

## Curriculum Vitae



### V.M. Pratt, Ph.D., FACMG

Director, Pharmacogenomics and Molecular Genetics Laboratories  
Associate Professor, Medical and Molecular Genetics  
Indiana University School of Medicine  
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Indianapolis IN 46202  
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Certification: American Board of Medical Genetics, 1996-present  
Clinical Molecular Genetics and Ph.D. Medical Genetics  
#96170.

State of Tennessee Medical Laboratory Director License, 1997  
#ML0000031479

New York State Department of Health Laboratory Director License,  
1998-present.  
#CQP33228.

National Provider Identifier: 1346283769

Work History: Associate Clinical Professor  
Director, Pharmacogenomics Laboratory  
Director, Molecular Genetics Laboratory  
Indiana University School of Medicine  
Department of Medical and Molecular Genetics  
Indianapolis IN 46202  
May 2013-present

Chief Director, Molecular Genetics  
(Director, February 2003-June 2006)  
Quest Diagnostics, Nichols Institute  
Chantilly VA 20151  
February 2003-April 2013

Adjunct Faculty National Institutes of Health  
National Institutes of Health  
2005-present

Director, Molecular Biology Laboratory  
(Associate Director, July 1998-July 1999)  
Laboratory Corporation of America  
Research Triangle Park NC  
July 1999-January 2003

Adjunct Assistant Professor, Pediatrics/Medical Genetics  
Medical Genetics Training Program Faculty  
Duke University  
July 1999-2003.

Adjunct Assistant Professor, Biology  
University of North Carolina - Greensboro  
September 2000-2003.

Director, DNA Diagnostic Laboratory  
Assistant Professor, Pediatrics  
Adjunct Assistant Professor, Pathology  
Meharry Medical College  
Nashville TN  
September 1996-June 1998.

Education: Henry Ford Hospital  
Medical Genetics and Birth Defects Center  
Detroit MI  
Postdoctoral Fellowship in Medical and Clinical Molecular Genetics  
July 1994-August 1996.

Indiana University School of Medicine  
Department of Medical and Molecular Genetics  
Indianapolis IN  
Ph.D. in Medical and Molecular Genetics,  
minor in Molecular and Cellular Biology  
July 1994.

Indiana University  
Bloomington IN  
B.S. Biology, minor in French  
May 1988.

Université Louis Pasteur, Institut Le Bel  
Strasbourg, France  
Diplôme de Relations Internationales (BA equivalent)  
June 1987.

Awards and Honors:

Quest Special Recognition Award, 2004, 2006, 2007.

Grants:

NHGRI U01 HG010245 (2018-2023), PI: T. Skaar and P. Dexter;  
OPTIMIZE study (Opioid Pharmacogenetics-guided Therapy  
Implementation to MaximIZe Effectiveness), a pragmatic, prospective,  
randomized, clinical trial. (IGNITE2); Co-Investigator

NHGRI U01HG007762 (2014-2018), PI: D. Flockhart/T. Skaar and P.  
Dexter; Embedding Clinical Pharmacogenomics in a Large Health Care  
System for the Underserved (IGNITE1); Co-Investigator

Walther Foundation IND#: 120762 (2014-2015), PI: C Albany; Phase Ib  
Study of oxcarbazepine plus morphine in patients with refractory  
cancer pain; Co-Investigator

COE grant, Meharry Medical College, April 1998.

Medical Education Research Grant, Henry Ford Hospital, January 1996.

Predoctoral grant from the Mental Health Research and Education, Inc.,  
March 1994.

Predoctoral Myelin Award recipient at the Gordon Research  
Conference, June 1992 and March 1994.

Predoctoral Grant-in-Aid Award recipient, Graduate School of Indiana  
University School of Medicine, June 1992

Predoctoral Medical School Scholarship, Indiana University School of  
Medicine, September 1988 to August 1989

Professional Organizations:

Member of the Association for Molecular Pathology, 2003-present.

President, 2019  
Program Chair, 2016  
Member of Economic Affairs, 2016-current  
Member of Professional Relations Committee, 2008-current  
Clinical Practice Committee, Chair 2007-2008  
Genetics, Chair 2006

Member of the New York Academy of Sciences, 2011.

Member of SERGG (Southeastern Regional Genetics Group), 1997-2000.

Fellow of the American College of Medical Genetics and Genomics,  
1996-present.

Member of the American Society of Human Genetics, 1992-2013.

Member of Sigma Xi, 1992-1994.

#### Professional Activities:

National Academy of Medicine / Institute of Medicine (IOM)

Board Member of the Genomics and Precision Health  
Roundtable, 2011-present

National Academy of Medicine/Institute of Medicine (IOM)

Committee Member on Policy Issues in the Clinical  
Development and Use of Biomarkers for Molecularly Targeted  
Therapies, 2015

Center for Medicare and Medicaid Services, Advisory Panel Member  
on Clinical Diagnostic Laboratory Tests, 2015-2018

Indiana University Institutional Review Board (IRB-02) Member, 2016-  
present.

American Medical Association (AMA) Current Procedural  
Terminology (CPT) Coding

Molecular Pathology Advisor (MPAG), 2012-present.

Proprietary Laboratory Assay Technical Advisor, 2016-present.

CodeBridge Advisor, 2014-2016.

Molecular Pathology Work Group, 2009-2016

Secretary of Health and Human Services (HHS)'s Advisory Committee

Heritable Disorders in Newborns and Children (SACHDNC)

Carrier Screening Workgroup, 2011-2013

Genetics, Health, and Society (SACGHS) for the Oversight of  
Genetic Testing, Member 2007.

