

UNIVERSITY OF PENNSYLVANIA - SCHOOL OF MEDICINE  
Curriculum Vitae

January 2003

Debra G.B. Leonard, M.D., Ph.D.

Office Address: 7.103 Founders Pavilion  
Hospital of the University of Pennsylvania  
3400 Spruce Street  
Philadelphia, PA 19104-4283

Education:

1976 B.A. Smith College, Northampton, MA (Biology)  
1987 Ph.D. Sackler Institute, Graduate School of Arts and Science,  
New York University, New York, NY (Biochemistry)  
1988 M.D. New York University School of Medicine, New York, NY

Postgraduate Training and Fellowship Appointments:

1988-91 Anatomic pathology resident, New York University Medical Center, New York  
1990-92 Post-doctoral fellow (David E. Levy, Ph.D.), Dept. of Pathology, New York  
University School of Medicine, New York, NY  
1991-92 Surgical pathology fellow, New York University Medical Center, New York, NY  
2002-2003 Fellow, Executive Leadership in Academic Medicine (ELAM) Program, MCP  
Hahnemann University, Philadelphia, PA

Faculty Appointments:

1992-96 Assistant Professor, Dept. of Pathology, Case Western Reserve University School  
of Medicine, Cleveland, OH  
1996-2000 Assistant Professor, Dept. of Pathology and Laboratory Medicine, University of  
Pennsylvania, Philadelphia, PA  
2000- Associate Professor, Dept. of Pathology and Laboratory Medicine, University of  
Pennsylvania, Philadelphia, PA

Hospital and Administrative Appointments:

1992-96 Director, Molecular Diagnostics Laboratory, Dept. of Pathology, The University  
Hospitals of Cleveland, Cleveland, OH  
1995-96 Chairperson, Performance Improvement Committee, Department of Pathology,  
The University Hospitals of Cleveland, Cleveland, OH  
1996 Chairperson, Clinical Support Quality Council, The University Hospitals of  
Cleveland, Cleveland, OH  
1995-96 Member, Performance Improvement Council, The University Hospitals of  
Cleveland, Cleveland, OH  
1996- Director, Molecular Pathology Laboratory, Dept. of Pathology and Laboratory  
Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA

Hospital and Administrative Appointments (continued):

1996- Director, Molecular Diagnostic Core Facility, Cancer Center, University of Pennsylvania, Philadelphia, PA

Specialty Certification:

1992 Board Certified, Anatomic Pathology, American Board of Pathology  
2001 Board Certified, Molecular Genetic Pathology, American Board of Pathology and American Board of Medical Genetics

Licensure:

1992-96 Ohio State Medical License (#63532)  
1996- Pennsylvania State Medical License (#58459)

Awards, Honors and Membership in Honorary Societies:

1981-87 National Research Service Award, Medical Scientist Training Program, Dept. of Health and Human Services  
1988 Member, Alpha Omega Alpha, Delta of New York, Medical Honor Society  
1997 Excellence in Teaching Award, University of Pennsylvania School of Medicine  
2001-Present Member, John Morgan Society, University of Pennsylvania School of Medicine

Membership in Professional and Scientific Societies and Committees:

National Societies:

Association for Molecular Pathology,  
Chair, Clinical Practice Committee, 1995-96  
President-Elect, President and Past President, 1999-2001  
Member, Professional Relations Committee, 2001-2002  
Chair, Professional Relations Committee, 2003-  
College of American Pathologists  
Member, Molecular Pathology Committee, 2002-  
Chair, Genetic Test Validation Working Group, 2002

Local Societies:

Cleveland Society of Pathologists, Member, 1992-96  
Case Western Reserve University Cancer Research Center, Member, 1993-96  
Case Western Reserve University AIDS Clinical Trials Unit, Staff, 1994-96  
Center for AIDS Research, Member; CMV Working Group, Leader, 1995-96  
University of Pennsylvania Cancer Center, Member, 1996-  
Center for AIDS Research, University of Pennsylvania, Member, 1999-  
Co-Director, Residency Program, Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA, 2002-

International Scientific Committees:

Honorary Advisor, Molecular Diagnostic Centre, National University Hospital, Singapore, March 2002- February 2003

National Scientific Committees:

- Member, Test Committee for Molecular Pathology, American Board of Pathology, 1997-
- Member, Clinical Advisory Committee, Qiagen Inc., 1997, 1999
- Consultant, Promega Corporation, 1998-2001
- Member, NIH Study Section, Small Business Innovative Research, 1999-
- Member, 4 Workshops on Mars Sample Handling, NASA, Bethesda, MD, 2000-2001;  
Subgroup Chair, 2001
- Ad Hoc Member, NCI Study Section, Training Grants, 2001
- Ad Hoc Member, Data Collection Working Group, Secretary's Advisory Committee on Genetic Testing (SACGT), Bethesda, MD, August 16, 2001
- Member, Scientific Advisory Board, Nanogen Inc., 2001-
- Member, Planetary Protection Advisory Committee, NASA, 2002-
- Member, Secretary's Advisory Committee on Genetics, Health and Society, Department of Health and Human Services, 2003-

Local Scientific Committees:

- Member, Clinical Trials Scientific Review and Monitoring Committee, University of Pennsylvania Cancer Center, 1996-2000
- Member, Scientific Advisory Committee, Genomics Institute, University of Pennsylvania, 2001-

Editorial Positions:

- 1995-1998 Editorial Board member, Molecular Diagnosis
- 1998-2000 Senior Associate Editor, Molecular Diagnosis
- 2001-2002 Editor-in-Chief, Molecular Diagnosis

Academic Committees:

