



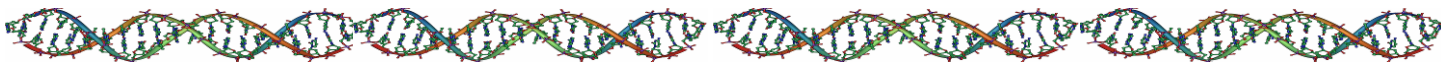
The Oldest Public Medical School in America



Division of Molecular Pathology, Department of Pathology, University of Maryland School of Medicine  
Molecular Diagnostics Laboratory, Laboratories of Pathology, University of Maryland Medical Center

# Molecular Profile

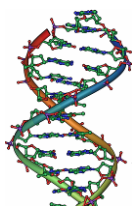
## A newsletter of Molecular Diagnostics & Molecular Pathology



Volume 3, Jan. 2009

### News highlights

- **Division of Molecular Pathology concluded its fourth annual symposium**
- **Molecular Diagnostics Laboratory is being selected as a Molecular Center for Excellence**
- **New molecular diagnostic tests for monitoring kidney transplantation**
- **MDL participates in a nation-wide Warfarin trial**



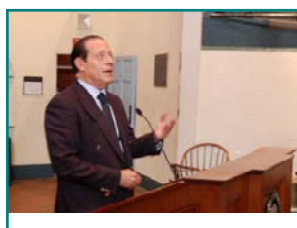
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### Symposium on “Individualized Molecular Testing for Personalized Medicine” Concluded

The Fourth Annual Symposium on Translational Research in Molecular Pathology has concluded in late October of 2008. Theme of the symposium was “Individualized Molecular Testing for Personalized Medicine”.

The symposium was held at the historic Davidge Hall. The symposium highlighted the most recent developments in individualized molecular testing and their clinical applications for personalized medicine. Dean E. Albert Reece, MD, PhD, MBA, Vice President for Medical Affairs, University of Maryland John Z. and Akiko K. Bowers Distinguished Professor and Dean, School of Medicine delivered introductory remarks and emphasized the importance of this symposium. Dr. William A. Haseltine, founder and president



of the William A. Haseltine Foundation and former President and

CEO of the Human Genome Sciences gave the keynote lecture on “Human Genomes and Beyond” Eight other nationally and internationally renowned scientists Drs. Lawrence J. Lesko (FDA), Toni I. Pollin (UMB), Emanuel F. Petricoin III (George Mason University), A. James Uzgiris (Siemens HealthCare Diagnostics), Henry A. Erlich (Roche Molecular System), Brian B. Spear (Abbott Labs), Wayne A. Rosenkrans (MIT) and Amy Brower (Hologic) gave lectures in this symposium.

Over 280 people represented 27 academic institutions, governmental agencies and private sectors participated in this symposium.

### Molecular Diagnostics Laboratory (MDL) is being selected as Molecular Center for Excellence (MCOE) by Roche Diagnostics

#### Cutting-edge molecular diagnostics testing to be expanded through strategic collaboration

INDIANAPOLIS (Roche Media Release, January 9, 2009)—Roche Diagnostics announced today the establishment of a strategic alliance with the University of Maryland School of Medicine and the University of Maryland Medical Center to operate a Roche Molecular Center of Excellence (MCOE) for the next five years.

As a nationally recognized Roche MCOE, the Medical Center’s molecular diagnostics laboratory will offer physicians and patients the most advanced molecular diagnostics technologies, such as Roche’s fully automated, real-time HIV viral load test, which was approved by the FDA in 2007.

Established in 2002, Roche’s MCOE Program is designed to create an alliance

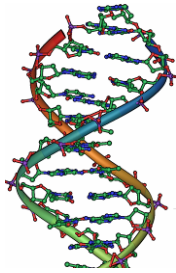
network that enables non-competing regional laboratories across the U.S. to collaborate and capitalize on scientific knowledge in molecular testing and, in turn, help accelerate the advancement of new test methods and technology.

“As a research-focused healthcare company, Roche is excited to welcome the University of Maryland into its Molecular Center of Excellence program for the collegial exchange of strategy and “best practices” in the field of molecular diagnostics,” said Whitney Green, Roche Diagnostics’ Senior Vice President of the U.S. Molecular Diagnostics division.

Under the leadership of Richard Y. Zhao, Ph.D., the University of Maryland Medical Center’s Molecular Diagnostics Laboratory has become nationally recognized for excellence in technology-

based research and clinical molecular diagnostics. The laboratory focuses on new prognostic and diagnostic tools for individualized molecular testing for personalized treatments in such key areas as infectious diseases, genetic and familial disorders, cardiovascular diseases and cancer. Dr. Zhao is also on the faculty of the University of Maryland School of Medicine.

The collaboration with Roche Diagnostics further enriches the university’s commitment to providing high-quality clinical services that support research and patient care, according to Sanford A. Stass, MD, University of Maryland School of Medicine professor and chair of the Department of Pathology. “With the combination of Roche’s cutting-edge technologies and our expertise in clinical molecular diagnostics, we will be able to offer the most advanced diagnostic testing to University of Maryland Medical Center clinicians and their patients,” he said.