**Journals:**

Journal of Molecular Diagnostics

Associate Editor 2010-present

Reviewer 2005-present

Genetic Testing and Molecular Biomarkers,

Editorial Board, 2009-present

Reviewer, 2006-present

Clinical Pharmacology & Therapeutics

Reviewer, 2017

Journal of Psychiatric Research

Reviewer, 2017

Drug Safety

Reviewer, 2017

Genetics in Medicine

Reviewer, 2015-present

Clinical Chemistry and Laboratory Medicine (CCLM),

Reviewer, 2013.

Cancer Genetics and Cytogenetics,

Editorial Board, 2009-2011

NIH's Office of Rare Disorders's Collaboration, Education and Test Translation (CETT) Review, Board Member, 2009-2010.

Center for Disease Control's (CDC's) Morbidity and Mortality Weekly Report (MMWR) on "Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions," Expert Advisor, 2008.

American Board Medical Genetics

Molecular Clinical Genetics Examination, Coding Reviewer 2009.

Molecular Clinical Genetics Examination, Item Writer 2007

Six Sigma

Lean Training, 2007.

Green Belt, 2004 (Certified 2005-present).

Expert Panelist for EurogenTest on Validation of Genetic Testing, Leuven, Belgium, 2007.

Essentials of Project Management Course, 2007.

Contributing author for Clinical Laboratory Standards Institute (CLSI) guidelines on "Validation and Verification of Qualitative Multiplex Assays (MM17)", 2006-2007.

Women Unlimited LEAD program, 2005-2006.

Expert Panelist for Genetic Testing Quality Control at the International Symposium on Reference Materials for Genetic Testing, Geel, Belgium, 2005.

Expert Panelist for Communicating Health Information Pertinent to Genetic Testing: The Clinical/Laboratory Interface, Scottsdale, AZ, 2005.

Co-Chair of the Association for Molecular Pathology FXperts to evaluate the performance of laboratory methods and produce validated controls for Fragile X syndrome, 2005-2007.

Alternate Representative for Virginia for New York Mid-Atlantic Consortium on Genetic and newborn Screen Services, Work Group 5B, 2005-2013.

Excellence in Leadership Training, 2005.

Dale Carnegie Leadership Training for Managers, 2004.

Committee member for Quest Diagnostics Human Genetics Best Practice Team, 2003-2013.

Committee member for Quest Diagnostics Quality Control Best Practice Team, 2003-2013. Chair of Quest Diagnostics Molecular sub-division Quality Control Best Practice Team, 2003-2013.

Expert Panelist for the CDC's Genetic Testing Reference Material (GeT-RM) Project, 2003-present.

Expert Panelist for Communication: Key to Appropriate Genetic Test Referral, Result Reporting and Interpretation, Mount Sinai School of Medicine-CDC contract, New York, NY, 2003.

Committee member for the ACMG CF mutation panel, 2002-2004.

Expert Panelist and Participant for: Develop and Pilot Test Process to Collect Positive Samples and Establish Stably Transformed Cell Lines for Use in Performance Evaluation and Quality Assurance of Human Molecular Genetic Testing, Duke-CDC contract, 2000-2003.

Expert Panelist for Performance Evaluation in Laboratory Molecular Genetic Testing, DynCorp-CDC contract, 1999.

Moderator of the Medical Science Graduate Council, 1992-1994.

Chair-person for the committee for medical science graduate students.

**PUBLICATIONS**  
**Referred Manuscripts**

1. **Pratt VM**, Cavallari LH, Del Tredici AL, Hachad H, Ji Y, Moyer AM, Scott SA, Whirl-Carrillo M, Weck KE. Recommendations for Clinical CYP2C9 Genotyping Allele Selection: A Report of the Association for Molecular Pathology. *J Mol Diag (submitted)*.
2. Vassy JL, Stone A, Callaghan JT, Mendes M, Meyer LJ, **Pratt VM**, Przygodzki RM, Scheuner MT, Wang-Rodriguez J, Schichman SA. Response to “Considerations for pharmacogenomic testing in a health system” by Gammal et al. *Genet Med (in press)*.
3. Cavallari1 LH, Van Driest SL, Prows CA, Bishop JR, Limdi NA, **Pratt VM**, Ramsey LB, Smith DM, Tuteja S, Duong BQ, Hicks JK, Lee JC, Owusu Obeng A, Beitelshes AL, Bell GC, Blake K, Crona DJ, Dressler L, Empey PE, Gregg RA, Hines LJ, Scott SA, Shelton RC, Weitzel KW, Peterson JF, Johnson JA, Skaar T.C. Multi-site Investigation of Strategies for the Clinical Implementation of *CYP2D6* Genotype-Guided Therapies. *Clin Pharmacol Ther (in press)*
4. Stansberry WM, Swart M, Medeiros EB, Shen F, Schneider B, Skaar TC, Kiel P, **Pratt VM**. Analytical Validation of Variants to Aid in Genotype-guided Therapy for Oncology. *J Mol Diag (in press)*.
5. Stansberry WM, Swart M, Medeiros EB, Skaar TC, **Pratt VM**. (2018). Report of confirmation of the rs7853758 and rs885004 haplotype in *SLC28A3*. *Genet Test Biomarkers* 22(11): 652-655. doi.org/10.1089/gtmb.2018.0194
6. Collins KS, **Pratt VM**, Stansberry WM, Medeiros EB, Kannegolla K, Swart M, Skaar TC, Chapman AB, Decker BS, Moorthi RN, Eadon MT. (2019). Analytical validity of a genotyping assay for use with personalized antihypertensive and chronic kidney disease therapy. *Pharmacogenetics and Genomics* 29(1):18–22. PMID: 30489456, DOI: 10.1097/FPC.0000000000000361
7. Fulton CR, Zang Y, Desta Z, Rosenman MB, Holmes AM, Decker BS, **Pratt VM**, Levy KD, Gufford BT, Dexter PR, Skaar TC, Eadon MT. Drug-Gene and Drug-Drug Interactions Associated with Tramadol and Codeine Therapy in the INGENIOUS Trial. *Pharmacogenomics J (in press)*. PMID: 30784356, DOI: 10.2217/pgs-2018-0205
8. Caudle KE, Keeling NJ, Klein TE, Whirl-Carrillo M, **Pratt VM**, Hoffman JM. (2018). Standardization can accelerate the adoption of pharmacogenomics: current status and the path forward. *Pharmacogenomics* doi.org/10.2217