- 1996 Search Committee member, Hematology/Coagulation Faculty, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 1997-98 Member, Combined Degree Advisory/Admissions Committee, University of Pennsylvania
- 1998-2001 Associate Director, Combined Degree Program, University of Pennsylvania
- 1998 Search Committee member, Microbiology Faculty, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 1998 Member, Review Committee for the Residency Advisory Committee, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 1998 Search Committee member, Hematology/Coagulation Faculty, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 1999 Chair, Search Committee, Associate Director, Molecular Pathology Laboratory, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 1999 Faculty 2000, Special Opportunities Working Group
- 2000-2000 Member, FOCUS on Women's Health Advisory Committee
- 2000 Search Committee member, Microarray Core Facility Director, Department of Pathology and Laboratory Medicine, University of Pennsylvania
- 2001-2002 Search Committee member, Clinical Chemistry Director, Department of Pathology and Laboratory Medicine, University of Pennsylvania

- 2001- Member, Executive Committee and Admissions Committee, Combined Degree Program, University of Pennsylvania
- 2002-2004 Member, Medical Faculty Senate Steering Committee, School of Medicine, University of Pennsylvania
- 2002-2004 Member, Faculty Senate Executive Committee, University of Pennsylvania
- 2002-2003 Member, Diversity Working Group, Strategic Planning Committee, School of Medicine, University of Pennsylvania

Major Teaching and Clinical Responsibilities:

Teaching:

1. Pathology 305, 2 hour Molecular Pathology Lecture, yearly
2. General Pathology, Laboratory Instructor
3. Cardiovascular System, Pathology Laboratory Instructor
4. Fellowship Training Program in Patient Oriented Research, Lecture on “Translation of Basic Science into Diagnostic Tests,” Emma Meagher, Program Director
5. Molecular Pathology Resident Rotation, Co-Director
6. Molecular Genetic Pathology Fellowship Program, Co-Director, ACGME accredited
7. Molecular Pathology Rotation, Genetic Counseling Students from Beaver College
8. Training site for Molecular technologists in the Master’s Degree Program at the University of Connecticut’s Molecular Diagnostic Sciences Clinical Education Program, 6-month rotation per student

Clinical:

1. Director, Molecular Pathology Laboratory, 12 months per year
2. Attending, Molecular Pathology Laboratory, 4 months per year

Lectures by Invitation:

International:

- April 19 & 20, 1999 “Spinal Muscular Atrophy” and “The Future of Genetic Testing,” Isala Conference on Applied Molecular Diagnostics, The Netherlands
- April 16, 2000 “Bone Marrow Engraftment Analysis: Adapting to the changing face of allogeneic bone marrow transplants,” International Society for Laboratory Hematology, Banff Springs, Alberta, Canada
- June 25-29, 2000 Series of 3 lectures on molecular pathology topics to be determined, Australian Institute of Medical Scientists National Pathology Conference, Sydney, Australia
- July 3-14, 2000 Visiting Professor for the National Manpower Development Program (2 weeks), Consultation for Molecular Diagnostics Center, National University Hospital, and lecture series, Singapore
- February 28, 2003 “The Impact of the Human Genome Project on Medical Practice of the Future,” Grand Rounds, National University Hospital, Singapore

National:

- September 27, 1995 "Molecular Biology in Diagnostic Hematopathology," American Society of Clinical Pathologists Teleconference
- November 11, 1995 "Detection of varicella zoster virus in cerebrospinal fluid from HIV-infected patients by polymerase chain reaction," Association for Molecular Pathology Meeting, Minneapolis, Minnesota
- November 27, 1995 "Development of a Molecular Pathology Test: Cytomegalovirus Polymerase Chain Reaction Assay," Grand Rounds, Department of Pathology, New York University Medical Center, New York, NY
- December 7, 1995 "Development of a Molecular Pathology Test: Cytomegalovirus Polymerase Chain Reaction Assay," Grand Rounds, Department of Pathology, Johns Hopkins University Medical Center, Baltimore, MD
- March 8, 1996 "Molecular Biology in Diagnostic Hematopathology," William Beaumont Hospital's 5th Annual Symposium, DNA Technology in the Clinical Laboratory, Royal Oak, Michigan
- October 17, 1996 "Use of Molecular Biology in Virology," CliniChem '96, Stamford, CT
- November 16, 1996 "Implications of FDA Regulations for Molecular Pathology," Association for Molecular Pathology Annual Meeting, Baltimore, MD
- September 13, 1997 "The Value of Viral Load Testing: Reimbursement and Economics," Viral Load Testing Conference, American Association for Clinical Chemistry, Dallas Fort Worth, TX
- October 17, 1997 "Impact of FDA Regulations on use of Reagents by Molecular Pathology Laboratories," Applied Biosystems, Inc, San Francisco, CA
- October 20, 1997 "HIV Viral Load Testing," Fall Meeting of the Western Branch, American Society for Microbiology, Amherst, NY
- October 30, 1997 "Current Aspects of Molecular Pathology," CliniChem-97, Philadelphia, PA
- November 14, 1997 "HIV- Beyond Viral Load Testing: Prognostic Indicators," Association for Molecular Pathology Annual Meeting, San Diego, CA
- April 3, 1998 "Spinal Muscular Atrophy," National Society of Genetic Counselors, Princeton, NJ
- July 31, 1998 "Genetic Testing for Spinal Muscular Atrophy," Families of SMA Meeting, Denver, CO
- August 3, 1998 "Impact of HIV Viral Load Testing," American Association of Clinical Chemistry 1998 Annual Meeting, Chicago, IL
- November 4, 1998 "The Future of Genetic Testing," AACC Clinical Chemistry Forum, Crystal City, VA
- November 5, 1998 "Bone Marrow Engraftment Analysis," Perkin Elmer/Applied Biosystems Workshop, Association for Molecular Pathology 1998 Annual Meeting, Crystal City, VA
- November 8, 1998 "Gene Patenting and Molecular Diagnostics," Association for Molecular Pathology Annual Meeting, Crystal City, VA
- June 12, 1999 "Genetic Testing for Spinal Muscular Atrophy," Families of SMA Meeting, Milwaukee, WI
- June 21, 1999 "Bone Marrow Engraftment Analysis," Promega Corporation, Madison, WI

