NIST-EDRN Workshop on Standards and Metrology for Cancer Diagnostics

Agenda

A National Institute of Standards and Technology and the Early Detection Research Network Joint Workshop on Standards, Methods, Assays, Reagents and Technologies (SMART) For Early Cancer Detection and Diagnosis

National Institute of Standards and Technology, Gaithersburg, Maryland
Green Auditorium

Thursday August 18, 2005

7:00 AM – 9:00 AM	Registration
8:00 AM	Coffee, NIST Cafeteria Posters and Exhibits in Hallways
NIST Green Auditorium	
8:30 – 8:45 AM	Welcome Moderator: **Peter Barker** National Institute of Standards and Technology **Peter Greenwald**, National Cancer Institute (tentative) **Willie May,** National Institute of Standards and Technology
8:45 – 9:00 AM	Charge to Participants: **Robert Goldberg,** National Institute of Standards and Technology **Sudhir Srivastava,** National Cancer Institute
Plenary Session: NIST Green Auditorium Moderator: **Paul Wagner,** National Cancer Institute Objective: *To identify promises and barriers (especially due to the lack of standards) in clinical application of biomarkers.*	
9:00 – 9:35 AM	NIST: Standards, Standard Reference Materials (SRMs) and Healthcare **Willie May,** National Institute of Standards and Technology
9:35 – 10:10 AM	Clinical Applications of Biomarkers **Lance Liotta,** George Mason University

10:10 – 10:30 AM	**Coffee and Posters** *Presentations on the progress and pitfalls in development and validation of biomarkers, including priorities for assays, technologies and standards*
10:30 – 11:00 AM	Serum/Plasma Proteomics for Clinical Applications in Early Cancer Detection **Gilbert Omenn**, University of Michigan
11:00 -11:30 AM	Epigenetics for Clinical Applications in Early Cancer Detection **Stephen Baylin,** Johns Hopkins University
11:30 –12:00 PM	Regulatory Aspects: *What will FDA require for new biomarker and new diagnostics submissions? How will proteomic and epigenomic approaches compete against existing products?* **Steve Gutman**, U. S. Food and Drug Administration
12:00 – 1:30 PM	**Lunch Break, Posters and Exhibits** NIST Poster Session: Proteomic Technologies and Data Analysis **Steve Stein** (MS and databases) **David Bunk** (chemistry tryptic analysis) **Fred Schwarz** (peptide standards) **Mike Welch** (preparation of SRMs) **Walt Liggett** (analysis of high complexity datasets)

Concurrent Sessions: NIST Conference Rooms A and C

Concurrent Session I: Proteomics (Conference Room A)

Early Cancer Detection: Proteomics Session – 1

Chairman: **Gilbert Omenn,** University of Michigan

Objectives:

- *Discusscomponents of proteomics, such as sampling, processing and laboratory performance, peptide identification, and protein assignment that can be enhanced with standards based on current state of the technologies and experience with ABRF standards development process*
- *Discuss what is available; what has been the user's experience, what are the needs?*
- *Discuss standards needed for platform comparisons and cross validation methods and issues in the development of specimens (serum, plasma, lysate) standards*

1:30 - 2:00 PM	Proteomic Technologies and the Need for Standards **Philip Andrews,** University of Michigan

2:00 – 3:00 PM	Prior and Ongoing Efforts for Developing Measurement Standards: Proteomics-based Technologies **Alexey Nesvizhskii,** Institute for Systems Biology **Daniel Chan,** Johns Hopkins University **Bruce Haywood**, BD Diagnostics
3:00 – 4:00 PM	Discussion and Recommendations Discussants: **Mollie Ullman-Cullere**, Harvard Partners **David Bunk**, National Institute of Standards and Technology
4:00 – 4:15 PM	**Coffee Break**
4:15 – 5:15 PM	Mass Spectrometry **Chip Petricoin**, George Mason University **Liang Li**, University of Alberta **Cathy Costello**, Boston University (tentative)
5:15 – 6:15 PM	Discussion and Recommendations
6:15 PM	**Adjourn**

Concurrent Session II: DNA Methylation (Conference Room C)
Early Cancer Detection: DNA-Methylation Session – 1
Chairman: **Steve Belinsky,** Lovelace Respiratory Institute

Objectives:

- *Discuss sensitivity differences between regular and nested, MSP, stochastic sampling, challenges with sputum Provide overview of applications and demands for the assay*
- *Discuss quantitative assays measuring methylation in adjacent tissue to examine the field effect and relate back to original EDRN platform comparison project*
- *Discuss differences in blood versus urine in screening, transitional epithelial cells from the bladder versus free DNA from the body.*
- *Discuss challenges for assessing methylation in stool and nipple aspirates, and strategies for MSP and effect on results***.**

