

**Microbiology Medical Devices Panel  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE**

**Holiday Inn, Gaithersburg  
November 10, 2016**

**Panel Chairperson**  
Angela Caliendo, M.D., Ph.D.

**Designated Federal Officer**  
Shanika Craig, M.H.A., M.B.A.

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- 8:00 a.m. Call to Order  
Conflict of Interest and Deputization to Voting Member Status Statements  
Panel Introductions
- 8:15 a.m. Introduction  
**Kristian Roth, Ph.D., Branch Chief**  
Division of Microbiology Devices  
Office of In Vitro Diagnostics and Radiological Health
- 8:30 a.m. **Dr. Ebbing Lautenbach, M.D., MPH, MSCE-Guest Speaker**  
University of Pennsylvania  
Antibacterial Resistance Leadership Group (ARLG) Presentation  
*“Challenges in Studying Rapid Diagnostic Tests in Outpatient Respiratory Tract Infections”*
- 8:50 a.m. Q & A
- 9:00 a.m. **bioMérieux Presentation**
- 10:00 a.m. Q & A
- 10:15 a.m. Break
- 10:30 a.m. FDA Presentation
- 11:30 a.m. Q & A
- 11:45 a.m. Lunch
- 12:45 p.m. Open Public Hearing\*
- 1:45 p.m. Panel Deliberations
- 2:45 p.m. Break
- 3:00 p.m. FDA Questions
- 5:00 p.m. Summations
- 5:30 p.m. Adjournment

\*Open Public Hearing – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.