- September 14, 1999 “The Impact of Disease Gene Patents on Clinical Practice,” IBC Conference on “Genetic Patenting,” Washington, D.C.
- September 23, 1999 “HIV Viral Load Testing,” American Society for Clinical Pathology Teleconference, Nationally broadcast
- September 26, 1999 “Advances in the Molecular Detection and Quantitation of Pathogens,” in “Breakthroughs in Pathology 1999,” American Society for Clinical Pathology National Meeting, New Orleans, LA
- October 19, 1999 “Genetic Testing for Spinal Muscular Atrophy,” 1999 Annual Education Conference, National Society for Genetic Counselors, Oakland, CA
- November 10, 1999 “Options for Ultrasensitive HIV Viral Load Testing,” LabMed-99 Conference, Albany, NY
- April 27, 2000 “Molecular Pathology at the Millenium,” Grand Rounds, Department of Pathology, University of Southern Florida, Tampa, FL
- October 12, 2000 “Bone Marrow Engraftment Analysis for Allogeneic Bone Marrow Transplantation Management,” New Advances in Early Detection of Occult Disease, Sixth Annual Cancer Symposium, Penn State College of Medicine, Hershey, PA
- February 21, 2001 “Bone Marrow Engraftment Analysis: Adapting to the Changing Face of Allogeneic Bone Marrow Transplants,” Pathology Grand Rounds, Emory University, Atlanta, GA (Distinguished Visiting Professor of Pathology)
- March 30, 2001 “Technical and Clinical Aspects of Bone Marrow Engraftment Analysis for Allogeneic Bone Marrow Transplantation,” Department of Pathology, University of Wisconsin, Milwaukee, WI
- May 12, 2001 “Disease Gene Patents: The Demise of Molecular Pathology?” 19<sup>th</sup> Annual Resident Research Symposium, University of Florida College of Medicine, Gainesville, FL
- May 9, 2002 “Basics of Molecular Pharmacogenetic Testing,” American Association of Clinical Chemists Conference “Pharmacogenomics: Improving Pharmacotherapy and Avoiding Adverse Drug Reactions,” Philadelphia, PA
- June 22, 2002 “Genetic Testing for Spinal Muscular Atrophy,” Families of SMA Meeting, Schaumburg, IL
- October 12, 2002 “Test Kits for Molecular Hematopathology,” American Society for Clinical Pathology, Annual Meeting 2002, Washington, DC.
- October 14, 2002 “Genetic Testing for Spinal Muscular Atrophy,” Current Advances in Molecular Diagnostics Conference, University of Virginia Health System, Charlottesville, VA
- Local:
- January 27, 1995 “Molecular Diagnostics Laboratory Testing,” Lecture to Infectious Disease Fellows and Residents, The University Hospitals of Cleveland, Cleveland, OH
- April 16, 1996 “Introduction to Molecular Pathology,” National Laboratory Week Lecture, Montgomery Hospital Medical Center, Norristown, PA

- January 13, 1997 “FDA Regulations for Pathology,” Grand Rounds, Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA
- April 15, 1997 “Molecular Biology: Where It Is Going in Laboratory Medicine,” National Laboratory Week, Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA
- December 2, 1997 “Spinal Muscular Atrophy: Translation of Basic Science into Patient Care,” Pathology Interest Group, University of Pennsylvania School of Medicine, Philadelphia, PA
- February 26, 1998 “Molecular Diagnosis,” Hematology/Oncology Fellows Conference, Hospital of the University of Pennsylvania, Philadelphia, PA
- October 8, 1998 “Role of the 5T Variant of the CFTR Gene in Cystic Fibrosis,” CF Clinic Conference, Children’s Hospital of Philadelphia, Philadelphia, PA
- October 26, 1998 “Molecular Pathology,” Thomas Jefferson School of Medicine, Medical Student Lecture
- November 19, 1998 “Spinal Muscular Atrophy,” Biology Class Lecture, and “Molecular Pathology,” Biology Department Seminar, Ursinus College, PA
- February 4, 1999 Molecular biology talk and demonstration, 4th grade Advanced Class, Garnet Valley Elementary School, Glen Mills, PA
- April 8, 1999 “Molecular Pathology,” Invited Medical School Lecture, Jefferson School of Medicine, Philadelphia, PA
- February 21, 2000 “Bone Marrow Engraftment Analysis,” Department of Pathology Seminar, Temple University School of Medicine, Philadelphia, PA
- February 28, 2000 “Gene Patents,” Grand Rounds, Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA
- April 17, 2001 “Bone Marrow Engraftment Analysis,” Department of Pathology Seminar, Children’s Hospital of Philadelphia, Philadelphia, PA
- February 20, 2002 “Genetic Testing for Spinal Muscular Atrophy,” St. Christopher Hospital, Philadelphia, PA
- October 10, 2002 “Highthroughput SNP Genotyping,” Infectious Disease Grand Rounds, University of Pennsylvania School of Medicine, Philadelphia, PA

Organizing Roles in Scientific Meetings:

- August 3, 1998 “Viral Load Testing: HIV and Beyond,” Edutrak Session, Organizer and Moderator, American Association of Clinical Chemistry 1998 Annual Meeting, Chicago, IL
- November 8, 1998 “Gene Patenting and Molecular Diagnostics,” Panel Discussion Organizer and Moderator, Association for Molecular Pathology Annual Meeting, Crystal City, VA

Bibliography:

Research Publications, peer reviewed:

1. Liberman, M.C., **Beil, D.G.**: Hair cell condition and auditory nerve response in normal and noise-damaged cochleas. *Acta Otolaryngol.* 88: 161-176, 1979.
2. Khanna, S.M., **Leonard, D.G.B.**: Basilar membrane tuning in the cat cochlea. *Science* 215: 305-306, 1982.

