

Curriculum Vitae

Mark J. Sarno, eJD

Scientist, Biostatistician, Inventor, Licensed Patent Agent

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PROFESSIONAL EXPERIENCE

Vision Clinical Research, LLC

Chief Executive Officer and Founder

2012-Present

Established a Clinical Research Organization (CRO) providing services in clinical study design and powering, protocol generation, case report form (CRF) and related study document generation including informed consent, institutional review board (IRB) submissions and communication, site selection and training, study management and monitoring, good clinical practice (GCP) compliance, query generation and resolution, data management (including electronic data capture), statistical analysis, quality assurance, and study report generation.

Vision Biotechnology Consulting

President and Founder

May 1996-Present

Established a consulting practice that provides services in drug and medical device development and intellectual property. Clients range from biotechnology start-up to global diagnostic and pharmaceutical companies. Clinical areas of consultation include cardiovascular disease, diabetes, oncology, rheumatology, metabolic bone disease, infectious disease, gastroenterology, chronic pain management, reproductive hormones, fetal aneuploidies, newborn screening for inherited disorders, thrombophilia and coagulation monitoring, male fertility, asthma and other respiratory disorders, and cognitive impairment disorders.

Key accomplishments and activities include:

- Design, direction, and performance of product development, clinical trial, biostatistical analysis, and regulatory sciences activities including authoring of regulatory submissions resulting in the approval of nine (9) new drug applications (NDAs), one (1) MAA approval, twenty-eight (28) approvals or clearances of *in vitro* diagnostic assays or medical devices, and seven (7) CE Mark certifications for medical devices
- Biostatistical analyses of key epidemiological studies including Atherosclerosis Risk in Communities (ARIC), the Rancho Bernardo study, The West of Scotland Coronary Prevention Study (WOSCOPS), the JUPITER study, and the REasons for Geographic and Racial Differences in Stroke (REGARDS)

- Design and biostatistical analyses of large Phase III drug trials including the REduction by DUtasteride of prostate Cancer Events (REDUCE)
- Design and biostatistical analyses of multiple pivotal medical device trials
- Database development, data management, and biostatistical analysis of large medical device and drug trials
- Expiration dating analysis for drug substances and drug products in support of regulatory submissions (CMC section)
- Pharmacokinetic analyses in support of regulatory submissions
- Direction of GMP manufacturing of investigational drugs
- Direction and troubleshooting of process development and scale-up of *in vitro* diagnostic reagents
- Design and analysis of CLIA laboratory method validation studies
- Extensive publication in high impact journals
- Composition of continuing medical education programs
- Patent agent support for devices, drugs, and methods

**NovaDx Incorporated,
Director, Product Development
March 1995-May 1996**

Established and implemented the overall product development process for a start up *in vitro* diagnostic manufacturer. This task included design and implementation of a project management process, generation of product designs and manufacturing documents, and implementation of Design Control

Key accomplishments and activities included:

- Managed the development of an immunoassay for YKL-40, a novel biochemical marker found in high amounts in individuals with Rheumatoid Arthritis and Osteoarthritis
- Managed technical aspects of business development negotiations resulting in licensing agreements with two corporate partners to manufacture manual and automated versions of the immunoassay for YKL-40

**Hybritech Incorporated
Research Scientist, Project Team Leader
1986-1995**

Led assay and process development teams in the development of multiple immunoassay products.

Key accomplishments and activities included:

- Developed fourteen (14) *in vitro* diagnostic immunoassays from antibody selection through scale-up, regulatory approval or clearance, and commercialization. Products successfully commercialized included: immunoenzymetric and/or immunoradiometric assays for IgE, Ferritin, Thyroid Stimulating Hormone, Prostatic Acid Phosphatase, Luteinizing Hormone, Follicle Stimulating Hormone, Group B Streptococcus, Prostate Specific Antigen, Creatine Kinase MB isoenzyme, and Colorectal Cancer Antigen CA-195.
- 2 years spent in a Manufacturing Technical Support capacity during which I was responsible for the manufacture of 10 diagnostic products including Hybritech's

highest volume products, the Prostate Specific Antigen (PSA) radioimmunometric and enzyme-immunometric assays.

