CURRICULUM VITAE

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PROFESSIONAL EXPERIENCE

2007 – 2009 **Principal Scientist, BD Diagnostics, Becton Dickinson Company**

2009 – present **Staff Scientist (corporate-wide title change; not a demotion), BD Diagnostics, Becton Dickinson Company**

(i) Responsible for the successful transfer and support of the existing BD EZ RSV product to BD's manufacturing plant in Suzhou, China. Served as both a liaison between the American and the Chinese teams and a mentor for the young Chinese workers there in manufacturing, QC, product support and R&D departments.

(ii) Responsible for the successful development, transfer and support of a new DIA (Digital ImmunoAssay) for RSV (Respiratory Syncytial Virus). This series of products, called the Veritor™ System, revolutionized the rapid diagnostics industry and totally removed the need for the error-prone human eye result reading through the use of an inexpensive, accurate and robust hand-held instrument. Served again as an important mentor for the young Chinese scientists.

(iii) Instrumental in generating and supplying massive amounts of data to the regulatory department for submission of the above-mentioned product to FDA for its clearance as well as CLIA waiver.

(iv) Responsible for the successful development of Veritor™ hMPV (human MetaPneumo Virus) assay.

(v) Responsible for showing feasibility of a combo Veritor™ RSV+hMPV assay.

2001 – 2007 **Director, Assay Development, Qualigen, Inc.**

(i) Responsible for developing and supporting a high-sensitivity plasma TSH assay for the FastPack™ chemiluminescent immunoassay system.

(ii) Responsible for developing and supporting a high-sensitivity serum free thyroxine assay for the FastPack™ chemiluminescent immunoassay system.

(iii) Responsible for developing and supporting a serum total testosterone assay for the FastPack™ chemiluminescent immunoassay system.

1996 - 2001 **Principal Scientist, Accumetrics, Inc.**

(i) Responsible for developing a fast and easy-to-use whole blood assay for monitoring the effect of GPIIbIIIa inhibitors on platelet function – the *Ultegra™* RPFA-TRAP assay.

(ii) Responsible for developing a fast and easy-to-use whole blood assay for monitoring the effect of aspirin on platelet function – the *Ultegra™* RPFA-ASA assay.

1993 - 1996 **Project Director / Principal Scientist**, **Quidel Corp.**

(i) Investigated different possibilities in saliva diagnostics, including pregnancy, ovulation (LH, FSH and progesterone) and H. pylori tests.

(ii) Developed a rapid test for sustained pregnancy, a whole blood one-step dip-stick progesterone test.

1990 - 1993 **Science Fellow, Biosite Diagnostics, Inc.**

1989 - 1990 **Staff Scientist, Biosite Diagnostics, Inc.**

Together with the three founding scientists, successfully developed the Triage™ ASCEND™ Multimmunoassay for the simultaneous detection of 7 drugs of abuse. I was responsible for putting all the chemical and immunochemical components together and making it work. I also showed feasibility of "time-gate" for prototype lateral flow assays. This was the foundation for later cardiac panel assays.

1988 - 1989 **Scientific Investigator / Project Manager, Hybritech, Inc.**

1986 - 1988 **Staff Scientist / Project Manager, Hybritech, Inc.**

In these two positions, I had been in charge of the development of an ICON assay for the hepatitis B surface antigen from start to finish; responsible for technically meeting the very stringent design goals – speed, simplicity and high sensitivity and specificity – as well as training and motivating staff and coordinating the various support groups.

1985 - 1986 **Senior Research Scientist , Hybritech, Inc.**

Contributed to the advancement of ICON technology and improvement of its manufacturability.

1984 - 1985 **Supervisor/Senior Research Scientist, Quidel, Inc.**

In charge of R&D of dip-stick technology for:

(i) immunoassays for drugs of abuse; an earned R&D contract from a major pharmaceutical company. Directed the R&D activities of a group of people and showed feasibilities of simultaneous multiple-drug detection on one dip-stick.

(ii) immunoassay for fecal CEA; directed the R&D activities of a group of people and established its clinical significance.

1982 - 1984 **Research Scientist, Quidel, Inc.**

Successfully developed the first OTC dip-stick pregnancy test. Responsible for inventing and advancing the dipstick technology, based on which other products followed: ovulation, Strep A and allergy tests.

Instrumental in the development of:

(i) a superior antibody-alkaline phosphatase conjugation chemistry.

(ii) protein immobilization chemistry on paper.

(iii) analytical methods to determine antibody affinities and immunoreactivities, and stabilities of differnt components in the dip-stick technology, and to QC these via reflectance spectroscopy.

1980 - 1982 **Research Scientist, Ames Division, Miles Laboratories.**

Responsible for the R&D of a physician's office diagnostic system – Seralyzer® – and its reagent strips. Using my analytical skills, I was able to, within a month on my job, determine the cause of instability of CK prototype reagent strips (a problem that had lingered around for years) and made it stable for years at room temperature. Advanced the theory of reflectance spectroscopy as applied to our particular system and removed a major generic flaw due to improper mathematical transformation of reflectance data.

