Multiplex Assays in Translational Medicine: Technologies, Applications, and Future Directions

by Olivia Scaros, PharmD

The development and growth of assay technologies has pushed translational medicine into a category unto itself. In a broad perspective on this field, this new report:

- Defines translational medicine by giving some historical background as well as providing personal definitions from experts in the field
- Discusses the evolution of assay technologies
- Reviews currently available assay technologies that apply directly to translational medicine
- Describes and evaluates current applications of these technologies to translational medicine

Continued on next page
Overview

- Provides case studies of clinicians currently using this technology in their research
- Discusses future directions of assay technologies for translational medicine
- Gives input from the FDA on translational medicine and assay technologies
- Provides interviews with experts in the field of both translational medicine and specific assay technologies
- Profiles premier companies active in the field

Assay technologies have been evolving since scientists first discovered they could measure glucose, insulin, and several hormones in the blood to help them diagnose disease. Early instruments such as the Ames Reflectance Meter, used for detecting glucose levels, have morphed into such sophisticated systems as flow cytometers. The Human Genome Project provided the basics for researchers to launch into the field of human genomics, and they needed the tools to accomplish this. DNA microarrays allowed for massively parallel gene expression analyses. Scientists soon discovered that while the genome-wide assays were extremely valuable, there were genes of interest that they had difficulty measuring when they got hundreds of data points from a microarray. Low- to mid-density assays have allowed scientists to pinpoint the genetic code for a variety of uses, from genetic heredity studies to drug metabolism and patient stratification.

### Multiplex Assays in Translational Medicine: Technologies, Applications, and Future Directions

Multiplex assays in translational medicine refer to the use of multiple assays simultaneously to detect and analyze multiple targets. These assays are crucial in translational medicine because they allow for a comprehensive assessment of a patient's condition, leading to more targeted and effective treatment strategies. Here are some key technologies and applications that have been pivotal in this field:

**Preclinical**
- IND/NDA: Companion diagnostics, biomarker validation
- PK/PD parameters, pathway analysis, dose selection, biomarker elucidation, next-generation compounds

**Clinical**
- Proof of concept, drug safety, biomarkers, patient selection process

Today, pharmaceutical companies are faced with many hurdles to get a discovered compound through drug development and finally to market. This report provides a thorough discussion of the roles multiplex assay technologies play in pursuing that goal.

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**About the Author:** Olivia Scaros, PharmD, graduated from the University of Illinois in 1988 with a Doctor of Pharmacy degree. She has been employed by various pharmaceutical firms, including Sandoz Pharmaceuticals, Bayer Corporation, and Pfizer, Inc., both as an employee and a consultant. For the past 16 years, Dr. Scaros’ main focus has been medical writing, including biotechnical reports, study reports, clinical protocols, articles, and other projects for the pharmaceutical industry.

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**Tables and Figures**

**Tables**
- Timeline of Early Technologies Used in the Pharmaceutical and Diagnostics Industries
- Timeline of Significant Events Relating to Mass Spectrometry
- Timeline of Microarray Milestones
- Selected Commercial, Positional Array-Based Multiplex Technologies
- Selected Companies Involved in PCR-Based Technologies
- Benefits of StaRT-PCR Method for Multigene Expression Measurement as Compared to Traditional Microarrays and PCR Technologies
- Selected Companies with Bead-Based Technologies

**Figures**
- Cycle of Translational Medicine in Clinical Research and Development Biomarker Discovery Can Lead to a Marketed Diagnostic Product Use of High-Throughput Technology and Low- to Mid-Density Assays
- Roche Diagnostics’ AmpliChip CYP450 Array, Based on Affymetrix GenChip Technology
- Roche Diagnostics’ AmpliChip Leukemia Test
- Agenda’s MammaPrint Test Technology
- Asper Biotech’s Genotyping Process
- Osmetech’s eSensor Cystic Fibrosis Carrier Screening Cartridge
- TaqMan Probe Chemistry
- Epigenomics’ Quantitative Methylation
- Genomic Health’s Oncotype DX’s Validated Use in Breast Cancer Patients
- OncoMethylome Sciences’ Product Pipeline
- OncoMethylome Sciences’ Patented Methylation-Specific PCR (MSP) Process
- Gene Express’ StaRT-PCR Process
- BD Biosciences’ Cytometric Bead Array Flex Set Assay Protocol Schematic
- High Throughput Genomics’ Assay Schema
- Luminex’s xMAP Technology
## Tables and Figures (cont.)