9. Cavallari LH, **Pratt VM**. (2018). Building evidence for clinical use of pharmacogenomics and reimbursement for testing. *Adv Mol Pathol* 1(1):125-134. doi.org/10.1016/j.yamp.2018.06.008
10. Levy KD, Blake K, Fletcher-Hoppe C, Franciosi J, Goto D, Hicks JK, Holmes AM, Kanuri SH, Madden EB, Musty M, Orlando L, **Pratt VM**, Ramos M, Wu R, Ginsburg G. Opportunities to implement a sustainable genomic medicine program: Lessons learned from the IGNITE Network. *Genet Med* (*in press*). PMID: 29997387, DOI:10.1038/s41436-018-0080-y
11. Vassy JL, Stone A, Callaghan JT, Mendes M, Meyer LJ, **Pratt VM**, Przygodzki RM, Scheuner MT, Wang-Rodriguez J, Schichman SA for the VHA Clinical Pharmacogenetics Subcommittee. (2019). Pharmacogenetic testing in the Veterans Health Administration: Policy recommendations from the VHA Clinical Pharmacogenetics Subcommittee. *Genet Med* 21:382–390. PMID: 29858578. DOI:10.1038/s41436-018-0057-x.
12. **Pratt VM**, Del Tredici AL, Hachad H, Ji Y, Kalman LV, Scott SA, Weck KE. (2018). Recommendations for Clinical *CYP2C19* Genotyping Allele Selection: A Report of the Association for Molecular Pathology. *J Mol Diag* 20(3):269-276. doi.org/10.1016/j.jmoldx.2018.01.011.
13. Empey PE, Stevenson JM, Tuteja S, Weitzel KW, Angiolillo DJ, Beitelshes AL, Coons JC, Duarte JD, Franchi F, Jeng LJB, Johnson JA, Kreutz RP, Limdi NA, Maloney KA, Obeng AO, Peterson JF, Petry N, **Pratt VM**, Rollini F, Scott SA, Skaar TC, Vesely MR, Stouffer GA, Wilke RA, Cavallari LH, Lee CR on behalf of the IGNITE Network. (2018). Multi-site investigation of strategies for the implementation of *CYP2C19* genotype-guided antiplatelet therapy. *Clin Pharmacol Ther* 104(4): 664-674. 29280137. PMID: PMC6019555. DOI: 10.1002/cpt.1006.
14. Numanagić I, Maliki S, Ford M, Qin X, Toji L, Radovich M, Skaar TC, **Pratt VM**, Berger B, Scherer S, Sahinalp SC. (2018). Allelic decomposition and exact genotyping of highly polymorphic and structurally variant genes. *Nature Communications* 9, Article:828. doi:10.1038/s41467-018-03273-1
15. Cavallari LH, Denny JC, Lee CR, Beitelshes AL Duarte JD, Kimmel SD, Voora D, McDonough CW, Gong Y, Dave CV, Wei WQ, **Pratt VM**, Alestock TD, Anderson RD, Ardati AK, Brott B, Brown L, Chumnumwat S, Clare-Salzler MJ, Coons JC, Cooper-DeHoff RM, Dillon C, Elsey AR, Hamadeh I, Harada S, Hillegass WE, Hines L, Horenstein RD, Howell LA, Jeng LJ, Keleman MD, Larson EA, Lee YM, Magvanjav O, Montasser M, Nelson DR, Nutescu EA, Nwaba D, Pakyz RE, Palmer K, Petry N, Quinn AH, Robinson SW, Schub J, Skaar TC, Smith DM, Starostik P, Sriramoju VB, Stevenson JM, Varunok N, Vesely MR, Wake D, Weck KE, Weitzel KW, Zhao RY,