3. **Leonard, D.G.B.**, Khanna, S.M.: Histological evaluation of damage in cat cochleas used for measurements of basilar membrane mechanics. *J. Acoust. Soc. Am.* 75: 515-527, 1984.
4. Khanna, S.M., **Leonard, D.G.B.**: Measurement of basilar membrane vibrations and evaluation of cochlear condition. *Hearing Res.* 23: 37-53, 1986.
5. Khanna, S.M., **Leonard, D.G.B.**: Relationship between basilar membrane tuning and hair cell condition. *Hearing Res.* 23: 55-70, 1986.
6. **Leonard, D.G.B.**, Ziff, E.B., Greene, L.A.: Identification and characterization of mRNAs regulated by nerve growth factor in PC12 cells. *Mol. Cell. Biol.* 7: 3156-3167, 1987.
7. **Leonard, D.G.B.**, Gorham, J.D., Cole, P., Greene, L.A., Ziff, E.B.: A nerve growth factor-regulated messenger RNA encodes a new intermediate filament protein. *J. Cell. Biol.* 106: 181-193, 1988.
8. Veals, S.A., Schindler, C., **Leonard, D.G.B.**, Fu, X.-Y., Aebersold, R.H., Darnell J.E., Jr., Levy, D.E.: Subunit of an IFN $\alpha$ -responsive transcription factor is related to IRF and Myb families of DNA binding proteins. *Mol. Cell. Biol.* 12: 3315-3324, 1992.
9. Purvis, S.F., Katongole-Mbidde, E., Johnson, J.L., **Leonard, D.G.B.**, Byabazaire, N., Luckey, C., Shick, H. E., Wallis, R., Elmets, C.A., Giam, C.-Z.: High incidence of Kaposi's Sarcoma-Associated Herpes Virus and Epstein-Barr Virus in tumor lesions and peripheral blood mononuclear cells from patients with Kaposi's Sarcoma in Uganda. *J. Infect. Dis.* 175: 947-950, 1997.
10. Burke, D.G., Kalayjian, R.C., Vann, V.R., Madreperla, S.A., Shick, H.E., **Leonard, D.G.B.**: Polymerase chain reaction detection and clinical significance of varicella-zoster virus in cerebrospinal fluid from human immunodeficiency virus-infected patients. *J. Infect. Dis.* 176: 1080-1084, 1997.
11. Garbern, J.Y., Cambi, F., Tang, X.M., Sima, A.A.F., Vallat, J.M., Bosch, E.P., Lewis, R., Shy, M., Sohi, J., Kraft, G., Chen, K.L., Joshi, I., **Leonard, D.G.B.**, Johnson, W., Raskind, W., Dlouhy, S.R., Pratt, V., Hodes, M.E., Bird, T., Kamholz, J.: Proteolipid protein is necessary in peripheral as well as central myelin. *Neuron* 19: 205-218, 1997.
12. Wang, Y.L., Chen, K.-L., Joshi, I., Kotloff, R.M., **Leonard, D.G.B.** and Wilson, R.B.: A novel missense mutation, R1283S, of the cystic fibrosis transmembrane conductance regulator gene in a 47-year-old African-American patient. *Molecular Diagnosis* 2: 205-208, 1997.
13. Addya, K., Wang, Y.L., **Leonard, D.G.B.**: Optimization of Apolipoprotein E Genotyping. *Molecular Diagnosis* 2: 271-276, 1997.
14. Felix, C.A., Megonigal, M.D., Chervinsky, D.S., **Leonard, D.G.B.**, Tsuchida, T., Kakati, S., Block, A.M., Fisher, J., Grossi, M., Salhany, K.I., Jani-Sait, S.N., and Aplan, P.D. Association of germline p53 mutation with MLL segmental jumping translocation in treatment-related leukemia. *Blood* 91: 4451-4456, 1998.
15. Wang, Y.L., Addya, K., Edwards, R.H., Rennert, H., Dodson, L., **Leonard, D.G.B.**, and Wilson, R.B. Novel bcl-2 breakpoints in patients with follicular lymphoma. *Diagnostic Molecular Pathology* 7: 85-89, 1998.
16. Sachais, B., Nachamkin, I., Mills, J., **Leonard, D.G.B.** Novel pncA mutations in pyrazinamide-resistant isolates of Mycobacterium tuberculosis. *Molecular Diagnosis* 3: 229-232, 1998.
17. Merz, J.F., **Leonard, D.G.B.**, Miller, E.R. IRB Review and Consent in Human Tissue Research. *Science* 283:1647-1648, 1999.