**Research Institute of Scripps Clinic
Research Assistant
1983-1986**

Basic research on folate and methotrexate transport in bacterial and mammalian cell lines

JOURNAL AFFILIATIONS

Reviewer – Clinical Chemistry

ADVISORY BOARDS

Scientific Advisory Board member - Iris Molecular Diagnostics

EDUCATION

Executive Juris Doctorate (eJD) with Honors

Conferred by Concord University
December 2008

Focus on Patent Law, Health Law, Bioethics, Medical Products Liability, Contracts, and Civil Procedure

Received award for outstanding legal writing

Bachelor of Arts (BA) in Biochemistry and Cell Biology

Conferred at the University of California at San Diego
June 1983

MEMBERSHIPS

United States Patent Bar

California Lawyers Association (Associate Membership, Intellectual Property Law Division)

Aircraft Owners and Pilots Association

USA Track and Field

BOOK CHAPTER

1. Laboratory support of pharmaceutical, *in vitro* diagnostics, and epidemiologic studies. Mark J. Sarno, Amar A. Sethi, Omar Laterza, Nader Rifai. Tietz Textbook of Clinical Chemistry 6th Edition. Elsevier B.V., Amsterdam, Netherlands. 2017.

RESEARCH PUBLICATIONS

1. Performance of a multianalyte “rule-out” assay in pregnant individuals with suspected preeclampsia. Costantine MM, Sibai B, Bombard AT, Sarno M, West H, Haas DM, Tita AT, Paidas MJ, Clark EAS, Boggess K, Grotegut C, Grobman W, Su EJ, Burd I, Saade G, Chavez MR, Paglia MJ, Merriam A, Torres C, Habli M, Macones G, Wen T, Bofil J, Palatnik A, Edwards RK, Haeri S, Oberoi P, Mazloom A, Cooper M, Lockton S, Hankins GD. *Hypertension* 2022;79 (in press).
2. Performance of a single use rapid point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Trichomonas vaginalis*; a cross-sectional study. Sheldon R. Morris, MD, MPH, Claire C. Bristow, PhD, MPH, MSc, Michael R. Wierzbicki, PhD, Mark Sarno, eJD, Lenore Asbel, MD, Audrey French MD, Charlotte A. Gaydos, MS, DrPH, Lydie Hazan, MD, Leandro Mena, MD, Purnima Madhivanan, MD MPH, Susan Philip, MD, MPH, Saara Schwartz, MD, Constance Brown MD, Pamela Kane DO, David Styers, BS, Toni Waymer, BA, and Jeffrey D. Klausner, MD, MPH for the STAR STI Clinical Trial Group. *Lancet Infectious Diseases* 2021;21:668-76.
3. Concordance for changes in asthma domain variables during short-term corticosteroid therapy. P. Silkoff, M. Sarno, S. Ssenyange, V. Balasubramanyam, B. Awabdy, R. Leard. *BMC Pulmonary Medicine* 2020;20:139.
4. Clinical precision, accuracy, number and durations of exhalations for a novel electrochemical monitor for exhaled nitric oxide. P. Silkoff, B. Awabdy, M. Sarno, S. Ssenyange, R. Leard. *Journal of Breath Research* 14(2019) 016011.
5. Novel centrifugal technology for measuring sperm concentration in the home. U.Y. Schaff, L.L. Fredriksen, J.G. Epperson, T. Quebral, S.N. Schaff, M.J. Sarno, B.R. Gilbert, M.J. Eisenberg, G.J. Sommer. *Fertility and Sterility* 2017;107:358-64.
6. Reflex PCA3 messenger ribonucleic acid testing: Validation of post biopsy urine samples and correlation with prostate biopsy findings in ~2000 patients. Jeffrey Brown, John Fulmer, Javier Romano, John Pownell, Wayne Rigler, Amery Wirtshafter, Mark Sarno, Scott Shappell. *Urology* 2014;84:1172-80.
7. Impact of NADiA® ProsVue™ PSA slope on secondary treatment decisions after radical prostatectomy. Judd Moul, James Porter, Naveen Kella, George Adams, Bernard Hertzman, Christopher Knoedler, David Chen, Jeffrey Yoshida, Edouard Trabulsi, Vipul Patel, Mark Sarno, Jonathan McDermed, Mark Reynolds. *Prostate Cancer Prostatic Dis* 2014;17:280-5.
8. NADIA ProsVue Prostate-specific antigen slope, CAPRA-S, and prostate cancer-specific survival after radical prostatectomy. Moul JW, Sarno MJ, McDermed JE, Triebell MT, Reynolds MA. *Urology* 2014;84:1427-33.
9. Value of NADiA® ProsVue™ and the CAPRA-S nomogram for predicting postprostatectomy clinical recurrence. Moul JW, Lilja H, Lance R, Vessella R, McDermed JE, Sarno MJ, Adams TH. *J Clin Oncol* 2013;31:S6.
10. NADIA® ProsVue™ PSA slope is an independent prognostic marker for identifying men at reduced risk for clinical recurrence of prostate cancer after radical prostatectomy. Judd W. Moul, Hans Lilja, O. John Semmes, Raymond S. Lance, Robert L. Vessella, Martin Fleisher, Clarisse Mazzola, Mark J. Sarno, Barbara Stevens, Robert E. Klem,