- Winterstein AG, Kreutz RP, Stouffer GA, Wilke RA, Empey PE, Limdi NA, Roden DM, Shuldiner AR, Johnson JA, Peterson JF. (2018). Prospective Clinical Implementation of CYP2C19-Genotype Guided Antiplatelet Therapy after PCI: a Multi-Site Investigation of MACE Outcomes in a Real-World Setting. *JACC: Cardiovascular Interventions* 11(2):181-191 (<https://doi.org/10.1016/j.jcin.2017.07.022>).
16. Cavallari LH, Beitelshes AL, Blake KV, Dressler LG, Duarte JD, Elsey A, Eichmeyer JN, Empey PE, Franciosi JP, Hicks JK, Holmes AM, Jeng L, Lee CR, Lima JJ, Limdi NA, Modlin J, Obeng AO, Petry N, **Pratt VM**, Skaar TC, Tuteja S, Voora D, Wagner M, Weitzel KW, Wilke RA, Peterson JF, Johnson JA. (2017). The Implementing Genomics in Practice (IGNITE) Pharmacogenetics Interest Group: An Opportunity for Building Evidence with Pharmacogenetic Implementation in a Real-World Setting. *Clin Transl Sci* 10:143-146 (doi:10.1111/cts.12456).
  17. Sperber NR, Carpenter JS, Cavallari L, Damschroder L, Cooper-DeHoff RM, Denny J, Ginsburg GS, Guan Y, Horowitz C, Levy K, Levy MA, Madden E, Matheny M, Pollin T, **Pratt VM**, Rosenman M, Voils CI, Weitzel K, Wilke RA, Wu R, Orlando LA. (2017). Challenges and Strategies for Implementing Genomic Services in Diverse Settings: Experiences from the Implementing GeNomics In PracTice (IGNITE) Network. *BMC Medical Genomics* 10(1):35 (DOI:0.1186/s12920-017-0273-2).
  18. Rosenman MB, Decker B, Levy KD, Holmes AM, **Pratt V**, Eadon M. (2017). Lessons learned when introducing pharmacogenomic panel testing into clinical practice. *Value Health*. 2017 Jan;20(1):54-59. (PMID: 28212969, DOI:10.1016/j.jval.2016.08.727).
  19. Joseph L, Cankovic M, Caughron S, Chandra P, Emmadi R, Hagenkord J, Hallam S, Jewell KE, Klein R, **Pratt VM**, Rothberg PG, Temple-Smolkin RL, and Lyon E. (2016). The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer: A Report of the Association for Molecular Pathology. *J Mol Diag* 18(5):605-619 (doi.org/10.1016/j.jmoldx.2016.05.007).
  20. Eadon M, Desta Z, Levy K, Decker B, Pierson R, **Pratt V**, Callaghan J, Rosenman M, Carpenter J, Holmes A, McDonald C, Benson E, Patil A, Vuppalanchi R, Gufford B, Dave N, Robarge J, Hyder M, Haas D, Kreutz R, Dexter P, Skaar T, and Flockhart D. (2016). Implementation of a pharmacogenomics consult service to support the INGENIOUS trial. *Clin Pharmacol Therapeutics* 100:63-66 (doi:10.1002/cpt.347).
  21. Kalman LV, Agúndez JAG, Appell ML, BlackJL, Bell G, Boukouvala S, Bruckner C, Bruford E, Caudle K, Coulthard S, Daly AK, Del Tredici, AL, den Dunnen JT, Drozda K, Everts R, Flockhart DA, Freimuth R, Gaedigk A, Hachad H, Hartshorne T, Ingelman-Sundberg M, Klein TE, Lauschke VM, Maglott DR, McLeod HL, McMillin GA, Meyer UA, Müller DJ, Nickerson DA, Oetting WS, Pacanowski M, **Pratt VM**,

- Relling MV, Roberts A, Rubinstein WS, Sangkuhl K, Schwab M, Scott SA, Sim SC, Thirumaran RK, Toji LH, Tyndale R, van Schaik RHN, Whirl-Carrillo M, Yeo KTJ, Zanger UM. (2016). Pharmacogenetic Allele Nomenclature: International Workgroup Recommendations for Test Result Reporting. *Clin Pharmacol Therapeutics* 99(2):172-185 (doi:10.1002/cpt.280).
22. **Pratt VM**, Everts R, Aggarwal P, Baak A, Beyer BN, Broeckel U, Hujsak P, Kornreich R, Liao J, Lorier R, Scott S, Smith CH, Toji LH, Turner A, Kalman LV. (2016). Characterization of 137 genomic DNA reference materials for 28 pharmacogenetic genes: A GeT-RM collaborative project. *J Mol Diag* 18:109-123 (doi:10.1016/j.jmoldx.2015.08.005).
23. Levy KD, **Pratt VM**, Skaar TC, Vance GH, Flockhart DA. (2015). FDA's draft guidance on laboratory-developed tests increases clinical and economic risk to adoption of pharmacogenetic testing. *J Clin Pharmacol* 55(7):7325-727 (DOI: 10.1002/jcph.492).
24. Numanagic I, Malikic S, **Pratt VM**, Skaar TC, Flockhart DA, Sahinalp SC. (2015). Cypiripi: exact genotyping of CYP2D6 and other highcopy number gene families using HTS data. *Bioinformatics* 31: i27-i34 (doi: 10.1093/bioinformatics/btv232).
25. **Pratt VM**, Beyer BN, Koller DL, Skaar TC, Flockhart DA, Levy KD, Vance GH. (2015). Report of new haplotype for ABCC2 gene; rs17222723 and rs8187718 in cis. *J Mol Diag* 17(2):201-205.
26. **Pratt, VM**. (2014). Are we ready for a blood-based test to detect colon cancer? *Clin Chem* 60(9):1141-1142 (DOI: 10.1373/clinchem.2014.227132).
27. Ferreira-Gonzalez A, Emmadi R, Day SP, Klees RF, Leib JR, Lyon E, Nowak JA, **Pratt VM**, Williams MS, Klein RD. (2014). Revisiting Oversight and Regulation of Molecular-Based Laboratory-Developed Tests. *J Mol Diag* 16(1):3-6 (doi: /10.1016/j.jmoldx.2013.10.00).
28. Wang JC, Vaccarello-Cruz M, Ross L, Owen R1, **Pratt VM**, Lightman K, Liu Y, Hafezi K, Cherif D, Sahoo T. (2013). Mosaic isochromosome 15q and maternal uniparental isodisomy for chromosome 15 in a patient with morbid obesity and variant PWS-like phenotype. *Am J Med Genet* 161(7):1695-1701 (DOI: 10.1002/ajmg.a.35939).
29. Lyon E, Gastier Foster J, Palomaki GE, **Pratt VM**, Reynolds K, Sábato MF, Vitazka P. (2012). Laboratory testing of CYP2D6 alleles for tamoxifen therapy. *Genet Med*. 14(12):990-1000 (doi: 10.1038/gim.2012.108).
30. Whole Genome Analysis Workgroup (Schrijver I, Aziz N, Farkas DH, Furtado M,

