2020 Virtual Focus Meeting Final Agenda

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, 55th Parallel (tiffany@55thparallel.com) Meeting Chair: Lesley Farrington/Janssen Dx (lfarring@its.jnj.com)
IVDD/R Update	IVDR – Where are we now (EU and UK CE marking)	9:00-9:45	Julien Senac, Ph.D., Global Director, IVD TUV SUD America
	IVDR - Intended Purpose	9:45-10:15	Volker Franzen, Sr. Director Regulatory & Governmental Affairs Qiagen GmbH
	IVDR - Clinical Evidence	10:15-10:45	Christian Zaugg, Global Head of Clinical Science in Centralised and Point of Care Solutions (CPS) Roche Dx, Switzerland
	Panel Discussion	10:45-11:00	Julien Senac, Volker Franzen, Christian Zaugg
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			

2020 Virtual Focus Meeting Final Agenda

Day 2 Agenda: Friday, October 16, 2020

All times are PST

Session	Topic	Time	Speaker
	Open Online Portal Welcome	8:45 PST	Meeting Chair: Tiffany D. Levin, 55th 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, *(MDIC Project Representative)* 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
BREAK 10:30-10:45			
COVID -19 Testing	Developing a rtPCR Test	10:45-11:15	Kelli Tanzella, Sr. Director of Regulatory Affairs 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
AMDM Wrap Up	Annual Meeting Summary	12:45-1:00	AMDM Board of Directors
CLOSING REMARKS			