



CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE

Virtual Meeting by Zoom webinar

Wednesday April 14, 2021

<u>Time (EDT)</u>	<u>Topic</u>		<u>Speaker/Moderator</u>
11:00	Call to Order/Welcome	1	Dr. Valerie Ng Dr. Reynolds Salerno
	Recognition of Outgoing Members:	2	
	<ul style="list-style-type: none"> • Dr. Marc Couturier • Dr. Steve Hinrichs • Dr. Jordan Laser • Dr. Thomas Lorey • Dr. Katherine Perez • Dr. Thomas Williams • Ms. Regina Van Brakle 		
	Recognition of New Members:		
	<ul style="list-style-type: none"> • Ms. Heather Duncan • Ms. Monique Spruill 		
11:20	Introductions/Conflict of Interest		Dr. Valerie Ng
11:30	CDC Update	3	Dr. Collette Fitzgerald
12:00	CMS Update	4	Ms. Monique Spruill
12:30	FDA Update	5	Dr. Timothy Stenzel
1:00	CLAC Recommendations Update	6 6a	Ms. Heather Stang/ Dr. Lisa Kalman
1:30	Laboratory Response Network (LRN) Overview	7	Dr. Julie Villanueva
2:00	BREAK (1 hour)		
	CLINICAL LABORATORY MEDICINE IN THE AGE OF COVID-19		
	Clinical Laboratory Perspectives on Laboratory Developed Tests		
3:00	Introduction to Topic	8 8a	Dr. Valerie Ng
3:10	Challenges and Opportunities Surrounding Laboratory Developed Tests as an Essential Component of the Pandemic Response	9	Dr. Matthew Binnicker
3:30	Moving Mountains: (R)Evolution of LDT Regulation in the Face of COVID-19	10	Dr. Dara Aisner
3:50	Public Comments		
4:05	Committee Discussion		Dr. Valerie Ng
5:40	Day One Wrap-Up		Dr. Valerie Ng
6:00	Adjourn		Dr. Valerie Ng



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Thursday April 15, 2021

<u>Time (EDT)</u>	<u>Topic</u>		<u>Speaker/Moderator</u>
11:00	Call to Order/Roll Call		Dr. Valerie Ng Dr. Reynolds Salerno
Application of Regulations during the COVID-19 Pandemic			
11:10	CMS Regulatory Changes during COVID-19 Pandemic	11	Ms. Monique Spruill
11:30	FDA Regulatory Changes during COVID-19 Pandemic	12	Dr. Timothy Stenzel
11:50	Lessons Learned from SARS-CoV-2 Testing Regulatory Flexibilities	13	Dr. Reynolds Salerno
12:10	Public Comments		
12:20	Committee Discussion		Dr. Valerie Ng
2:00	BREAK (1 hour)		
Expansion of Point-of-Care Testing, Self-Collection, and Self-Testing			
3:00	The Expansion of Point-of-Care Testing During the COVID-19 Pandemic	14 14a	Ms. Nancy Anderson
3:20	FDA Overview of Point-of-Care Testing, Home Collection and Testing	15	Dr. Timothy Stenzel
3:40	Public Comments		
3:50	Committee Discussion		Dr. Valerie Ng
5:30	Future CLICAC Topic Discussion		Dr. Valerie Ng
6:00	Adjourn		Dr. Valerie Ng