- Ferreira-Gonzalez A, Grenier TC, Grody WW, Kant JA, Klein RD, Leonard DGB, Lubin IM, Mao R, Nagan N, **Pratt VM**, Sobel ME, Voelkerding KV, Gibson JS). (2012). Opportunities and Challenges associated with Clinical Diagnostic Genome Sequencing: A White Paper. *JMolDiag* 14(6):525-540.
31. Whole Genome Analysis Workgroup (Gibson J, Aziz N, Bayrak-Toydemir P, Cotter P, Farkas DH, Ferreira-Gonzalez A, Furtado M, Grenier TC, Hambuch T, Klein RD, Leonard DGB, Lyon E, Mann KP, Mao R, Nagan N, **Pratt VM**, Schrijver I, Sobel ME, Voelkerding KV, William MS). (2011). The Association for Molecular Pathology's approach to supporting a global agenda to embrace personalized genomic medicine. *JMolDiag* 13(3):249-251.
  32. Strom CM, Crossley B, Buller-Buerkle A, Jarvis M, Quan F, Peng M, Muralidharan K, **Pratt VM**, Redman J, Sun W. (2011). Cystic fibrosis testing 8 years on: Lessons learned from carrier screening and sequencing analysis. *Genet Med* 13(2):166-172.
  33. **Pratt VM**, Zehnbauser B, Amos Wilson J, Baak R, Babic N, Bettinotti M, Buller A, Butz K, Campbell M, Civalier C, El-Badry A, Farkas DH, Lyon E, Mandal S, McKinney J, Muralidharan K, Noll L, Sander T, Shabbeer J, Smith C, Telatar M, Toji L, Vairavan A, Vance C, Weck KE, Wu AHB, Yeo KTJ, Zeller M, Kalman L. (2010). Characterization of 107 genomic DNA reference materials for *CYP2D6*, *CYP2C19*, *CYP2C9*, *VKORC1* and *UGT1A1*: A GeT-RM and Association for Molecular Pathology collaborative project. *J Mol Diag.* 12(6):835-846.
  34. Gaedigk A, Jaime LKM, Bertino JS, Bérard A, **Pratt VM**, Bradford LD, Leeder JS. (2010). Identification of novel *CYP2D7-2D6* hybrids: non-functional and functional variants. *Front Pharmacol* 1:1-12 (doi:10.3389/fphar.2010.00121).
  35. Mattocks CJ, Morris M, Matthijs G, Swinnen E, Corveleyn A, Dequeker E, Müller C, **Pratt V**, Wallace AJ. (2010). A standardized framework for the validation and verification of clinical molecular genetic tests. *Eur J Hum Genet* 18:1276-1288 (doi:10.1038/ejhg.2010.101).
  36. Barker SD, Bale S, Buller A, Das S, Friedman K, Godwin AK, Grody WW, Highsmith E, Kant JA, Lyon E, Mao R, Monaghan KG, Payne DA, **Pratt VM**, Schrijver I, Shrimpton AE, Spector E, Telatar M, Toji L, Weck K, Zehnbauser B, Kalman LV. (2009). Development and characterization of reference materials for *MTHFR*, *SERPINA1*, *RET*, *BRCA1*, and *BRCA2* genetic testing. *J Mol Diag.* 11(6):553-561.
  37. Sepulveda AR, Jones D, Ogino S, Samowitz W, Gulley ML, Edwards R, Levenson V, **Pratt VM**, Yang B, Nafa K, Yan L, Vitazka P. (2009). CpG Methylation Analysis - Current Status of Clinical Assays and Potential Applications in Molecular

Diagnostics: A Report of the Association for Molecular Pathology. *Mol Diag.* 11(4):266-278.

