EXHIBIT 1

CURRICULUM VITAE

ROGER D. KLEIN, MD, JD, FCAP
5699 North Centerpark Way #638
Glendale, WI 53217
roger.klein@bcw.edu

Education:

B.A.	Case Western Reserve University Chemistry, *magna cum laude*	1984
M.D.	Case Western Reserve University	1990
J.D.	Yale Law School	1996

- LSAT > 99th percentile
- Honors 9/20 possible courses
- Articles Editor, Yale Journal on Regulation
- Olin Fellow: Law, Economics and Public Policy

Career:

2008 – Present, Medical Director, Molecular Oncology, BloodCenter of Wisconsin; Clinical Assistant Professor, Pathology, Medical College of Wisconsin, Milwaukee, WI

2007 - 2008, Medical Director, Molecular Diagnostics; Attending Physician, Flow Cytometry, Coagulation, and Hematology. H. Lee Moffitt Cancer Center & Research Institute; Assistant Professor, Department of Oncologic Sciences, University of South Florida Medical School, Tampa, FL

- Promoted to Medical Director, Diagnostic Laboratories

2006 - 2007, Research Affiliate, Ethical, Legal and Social Implications of the Human Genome Project, Department of Genetics, Yale University School of Medicine, New Haven, CT

2005 – 2006, Molecular Genetic Pathology Fellow, Mayo Clinic, Rochester, MN

2004 – 2005, Postdoctoral Fellow, Molecular Genetics, DNA Diagnostics Laboratory, Yale University School of Medicine, New Haven, CT

2003 – 2004, Clinical Microbiology Fellow, Yale University School of Medicine, New Haven, CT

2001 – 2003, Laboratory Medicine Resident, Yale-New Haven Hospital, Yale University School of Medicine, New Haven, CT

- 2002 ASCP Pathology Resident In-service "RISE" Examination: As first-year resident, scaled total score 481 (>95th percentile), scores above 4th year resident mean (476) in 8/10 categories and total score.
- 2003 ASCP Pathology Resident In-service "RISE" Examination:

As second year resident, scaled total score 511; Special Techniques score (Molecular Pathology and Flow Cytometry) 667 (5^{th} year mean 484); Transfusion Medicine score 570 (5^{th} year mean 487); scores above 5^{th} year mean (480) in 6/7 categories and total score.

1998 – 2001, Attorney/Consultant, Roger D. Klein, MD JD, Moreland Hills, OH

- Appellate Litigation: prepared numerous legal briefs for state and federal courts of appeals, state supreme court, and U.S. Supreme Court.

1996 – 1998, Family and Occupational Physician, MedCenter, Cleveland, OH

1995, Summer Associate, Kaye, Scholer, Fierman, Hays & Handler, New York, NY

- Intellectual Property Litigation Department.
- Offer of permanent employment received.

1994 – 1996, Clinical Fellow, Emergency Medicine, Yale-New Haven Hospital, Yale University School of Medicine, New Haven, CT

1992 – 1993, Physician, Physician Staffing, Cleveland, OH

1991-1992, Intern, Internal Medicine, Mt. Sinai Medical Center, Case Western Reserve University, Cleveland, OH

Board Certification:

Clinical Pathology, September 2005 (score in highest category); Molecular Genetic Pathology, September 2007; Board Eligible, Medical Microbiology; Ohio Bar, Admitted 1998 (Ohio Bar Examination score 485, 95^{th} percentile; Multistate Bar Examination score 166, 96^{th} percentile); District of Columbia Bar, Admitted 2009. Medical licensure in Ohio, Florida, and Wisconsin

Professional Honors:

Phi Beta Kappa
Phi Alpha Theta
Selectee and Travel Scholarship Award winner, Institute for Justice Law Student Conference, 1994
Paul E. Strandjord Young Investigator Award, Academy of Clinical Laboratory Physicians and Scientists, 2004
Paul E. Strandjord Young Investigator Award, Academy of Clinical Laboratory Physicians and Scientists, 2005
Paul E. Strandjord Young Investigator Award, Academy of Clinical Laboratory Physicians and Scientists, 2006

Travel Award, XXIV International Association for Comparative Research on Leukemia and Related Diseases (IACRLRD) Symposium, 2009

Committees and Advisory Panels

Government Sponsored

Molecular and Clinical Genetics Panel, Medical Devices Advisory Committee, Food and Drug Administration (FDA), Consultant, 2008 - present

Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group, Centers for Disease Control and Prevention (CDC), Member 2008 – present