- Jonathan E. McDermid, Melissa T. Triebell, and Thomas H. Adams. *Urology* 2012;80:1319-27.
11. Robustness of ProsVue™ linear slope for prediction of reduced risk for prostate cancer recurrence: Simulation studies on effects of analytical imprecision and sampling time variation. Mark J. Sarno and Charles S. Davis. *Clin Biochem* 2012;45:1479-84.
 12. Nucleic acid detection immunoassay for prostate-specific antigen based on immuno-PCR methodology. Jonathan E. McDermid, Ron Sanders, Stephen Fait, Robert E. Klem, Mark J. Sarno, Thomas H. Adams, and Eleftherios P. Diamandis. *Clin Chem* 2012;58:732-40.
 13. Prostate cancer gene 3 Score predicts prostate biopsy outcome in men receiving dutasteride for prevention of prostate cancer; results from the REDUCE trial. Sheila Aubin, Jennifer Reid, Mark Sarno, Amy Blase, Jacqueline Aussie, Harry Rittenhouse, Roger Rittmaster, Gerald Andriole, Jack Groskopf. *Urology* 2011;78:380-5.
 14. PCA3 molecular urine test for predicting repeat prostate biopsy outcome in populations at risk: Validation in the placebo arm of the dutasteride REDUCE trial. Jack Groskopf, Sheila M.J. Aubin, Jennifer Reid, Mark J. Sarno, Amy Blase, Jacqueline Aussie, Harry Rittenhouse, Roger Rittmaster. *J Urol* 2010;184:1947-52.
 15. The Confusing Calculus of the Benefit/Risk Ratio in Pharmaceutical Research – Ethical Questions and Possibilities for Reform. Mark J. Sarno. *Update to Food and Drug Law Journal* 2010; Issue 1.
 16. Lipoprotein-associated phospholipase A2 (Lp-PLA2) is an independent predictor of incident coronary heart disease in an apparently healthy elderly population: the Rancho Bernardo Study. Lori Daniels, Gail Laughlin, Mark J. Sarno, Ricki Bettencourt, Robert L. Wolfert, and Elizabeth Barrett-Connor. *J Am Coll Cardiol* 2008;51:913-9.
 17. A multicenter evaluation of the PCA3 molecular urine test: preanalytical effects, analytical performance, and diagnostic accuracy. Lori J. Sokoll, William Ellis, Paul Lange, Jennifer Noteboom, Debra J. Elliott, Ina L. Deras, Amy Blase, Seongjoon Koo, Mark Sarno, Harry Rittenhouse, Jack Groskopf, Robert L. Vessella. *Clin Chim Acta* 2008;389:1-6.
 18. B7-H4 is over-expressed in early-stage ovarian cancer and is independent of CA125 expression. Iris Simon, Dionyssios Katsaros, Irene Rigault de la Longrais, Marco Massobrio, Andreas Scorilas, Nam W. Kim, Mark J. Sarno, Robert L. Wolfert, and Eleftherios P. Diamandis. *Gynecol Oncol* 2007;106:334-41.
 19. B7-H4 is a novel membrane-bound protein and a candidate serum and tissue biomarker for ovarian cancer. Iris Simon, Shaoqiu Zhuo, Laura Corral, Eleftherios P. Diamandis, Mark J. Sarno, Robert L. Wolfert, and Nam W. Kim. *Cancer Res* 2006;66:1570-5.
 20. Evaluation of B7-H4 (DD-O110) as a prognostic marker in tissue and serum of ovarian cancer patients. Iris Simon, Nam Kim, Eleftherios P. Diamandis, Mark J. Sarno, and Robert L. Wolfert. Presented at 2005 American Association for Cancer Research meeting.
 21. Circulating 1,5-anhydroglucitol levels in adult patients with diabetes mellitus reflect longitudinal changes of glycemia: a US trial of the GlycoMark™ assay. Janet B. McGill, Thomas G. Cole, William Nowatzke, Shannon Houghton, Erika B. Ammirati, Theresa Gautille, and Mark J. Sarno. *Diabetes Care* 2004;27:8:1859-65.

