

Facilitating Development and Utilization of Genome-Based Diagnostic Technologies: A Workshop

November 15, 2011

**The Keck Center of the National Academies
500 Fifth St., N.W.
Washington, DC 20001**

Workshop Objective:

- To address the differences in evidence required for clinical use, regulatory oversight and coverage for a laboratory test, as well as laboratory test reimbursement, with the goal of clarifying a pathway for successfully bringing a test to clinical use for the benefit of patients.

Focal Questions:

- What are your views of the described barriers to successful genomic test development?
 - What are potential solutions?
 - What are the obstacles to achieving those solutions?
 - How can we overcome those obstacles?
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7:45 A.M. Working Breakfast

8:30 A.M. Welcoming Remarks

Wylie Burke, *Roundtable Chair*
Professor and Chair
Department of Bioethics and Humanities
University of Washington

8:35 A.M. Charge to Workshop Speakers and Participants

Robert McCormack, *Workshop Co-Chair*
Head of Technology Innovation and Strategy
Veridex, LLC

8:45 A.M. **Review of November 2010 workshop “Generating Evidence for Genomic Diagnostic Test Development” and Statement of Problem**

Debra Leonard, *Workshop Co-Chair*
Professor and Vice Chair, Department of Pathology and
Laboratory Medicine
Director of the Clinical Laboratories
Weill Cornell Medical Center

SESSION I: ADVANCING DIAGNOSTIC DEVELOPMENT

Session Focus: Recommendations for advancing the development and utilization of molecular diagnostics.

9:15 A.M. **Advancing utility and adoption of clinical genomic diagnostics – Part I**

Moderator: Robert McCormack, Veridex, LLC

Daniel Hayes
Clinical Director of the Breast Oncology Program and Stuart B.
Padnos Professor in Breast Cancer Research
University of Michigan Comprehensive Cancer Center

Muin Khoury
Director, National Office of Public Health Genomics
Centers for Disease Control and Prevention

Laura Van't Veer
Angela and Shu Kai Chan Endowed Chair in Cancer Research
Leader, Breast Oncology Program
Director, Applied Genomics
UCSF Helen Diller Family Comprehensive Cancer Center

Russel K. Enns
Chief Regulatory Officer
Cepheid

10:15 A.M. **Discussion with Speakers and Attendees**

10:45 A.M. BREAK (15 minutes)

11:00 A.M. **Advancing utility and adoption of clinical genomic diagnostics – Part II**

Moderator: **Debra Leonard, Weill Cornell Medical Center**

Steven Shak
Chief Medical Officer
Genomic Health, Inc.

Mark Gorman
Director of Survivorship Policy
National Coalition for Cancer Survivorship

Nicholas Conti
Vice President, Business Development
Quest Diagnostics

Sue Siegel
General Partner
Mohr Davidow

12:00 P.M. **Discussion with Speakers and Attendees**

12:30 P.M. LUNCH

1:15 P.M. **Advancing utility and adoption of clinical genomic diagnostics – Part III**

Moderator: **Robert McCormack, Veridex, LLC**

Bruce Quinn
Senior Health Policy Specialist
Foley Hoag LLP

Sean Tunis
Director
Center for Medical Technology Policy

Louis Hochheiser
Medical Director Clinical Policy
Humana, Inc.

2:00 P.M. **Discussion with Speakers and Attendees**

SESSION II: PATHS FORWARD

2:30 P.M. **Evaluating paths forward for advancing molecular diagnostics through regulatory and reimbursement policy**

Moderator: Debra Leonard, Weill Cornell Medical Center

Alberto Gutierrez
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Louis Jacques
Director, Coverage & Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services

3:20 P.M. BREAK

3:30 P.M. **Discussion with Speakers and Attendees**

SESSION III: FACILITATING CONVERGENCE

Session Focus: Identifying areas of contention and developing potential solutions for advancing molecular diagnostics

Moderator: Wylie Burke, University of Washington

4:15 P.M. Panel Discussion with Prior Speakers

SESSION IV: FINAL REMARKS

5:30 P.M. **Concluding Remarks**

Robert McCormack, *Workshop Co-Chair*
Head of Technology Innovation and Strategy
Veridex, LLC

Debra Leonard, *Workshop Co-Chair*
Professor and Vice Chair, Department of Pathology and
Laboratory Medicine
Director of the Clinical Laboratories
Weill Cornell Medical Center

5:45 P.M. **Adjourn**