



2020 Virtual Focus Meeting Agenda
as of 9.16.20

Day 1 Agenda: Friday October 9, 2020
All times are PST

Session	Topic	Time	Speaker
Welcome	Open Online Portal Welcome	8:45 PST	Meeting Chair: Tiffany D. Levin, 55 th Parallel (tiffany@55thparallel.com)
			Meeting Chair: Lesley Farrington/Janssen Dx (lfarring@its.inj.com)
IVDD/R Update	IVDR – Where are we now	9:00- 9:30	Julien Senac, Ph.D., Global Director, IVD TUV SUD America
	IVDR Intended Purpose	9:30- 10:15	Volker Franzen, Sr. Director Regulatory & Governmental Affairs Qiagen GmbH
	IVDR Clinical Evidence	10:15- 11:00	Christian Zaugg, Global Head of Clinical Science in Centralised and Point of Care Solutions (CPS) Roche Dx, Switzerland
BREAK 11:00-11:15			
Molecular Updates	Clearance of PgDx Elio Tissue Complete	11:15- 11:45	Jennifer Dickey, Vice President of Regulatory & Quality Personal Genome Diagnostics (PGDx)
	Sample Collection Considerations	11:45- 12:15	Yarmela Pavlovic, Partner Manatt, Phelps & Phillips, LLP
	Foundation One CDx HRR-mutated mCRPC Approval	12:15- 12:45	Varun Pattani, Associate Director Foundation Medicine
CLOSING REMARKS			



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Day 2 Agenda: Friday, October 16, 2020

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Session	Topic	Time	Speaker
	Open Online Portal Welcome	8:45 PST	Meeting Chair: Tiffany D. Levin, 55 th Parallel (tiffany@55thparallel.com) Meeting Chair: Lesley Farrington/Janssen Dx (lfarring@its.jnj.com)
COVID-19 Regulatory Developments	EUA for COVID19	9:00-9:30	Jeff Gibbs, Director Hyman, Phelps & McNamara, P.C.
	Conversion of Emergency Use Authorization using RWE [EUA to 510(k)]	9:30-10:00	Sue Dahlquist, <i>(MDIC Project Representative)</i> Senior Director, Global Strategic Regulatory & Clinical Affairs Thermo Fisher Scientific, Inc.
	Updates from COVID-19 Diagnostic Evidence Accelerator	10:00-10:30	Susan Winckler, CEO, Reagan-Udall Foundation Carla Rodriguez-Watson, Ph.D., Scientific Director IMEDS/Reagan-Udall Foundation
BREAK 10:30-10:45			
COVID -19 Testing	Developing a rtPCR Test	10:45-11:15	Speaker from Thermo Fisher Scientific, Inc.
	Bringing a Serology Antibody Test to Market (Pandemic Mode)	11:15-11:45	Tammy Dean, Manager, Regulatory Affairs Roche Diagnostics
	Update on COVID-19 Testing	11:45-12:15	Harvey Kaufman, Quest Diagnostics
	Potential for single cell sequencing, including TCR/BCR	12:15-12:45	Jim Heath, Institute of Systems Biology
Wrap Up	Annual Meeting Summary	12:45-1:00	AMDM Board of Directors

CLOSING REMARKS