18. Bell, K.A., Van Deerlin, V.M.D., Addya, K., Clevenger, C.V., Van Deerlin, P.G., **Leonard, D.G.B.**: Molecular genetic testing from paraffin-embedded tissue distinguishes non-molar hydropic abortion from hydatidiform mole. *Molecular Diagnosis* 4: 11-19, 1999.
19. Burke, D.G., **Leonard, D.G.B.**, Imperiale, T.F., Valdez, H., Karaman, B., Shick, E., Kalayjian, R.C.: The utility of clinical and radiographic features in the diagnosis of cytomegalovirus central nervous system disease in AIDS patients. *Molecular Diagnosis* 4: 37-43, 1999.
20. Porter, D.L., Connors, J.M., Van Deerlin, V.M.D., Duffy, K.M., McGarigle, C., Saidman, S., **Leonard, D.G.B.**, Antin, J. A Pilot Trial of Donor Leukocyte Infusions as Primary Adoptive Immunotherapy for Patients with Malignancies. *J Clin Oncol*, 17:1234-1243, 1999.
21. Wulf, G.M., Van Deerlin, V.M.D., **Leonard, D.G.B.**, and Bauer, K.A. Thrombosis in a patient with combined homozygosity for the factor V Leiden mutation and a mutation in the 3'-untranslated region of the prothrombin gene. *Blood Coagulation and Fibrinolysis* 10: 1-4, 1999.
22. Whittaker, M.H., Farkas, D.H., Kaul, K.L., Shrimpton, A.E., and **Leonard, D.G.B.** Association for Molecular Pathology Statement: Recommendations for in-house development and operation of molecular diagnostics tests. *Am J Clin Pathol* 111: 449-463, 1999.
23. **Leonard, D.G.B.** The Future of Molecular Genetic Testing. *Clin Chem* 45: 726-731, 1999.
24. Chen K.-L., Wang Y.L., Rennert H., Joshi I., Mills J.K., **Leonard D.G.B.**, and Wilson R.B. Duplications and De Novo Deletions of the SMN1 Gene Demonstrated by Fluorescence-Based Carrier Testing for Spinal Muscular Atrophy. *Am. J. Med. Genet.* 85: 463-469, 1999.
25. Lieberman, A.P., Trojanowski, J.Q., **Leonard, D.G.B.**, Chen K.-L., Barnett, J.L., Leverenz, J.B., Bird, T.D., Robitaille, Y., Malandrini, A., Fishbeck, K.H. Ataxin 1 and ataxin 3 in neuronal intranuclear inclusion disease. *Annals of Neurology* 46: 271-273, 1999.
26. Rennert, H., Golde, T.E., Wilson, R.B., Spitalnik, S.L., Van Deerlin, V.M.D., **Leonard, D.G.B.** A novel, non-nested RT-PCR test for the detection of t(15;17) translocations: A comparative study of RT-PCR, Cytogenetics and FISH. *Molecular Diagnosis* 4: 195-209, 1999.
27. Patel, J.B., **Leonard, D.G.B.**, Pan, X., Musser, J.M., Berman, R.E., Nachamkin, I. Sequence-Based Identification of Mycobacterium Species Using the MicroSeq 500 16S rDNA Bacterial Identification System. *J Clin Microbiol* 38: 246-251, 2000.
28. Megonigal, MD, Cheung, N.-K.V., Rappaport, E.F., Nowell, P.C., Wilson, R.B., Jones, D.H., Addya, K., **Leonard, D.G.B.**, Kushner, B.H., Williams, T.M., Lange, B.J., Felix, C.A. Detection of leukemia-associated MLL-GAS7 translocation early during chemotherapy with DNA topoisomerase II inhibitors. *Proc. Natl. Acad. Sci. USA* 97: 2814-2819, 2000.
29. Wu, H., Wasik, M.A., Przybylski, G.K., Finan, J., Haynes, B., Moore, H., **Leonard, D.G.B.**, Montone, K.T., Naji, A., Nowell, P.C., Kamoun, M., Tomaszewski, J.E., Salhany, K.E.. Hepatosplenic  $\gamma\delta$  T-Cell Lymphoma as a late-onset Posttransplant Lymphoproliferative Disorder in Renal Transplant Patients. *Am J Clin Path* 113: 487-496, 2000.
30. Przybylski, G.K., Wu, H., Macon, W.R., Finan, J., **Leonard, D.G.B.**, Felgar, R.E. DiGiuseppe, J.A., Nowell, P.C., Swerdlow, S.H., Kadin, M.E., Wasik, M.A., Salhany, K.E. Hepatosplenic and Subcutaneous Panniculitis-like  $\gamma\delta$ T-Cell Lymphomas are Derived From Different V $\delta$  Subsets of  $\gamma\delta$  T-Cells. *J Mol Diagn (Am J Path, part B)* 2: 11-18, 2000.

31. Rhodes, R.B., Lewis, K., Shultz, J., Huber, S., Voelkerding, K.V., **Leonard, D.G.B.**, Tsongalis, G.J., Kephart, D.D. Analysis of the Factor V Leiden Mutation Using the READIT Assay. *Molecular Diagnosis* 6: 55-61, 2001.
32. Patrizio, P., **Leonard, D.G.B.**, Chen, K.-L., Hernandez-Ayup, S., Trounson, A.O. Larger trinucleotide repeat size in the androgen receptor gene of infertile men with extremely severe oligozoospermia. *J Andrology* 22(3): 444-48, 2001.
33. Porter, D.L., Luger, S.M., Duffy, K.M., Stadtmauer, E.A., Laport, G., Schuster, S.J., Orloff, G., Tsai, D., McDaid, K., Addya, K., **Leonard, D.G.B.** and Antin, J.H. Allogeneic Cell Therapy for Patients Who Relapse After Autologous Stem Cell Transplantation. *Biol Blood and Marrow Transpl* 7:230-238, 2001.
34. Luo, V., Lessin, S.R., Wilson, R.B., Rennert, H., Tozer, C., Benoit, B. and **Leonard, D.G.B.** Detection of Clonal T-cell Receptor  $\gamma$  Gene Rearrangements Using Fluorescent-based PCR and Automated High resolution Capillary Electrophoresis. *Molecular Diagnosis* 6(3): 169-179, 2001.
35. French L.E., Lessin S.E., Addya K., Denardo B., Margolis D.J., **Leonard D.G.B.**, Rook A.H. Identification of Clonal T Cells in the Blood of Patients with Systemic Sclerosis: Positive Correlation with Response to Photopheresis. *Arch Dermatol* 137: 1309-1313, 2001.
36. Maus, M.V., Thomas, A.K., **Leonard, D.G.B.**, Allman, D., Addya, K., Schlienger, K., Riley, J.L., June, C.H. "Ex vivo expansion of polyclonal and antigen-specific cytotoxic T lymphocytes by artificial APCs expressing ligands for the T cell receptor, CD28 and 4-1BB." *Nature Biotechnology* 20: 143-148, 2002.
37. Merz, J.F., Kriss, A., **Leonard, D.G.B.**, Cho, M.K. Patenting and licensing of genetic tests: The case of hemochromatosis. *Nature* 415: 577-579, 2002.
38. Ogino, S., **Leonard, D. G. B.**, Rennert, H., and Wilson, R. B. Spinal Muscular Atrophy genetic testing experience at an academic medical center. *J. Mol. Diagnostics* 4: 53-58, 2002.
39. Ogino, S., **Leonard, D. G. B.**, Rennert, H., Ewens, W. J., and Wilson, R. B. Genetic risk assessment in carrier testing for Spinal Muscular Atrophy. *Am. J. Med. Genet.* 110: 301-307, 2002.
40. **Leonard, D.G.B.**, Travis, L.B., Addya, K., Dores, G.M., Holowaty, E.J., Bergfeldt, K., Malkin, D., Kohler, B.A., Lynch, C.F., Wiklund, T., Stovall, M., Hall, P., Slater, D.J., Felix, C.A. p53 Mutations in leukemia and myelodysplastic syndrome after ovarian cancer. *Clinical Cancer Research* 8: 973-985, 2002.
41. Ogino S., Gao S., **Leonard D.G.B.**, Paessler M., Wilson R.B. Inverse correlation between SMN1 and SMN2 copy numbers: Evidence for gene conversion from SMN2 to SMN1. *Eur. J. Hum. Genet.* (In Press).