*Our goal is to meet the molecular diagnostic needs of physicians and to improve our patient care at the UMMC community, your feedback is important to us*

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<http://medschool.umaryland.edu/molecularpath/default.asp>

**Division of Molecular Pathology (DMP) Faculty and Staff News**

[Feng Jiang, MD, PhD](#), assistant professor, received a one-year \$40,000 University of Maryland Statewide Health Network/ Maryland Department of Health and Mental Hygiene award for “Early Detection of Lung Cancer in African Americans Exposed to Secondhand Smoke;” a one-year \$30,000 grant from the Wendy Will Case Cancer Fund, Inc. for “Sputum Test to Identify Lung Cancer Patients at Risk for Recurrence;” and a three-year \$325,500 Flight Attendant Medical Research Institute Clinical Innovator Award for “Early Detection of Lung Cancer in African Americans Exposed to Second Hand Smoke.” In addition, Dr. Jiang received a two-year \$150,000 R03 grant for his project entitled “Magnetic Enrichment for Genetic Detection of Carcinoma Cells in Sputum” and a two-year \$320,000 R21 grant for his project entitled “Nanogenetic Test for the Early Stage Lung Cancer,” both from the National Cancer Institute.



[James Mixson, MD](#), associate professor, Department of Pathology, received a one-year \$89,999 award from Maryland Industrial Partnerships for his work entitled “Therapy of Candida with HK-fluconazole Conjugates.



[Richard Y. Zhao, PhD](#), associate professor, received a two-year \$187,500 R21 grant from the National Institute of Neurological Disorders and Stroke for his work entitled “Fission Yeast as a HTS Platform for New Molecular Probes of HIV-1, VPR-mediated Activities.” and a one-year \$99,997 award from Maryland Industrial Partnerships for “A Novel Bacterial Vaginosis Test”.



Dr. Zhao chaired a session on “Diagnostics, Biomarkers and Personalized Medicine” at the 10th Shanghai International Forum on Biotechnology & Pharmaceutical Industry/13th CBA Annual Conference in Shanghai, China, in 2008. In addition, Dr. Zhao presented “Single Molecule Detection for Molecular Diagnostics and Individualized Testing” at the Discovery2Diagnostics (D2D) Conference organized by the IBC Life Sciences, in San Diego, California, in October 2008.

**New Molecular Polyoma BK / JC Viral Load Quantification Test for Kidney Transplantation**

A new BK/JC multiplex real-time PCR assay has recently been included to the Molecular Diagnostic Laboratory (MDL) testing menu. These new tests offer rapid and quantitative detections of two human polyomaviruses, i.e., BK virus (BKV) and JC virus (JCV) in urine and plasma compartment of blood samples. To order these tests, 5 mL fresh urine collected in a sterile container and/or 3-5 mL whole blood collected in an EDTA tube (purple top) are required.

Infection of the BKV or JCV at present represents a diagnostic and therapeutic challenge in the transplant patient (TP). Most of the primary BKV

infection occurs in the early childhood without specific symptoms and remains latent in renal cells, urinary tract epithelium and B lymphocytes for life, its reactivation arises largely due to the use of new and potent immunosuppressive drugs that often cause severe clinical complications such as tubulointerstitial nephropathy (BKVN) in the renal TP and hemorrhagic cystitis in bone marrow transplant patients. Different from BKV, reactivation of JCV mainly affects the nervous system and has been associated with progressive multifocal leukoencephalopathy (PML) in the HIV+ patients although JCV has also been implicated in BKVN.

With this new detection system, the BKV and JCV can be detected simultaneously. The detection limit of these new tests will be 7,000 copies/mL for plasma and 15,000 copies/mL for urine with the linear dynamic range between 7,000/15,000 copies and 10 billion copies/mL. To order these tests in the hospital Cerner Millennium system, please make sure to choose the “**JC/BK Virus**” test on the test menu. For additional information or questions, please contact Cynthia Glaser, Supervisor of the MDL, extension 8-8539 or Dr. Richard Zhao, MDL Director at 6-6300/8-0054 [Luis Rubio].

**UMMC has been selected as one of the twelve clinical sites in the nation for a genotype-guided clinical trial for Warfarin/Coumadin Therapy (GGDWT)**

Warfarin/Coumadin® is one of the most widely prescribed drugs for the prevention and treatment of arterial and venous thromboembolic disorders. Major risk of using this drug is bleeding that occurs in 1.2-7/100 patients. One solution to avoid bleeding is to lower the dose by identifying those patients who are sensitive to Warfarin/Coumadin®. This can be accomplished by genetic polymorphic analysis of the CYP2C9 (CYP2C9\*2 and CYP2C9\*3) and VKORC1 (-1639/3673) genes. However, there is no general consensus or

recommendation on the best use of these genotypic tests. Sponsored by the National Heart Lung and Blood Institute, a nation-wide clinical trial is underway. UMMC has been selected (PI: Richard Horenstein) as one of the twelve clinical sites in the nation for this trial. Dr. Richard Zhao, Director of the Molecular Diagnostics Laboratory, has been invited to serve on the COAG (Clarification of Optimal Anticoagulation through Genetics) genotyping committee that is responsible for planning and implementation of the trial. All of the local CYP2C9 and VKORC1 testing will be carried out at the Molecular Diagnostics Laboratory.

**New DMP Travel Award**

To encourage active research and scientific presentation on molecular diagnostics and molecular pathology, the Division of Molecular Pathology has established an annual DMP travel award (up to \$1,500) to support a technologist, graduate student or post-doctoral trainee to present his/her scientific findings at a well-recognized national conference. Application deadline is April 1. Application should include documentation of accepted presentation by the conference organizer with a copy of the abstract. The awardees must be the first and presenting author and a member of a DMP laboratory. To apply, please send the necessary documentations and email them to Dr. Dean Mann, the DMP Travel Award Committee Chair ([dmann001@umaryland.edu](mailto:dmann001@umaryland.edu)).

