

Background Information for November 2-3, 2016 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. Additional meeting information including the agenda and presentations can be found at <http://www.cdc.gov/cliac/>.

HHS Agency Updates

We have decreased the time allotted for agency updates. We are asking CLIAC members to review each agency presentation prior to the start of the meeting on November 2, 2016. As they become available, updates from the CDC, CMS, and FDA can be found at <http://www.cdc.gov/cliac/> under Presentations & Other Documents.

Cytology Workload

- FDA Tips and Articles on Device Safety, “How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices” available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm>
- “Time Consumed by Microscopic and Nonmicroscopic Task in Image-assisted Gynecologic Screening: Implications for Workload Assessment” available at <http://onlinelibrary.wiley.com/doi/10.1002/cncy.21711/epdf>

IOM Workgroup Update: Communication of Test Results

- Examples of guidance for the framework include 2015 VHA Directive 1088 policy on communicating test results available at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3148.
- Examples of guidance include “Test Results Reporting & Follow-up” ONC SAFER Guide available at <https://www.healthit.gov/safer/guide/sg008>.