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 Clincal 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
Univeristy 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 af 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 or 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
Referreed 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, Beitelshees 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, Beitelshees 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. PMCID: 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, Beitelshees 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, Beitelshees 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 CYPD26 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**, Zehnbauer 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, Zehnbauer 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, Rohlfs 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, Rohlfs 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, Rohlfs 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**, Rohlfs 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.

48. Monaghan KG, Highsmith WE, Amos J, **Pratt VM**, Roa B, Friez M, Pike-Buchanan LL, Buyse IM, Redman JB, Strom CM, Young CM and Sun W. (2004). Genotype-phenotype correlation and frequency of the 3199del6 cystic fibrosis mutation among I148T carriers: results from a collaborative study. Genet Med 6(5):431-438.

49. Bernacki SH, Farkas DH, Shi W, Chan V, Liu Y, Beck JC, Bailey KS, **Pratt VM**, Monaghan KG, Matteson KJ, Schaefer FV, Friez M, Shrimpton AE, Stenzel TT. (2003). Bioelectronic sensor technology for detection of cystic fibrosis and hereditary hemochromatosis mutations. Arch Pathol Lab Med 127(12):1565-1572.

50. Brown NM, Bernacki S, **Pratt VM**, Stenzel TT. (2001). Fluorescent, multiplexed, automated, primer-extension assay for 3120+1G→A and I148T. Clin Chem 47:2053-2055.

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3. Stansberry WM, Collins KS, Medeiros EB, Swart M, Skaar TC, Decker BS, Eadon, MT, **Pratt VM**. (2018). Confirmation of cis inheritance of variants in ABCB1, SHROOM3, and SLC28A3 during the validation of a targeted genotyping assay. AMP (poster presentation).

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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. Personlized 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.
CLIAC, 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 21st 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*
- β-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, congential 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