- Schematic of the Overall Structure of Molecular Probes’ Qdot Nanocrystal Conjugate
- BioRad’s BioPlex 2200 ANA Screen
- Monogram Biosciences’ eTag Technology
- From Diagnosis to Treatment (Dx2Tx)

## Appendix Figures

- Organizations Represented by Respondents
- Functional Areas

## Table of Contents

### Chapter 1: Introduction: Definition of Translational Medicine and How Assay Technologies Affect its Course

1.1. Scope of the Report
1.2. Translational Medicine: Beginnings and Biomarkers

### Chapter 2: The History of Assay Technologies

2.1. Early Technologies
2.2. Mass Spectrometry
2.3. DNA Microarrays

### Chapter 3: Products and Applications of Multiplex Assays for the Advancement of Translational Medicine

3.1. Microarrays
3.2. Protein Microarrays

### Chapter 4: Two Case Studies Involving Multiplex Assay Technologies Applied to Translational Medicine

4.1. Blood Testing Technology to Discover Serum Protein Markers for Early Detection of Ovarian Cancer
4.2. StaRT-PCR to Assess Genes Associated with Cisplatin Chemoresistance

### Chapter 5: Future Directions of Multiplex Assay Technologies Applied to Translational Medicine

5.1. Translating Discoveries Made in Animal Models to Humans
5.2. Discoveries in Pharmacogenomics
5.3. Assay Technologies in Disease Diagnosis
5.4. Translational Research to Help in Disease Prevention
5.5. More “System”-Oriented Assay Technologies
5.6. The Growth of Personalized Medicine Companies

### Chapter 6: FDA Perspective on Multiplex Assay Technologies in Translational Medicine

6.1. Critical Path Initiative (CPI)
6.2. Oncology Biomarker Qualification Initiative (OBQI)
6.3. Predictive Safety Testing Consortium (PSTC)

### Chapter 7: Expert Interviews

Guido Greentzm, PhD, Pres., PBS PharmaBioServices, France
David Lester, PhD, Sr. VP of Strategy & Corp. Dev., Gene Express, Toledo, OH
Bruce Litman, MD, Pres., Translational Medicine Associates; Formerly Global Head of Translational Medicine, Pfizer Global R&D, New London, CT
Francesca M. Marincola, MD, Chief, Infectious Disease & Immunogenetics Section, Dept. of Transfusion Medicine, NIH
Gil Mor, MD, PhD, Assoc. Prof., Dept. of OB/GYN & Reproductive Sciences, Yale Univ. School of Medicine
Deborah J. Neff, Pres. and CEO, Pathwork Diagnostics, Sunnyvale, CA
Scott Patterson, PhD, Ex. Dir. of Medical Sciences, Amgen, Thousand Oaks, CA
Wendy Sanhai, PhD, Sr. Scientific Advisor, Office of the Commissioner, FDA

### Chapter 8: Selected Company Profiles

- Affymetrix
- Agendia
- Asper Biotech
- Biosite
- Epigenomics
- Gene Express, Inc.
- Genomic Health
- High Throughput Genomics
- Luminex Corporation
- Monogram Biosciences
- OncoVariate Sciences
- Osmetech
- PamGene
- Random Laboratories
- Stratos Biosystems
- Xceed Molecular
- Zeptosens

### Appendix: Insight Pharma Reports Multiplex Assays Survey—December 2007

### References

### Company Index with Web Addresses
Molecular Diagnostics: A Rapidly Shifting Commercial and Technology Landscape

Molecular Diagnostics are now being used for a wide range of applications, including human and veterinary clinical molecular diagnostic testing, identity testing, forensic testing, and histocompatibility testing. Within these broad disease areas, molecular diagnostics tests have a wide range of applications, including:

- Identification of individuals who are at increased risk of developing certain disorders
- Screening apparently healthy populations
- Diagnosis
- Determining prognosis, such as with cancer
- Personalized medicine applications, including pharmacogenetic tests such as drug metabolism tests to avoid adverse drug effects and companion diagnostics to identify patients who will respond to a specific drug
- Monitoring response to therapy

This report focuses on human clinical molecular diagnostics and provides a thorough discussion of the many companies involved in molecular diagnostics and their commercial products either on the market or in development for these applications. It also includes results from a Web survey of individuals involved in molecular diagnostics research, development, and use.

This report is an essential tool for anyone involved in the discovery, validation, development, or commercialization of disease-related biomarkers. To view a table of contents and executive summary, please visit www.InsightPharmaReports.com

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