Professional

Point of Care Testing Committee, College of American Pathologists 2003, 2004

CAP/ACMG Biochemical & Molecular Genetics Resource Committee, College of American Pathologists 2006, 2007

Professional Relations Committee, Association for Molecular Pathology 2008 – present

Economic Affairs Committee, Association for Molecular Pathology 2008 - present

Molecular Oncology Resource Committee, College of American Pathologists 2008- present

Chairperson, Ad Hoc Committee on Laboratory Developed Tests, Association for Molecular Pathology 2009

Subcommittee on Establishing Molecular Testing in Clinical Laboratory Environments, Clinical Laboratory Standards Institute (CLSI) 2009 – present

Patient Safety and Performance Measures Committee Working Group on Gene Patents, College of American Pathologists, 2009
FDA Biospecimens Project Working Group, College of American Pathologists 2009

Boards: Pharmacogenomics (Future Medicine), Editorial Advisory Board 2008

Publications:

Klein R D. Daubert v. Merrell Dow: Scientific Evidence in the Courtroom. JAMA. 1994; 271:1578.

Yilmaz Y, Klein R, Qumsiyeh M. Trisomy 6 acquired in lymphoid blast transformation of CML with t(9;22). Cancer Genet Cytogenet. 2003; 145(1):86-7.

Klein RD, Howe J, Magriples U, McPhedran P. Eclampsia in a woman homozygous for the prothrombin G20210A mutation. Thromb and Haemost 2004; 91:201-202.

Klein RD, Salih S, Bessoni J, Bale AE. Clinical testing for multiple endocrine neoplasia type 1 in a DNA diagnostic laboratory. Genet Med 2005;7:131-138.

Klein RD, Campbell S, Howanitz PJ. CAP Point of Care Checklist Frequently Asked Questions. Point of Care 2005;4:75-85.

Klein RD, Dykas DJ, Bale AE. Clinical testing for the nevoid basal cell carcinoma syndrome (NBCCS) in a DNA diagnostic laboratory. Genet Med 2005;7:611-619.

Campbell S, Klein RD. Waived Tests and Testing. Clin Microbiol Newsl 2006;28:89-93.

Klein RD, Campbell S. Health Care Fraud and Abuse Laws. Arch Pathol Lab Med 2006;130:1169-1177.

Klein RD, Thorland EC, Gonzales PR, Beck PA, Dykas DJ, McGrath J, Bale AE.A multiplex assay for the detection and mapping of complex glycerol kinase deficiency. Clin Chem 2006;52:1864-1870.

Campbell S, Klein RD. HIV Testing At Home: Boon or Bane? J Clin Microbiol 2006;44:3473-3476.

Klein RD, Kant JA. Opportunity Knocks: The Pathologist as Laboratory Genetics Consultant. Arch Pathol Lab Med 2006;130:1603.

Klein RD. Medical-Process Patents. N Engl J Med 2007;356:753-754.

Klein RD. Gene Patents Jeopardize Genetic Testing. Genetic Engineering and Biotechnology News 2007; 27(9):12.

Klein RD. Hereditary Breast and Ovarian Cancer: The BRCA1 and BRCA2 Genes. NewsPath, May 2007. College of American Pathologists, Chicago, IL. Available at http://www.CAP.org.

Klein RD. The Pain-protective Haplotype: Introducing the Modern Genetic Test. Clin Chem 2007;53:1007-1009.

Klein RD, Mahoney MJ. Medical-Legal Issues in Prenatal Diagnosis. Clin Perinatol 2007;34:287-297.

Klein, RD. Gene Patents and Genetic Testing in the United States. RAJ Devices 2007;15:241-244.

Klein, RD. Gene Patents and Genetic Testing in the United States. RAJ Pharma 2007;18:531-534.

Klein RD. Gene Patents and Personalized Medicine. Personalized Medicine 2007;4:237-241.

Klein RD. Gene Patents and Genetic Testing. Adv Admin Lab 2007;16:18-20.

Klein, RD. Gene Patents and Genetic Testing in the United States. Nat Biotechnol 2007;25:989-990.

Klein RD. Gene Patents and Genetic Testing in the United States. Drug and Market Development 2007;18:26-28.

Klein RD, Mahoney MJ. LabCorp v. Metabolite Labs: The Supreme Court Listens, but Declines to Speak. J Law Med Ethics 2008;36:141-9.

