

November QIF Call: CLIA Checklist

Wednesday, November 10, 2021

Funding Disclaimer

This publication was supported by Cooperative Agreements #NU60OE000103 and NU60OE000104, 100% funded by the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the US Department of Health and Human Services.



Acknowledgments



CLIA Workgroup

APHL Members

Hyder Al Janabi

Leann Covington

Analiza Gross

Rajesh Parmar

Kimyatta Smith

Mary Bonifas

Gillian Edwards

Lydia Mikhail

Kathy Ross

Tamara Theisen

Bonita Bryant

Laurie Gregg

Laura Naught

Deborah Severson (Laboratory
Systems and Standards committee
chair)

APHL Staff

Kuki Hansen

Lorelei Kurimski

Tina Su

Andrea Wright



CLIA Workgroup

APHL would like to acknowledge the following CDC staff for their contributions to this project:

Nancy Anderson
Meredith Korth, CQA (ASQ),
Booz Allen Hamilton

Víctor R. De Jesús, PhD
Atis Muehlenbachs

Marie Earley, PhD
Marranda S. Scott

APHL would also like to thank CMS CLIA staff for providing feedback and expertise.



Call Agenda

1. Project background: Meredith Korth (Booz Allen Hamilton)
2. Benefits of using the tool: Deb Severson (Fairfax County, VA PHL)
3. Demonstration of the tool: Rajesh Parmar (South Dakota - Animal Disease Research & Diagnostics Laboratory) and Bonita Bryant (Minnesota PHL)
4. Next steps: Tina Su (APHL)
5. Q/A



Project Background

- CLIA Internal Assessment program
 - Key quality assessment activity performed by our CDC Infectious Diseases Laboratories through the CLIA Compliance Program
- CLIA Internal Assessment Checklist and Guidance document
 - Developed to support the CLIA Internal Assessment program
 - Provides insight into areas needing training and guidance and allows for tracking and trending over time
- APHL Workgroup collaboration
 - The CLIA Checklist Tool was developed as a quality improvement tool for internal “self” assessments of CLIA lab activities.

Benefits of Using the Tool

- Provides systematic and consistent approach to preparing for audits
 - Internal Audits
 - External Audits
- Engage staff in QA process
- Identifies gaps/areas for improvement
- Maintain updated QMS
- Ensure adequate documentation/evidence that regulatory requirements are met
- Provide examples of documents, resources to demonstrate compliance with regulations
- Avoid financial penalties, operational stoppages

Demonstration



Next Steps

- Upload QIF webinar file and slides to QIF archive page
- Send out QIF call evaluation survey
- Work with APHL Communications to publish final version of the tool
- Update CLIA website with new materials related to this checklist
- Promote tool through APHL eUpdate and Quality Assurance Community

Q & A



Questions?

Contact Tina Su at
bertina.su@aphl.org