1:30 – 2:00 PM	Requirements for Reliability, Reproducibility, Quantitation, Sensitivity, and Specificity for methylated DNA Biomarkers **Steve Belinsky**, Lovelace Respiratory Institute
2:00 - 3: 00 PM	EDRN Experience in Quantitative Measurements of Epigenetic Modification - Hyper and Hypomethylation in Cancer Detection and Diagnosis **Adi Gazdar**, UT Southwestern Medical Center **Paul Cairns**, Fox Chase Cancer Institute
3:00 – 4:00 PM	Standard Specimens for detection and analysis of methylated DNA in body fluids and exfoliated cells **James Herman**, Johns Hopkins University
4:00 – 4:15 PM	**Coffee Break**

4:15 – 4:45 PM	Challenges and solutions in detection of epigenetic modification **Jean Pierre Issa**, M.D. Anderson Cancer Center
4:45 – 5:15 PM	High throughput platforms for detection of methylation in candidate genes **Pearlly Yan**, Ohio State University
5:15 – 5:35 PM	Address issue of LCMS versus standard bisulfite sequencing **Mathias Ehrich**, Sequenome
5:35 – 5:55 PM	Development of a validated clinical assay for methylation **Katja Bierau**, OncoMethylome Sciences SA
5:55 – 6:15 PM	Pyrosequencing **Rene L. Myers**, Biotage
6:15 PM	**Adjourn**

Friday August 19, 2005

NIST Green Auditorium **Combined Session: Synergizing Standards with Clinical Application** Clinical Reference Materials for Biomarker Discovery and Validation Moderator: **Jacob Kagan**, National Cancer Institute	
8:00 - 8:20 AM	Why Clinical Reference Materials **Ziding Feng**, Fred Hutchison Cancer Research Center
8:20 – 8:50 AM	Clinical Reference Materials: How would this vary with clinical questions? Lung cancer as an example **Bill Bigbee**, University of Pittsburgh
8:50 – 9:45 AM	Panel Discussion on Clinical Reference Materials and Logistical Challenges Discussion leader: **Bill Grizzle**, University of Alabama Topics include: *Will the same specimen collection serve needs of both DNA methylation and proteomics? What similarities should be designed into the standards for DNA methylation and for proteomics?* *Adhering to standards without compromising patient care; criteria for access to Reference Samples (preliminary data, epidemiological criteria, assay reproducibility, sensitivity and specificity); collection and storage issues; patient acceptance and IRB approval* Panelists: **Adi Gazdar**, UT Southwestern Medical Center **Steve Belinsky**, Lovelace Respiratory Institute

	Philip Andrews, University of Michigan
9:45 – 10:00 AM	**Coffee, Posters, Move to Separate Discussion Rooms** (Proteomics Lecture Room A; Methylation Lecture Room D)

Concurrent Session I: Proteomics (Lecture Room A) **Early Cancer Detection: Proteomics Session – 2** **Chairman: Gilbert Omenn,** University of Michigan	
10:00 – 11:00 AM	Antibody and Protein Arrays **Brain Haab,** Van Andel Research Institute **Arul Chinniayan**, University of Michigan **Richard Zangar,** Pacific Northwest National Laboratories
11:00 – 11:30 AM	Discussion and Recommendations
	Discussant: **Michael Amos**, Advanced Technology Program, National Institute Standards and Technology
11:30 – 12:00 PM	Discussion and Recommendations for White Paper on Proteomics Standards
12:00 PM	**Adjourn**

Concurrent Session II: DNA Methylation (Lecture Room D) **Early Cancer Detection: DNA Methylation Session - 2**	
10:00 – 10:10 AM	Introduction **Jacob Kagan,** National Cancer Institute
10:10 – 11:45 AM	Group Discussions Chairman: **Steve Belinsky,** Lovelace Respiratory Institute Discussion of each of the following topics will be lead by two of the invited speakers. • *Limitations of current technologies? Accuracy, sensitivity, reproducibility, high throughput, speed and cost* • *What are the main problems for establishing standards for measuring methylated DNA markers for cancer detection and diagnosis? What does a quantitative MSP assay add to detection and diagnosis of disease?* • *Is cross validation needed among platforms? Should the platform depend on the*

	tissue/biological fluid being assessed? What should be the standard for acceptance? Cost? Meeting minimum standards for classifying cancer from non-cancer? High throughput? • *Standard specimens for Clinical comparisons – Can we collect and bank large quantity of standard materials for specific cancers?*
11:45 – 12:00 PM	Preparation of recommendations in the form of a white paper
12:00 PM	**Adjourn**