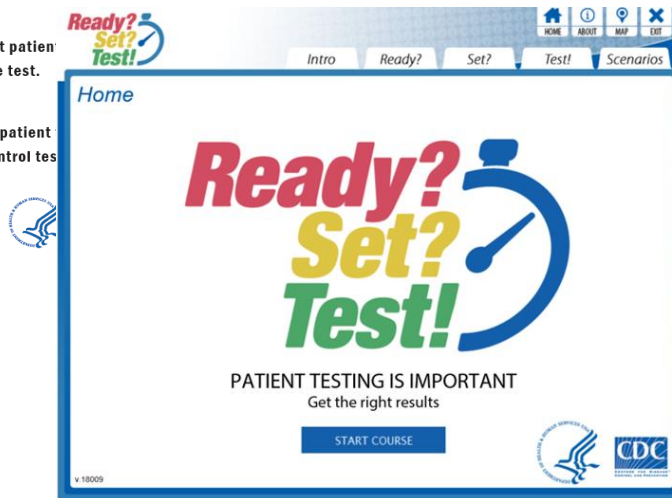
## PATIENT TESTING IS IMPORTANT.

**READY?  
SET?  
TEST!**

### Get the right results.

- Have the latest instructions for ALL of your tests.
- Know how to do tests the right way.
- Know how and when to do quality control.
- Make sure you do the right test on the right patient.
- Make sure the patient has prepared for the test.
- Collect and label the sample the right way.
- Follow instructions for quality control and patient.
- Keep records for all patient and quality control tests.
- Follow rules for discarding test materials.
- Report all test results to the doctor.

<http://www.cdc.gov/dls/waivedtests>



**To Test  
or  
Not to  
Test?**

### Considerations for Waived Testing

<http://www.cdc.gov/clia/Resources/WaivedTests/>

**READY?  
SET?  
TEST!**

### PATIENT TESTING IS IMPORTANT. Get the right results.

<http://www.cdc.gov/clia/Resources/WaivedTests/>

**¿Preparado?  
¿Listo?  
¡Ya!**

**REALIZAR PRUEBAS AL PACIENTE  
ES IMPORTANTE.**

Obtenga los resultados correctos

<http://www.cdc.gov/dls/waivedtests>

**Realizar pruebas al paciente es importante**

Obtenga los resultados correctos

• Obtenga las instrucciones más recientes para TODOS sus pruebas.

• Sepa cómo realizar las pruebas de manera correcta.

• Sepa cómo y cuándo hacer un control de calidad.

• Asegúrese de realizar la prueba correcta al paciente correcto.

• Asegúrese de que el paciente se haya preparado para la prueba.

• Recabele y etiquete la muestra de manera correcta.

• Siga las instrucciones para las pruebas de control de calidad y

• Lleve registros de todas las pruebas del paciente y de los resultados de las pr

• Siga las reglas para la eliminación de los materiales de las pr

• Informe al médico de todos los resultados de las pruebas.

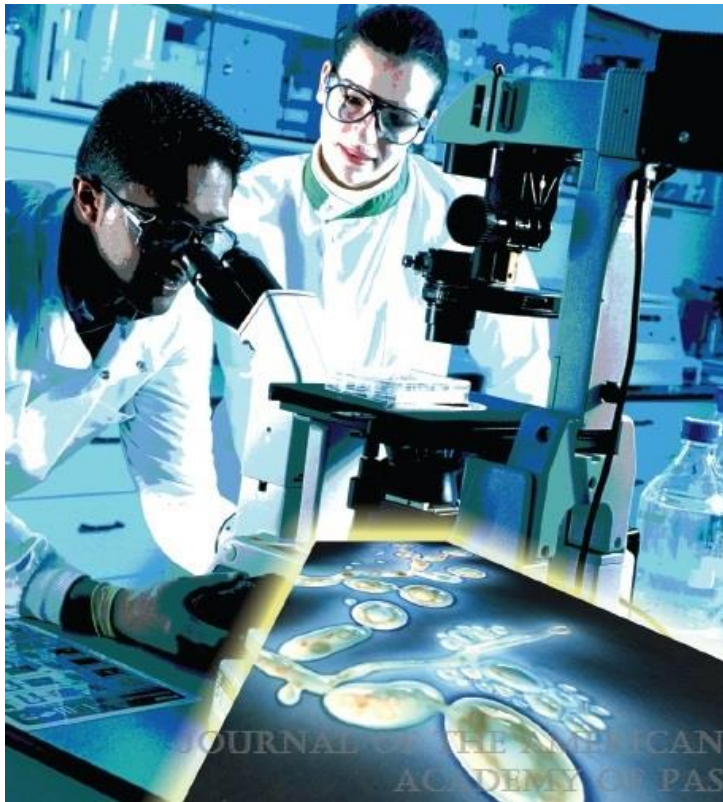
<http://www.cdc.gov/dls/waivedtests>

**¿Realizar  
pruebas  
o  
no realizar  
pruebas?**

**Consideraciones para la  
realización de pruebas exentas**

<http://www.cdc.gov/dls/waivedtests>

# Provider-Performed Microscopy (PPM) Procedures



From Brown et al., "Provider-performed microscopy empowers Pas at the point of care," Journal of the American Academy of PAs, March 2018, Vol. 31, Issue 3, 19-24.