Klein RD, Jin L, Rumilla K, Young WF, Lloyd RV. Germline *SDHB* mutations are common in patients with apparently sporadic sympathetic paragangliomas. Diagn Mol Pathol 2008;17:94-100.

Klein RD. Genetic Testing and Primary Care. JAMA 2008;299:2275.

Klein RD, Lloyd RV, Young WF. Hereditary Paraganglioma-Pheochromocytoma Syndromes. In: GeneReviews at GeneTests: Medical Genetics Information Resource (database online). Copyright, University of Washington, Seattle. 1997-2007. http://www.genetests.org.

Erickson ML, Champion MH, Klein R, Ross RL, Neal ZM, Snyder EL. Management of Blood Shortages in a Tertiary Care Academic Medical Center: The Yale New Haven Hospital Frozen Blood Reserve. Transfusion 2008;48:2252-63.

Klein RD. Analysis: Secretary's Advisory Committee on Genetics, Health, & Society Report falls short. Hum Pathol 2009;40:147-55.

Klein RD. Interview. Pharmacogenomics 2009;10:9-12.

Klein RD, Marcucci G. Familial Acute Myeloid Leukemia (AML) with Mutated *CEBPA*. In: GeneReviews at GeneTests: Medical Genetics Information Resource (database online). Copyright, University of Washington, Seattle. 1997-2007. http://www.genetests.org (in press).

Book Chapters

Klein RD and Edberg SC. Applications, Significance of and Methods for the Measurement of Antimicrobial Concentrations in Human Body Fluids. In: Lorian V. ed. Antibiotics in Laboratory Medicine. 5th ed. Baltimore, MD: Williams & Wilkins 2005.

Abstracts

Klein RD, Bessoni, J, Bale AE. MEN1 testing in a clinical diagnostic laboratory. Presented at American Society of Human Genetics Annual Meeting 2003.

Klein RD, Fitzgerald C, Pruckler J, Bell S, Edberg SC, Braden C. *Campylobacter Concisus* in Unexplained Diarrhea. Presented at American Society for Microbiology General Meeting 2004.

Klein RD, Bell S, Edberg SC. *Campylobacter Concisus* in Unexplained Diarrhea: Identification by Genus Specific 16S Ribosomal Gene Sequencing. Oral presentation at Academy of Clinical Laboratory Physicians and Scientists Annual Meeting 2004. Am J Clin Path 2004;122:454.

Klein RD, Bell S, Edberg SC. Genus Specific PCR and Partial 16s rRNA Gene Sequencing for the Direct Detection of *Campylobacter* Species in Human Feces. Presented at CAP Annual Meeting 2004. Arch Pathol Lab Med. 2005;129:554.

Klein RD, Ghofrani M, Bale A, Duffy T, Howe JG. Hepatosplenic T-cell lymphoma in a 71-year-old man with X-linked lymphoproliferative disease. Presented at American Society of Human Genetics Annual Meeting 2004.

Klein RD, Bell S, Harris L, Edberg SC, Heimer R. Surveillance for *Listeria monocytogenes* in Unexplained Diarrhea. Presented at Association for Molecular Pathology Annual Meeting 2004. JMD 2004;6:424.

Klein RD, Salih S, Dykas D, Bale AE. Clinical MEN1 Testing in a DNA Diagnostics Laboratory. Presented at Association for Molecular Pathology Annual Meeting 2004.

Klein RD, Dykas DJ, Bale AE. Clinical testing for the nevoid basal cell carcinoma syndrome (NBCCS) in a DNA diagnostic laboratory. Oral presentation at Academy of Clinical Laboratory Physicians and Scientists Annual Meeting 2005.

Klein RD, Bell S, Hirshon JM, Edberg SC, Heimer R. Surveillance for *Listeria Monocytogenes* in Outpatients with and without Diarrhea. Oral presentation at Academy of Clinical Laboratory Physicians and Scientists Annual Meeting 2005.

Klein RD, Dykas DJ, Bale AE. Clinical testing for the nevoid basal cell carcinoma syndrome (NBCCS) in a DNA diagnostic laboratory. Presented at Association for Molecular Pathology Annual Meeting 2005.

Klein RD, Dykas DJ, McGrath J, Bale AE. Normal CK level in a patient with a complex glycerol kinase deficiency deletion extending into the *DMD* gene. Presented at the American College of Medical Genetics 2006 Annual Meeting.

Klein RD, Jin L, Rumilla K, Lloyd RV. *SDHB* mutations in malignant extraadrenal pheochromocytomas. Oral presentation at Academy of Clinical Laboratory Physicians and Scientists Annual Meeting 2006.

