

Background Information for November 18-19, 2015 CLIAC Meeting

We are providing background information and some links for topics that will be discussed during the upcoming CLIAC meeting. We recommend you review the attached information prior to attending the meeting to facilitate your engagement in the Committee Discussions. The links can serve as informational resources not only for the upcoming meeting but for CLIA and CDC information in general.

HHS Agency CLIA Websites

- CDC CLIA: <http://wwwn.cdc.gov/clia/>
- CMS CLIA: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia>
- FDA CLIA: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm>

ONC Laboratory Interoperability Action Plan

- Ms. Karen Dyer's "Laboratory Interoperability Plan" presentation to CLIAC on April 15, 2015. Presentation: http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Addenda/cliac0415/6_DYER_ONC%20Laboratory%20Interoperability%20Plan.pdf and CLIAC Summary (page 12): http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/CLIAC_Summary/cliac0415_summary.pdf

Noninvasive Prenatal Testing

Institute of Medicine (IOM) Committee Report: *Improving Diagnosis in Health Care*

- *Improving Diagnosis in Health Care*, a continuation of the landmark Institute of Medicine reports *To Err Is Human: Building A Safer Health System* (2000) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) finds that diagnosis—and, in particular, the occurrence of diagnostic errors—has been largely unappreciated in efforts to improve the quality and safety of health care. The result of this inattention is significant: The committee concluded that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences. Urgent change is warranted to address this challenge. <http://iom.nationalacademies.org/reports/2015/improving-diagnosis-in-healthcare>

Other Useful Links

- CDC Center for Surveillance, Epidemiology, and Laboratory Services <http://www.cdc.gov/ophss/CSELS/index.html>
- CDC Laboratory Training Branch: <http://www.cdc.gov/labtraining/>