38. **Pratt VM**, Caggana M, Bridges C, Buller AM., DiAntonio L, Highsmith WE, Holtegaard LM, Muralidharan K, Rohlfes EM, Tarleton J, Toji L, Barker SD, Kalman LV. (2009). Development of Genomic Reference Materials for Cystic Fibrosis Genetic Testing. *J Mol Diag.* 11(3):186-193.
39. Schwartz KM, Pike-Buchanan LL, Muralidharan K, Redman JB, Amos Wilson J, Jarvis M, Cura MG, **Pratt VM**. (2009). Identification of Cystic Fibrosis (CF) Variants by PCR/Oligonucleotide Ligation (OLA) Assay. *J Mol Diag.* 11(3):211-215.
40. Burken MI, Wilson KS, Heller K, **Pratt VM**, Schoonmaker MM, Seifter E. (2009). The Interface of Medicare Coverage Decision-Making and Emerging Molecular-Based Laboratory Testing. *Genet Med.* 11(4):225-231.
41. Lubin IM, McGovern MM, Gibson Z, Gross SJ, Lyon E, Pagon RA, **Pratt VM**, Rashid J, Shaw C, Stoddard L, Trotter TL, Williams MS, Amos Wilson J, Pass K. (2009). Clinician Perspectives about Molecular Genetic Testing for Heritable Conditions and Developing a Clinician-Friendly Laboratory Report. *J Mol Diag.* 11(2):162-171.
42. Amos Wilson J, **Pratt VM**, Phansalkar A, Muralidharan K, Highsmith Jr WE, Beck JC, Bridgeman S, Courtney EM, Epp L, Ferreira-Gonzalez A, Hjelm NL, Holtegaard LM, Jama MA, Jakupciak JP, Johnson MA, Labrousse P, Lyon E, Prior TW, Richards CS, Richie KL, Roa BB, Rohlfes EM, Sellers T, Sherman SL, Siegrist KA, Silverman LM, Wiszniewska J, Kalman LV. (2008). Consensus Characterization of 16 *FMR1* Reference Materials: A Consortium Study by the Fragile Xperts. *J Mol Diag* 10(1):2-12.
43. McGinniss MJ, Chen R, **Pratt VM**, Buller A, Quan F, Strom CM, Crossley B. (2007). Development of a Web-based Query Tool for Quality Assurance of Clinical Molecular Genetic Test Results. *J Mol Diag* 9(1):95-98.
44. Bernacki SH, Beck JC, Stankovic AK, Williams LO, Amos J, Snow Bailey K, Farkas DH, Friez MJ, Hantash FM, Matteson KJ, Monaghan KG, Muralidharan K, **Pratt VM**, Prior TW, Richie KL, Rohlfes EM, Schaefer FV, Shrimpton AE, Spector EB, Stolle CA, Strom CM, Thibodeau SN, Cole EC, Goodman BK, Stenzel TT. (2005). Genetically characterized positive control cell lines derived from residual clinical blood samples. *Clin Chem* 51: 2013-2024.
45. Chen B, O'Connell CD, Boone DJ, Amos JA, Beck JC, Chan MM, Farkas DH, Lebo RV, Richards CS, Roa BB, Silverman LM, Barton DE, Bejjani BA, Belloni D, Bernacki SH, Brown NM, Aviles-Caggana M, Charache P, Dequeker E, Ferreira-Gonzalez A,

- Friedman KJ, Greene CL, Grody WW, Highsmith, Jr. WE, Hinkel C; Lubin IM, Lyon E, Noll WW, Payne D, **Pratt VM**, Reid Y, Rundell C, Schneider E, Terry P, Willey A, Willey J, Williams LO, Winn-Deen E, Wolff DJ. (2005). Developing a Sustainable Process to Provide Quality Control Materials for Genetic Testing. *Genet Med* 7(8):534-549.
46. Brown NM, **Pratt VM**, Buller A, Pike-Buchanan L, Redman JB, Sun W, Chen R, Crossley B, McGinniss MJ, Quan F, Strom CM. (2005). Detection of 677CT/1298AC "Double Variant" Chromosomes: Implications for interpretation of MTHFR genotyping results. *Genet Med* 7(4):278-282.
47. Watson MS, Cutting GR, Desnick RJ, Driscoll DA, Klinger K, Mennuti M, Palomaki GE, Popovich BW, **Pratt VM**, Rohlfes EM, Strom CM, Richards CS, Witt DR, Grody WW. (2004). Cystic fibrosis population carrier screening: 2004 revision of American College of Medical Genetics mutation panel. *Genet Med* 6(5):387-391.
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### **Invited Speaker**

**CPT Coding for Transplant Testing.** InformedDNA webinar, October 2018.

**Laboratory and Test Quality, Compared.** Genetic Health Information Network Summit, October 2018.

**The ABCs of CPT Coding.** Association for Molecular Pathology webinar, September 2018.

**Global Dx Insights: Policy and Prediction for Diagnostics.** Cambridge Health Institute, NextGen DX Summit, August 2018.

**What is PAMA and why do I need to know about it?** American Society of Microbiology, June 2018

**PAMA: 2017 Update.** Citi Conference, April 2018

**CYP2C19 Genotyping Recommendations: AMP PGx Working Group.** Clinical Pharmacogenetics Implementation Consortium, March 2018.

**PAMA: 2017 Update.** JP Morgan Conference, January 2018

**PAMA: 2017 Update.** Association for Molecular Pathology Investor meeting, November 2017

**CYP2C19 Genotyping Recommendations: AMP PGx Working Group.** Association for Molecular Pathology, November 2017

**ADLT versus PLA codes: Are there any winners?** Cambridge Health Institute, NextGen DX Summit, August 2017.

**Pharmacogenetics.** Blue Cross/Blue Shield Association, April 2017.

**Overview of the AMA Molecular Pathology CPT codes and Reimbursement.** University of Florida Precision Medicine Conference, March 2017.

**Reimbursement Stories in Molecular Pathology.** Cambridge Health Institute, Molecular Medicine TRI-CON, February 2017.

**Opening and Closing Remarks for AMP Annual Meeting.** Association for Molecular Pathology, November 2016.

**Navigating the Regulatory Environment in Clinical Laboratory Testing.** Feedback of Individual Genetic Research Findings in African Genomics Research: developing a policy for H3Africa meeting, Mauritius, October 2016.

**The Spectrum of Clinical Utility for Inherited Conditions.** Association for Molecular Pathology Webinar series, October 2016.

