



**Clinical Chemistry and Clinical Toxicology Devices Panel
of the
MEDICAL DEVICES ADVISORY COMMITTEE
Alere Technologies, Inc., Alere Afinion HbA1c Dx
July 22, 2016**

Panel Chairperson

Karol E. Watson, M.D., Ph.D.

Designated Federal Officer

Patricio G. Garcia, M.P.H.

08:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
08:10 a.m.	Guest Speaker (Robert E. Ratner, M.D., F.A.C.P., F.A.C.E.) - American Diabetes Association (30 min)
08:40 a.m.	Q&A Guest Speaker
08:45 a.m.	Sponsor Presentation
10:15 a.m.	Q&A Sponsor
10:30 a.m.	Break
10:45 a.m.	FDA Presentation
12:15 p.m.	Q&A FDA
12:30 pm	Lunch
1:30 p.m.	Open Public Hearing*
2:15 p.m.	Panel Deliberations
3:15 p.m.	Break
3:30 p.m.	FDA Questions
5:40 p.m.	FDA and Sponsor Summations
6:00 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.