22. Evaluation of an assay for 1,5-anhydroglucitol (Glycomark™) and determination of reference intervals on the Hitachi 917 analyzer. William Nowatzke, Mark Sarno, Nathan Birch, Douglas Stickle, Tanya Eden, and Thomas G Cole. *Clinica Chimica Acta* 2004;350:201-9.
23. Cln101 and Ovr110 as novel serum markers for detection of ovarian cancer. N. W. Kim, I. Simon, X. Duan, T. Kuo, L. Corral, A. Nguyen, R. A. Macina, M. J. Sarno, R. L. Wolfert, 2004 American Society of Clinical Oncology 40th Annual Meeting Proceedings;23:455.
24. Application of Novel and Traditional Serum Markers in Univariate and Multivariate Analysis to Improve the Sensitivity and Specificity of Cancer Detection. Iris Simon, Rong A. Fan, Charis E. Lawrenson, Xiaozhu Duan, Theresa Kuo, Laura Corral, Shirley Vong, David Lowe, Danny Terwey, Laurence Fayadat, Roberto Macina, Mark J. Sarno, Robert L. Wolfert, and Nam W. Kim. 2004 EDRN Annual Workshop Abstract.
25. Intermediate-term changes in serum 1,5-anhydroglucitol (GlycoMark) predict long-term changes in glycosylated hemoglobin (A1c) in patients with Type 1 and 2 diabetes mellitus. Sarno M, Cole T, Nowatzke W, McGill J. Presented at American Diabetes Association Annual Meeting, May 2004.
26. Application of Novel and Traditional Serum Biomarkers in Univariate and Multivariate Analysis to Improve the Sensitivity and Specificity of Cancer Detection. Iris Simon, Rong A. Fan, Xiaozhu Duan, Charis E. Lawrenson, Theresa Kuo, Laura Corral, Shirley Vong, David Lowe, Danny Terwey, Laurence Fayadat, Roberto Macina, Mark J. Sarno, Robert L. Wolfert, and Nam W. Kim. 2004 ISOBM Annual Meeting Abstract.
27. Detection of novel membrane protein in serum: Ovr110, a potential serum marker for early detection of ovarian cancer. Iris Simon, Nam W. Kim, Theresa Kuo, Laura Corral, Shirley Vong, David Lowe, Mark J. Sarno, Robert L. Wolfert. 2004 American Association of Cancer Research 95th Annual Meeting Proceedings;45:93.
28. Characterization of Lng105/napsin A in human serum: potential diagnostic utility in lung cancer. Rong A. Fan, Nam W. Kim, Daniel Bedinger, Paul Miller, Laurence Fayadat, Roberto Macina, Mark Sarno, Robert L. Wolfert. 2004 American Association of Cancer Research 95th Annual Meeting Proceedings;45:93.
29. Detection of Pro108/Spondin-2 protein in serum: A novel serum marker for cancer. Iris Simon, Charis A. Lawrenson, Nam W. Kim, Daniel Bedinger, Danny Terwey, Mark J. Sarno, Robert L. Wolfert. 2004 American Association of Cancer Research 95th Annual Meeting Proceedings;45:97.
30. Biological variability and specificity of lipoprotein-associated phospholipase A2 (Lp-PLA2), a novel marker of cardiovascular risk. Robert L. Wolfert, Nam W. Kim, Reed G. Selby, Mark J. Sarno, G. Russell Warnick, Krishnankutty Sudhir. Presented at American Heart Association 2004.
31. Serum 1,5-Anhydroglucitol (GlycoMark™), a New Potential Marker of Glycemia: A Longitudinal Study of Adult Patients with Diabetes Mellitus. Janet McGill, Thom Cole, William Nowatzke, Shannon Houghton, Theresa Gautille, and Mark Sarno. Presented at Diabetes Technology and Therapeutics Annual Meeting, November 2003.
32. Pharmacokinetics and glucodynamics of rapid, short, and intermediate acting insulins: a randomized controlled trial comparing jet injection to needle syringe. Mark Sarno, Jo Bell, and Steve Edelman. *Diabetes Technology and Therapeutics* 2003;4:6:863-6.