#### Textbooks

1. Diagnostic Molecular Pathology. **Leonard, D.G.B.**, Editor. Elsevier Science, Philadelphia, PA (In Press).

#### Research Publications, non-peer reviewed:

1. Khanna, S.M., **Leonard, D.G.B.**: Laser interferometric measurement of basilar membrane vibrations in cats using a round window approach, in *Optics in biomedical sciences*. G. Von Bally and P. Greguss, eds. Springer series in optical sciences, Springer-Verlag, Berlin/Heidelberg, pp. 88-91, 1982.

2. Khanna, S.M., **Leonard, D.G.B.**: An interpretation of the sharp tuning of the basilar membrane mechanical response, in *Mechanics of hearing*. E. de Boer and M.A. Viergever, eds. Delft University Press, Delft, pp. 177-181, 1983.
3. **Leonard, D.G.B.**: The identification and characterization of messenger RNAs regulated by nerve growth factor in PC12 cells. Ph.D. thesis, Graduate School of Arts and Sciences, New York University, NY, 1987.
4. Veals, S.A., Kessler, D.S., Josiah, S., **Leonard D.G.B.**, Levy, D.E.: Signal transduction pathway activating interferon-alpha-stimulated gene expression. *Brit. J. Hematol.* 79, Suppl. 1: 9-13, 1991.
5. Wulf, G.M., Van Deerlin, V.M.D., **Leonard, D.G.B.**, and Bauer, K.A. Thrombosis in a patient with combined homozygosity for the factor V Leiden mutation and a mutation in the 3'-untranslated region of the prothrombin gene. *Clinical Hemostasis Review*, March, 1999.

Editorials, Reviews and Letters:

1. **Leonard, D.G.B.**: Clinical News Update: FDA proposal for classification of "Analyte-specific Reagents." *Mol. Diag.* 1: 153-154, 1996.
2. Garrett, C.T., **Leonard, D.G.B.**: Clinical News Update: Regulation of Analyte-specific Reagents. *Mol. Diag.* 1: 276-277, 1996.
3. Henghold, W.B. 2nd, Purvis, S.F., Schaffer, J., **Leonard, D.G.B.**, Giam, C.Z., Wood, G.S.: Kaposi sarcoma-associated herpes virus/human herpesvirus type 8 and Epstein-Barr virus in iatrogenic Kaposi sarcoma (letter). *Archives of Dermatology* 133: 109-111, 1997.
4. Merz, J.F., Cho, M.K., Robertson, M.A., **Leonard, D.G.B.**: Disease gene patenting is a bad innovation. *Molecular Diagnosis* 2: 299-304, 1997.
5. Merz, J.F., Cho, M.K., **Leonard, D.G.B.** Testing for Alzheimer's (letter). *Science* 281: 1285i, 1998.
6. Warshawsky, I., **Leonard, D.G.B.** Laboratory testing for leukemias and lymphomas. *Clinical Laboratory News* 25: 8-9, 1999.
7. Warshawsky, I., **Leonard, D.G.B.** Laboratory testing for leukemias and lymphomas. *LabMedica Internationsl* 17(3): 8-10, 2000.
8. Chu, C.S., Wheeler, J.E., Menzin, A.W., **Leonard, D.G.B.**, and Rubin, S.C. Primary peritoneal carcinoma: A review of the literature. *Obstetrical and Gynecological Survey* 54: 323-335, 1999.
9. Patrizio, P., and **Leonard, D.G.B.** Expansion of the CAG Trinucleotide repeats in the androgen receptor gene and male infertility: A controversial association. *J Androl* 22(5): 748 (2001).

Chapters:

1. Khanna, S.M., **Leonard, D.G.B.** Basilar membrane response measured in damaged cochleas of cats, in Mathematical Modeling of the Hearing Process. M.H. Holmes and L.A. Rubinfeld, eds, Springer-Verlag, New York, pp. 70-84, 1980.
2. **Leonard, D.G.B.**, and Traber, P.G. Molecular biologic approaches to the diagnosis of gastrointestinal diseases, in Textbook of Gastroenterology, Third Edition. T. Yamada, D.H. Abers, C. Oisyang, D.W. Powel and L. Lane, eds., J.B. Lipincott Co., Philadelphia, pp. 2628-2642, 1999.

