

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE
DRAFT Agenda

2500 Century Center Blvd., Auditorium 1200A
Atlanta, GA 30345

Wednesday, November 5, 2014

<u>Time</u>	<u>Index*</u>	<u>Topic</u>	<u>Speaker/Moderator</u>
8:30		Call to Order/Welcome	Dr. Devery Howerton Dr. Burton Wilcke
8:40		Introductions/Conflict of Interest	Dr. Burton Wilcke
8:50		Advisory Committee Process Review	Dr. Devery Howerton
9:00		CDC Update (includes Committee discussion)	Dr. Barb Zehnbauer
9:20		CMS Update (includes Committee discussion)	Ms. Karen Dyer
9:40		FDA Update (includes Committee discussion)	Dr. Alberto Gutierrez
10:00		BREAK (~ 15 minutes)	
		CLIA Waived Testing	
10:15		Historical Background	Ms. Nancy Anderson
10:35		FDA CLIA Waiver Approval Process and Criteria	Dr. Prakash Rath
10:55		CMS Waived Testing Update	Ms. Daralyn Hassan
11:15		Public Comments – Waived Testing	
11:30		CLIAC Discussion-CLIA Waived Testing	Dr. Burton Wilcke
12:30		LUNCH (~ 45 minutes)	
		Virtual Crossmatching for Transplantation	
1:15		Introduction - Virtual Crossmatch	Ms. Penelope Meyers
1:30		Virtual Crossmatch Workgroup Report	Dr. Robert Bray
2:30		Public Comments - Virtual Crossmatch	
2:45		BREAK (~ 15 minutes)	

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3:00	CLIAC Discussion – Virtual Crossmatch Workgroup Report	Dr. Burton Wilcke
4:45	Public Comments - General	
5:00	Adjourn	Dr. Burton Wilcke

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Thursday, November 6, 2014

<u>Time</u>	<u>Index*</u>	<u>Topic</u>	<u>Speaker/Moderator</u>
8:30		Call to Order	Dr. Devery Howerton Dr. Burton Wilcke
8:40		CDC OID Board of Scientific Counselors Update (includes Committee discussion)	Dr. Robert Sautter
9:00		FDA Draft Guidance on Laboratory Developed Tests	Dr. Alberto Gutierrez
9:20		Public Comments – Laboratory Developed Tests	
9:30		CLIAC Discussion – Laboratory Developed Tests	Dr. Burton Wilcke
9:50		BREAK (15 minutes)	
		Laboratory Biosafety in the United States	
10:05		CDC Laboratory Safety Improvement Workgroup and the Impact on Clinical Laboratories	Dr. Mike Bell
10:25		Ebola Outbreak Response – CDC Testing and Guidance for Clinical Laboratories	Dr. Toby Merlin
10:45		CLIAC Discussion - Ebola Response	Dr. Burton Wilcke
		Public Comments	
11:30		Meeting and Recommendations Summary	
11:45		Announcements	Dr. Burton Wilcke
12:00		Adjourn	Dr. Burton Wilcke

Future Meeting Dates:

- April 14-15, 2015
- November 4-5, 2015