## PROVIDER- PERFORMED MICROSCOPY PROCEDURES

A Focus on Quality Practices

<http://www.cdc.gov/clia/Resources/PPMP>

Center for Surveillance, Epidemiology, and Laboratory Services  
Division of Laboratory Systems





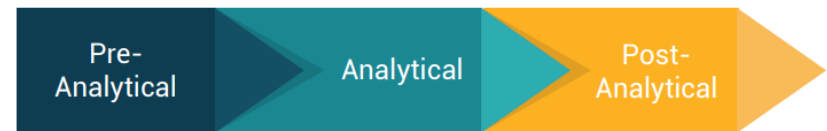
# Individualized Quality Control Plan (IQCP)



## DEVELOPING AN IQCP A STEP-BY-STEP GUIDE








U.S. Department of Health and Human Services



Specimen \* Test System \* Reagents \* Environment \* Testing Personnel



# DLS Laboratory Training

	Description	Additional Information
	<p><a href="#">Algorithms in Diagnostic Molecular Parasitology</a></p> <p>Learn the tools necessary to make evidence-based decisions relative to implementing and performing molecular methods to diagnose parasitic diseases.</p>	<p>Live Event: 9/25/19 – 9/27/19 Level: Basic Registration Closes: 7/8/19</p>
	<p><a href="#">Diagnostic Parasitology I: Intestinal Organisms &amp; Arthropods</a></p> <p>Learn how to detect and identify medically important intestinal helminths, intestinal protozoa, and arthropods.</p>	<p>Live Event: 10/22/19 – 10/25/19 Level: Intermediate Registration Closes: 7/30/19</p>
	<p><a href="#">Diagnostic Parasitology II: Bloodborne &amp; Tissue Parasites</a></p> <p>Learn how to detect and identify blood and tissue parasites. Lectures and hands-on laboratory exercises will target <i>Plasmodium</i> spp., <i>Babesia</i> spp., microfilariae, <i>Leishmania</i> spp., and <i>Trypanosoma</i> spp.</p>	<p>Live Event: 10/28/19 – 10/31/19 Level: Intermediate Registration Closes: 7/30/19</p>
	<p><a href="#">Antimicrobial Susceptibility CLSI Standards</a></p> <p>Learn about the supplemental tables that correlate with the standards and the interpretive criteria for antimicrobials recommended for testing a variety of bacteria. This course provides essential information for those new to antimicrobial susceptibility testing and serves as an important refresher for experienced laboratory professionals</p>	<p>On-demand eLearning Level: Basic</p>
	<p><a href="#">Antimicrobial Susceptibility Testing Methods (AST)</a></p> <p>Learn technical and regulatory considerations for any method of medical laboratory antimicrobial susceptibility testing. This course provides essential information for those new to antimicrobial susceptibility testing and an important refresher for laboratory professionals</p>	<p>On-demand eLearning Level: Basic</p>

[www.cdc.gov/labtraining/](http://www.cdc.gov/labtraining/)

# Biosafety Cabinet Course

## Fundamentals of Working Safely in a Biosafety Cabinet

CDC's NEWEST LABORATORY SAFETY COURSE



Centers for Disease Control and Prevention





# Centrifuge Course

# Working Safely with Centrifuges

CDC's NEWEST LABORATORY SAFETY COURSE



Centers for Disease Control and Prevention



# Chemical Fume Hood Course

## New Chemical Fume Hood

Course Available



Centers for Disease Control and Prevention

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[www.train.org/cdctrain/welcome](http://www.train.org/cdctrain/welcome)



