

Public Workshop - In Vitro Diagnostic Testing for Direct Oral Anticoagulants, October 26, 2015

The Food and Drug Administration (FDA) is announcing a public workshop entitled “In Vitro Diagnostic Testing for Direct Oral Anticoagulants”. The objective of the workshop was to discuss analytical performance requirements for the diagnostic assessment of direct oral anticoagulants (DOACs), and the clinical circumstances under which patients receiving these agents would require testing. Specifically, this workshop aimed to 1) evaluate the impact of DOACs on traditional coagulation testing results; 2) identify clinical circumstances where testing of DOACs anticoagulant activity or concentration would be relevant; 3) discuss clinically meaningful interpretation of coagulation testing results for patients on DOACs; and 4) review the regulatory requirements for granting clearance for in vitro diagnostic devices intended for coagulation testing in patients treated with DOACs.

- [Date, Time and Location](#)
 - <https://www.federalregister.gov/articles/2015/08/26/2015-21095/meetings-in-vitro-diagnostic-testing-for-direct-oral-anticoagulants-public-workshop>
 - [Webcast Archive](#)
 - [Agenda](#)
 - [Contact Us](#)
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Date, Time and Location

This meeting was held October 26, 2015, beginning at 9:00 am – 5:00 pm at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31, Room 1503 (the Great Room)
Silver Spring, MD, 20993

The meeting was webcast.

Webcast Archive

- [Webcast Part 1 \(https://collaboration.fda.gov/p3resh38eo7/\)](https://collaboration.fda.gov/p3resh38eo7/)
- [Webcast Part 2 \(https://collaboration.fda.gov/p2ay67rihei/\)](https://collaboration.fda.gov/p2ay67rihei/)
- [Webcast Part 3 \(https://collaboration.fda.gov/p4vgrykr4q8/\)](https://collaboration.fda.gov/p4vgrykr4q8/)
- [Webcast Part 4 \(https://collaboration.fda.gov/p73kgxdoo4h/\)](https://collaboration.fda.gov/p73kgxdoo4h/)

Agenda

AM Session

Time	Event	Speaker
9:00– 9:10am	Introduction and Welcome (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473307.pdf)	Leonthena Carrington, FDA/CDRH
Laboratory and Clinical Perspectives		
9:10am– 9:30am	Overview of DOACs and their clinical indications	Robert Califf, FDA
9:30– 9:50am	Challenging Cases Involving Emergency Department Patients on Novel Oral Anticoagulants (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473309.pdf)	Frederick Korley, Johns Hopkins
9:50– 10:00am	Measurement of the DOACs: Basic Principles and Attributes of an Ideal Assay (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473311.pdf)	Adam Cuker, University of Pennsylvania
10:00– 10:20am	Methods for measuring Direct Oral Anticoagulants (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473312.pdf)	Dorothy Adcock-Funk, Colorado Coagulation
10:20– 10:40am	The clinical laboratory establishing and offering a DOAC measurement test: What's important? (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473313.pdf)	Robert Gosselin, University of California, Davis
10:40– 10:50am	Questions for speakers	
10:50– 11:10am	Break	

11:10– 11:30am	When are tests for DOAC measurement clinically needed and how to interpret and use the results (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473315.pdf)	Stephan Moll, University of North Carolina, Chapel Hill
11:30– 11:40am	Measurement of the DOACs: Suggestions and Guidance Statements (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473316.pdf)	Adam Cuker, University of Pennsylvania
11:40am– 12:00pm	New Oral Anticoagulants Pharmacokinetics, Pharmacodynamics, and Exposure-Response (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473317.pdf)	Martin Rose and Jeffry Florian, FDA/CDER
12:00– 12:10pm	Questions for speakers	
12:10– 1:00pm	Lunch	

PM Session

Time	Event	Speaker
Commercial Development		
1:00– 1:20pm	In Vitro Diagnostic Testing for Direct Oral Anticoagulants (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473318.pdf)	Bryan Lulicht, Perosphere
1:20– 1:40pm	Development of Assays for the Testing of Direct Oral Anticoagulants (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473319.pdf)	Mark Triscott, Instrumentation Laboratory
1:40– 2:00pm	DOAC Detection on TEG®6s (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473321.pdf)	Marc Doubleday, Haemonetics
2:00– 2:20pm	Testing for Direct Oral Anticoagulants-An IVD Perspective (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473322.pdf)	Francois Depasse, Daniel Kaczor, Stago
2:20– 2:30pm	Questions for speakers	
2:30– 2:50pm	Break	
FDA Perspective		
2:50– 3:10pm	Test Outputs and Interpretation (/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473323.pdf)	Marina Kondratovich, FDA/CDRH
3:30–	Regulatory Considerations	Abraham Tzou,

3:50pm	(/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM473324.pdf)	FDA/CDRH
3:50– 4:00pm	Questions	
4:00– 4:30pm	Panel Discussion	
4:30– 4:45pm	Meeting Wrap-Up and Adjourn	Leonthena Carrington, FDA/CDRH

Contact Us

For questions regarding workshop content please contact:

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