**Population-based Approaches to Precision Medicine.** VA Precision Medicine Conference, August 2016.

**The Laboratory View on the Impact of LDT Regulation.** American Association of Clinical Chemistry, August 2016.

**Navigating the Reimbursement Environment in Clinical Laboratory Testing**  
Diagnostic Marketing (DxMA) Association Conference, April 2016

**Navigating the Regulatory and Compliance Environment in Clinical Laboratory Testing.** Blue Cross/Blue Shield Association, April 2016

**CPT Armageddon Two Years Later: Are the New Codes Working?**  
Cambridge Health Institute, Molecular Medicine TRI-CON, March 2016

**Protecting Access to Medicare Act (PAMA) Update.** JP Morgan Conference, January 2016

**2016 CPT Coding Update for Advanced Molecular Diagnostics.** Diagnostics Coverage and Reimbursement Conference, December 2015



**Protecting Access to Medicare Act (PAMA) Update.** Association for Molecular Pathology Investor Meeting, November 2015

**Understanding CPT Coding of Genetic Tests.** Blue Cross/Blue Shield Association, October 2015

**Development of the new AMA Molecular Pathology CPT codes.** Institute of Medicine Genomics Roundtable, July 2015

**Economics in Pharmacogenomics: An Implementation Reality Check.** Personalized Medicine Summit, British Columbia CANADA, June 2015

**Adapting Regulation to Meet the Needs of the Exponential Growth of the Molecular Testing Era.** Fifth Annual Conference of the Association for Value-Based Cancer Care, May 2015

**Lecture 1: Molecular Techniques, Lecture 2: Pharmacogenetics.** AMP Molecular Genetic Pathology Review Course, April/May 2015

**Navigating the Regulatory and Compliance Environment of Starting a NGS Laboratory.** Cambridge Health Institute, Molecular Medicine TRI-CON, February 2015

**A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Genomic Medicine,** Cambridge Health Institute, Evidence-based Reimbursement Summit, November 2014

**GeT-RM Pharmacogenetics Characterization Study (PGX2),** Association for Molecular Pathology/GeT-RM Meeting, November 2014

**A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Genomic Medicine,** California Clinical Laboratory Association Conference, October 2014

**Development of the new AMA Molecular Pathology CPT codes,** Association of Genetic Technologists Conference, June 2014

**Development of the new AMA Molecular Pathology CPT codes,** Diagnostics Coverage and Reimbursement Conference, February 2014

**Navigating the Regulatory Environment of Starting a NGS Laboratory** Cambridge Health Institute, Molecular Medicine TRI-CON, February 2014

**Development of the new AMA Molecular Pathology CPT codes** Diagnostics Coverage and Reimbursement Conference, December 2013

**Development of the new AMA Molecular Pathology CPT Codes**

Cambridge Health Institute, Evidence-based Reimbursement Summit, October 2013

**GeT-RM Pharmacogenetics Characterization Study (PGX1)**

EuroGentest Reference Materials Symposium, September 2013

**Developing the Genetic Testing Infrastructure, the Clinical Laboratory Perspective**

M-CERSI Regulatory Issues in Next-Generation Medicine and Pharmacogenomics, September 2013

**Reimbursement Issues with Multiplex Molecular/NGS Assays and Reimbursement of Cancer Genomic Analysis**

Cambridge Health Institute, Next Generation Diagnostics Summit, August 2013

**Molecular CPT Coding Structure for Oncology and Genetic Testing Reveals (almost ) All**

Association for Molecular Pathology, November 2011.

**Analytical Validation**

American College of Medical Genetics, March 2011

**AMP Response to NIH GTR RFI - Survey of Clinical Molecular Laboratories.**

CLIAAC, March 2011.

**AMP Response to NIH GTR RFI - Survey of Clinical Molecular Laboratories.**

Association for Molecular Pathology, November 2010.

**Case Report: CYP2D6 Family Study**

Association for Molecular Pathology, November 2010.

**Genetic Testing in the 21<sup>st</sup> Century.**

St. Joseph Hospital (Paterson NJ) Ob-Gyn Grand Rounds, June 2010.

**Personalizing Medicine through Pharmacogenetics.**

Association of Genetic Technologists, June 2010.

**Triplet Repeat Disorders**

AMP-AACC Molecular Pathology Essentials Course: Principles and Practice, May 2010.

**Trends in Genetic Testing.**

Carefirst Grand Rounds, January 2010.

**New CDC Guideline for Molecular Genetic Testing for Heritable Diseases**

Association for Molecular Pathology, Nov. 2009.

**Case Report: Roche Amplichip®No calls for CYP2D6**  
Association for Molecular Pathology, Nov. 2009.

**Trends in Genetic Testing.**  
Independence Blue Cross Grand Rounds, May 2008.

**Personalizing Medicine Through Diagnostics.**  
World Health Care Congress, April 2008.

**Inherited Thrombophilia.**  
West Virginia Clinical Laboratory Societies, Oct. 2007.

**Inherited Thrombophilia.**  
American Association of Clinical Chemistry, July 2007.

**Case Report: Non-contiguous deletions on Y chromosome in patients with azoospermia.**  
Association for Molecular Pathology, Nov. 2006.

**Review of cystic fibrosis.**  
American Association of Clinical Chemistry, July 2006.

**Automating a Molecular Laboratory.**  
Association of Genetic Technologist, June 2006.

**Genetic Susceptibility to Venous Thrombosis.**  
Clinical Laboratory Science Society of Central New England, May 2004.

**DNA Banking and Privacy.**  
North Carolina State University Symposium, Genetics and the New Millenium  
October 2001.

**Inherited Thrombophilia: Factor V Leiden and Factor II/Prothrombin**  
Laboratory Corporation of America Teleconference 99-LT024  
September 1999.

