



**Clinical Chemistry and Clinical Toxicology Devices Panel  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE  
SOLVD Health for the *AvertD* test  
October 20, 2022**

**Panel Chairperson**

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

**Designated Federal Officer**

James Swink

09:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
09:15 a.m.	Training on De Novo Program
09:25 a.m.	Breakthrough Device Designation Program
09:35 a.m.	Clarifying Questions for the Panel
09:40 a.m.	Sponsor Presentation
10:40 a.m.	Q&A Sponsor
10:55 a.m.	Break
11:00 a.m.	FDA Presentation
12:00 p.m.	Q&A FDA
12:15 pm	Lunch
1:00 p.m.	Open Public Hearing*
2:15 p.m.	Panel Deliberations
3:15 p.m.	Break
3:30 p.m.	FDA Questions
5:30 p.m.	FDA and Sponsor Summations
5:50 p.m.	Vote
6:30 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.