# Emerging Technologies



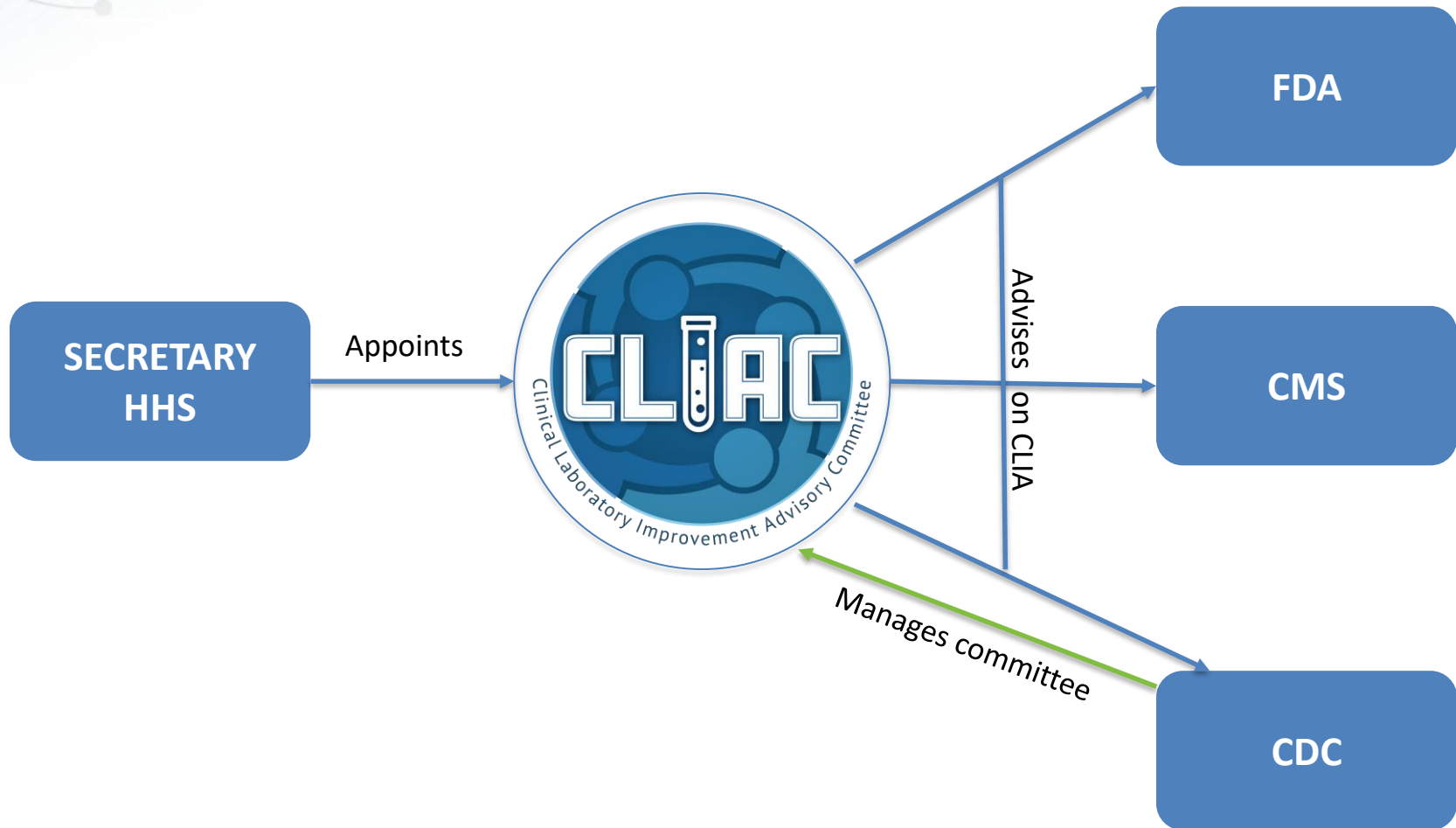
Advanced technology is increasingly part of the *clinical laboratory*.



# Clinical Laboratory Improvement Advisory Committee (CLIAC)



# CLIAC Structure and Membership



# Highlights from April 2019 CLIAC Meeting

**April 10-11, 2019 in Baltimore**

Personnel Regulations Workgroup

Nontraditional Testing Workflow Model Workgroup

Next Generation Sequencing (NGS) Workgroup



# Register Now: CLIAC Fall Meeting



## **CLIAC 2019** Fall Meeting

November 6-7, CDC's Roybal Campus, Atlanta, GA



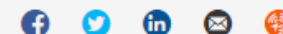
# November 2019 CLIAC Meeting: Public Comment Session

- Are bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings?
- What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging laboratory technologies and nontraditional testing workflow models, including next generation sequencing, biomarker testing, metagenomics, and others?
- What data are available that could assist in answering how CLIA may need to be revised or where guidance may be needed to ensure the accuracy and reliability of emerging technologies?

# Visit CLIAC online at [cdc.gov/CLIAC](https://cdc.gov/CLIAC)!

## Clinical Laboratory Improvement Advisory Committee (CLIAC)

CLIAC Home



### CLIAC Home

Meeting +

Membership +

CLIAC Charter

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CLIA

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### Participate in Public Comment on Emerging Technologies and the Clinical Laboratory

At the November 6-7, 2019 meeting, CLIAC is specifically soliciting public comments to address the questions below. Information provided via public comments will not be considered advice directly addressed to HHS. Rather, it will be used by CLIAC to inform their deliberations and recommendations to HHS and to help focus a CLIAC workgroup that will be convened in response to an April 2019 CLIAC recommendation that such a workgroup be charged with providing input to CLIAC in advising how CLIA might be updated.

1. Are bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings?
2. What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging laboratory technologies and nontraditional testing workflow models, including next generation sequencing, biomarker testing, metagenomics, and others?
3. What data are available that could assist in answering how CLIA may need to be revised or where guidance may be needed to ensure the accuracy and reliability of emerging technologies?

In general, each individual or group requesting to make oral comments will be limited to a total time of ten minutes (unless otherwise indicated). Written comments can also be provided up to the first day of the meeting. Send comments to [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov).

[Register for the Meeting](#)



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

Nancy Anderson: 404-498-2741 or [nla0@cdc.gov](mailto:nla0@cdc.gov)

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