Klein RD, Jin L, Rumilla K, Lloyd RV. *SDHB* and *SDHD* mutations in malignant pheochromocytomas. Presented at the American Society of Human Genetics 2006 Annual Meeting.

Klein RD, Jin L, Rumilla K, Lloyd RV. *SDHB* and *SDHD* mutations in malignant pheochromocytomas. Presented at the Association for Molecular Pathology 2006 Annual Meeting.

Invited Presentations

Symposium on Gorlin Syndrome, Nevoid Basal Cell Carcinoma and Basal Cell Carcinoma Syndrome, Society for Investigative Dermatology Annual Meeting 2005, St. Louis, MO: "Molecular Approaches to Diagnosis of the Nevoid Basal Cell Carcinoma Syndrome"

Association for Molecular Pathology, Orlando, FL, 2006 Annual Meeting: "Patent Law and Genes"
H. Lee Moffitt Cancer & Research Institute, Division of Hematopathology and Laboratory Medicine, April 2007, Tampa FL: "*SDHD* and *SDHB* mutations in malignant paragangliomas"

H. Lee Moffitt Cancer Center and Research Institute/USF College of Medicine Second Annual Cutaneous Lymphoma Symposium 2008, Lake Buena Vista, FL: "Molecular Pathology Role in Early & Late CTCL and PTCLs" and "Molecular Pathology and Applications in Dx and Management of Cutaneous Lymphomas – B and T Cell Type"

USF College of Medicine, Eighth Annual Symposium on Bioethics, Tampa, FL, 2008: Panelist, Bioethics and Genomics, in "Medical Ethics in the University Community: A Potpourri"

H. Lee Moffitt Cancer Center and Research Institute/USF College of Medicine Second Annual Total Cancer Care Summit 2008, San Juan, Puerto Rico: Chairperson, "Current State-of-the-Art Diagnostics"

Emory University School of Medicine, Department of Genetics Grand Rounds, January 2009, Atlanta, GA: "Gene Patents and Genetic Testing in the United States"

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Genetic and Genomic Testing, February 2009, Baltimore, MD: Comments on behalf of the Association for Molecular Pathology

Association for Molecular Pathology, Molecular Genetic Pathology Review Course, May 2009, Rockville, MD: "Laboratory Regulation and Management" and "Molecular Coagulation"

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Screening Genetic Tests, May 2009, Baltimore, MD: Comments on behalf of the Association for Molecular Pathology

Association for Molecular Pathology, Orlando, FL, 2009 Annual Meeting: Panelist, "Gene Patents: The Current Environment and How We Got Here"

Public Comments Submitted

Secretary's Advisory Committee on Genetics, Health and Society, U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services, Draft Report, December 2007

Secretary's Advisory Committee on Genetics, Health and Society: Gene Patents and Licensing Practices and Patient Access to Genetic Tests, Draft Report, March 2009

Agency for Healthcare Research and Quality, Draft Report Quality, Regulation and Clinical Utility of Laboratory-developed Tests, September 2009

United States Patent and Trademark Office's (USPTO) request for comments on its "Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility," September 2009

Teaching

Yale School of Medicine Physician Associate Program Hematology Lecture Series: "Coagulopathies, Hereditary and Acquired" (2001, 2002)

Yale School of Medicine, Medical Student Hematology (2002) and Microbiology (2001, 2003) Laboratory Courses

Yale School of Medicine, Medical Student Genetics Course (2005)

H. Lee Moffitt/University of South Florida Hematopathology Training Program, Faculty Member, Coagulation and Molecular Diagnostics

Professional Activities and Affiliations (Past and Present)

Academy of Clinical Laboratory Physicians and Scientists, American Association for the Advancement of Science, American Association of Blood Banks, American Association of Clinical Chemistry, American Bar Association, American College of Medical Genetics, American Medical Association, American Society for Microbiology, American Society for Clinical Pathology, American Society of Human Genetics, American Society of Hematology, American Society of Law, Medicine and Ethics, Association for Molecular Pathology, Cleveland Academy of Medicine, Cleveland Bar Association, College of American Pathologists, Cuyahoga County Bar Association, Food and Drug Law Institute, Ohio State Medical Association, Patent and Trademark Office Society. Articles Reviewer: *Primary Care Reports*; *Thrombosis and Haemostasis*; *Human Pathology; Journal of Molecular Diagnostics*; *Clinical Chemistry; Genetic Testing; Personalized Medicine; Pharmacogenomics*