33. Serum 1,5-anhydroglucitol (Glycomark™), a new marker of glycemia: cross-sectional comparison to established markers of glycemia in healthy subjects and patients with diabetes mellitus. Janet McGill, Thomas Cole, William Nowatzke, and Mark Sarno. Presented at American Diabetes Association Annual Meeting, June 2003.
34. Technical Evaluation and Reference Interval Determination of 1,5-Anhydroglucitol using the GlycoMark(TM) Assay. Nowatzke WL, Sarno M, Stickle DF, Eden TR, Birch NC and Cole TG. *Clinical Chemistry* 2003; 49 (Supplement):A46.
35. Toxicology and toxicokinetics of acute and subchronic administration of histamine dihydrochloride in rats. Linda Karavodin, Rodney Jensen, Mark Sarno, and Kurt Gehlsen. *Drug and Chemical Toxicology* 2003;26:1:35-49.
36. Biological variability of lipoprotein-associated phospholipase A2 (Lp-PLA2), C-reactive protein (CRP), and traditional lipid markers of cardiovascular risk. Nam W. Kim, Mark J. Sarno, G. Russell Warnick, and Robert L. Wolfert. 2003 American College of Cardiology Annual Proceedings.
37. Pharmacokinetics of histamine dihydrochloride: Implications for combined therapy with interleukin-2. Mark Middleton, Mark Sarno, Sanjiv S. Agarwala, John Glaspy, Aziz Laurent, Kelly McMasters, Peter Naredi, Steven O'Day, Eric Whitman, Sarah Danson, Rebecca Cosford, and Kurt Gehlsen; *Journal of Clinical Pharmacology* 2002;42:7:774-81.
38. Histamine pharmacokinetics in tumor and host tissues after bolus-dose administration – a study in rat. Magnus Rizell, Peter Naredi, Per Lindner, Kristoffer Hellstrand, Mark Sarno, Per-Anders Jansson. *Life Sciences* 2002; 70:969-76.
39. Excretion of sweat and urine pyridinoline crosslinks in healthy controls and subjects with established metabolic bone disease; Mark Sarno, Laura Sarno, David Baylink, Barbara Drinkwater, Sally Farley, Michael Kleerekoper, Robert Lang, Joan Lappe, Angelo Licata, Michael McClung, Paul Miller, Susan Natrass, Robert Recker, Elliot N. Schwartz, Fred Singer, Joseph R. Tucci, Richard Wasnich, Sandi Wolf, Helen Powell, Gayle Tjersland, and G. Russell Warnick. *Clinical Chemistry and Laboratory Medicine* 2001;39:3:223-8.