3. Patrizio, P. and **Leonard, D.G.B.** Mutations of the cystic fibrosis gene and congenital absence of the vas deferens, in The Genetic Basis of Male Infertility. K. McElreavey, ed., Springer-Verlag, Heidelberg, Germany, pp. 175-186, 1999.
4. Van Deerlin, V.M.D., and **Leonard, D.G.B.** Bone marrow engraftment analysis after allogeneic bone marrow transplantation, in Clinics in Laboratory Medicine: Acute Leukemias, 20 (1). D. Crisan, ed., W.B. Saunders, Philadelphia, PA, pp. 197-225, 2000.
5. **Leonard, D.G.B.** Introduction to Molecular Pathology, in Diagnostic Molecular Pathology. **D.G.B. Leonard**, ed. Elsevier Science, Philadelphia, PA, pp. 1-4 (In Press).
6. Rennert, H., and **Leonard, D.G.B.** Basic Principles of Molecular Biology, in Diagnostic Molecular Pathology. **D.G.B. Leonard**, ed. Elsevier Science, Philadelphia, PA, pp. 5-23 (In Press).
7. Rennert, H., and **Leonard, D.G.B.** Molecular Methods in the Diagnostic Laboratory, in Diagnostic Molecular Pathology. **D.G.B. Leonard**, ed. Elsevier Science, Philadelphia, PA pp. 25-25-51 (In Press).
8. **Leonard, D.G.B.** The Future of Molecular Pathology, in Diagnostic Molecular Pathology. **D.G.B. Leonard**, ed. Elsevier Science, Philadelphia, PA, pp. 189-196 (In Press).

Alternative Media:

1. Quoted in CAP Today 11 (12), December 1997, page 25, "How viral load's measures up," by William Check.
2. WCAU-TV (NBC), News 10, video recording for report on DNA Testing, December 12, 1997.
3. Quoted in Clinical Laboratory News 24 (11), November 1998, pages 16-17, "Commercializing the Human Genome: Will Gene Patenting Hinder Future Testing?" by Sue Auxter.
4. National Public Radio series, The DNA Files, Gene Patents, by John Rudolph, March, 1999.
5. Quoted in Laboratory Medicine 30(3), March 1999, "New Chip on the Block: The Arrival of Biochip Technology," by Mary Jane Friedrich.
6. Quoted and pictured in cover story for Sunday Chicago Tribune, September 12, 1999, "Taking License with Your Genes," by Ronald Kotulak.
7. Quoted in Bunk, S. "Researchers feel threatened by disease gene patents." The Scientist, October 11, 1999, pg. 7.
8. National Public Radio Report on Gene Patents by Richard Harris, aired on November 3, 1999.
9. CBS Evening News, Eye on America report by Wyatt Andrews on Human Genome Project and Gene Patents, November 9, 1999.
10. Featured in cover story for Sunday Philadelphia Inquirer, February 13, 2000, "The Great Gene Grab: Firms Toss Researchers for a Loop," by Andrea Knox.
11. Quoted and pictured in News Story, March 6, 2000, "Biotech faces evolving patent system: Legal, regulatory and business developments help some, worry others," by Douglas Steinberg.
12. Quoted in Salon.com article, March 7, 2000, "Who owns your DNA?" by Arthur Allen.
13. Quoted in U.S. News & World Report, May 8, 2000, Article on Funeral Home DNA Storage Service by Mary Brophy Marcus.
14. Quoted and pictured in the Boston Globe Magazine article "Corporate Takeover" on gene patent issues, on February 24, 2002, by Kimberly Blanton.

15. National Public Radio, Segment on Gene Patents in Market Place, Helen Palmer, December 26, 2002.

Abstracts (Previous 3 Years):

