

WARREN H. MALTZMAN, Ph.D.

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MOLECULAR DIAGNOSTICS LEADER

Demonstrated expertise in moving innovative concepts in molecular diagnostics and therapeutics from the bench to the bedside. Key strength is the integration of a wide variety of information into coherent research and diagnostics programs. Has led the application of molecular approaches to product development and their cost-effective utilization in clinical diagnostics laboratories. Brings extensive experience in regulatory compliance (FDA, College of American Pathologists, CLIA) and early stage ventures to bear on alignment of strategic goals with laboratory design and operation.

PROFESSIONAL EXPERIENCE

Barsett Consulting Lake Barrington, IL 2007-present
PRINCIPAL

- Provides guidance on molecular oncology and diagnostics to early stage companies, and their potential investors.
- Assures coordinated presentation of companies to investors; provides practical and strategic input on the laboratory layout, infrastructure, and protocols to maximize efficiency and assure regulatory compliance.
- Companies served range from diagnostics to clinical research organizations.

Diamics, Inc. Novato, CA 2005-2006
CHIEF SCIENTIFIC OFFICER & SENIOR VICE-PRESIDENT, R & D

- Developed a novel approach to cervical cancer screening in developing countries.
- Co-founder of the company responsible for the design, staffing, and growth of the laboratory.
- Developed strategic partnerships leveraging company's intellectual properties, licenses, and developed products.
- Coordinated clinical trials of the screening system and its components, including 510(k) approval for cervical sample collection device.

Molecular Diagnostics, Inc. Chicago, IL 2003-2005
VICE-PRESIDENT, MOLECULAR TECHNOLOGY

- As chief scientist, prepared the company's slide based test platform for cervical cancer screening for clinical trial and review by the FDA.
- Provided scientific and strategic direction for project, and positioning for future development of the platform beyond cervical cytology and the domestic market.

Quantitative Diagnostic Laboratories, Westmont, IL
DIRECTOR, RESEARCH AND DEVELOPMENT

2002-2003

- Directed FDA-compliant laboratory performing cell and tissue based assays for pharma clients and served as coordinator for data entry into pharma-specific clinical data forms as well as managed the development of a 21 CFR Part 11 compliant laboratory information system for capture of test results.
- Developed companion diagnostics and approaches for new cancer drugs in support of major pharmaceutical companies including Glaxo, Pfizer, and Astrazeneca.
- Responsible for the implementation of Quality Assurance Program for QDL's pharmaceutical and reference laboratory work, and the transitioning of protocols to Ventana Medical Systems (parent company of QDL) for use in routine automated diagnostic and prognostic assays.
- Developed diagnostic algorithms for the categorization of breast cancer samples for patient treatment.

Zola Medical Communications, Englewood Cliffs, NJ
FREELANCE MEDICAL WRITER

2001-2002

- Preparation of white papers and review articles for clients in pharmaceutical industry on topics ranging from drugs for treatment of glaucoma to the role of point-of-care tests in women's health.

Molecular Staging, Incorporated, Allendale, NJ
DIRECTOR, MOLECULAR PATHOLOGY

1998-2000

- Established, equipped, and staffed laboratory.
- Initiated program to use proprietary DNA amplification technology (RCAT), based upon rolling circle replication, for the sensitive and specific detection of nucleic acid and protein targets in cells and tissues.
- Directed research and development effort that reduced to practice the use of RCAT for flow cytometry on dispersed cells, and immunocytochemistry and in situ hybridization as applied to routinely fixed tissue specimens.

Quest Diagnostics Incorporated, Teterboro, NJ
TECHNICAL DIRECTOR

1991-1997

Molecular Tissue Pathology and Anatomic Pathology

- Managed College of American Pathologists (CAP) and New York State Department of Health (NYSDOH)- accredited clinical laboratory, including budget, staffing, and specimen flow.
- Led technology transfer for automated and manual immunohistochemical assays to Quest-affiliated laboratories, supporting high volume breast cancer testing throughout the Quest system.
- Directed the development of new diagnostic assays using immunohistochemistry and in situ hybridization.
- Prepared validation plans, according to standard procedure of my own device, for CAP and NYSDOH review of analytic specific reagent tests performed for a large number of molecular biomarkers (>100) using manual and automated approaches incorporating immunological and nucleic acid-based approaches.

- Prepared standardized laboratory manual for all diagnostic tests performed by high complexity CLIA laboratory including routine procedures and maintenance; responsible for annual review and updating.

PRIOR TO 1990

Enzo Biochem, Inc.

DIRECTOR OF TECHNOLOGY DEVELOPMENT

Managed the development of tests for human immunodeficiency virus, human papillomavirus, and other pathogens.

Waksman Institute of Microbiology & Department of Biological Sciences

Rutgers-The State University

ASSISTANT PROFESSOR/ADJUNCT PROFESSOR

- Utilized protein-protein interaction studies to provide critical insights into the role of the p53 protein in normal cellular growth and cancer.

Leukemia Society of America, New York, NY

CONSULTANT

State University of New York at Stony Brook Medical School,

Department of Microbiology

RESEARCH ASSOCIATE

Princeton University, Department of Biochemical Sciences,

AMERICAN CANCER SOCIETY POSTDOCTORAL FELLOW

EDUCATION

Ph.D., Molecular Biology
University of California at Berkeley

B.A. Biology
University of California at Santa Barbara

MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS

American Association for the Advancement of Science

New York Academy of Science

Association of Molecular Pathology

KEY REPRESENTATIVE PUBLICATIONS

- Linzer,D.I.H., **Maltzman,W.**, and Levine,A.J. 1979. The SV40 A-gene product is required for production of a 54,000 MW cellular tumor antigen. *Virology* **98**, 308-318.
- Oren,M., **Maltzman,W.**, and Levine,A.J. 1981. Post-translational regulation of the 54K cellular tumor antigen in normal and transformed cells. *Molecular and Cellular Biology* **1**, 101-110.
- Maltzman,W.**, Oren,M., and Levine,A.J. 1982. The structural relationships between 54,000 MW cellular tumor antigens detected in viral and nonviral transformed cells. *Virology* **112**, 145-156.
- Maltzman,W.**, and Czyzyk,L. 1984. UV irradiation stimulates levels of p53 cellular tumor antigen in nontransformed mouse cells. *Molecular and Cellular Biology* **4**, 1689-1694.
- Rapier,J.M., Villamarzo,Y., Schochetman,G., Ou,C.-Y., Brakel,C., Donegan,J., **Maltzman,W.**, Lee,S., Kirtikar,D., and Gatica,D. 1993. A non-radioactive colorimetric microplate hybridization assay for the detection of amplified HIV DNA . *Clinical Chemistry* **39**, 244-247
- Gusev,Y., Sparkowski,J., Raghunathan, A., Ferguson,H., Montano,J., Bogdan,N., Schweitzer,B., Wiltshire,S., Kingsmore,S.F., **Maltzman,W.** and Wheeler,V. 2001. Rolling circle amplification- a new approach to increase sensitivity for immunohistochemistry and flow cytometry. *American Journal of Pathology*, **159**, 63-69.
- Smith,B.L., Chin,D., **Maltzman,W.**, Crosby,K., Hortobagyi,G.N. and Bacus,S.S. 2004. The efficacy of Herceptin therapies is influenced by the expression of other erbB receptors, their ligands and the activation of downstream signalling proteins. *British Journal of Cancer*, **91**, 1190-1194.

PATENTS

- United States Patent Application 20060189893. Systems and methods for detecting abnormal cells. **Maltzman,W.**; Gombrich,P., Dimonte,E., Eaton,E., and Larson,E.