40. Clinical immunogenicity of measles, mumps, and rubella vaccine MMRII delivered by the Injex jet injector: comparison with standard syringe injection; Mark Sarno, Erich Blase, Carl Schirmer, and Daniel Trujillo; *Pediatric Infectious Disease Journal* 2000; 19:9:839-42
41. A collection method and high-sensitivity enzyme immunoassay for sweat pyridinoline and deoxypyridinoline crosslinks; Mark Sarno, Helen Powell, Gayle Tjersland, Donald Schoendorfer, Holden Harris, Kimberly Adams, Peggy Ogata, and G. Russell Warnick; *Clinical Chemistry* 1999; 45:9:1501-9.
42. Clinical utility of Osteopatch™ sweat pyridinoline; R. Nuti, R. Caudarella, E. Fiore, G. Isaia, X. Ortolani, G. Tjersland, M. Sarno, R. Warnick; *Bone* 1998;23:S627.
43. Osteopatch™ sweat pyridinoline is elevated in women with established osteoporosis; L. Sarno, D. Baylink, B. Drinkwater, S. Farley, M. Kleerekoper, J. Lappe, M. McClung, S. Natrass, R. Recker, E. Schwartz, R. Wasnich, G. Tjersland, G. R. Warnick, M. Sarno; *Bone* 1998;23:S514.
44. Bone resorption markers quantified by sensitive immunoassays in non-occlusive multi-day Osteopatch™ sweat collections; G. Russell Warnick, Byron Doneen, Gayle Tjersland, Helen Powell, Mark Sarno, Holden Harris, Peggy Ogata, and Kim Adams; *Journal of Bone and Mineral Research* 1997;12:Supplement 1:S499.

45. Development of a serum ELISA for YKL-40 (Chondrex™) and its application in Osteoarthritis; Sarno M.J., Scott T.A., Whaley J., Swindlehurst C.A., Price P.A., Cohen, P.; Arthritis & Rheumatism 1995;38:S240.
46. Characterization of a new enzyme immunoassay for Free Deoxyypyridinoline in Serum, R. Nielsen, D. Broyles, S. Harvey, C. Shaffer, B. Bussett, M. Sarno, B. Kress. Journal of Bone and Mineral Research 1995;10:Supplement 1:S270.
47. Activation of a Rabbit Liver Progesterone 6-Beta-Hydroxylase by Substrate or Alpha Naphthoflavone, G. E. Schwab, M. Sarno, J. Singh, L. E. Vickery, E. F. Johnson. Presented at Federal Proceedings of the American Society of Biological Chemists, June 1986.
48. Genetic Evidence for Glucitol-Specific Enzyme III, an Essential Phosphocarrier Protein of the Salmonella typhimurium Glucitol Phosphotransferase System. Mark J. Sarno, L. Gregory Tenn, Anjana Desai, A. Michael Chin, Frank C. Grenier, and Milton H. Saier, Jr.; The Journal of Bacteriology 1984:953-5.



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