1. Patrizio, P., Trounson, A.O., Chen, K.-L., Hernandez-Ayup, Leonard, D.G.B. Larger trinucleotide repeat size in the androgen receptor gene of infertile males with severely disturbed spermatogenesis. American Society of Reproductive Medicine Annual Meeting, Toronto, Canada, September 25-30, 1999.
2. Vergilio, J., Porter, D., Leonard, D.G.B., Duffy, K., Addya, K., Pletcher, H., Moore, J.. Combined flow sorting and molecular engraftment analysis. Clinical Cytometry Society, 14th Annual Clinical Applications of Cytometry, Palm Springs, CA, September 26-29, 1999.
3. Van Deerlin, V.M.D., Tozer, C.S., Addya, K., Rennert, H., Leonard, D.G.B.. High-order multiplex short tandem repeat PCR reactions are not as sensitive as monoplex or quadriplex reactions for detection of mixed chimerism. Association for Molecular Pathology Annual Meeting, St. Louis, MO, November 4-7, 1999.
4. Kephart, D.D., Rhodes, R.B., Lewis, K., Shultz, J., Huber, S., Voelkerding, K.V., Leonard, D.G.B., Tsongalis, G.J. High-Throughput, Multiplex Analysis of Genes Involved in Thrombotic Disease using a Novel Molecular Screening Tool. Association for Molecular Pathology Annual Meeting, St. Louis, MO, November 4-7, 1999.
5. Wilson, R.B., Mills, J., Tozer, C., Rennert, H., Leonard, D.G.B. Polymorphism in primer binding site for HFE gene PCR reduces amplification from polymorphic allele. Association for Molecular Pathology Annual Meeting, St. Louis, MO, November 4-7, 1999.
6. Rennert, H., Chen, K.-L., Dong, H.-J., Tozer, C., Wilson, R.B., Leonard, D.G.B.. A novel single nucleotide insertion in intron 6 of the SMN gene identified by carrier testing. Association for Molecular Pathology Annual Meeting, St. Louis, MO, November 4-7, 1999.
7. Porter DL, Luger S, Stadtmauer E, Laport G, Schuster S, Duffy K, Leonard DGB, Antin J. Allogeneic cell therapy (ACT) after autologous hematopoietic stem cell transplantation (AHSCT). Tenth International Symposium on Autologous Blood and Marrow Transplantation, Dallas, TX. July 11-14, 2000.
8. Porter DL, Leonard DGB, Duffy KM, McDaid K, Laport GG, Luger S, Stadtmauer EA, Schuster S, Demuth W, Moore J, Emerson SG. Dendritic cell chimerism after allogeneic bone marrow transplantation. 42<sup>nd</sup> American Society of Hematology Annual Meeting, San Francisco, December 2000.
9. Porter DL, Luger S, Duffy K, Orloff G, Tsai D, Stadtmauer E, Laport G, Schuster S, McDaid K, Addya K, Leonard DGB, Antin J. Allogeneic cell therapy (ACT) after relapse from autologous stem cell transplantation (autoSCT). 42<sup>nd</sup> American Society of Hematology Annual Meeting, San Francisco, CA, December 2000.
10. Ogino S., Rennert H., Leonard, D.G.B., Wilson R.B. Spinal muscular atrophy (SMA) genetic testing experience. Annual Meeting of the Association for Molecular Pathology, Philadelphia, PA, November 15-18, 2001.
11. Ogino S., Leonard, D.G.B., Rennert H., Ewens W.J., Wilson R.B. Genetic risk assessment in spinal muscular atrophy (SMA) carrier testing. Annual Meeting of the Association for Molecular Pathology, Philadelphia, PA, November 15-18, 2001.
12. Beers L, Lo Re V., Leonard D.G.B., Kostman J., Gross R. Lack of early impact of low detectable HIV viral load on treatment and outcome. 41st ICAAC, Chicago, IL, September 22-25, 2001.

13. Beers L., Lo Re V., Leonard D.G.B., Kostman J, Gross R., Low-Level Detectable HIV on Antiretroviral Therapy-Treatment: Modifications and Outcomes, International Conference on Pharmacoepidemiology, Edinburgh, Scotland, August 18-21, 2002.
14. Manno, C.S., Glader, B., Hutchison, S., Dake, M., Razavi, M., Herzog, R.W., McClelland, A., Rustagi, P., Johnson, F., Rasko, J.E.J., Hoots, K., Blatt, P., Leonard, D.G.B., Addya, K., Konkle, B., Chew, A., Couto, L.B., Arruda, V.R., Kaye, R., Ozelo, M.Z., Pierce, G., High, K.A., Kay, M.A. A phase I/II trial of AAV-mediated, liver-directed gene transfer for hemophilia B. International Society on Thrombosis & Haemostasis XIX Congress and 49<sup>th</sup> Annual SSC Meeting. Birmingham, England, July 12-18, 2003.

CURRENT GRANT SUPPORT

5P30 CA16520-25 Glick (PI) 7/1/01 – 6/30/02 10%  
NIH \$1,921,619

University of Pennsylvania Cancer Center Support Grant

This grant supports the cancer research effort of the University of Pennsylvania Cancer Center. Dr. Leonard directs the Molecular Diagnostic Core of this grant.

1 R01 HG 02034 Cho (PI) 7/1/00 - 6/30/03 5%  
NIH/NHGRI \$250,107

Effects of Gene Patents on Genetic Testing and Research

The major goals of this project are to determine the effects of patenting of genetic tests on the provision of clinical genetic testing services and on genetics research.

R25 CA87812 Barr (PI) 7/1/01 – 6/30/06 10%  
NIH/NCI \$189,000

Cancer Molecular Pathology Training Program

This training grant is designed to train postdoctoral MD fellows in cancer molecular research using an interdisciplinary approach from oncologists, pathologists, researchers and innovative technologies.

RFP C01-0032 Leonard (PI) 2002-05 10%  
National Marrow Donor Program \$191,242

Combined flow sorting and Bone Marrow Engraftment Analysis studies for a clinical trial of T-cell inactivation for unrelated donor transplants. The study is sponsored by the National Marrow Donor Program with Cerus Corporation.

RFP C01-0032 Leonard (PI) 2002-05 5%  
National Marrow Donor Program \$95,750

CDR3 Spectratyng analysis of the T cell populations for a clinical trial of T-cell inactivation for unrelated donor transplants. The study is sponsored by the National Marrow Donor Program with Cerus Corporation.

PENDING GRANT SUPPORT

None

PAST GRANT SUPPORT

Quantitative PCR for cytomegalovirus (CMV) DNA from blood as a predictor for clinical relapse of CMV retinitis in AIDS patients. Center For AIDS Research Development Award, CWRU Center for AIDS Research Grant, Co-Principal Investigator with John T. Carey, MD, \$10,000, 1994-95

Detection of occult breast carcinoma cells in stem cell collections from breast cancer patients by RT-PCR of cytokeratin 19 mRNA. American Cancer Society, Cuyahoga County Unit, Principal Investigator, \$15,000, 1995-96

Analysis of archival stem cell collections from breast cancer patients by a cytokeratin 19 RT-PCR assay. Pilot Project Award, University of Pennsylvania Cancer Center, Principal Investigator, \$10,000, 1996-98

Quantitative MRI and 1H-MRS in Traumatic Brain Injury, Robert Grossman, PI, NIH, R01, Co-Investigator, \$2,180,151, 1998-2000

Associate Director, Medical Scientist Training Program, University of Pennsylvania, NIH Training Grant, 4% salary support, 1998-01