POSTDOCTORAL RESEARCH EXPERIENCE

1978 – 1980 **Molecular Biology Institute, UCLA; with Professor Fred C. Fox**
Studied the enkaphalin receptor system.

1976 – 1978 **The Department of Molecular Biophysics and Biochemistry, Yale University; with Professor Frederic M. Richards**
Studied the glucose transport system of the red blood cell.

GRADUATE RESEARCH EXPERIENCE

1971 – 1976 **The Division of Chemistry and Chemical Engineering, California Institute of Technology; with Professor Michael A. Raftery**
Studied the molecular mechanism of human hemoglobin using F^{19} NMR;
Studied structure and function of the acetylcholine receptor system.

EDUCATION

1971 - 1976 Ph.D. (1977) in Chemistry, California Institute of Technology, Pasadena, California
1966 - 1970 B.Sc. in Chemistry, National Taiwan University, Taipei, Taiwan, Republic of China

PATENTS

1. **Theodore T. Lee** (1981) MOI filed.
A Simple Method for the Determination of Concentration of a Substance which Is Distributed between a Scattering Medium and an Overlaying Medium with Negligible Scattering by Reflectance Measurement.

2. David H. Katz, Steven W. Cooper, **Theodore T. Lee** and Shung-ho Chang (1985)
U.S. Patent Number 4,496,654
Detection of HCG with Solid Phase Support Having Avidin Coating.

3. **Theodore T. Lee** and David H. Katz (1985)
European Patent Publication #0203238A1, Application #85307785-7 (October 28, 1985)
Assay for Drugs of Abuse.

4. **Theodore T. Lee**, Richard Anderson, Ken Buechler and Gunars Valkirs (1991)
Cross-talk Inhibitors and Their Uses.

5. Dennis A. Durbin, **Theodore T. Lee**, Boris I. Ratnikov, Robert S. Hillman and Jeffrey W. Smith (1999)
U.S. Patent Number 5,922,551
Agglutrimetric Platelet Binding Assays in Blood

6. **Theodore T. Lee** and Dennis A. Durbin, U.S. Patent Pending (1999)
Use of Near-Infrared Light in Monitoring Reactions in Blood

7. **Theodore T. Lee** and James L. Wyatt, U.S. Patent Application (2001)
Use of the Cationic-Propyl Gallate in a Rapid Platelet Function Assay

INDUSTRIAL PUBLICATIONS

1. **Theodore T. Lee** and S.T. Chen, *Clinical Chemistry, 27, 1027 (1981).*
   Abstract for Poster Session at 1981 AACC Meeting.
   A Solid-phase Strip Test for the Determination of Total CPK Activity in Serum with the Ames Seralyzer®.

2. Richard R. Anderson, **Theodore T. Lee**, Dorothy C. Saewert, Kathleen M. Sowden and Gunars E. Valkirs, *Clinical Chemistry, 32, 1692 (1986).*
   Internally Referenced ImmunConcentration™ Assays.

3. **Theodore T. Lee**, Susan Sullivan and Sheryl Harvey,
   Abstract for Poster Session at 1989 AACC Meeting.
   A Rapid Semiquantitative Test for Hepatitis B Surface Antigen Using the ICON Reader®.

4. K. Buechler, S. Moi, B. Noar, D. McGrath, J. Villela, M. Clancy, A. Shenhav, A. Collymore, G. Valkirs, **T. Lee**, R. Neynaber, M. Walsh, J. Wallaeger, A.F. Ahmuty, M. Nowakowski, J. Buechler, N. Stiso and R. Anderson,
   Abstract for Poster Session at 1991 Oakridge Conference.
   A New Competitive Immunoassay for the Simultaneous Detection of Drugs of Abuse.

5. K. Buechler, S. Moi, B. Noar, D. McGrath, J. Villela, M. Clancy, A. Shenhav, A. Collymore, G. Valkirs, **T. Lee**, J. Bruni, M. Walsh, R. Hoffman, A. Ahmuty, M. Nowakowski, J. Buechler, M. Mitchell, D. Boyd, N. Stiso and R. Anderson,
   Abstract for Poster Session at 1992 Oakridge Conference.
   Triage™ ASCEND™ Multimmunoassay for the Simultaneous Detection of 7 Drugs of Abuse.

6. J.F. Bruni, K. Buechler, S. Moi, B. Noar, D. McGrath, J. Villela, M. Clancy, A. Shenhav, A. Collymore, G. Valkirs, **T. Lee**, M. Walsh, R. Hoffman, F. Ahmuty, M. Nowakowski, J. Buechler, M. Mitchell, D. Boyd, N. Stiso and R. Anderson,
   Abstract for Poster Session at 1992 AACC Meeting.
   Evaluation of the Triage™ Panel for Drugs of Abuse Test for the Simultaneous Detection of 7 Drugs of Abuse.

7. Jeffrey W. Smith, PhD; Steven R. Steinhubl, MD; A. Michael Lincoff, MD; Jacqueline C. Coleman, PhD; **Theodore T. Lee**, PhD; Robert S. Hillman, PhD; Barry Coller, MD; *Circulation, 1999; 99:620-625.*
   Rapid Platelet-Function Assay, An Automated and Quantitative Cartridge-Based Method.

(Academic publications will be provided upon request)