## EXPERIENCE

### Molecular Laboratory Techniques and Interpretation:

- 18q- (*DCC* ; colorectal cancer)
- *ABCC2*
- *ABCC4*
- Acute promyelocytic leukemia (APL) (*PML/RARA*)
- Alpha-1 Antitrypsin (*SERPINA1*)
- Apolipoprotein E (*APOE*)
- *BCL2*
- *BCR/ABL1*
- $\beta$ -Thalassemia (*HBB*)
- Bloom syndrome (*BLM*)
- Canavan disease (*ASPA*)
- Congenital Bilateral Absence of the Vas Deferens (*CFTR*)
- Connexin 26 (*GJB6*)
- Cystic fibrosis (*CFTR*)
- Cytochrome P450 (*CYP2D6*, *CYP2C19*, *CYP2C9*, *CYP3A4*, *CYP3A5*, *CYP4F2*, *CYP2B6*, *CYP2C8*)
- *DPYD*
- *F2*, Prothrombin
- *F5* (Leiden variant)
- Familial adenomatous polyposis (FAP) (*APC*)
- Familial dysautonomia (Riley-Day syndrome) (*IKBKAP*)
- Fanconi anemia, type C (*FANCC*)
- Fragile X syndrome (*FMR1*)
- Gaucher disease (*GBA*)
- Hereditary hemochromatosis (*HFE*)
- Hereditary nonpolyposis colorectal cancer (HNPCC)
- *HLAB\*57:01*
- Huntington disease (*HTT*)
- Limb-girdle muscular dystrophy (*CAPN3*)
- Maternal cell contamination
- Medium chain acyl-CoA dehydrogenase deficiency (*ACADM*)
- Methylenetetrahydrofolate reductase (*MTHFR*), thermolabile variant
- Microsatellite instability
- Multiple endocrine neoplasia 2A and 2B (*RET*)
- Myotonic dystrophy (*DMPK*)
- Neurofibromatosis, Type I (*NF1*)
- Niemann-Pick disease, type A and B (*SMPD1*)
- Pelizaeus-Merzbacher disease (*PLP*)
- Prader-Willi/ Angelman syndrome (*SNRPN/UBE3A*)

- Septin-9, methylated (*SEPT9*)
- *SERPINE1* (PAI)
- Sickle cell anemia (hemoglobin A, S, and C) (*HBB*)
- *SLCO1B1*
- Spinal muscular atrophy (*SMN1/SMN2*)
- T&B cell gene rearrangements (*IGH@, TCRB*)
- Tay-Sachs disease (*HEXA*)
- *TPMT*
- Twin zygosity
- *UGT1A1*
- *UGT1A9*
- *UGT2B7*
- *VKORC1*
- Y Chromosome microdeletions (*DAZ*)

Prenatal Diagnosis of Direct and Cultured Amniocytes and CVS

Allele Specific Oligonucleotide (ASO) Analysis (by radioactive and nonradioactive Methods; includes line probe assays/linear arrays))

Allele-specific PCR

Copy number analyses

PCR

DNA Sequencing (double and single strand)

Heteroduplex Analysis by Mutation Detection Enhancement (MDE) Gel Electrophoresis

Invader Technology

Melt curve analyses

Microarray technology (Affymetrix system, QuantStudio Open Array)

Microsatellite (GT/CA) Repeat Analysis

Oligonucleotide Ligation Assay (OLA)

Protein Truncation Assay

Restriction Enzyme Analysis (Gel and Capillary Electrophoresis)

Reverse Transcript PCR (RT-PCR)

RNA Single-strand Conformation Polymorphism (rSSCP)

Single Nucleotide Primer Extension (SNuPE)/ Allele-specific primer extension (ASPE)

Single-strand Conformation Polymorphism (SSCP)

Southern Blot Analysis (by radioactive and nonradioactive methods)

TaqMan assays

Other Standard Molecular Biology Techniques

Clinical Genetics:

Diagnosis, risk assessment, counseling and management of patients with genetic disorders, congenital malformations, dysmorphic features and mental retardation. Patients were seen daily in genetics clinic, neurogenetics clinics, neurofibromatosis clinics,

skeletal dysplasia clinic, Pelizaeus-Merzbacher disease clinic, in-patient consultations, field clinics, teratogen telephone consultations, and prenatal clinics.

**Teaching:**

Course Instructor

Q613 (2 credit hours) - Molecular and Biochemical Genetics Laboratory for Genetic Counseling,  
Indiana University School of Medicine  
Fall 2015-present

Lecturer

Q612 (3 credit hours) - Molecular and Biochemical Genetics  
Indiana University School of Medicine  
Spring 2015-present

Course Instructor

K501 (1 credit hour) - Medical Genetics for Physician Assistants  
Indiana University School of Medicine  
Fall 2015

Lecturer

Q620 (3 credit hours) - Cytogenetics  
Indiana University School of Medicine  
Spring 2014-present (offered every 2 years)

Lecturer

Q640 (3 credit hours) - Molecular Genetics  
Indiana University School of Medicine  
Fall 2013

Trained technicians, fellows, graduate students, undergraduate students, and high school students in molecular laboratory techniques

Lecturer

Introduction to Clinical Medicine  
Howard University Medical School  
Fall 2006.

Lecturer

National Institutes of Health Fellowship Training Program  
National Institutes of Health - Bethesda  
Spring 2005-present.

Course Instructor  
Genetic Counseling Training Program Faculty  
University of North Carolina – Greensboro  
Fall 2000-2003.

Medical Genetics Training Program Faculty  
Duke University  
Fall 1998-2003.

Medical Technologist Training Program  
University of North Carolina – Chapel Hill  
Fall 1999-2003.

SERGG Clinical Molecular Genetics Board Review Course  
Charlotte NC  
April 1999.

Lecturer  
Introduction to Clinical Medicine  
Meharry Medical College  
Fall 1997.

Discussion Leader  
Graduate Research Elective  
Meharry Medical College  
Fall 1996

Discussion Leader  
Medical Genetics,  
Wayne State University School of Medicine  
Spring 1996.

Lecturer  
Medical genetics for medical students.  
Medical Genetics Laboratory III,  
Indiana University School of Medicine  
Fall 1992 and 1993.  
Basic molecular genetic techniques for genetic counseling students.

## REFERENCES

**Available upon request**