

GABRIELLA LAKOS M.D., Ph.D., D(ABMLI)

PROFESSIONAL PROFILE

Goal-oriented, creative MD/PhD with comprehensive experience in academic, diagnostic laboratory, research and IVD industrial settings.

Experienced Medical Director with proven track record of maintaining successful scientific program and effective commercial and customer support. Major contributor to medical aspects of new product development and on-market product quality issues.

Successful project leader in IVD device development and commercialization, proficient in design control, design change and life-cycle management activities. Direct, firsthand experience with a wide range of in vitro diagnostic applications, coupled with excellent technical skills and solid knowledge of the IVD regulatory environment. Thorough understanding of FDA processes and procedures, and collaborative relationship with FDA reviewers.

Ambitious self-starter, supported by a unique combination of practical and theoretical knowledge and “think outside the box” attitude. Strong scientific credentials with proven abilities to design, execute and interpret clinical and translational studies. Performance is demonstrated by the successful development and commercialization of many IVD assays and more than 100 peer-reviewed publications and book chapters. Active in professional organizations (AACC, AMLI), board certified by the American Board of Medical Laboratory Immunology.

PROFESSIONAL EXPERIENCE

Senior Associate Medical Director *Abbott Diagnostics, Hematology, Santa Clara, CA, 2016 July – present*

- Manage the Medical and Scientific Affairs team
- Responsible for Abbott Hematology scientific and publication strategy
- Support product development activities by creating Medical Platform Documents, providing input for product requirements, verification and validation protocols, and verification and validation acceptance criteria
- Responsible for planning, managing and executing scientific studies, and for strategic relationship with key opinion leaders
- Support the commercial team by training, by scientific customer interactions and by creating proof sources
- Provide clinical consultation for health care providers and internally for complaint resolution
- Participant and approver for Risk Management activities; create risk-benefit statement
- Responsible for creating Health Hazard Assessments

Medical Director *Inova Diagnostics, Inc., San Diego, CA, 2012 December – 2016 July*

- Developed professional relationship with clinical laboratories at the Medical Director (or equivalent) level
- Promoted and supported scientific collaborations and marketing objectives, and supported Inova’s Diagnostics publication efforts
- Created and maintained system for planning, managing and executing scientific studies and commercial evaluations
- Provided clinical consultation
- Created Health Hazard Assessments
- Participated in Risk Management activities

Director of Assay Development *Inova Diagnostics, Inc., San Diego, CA, 2011 June – 2016 July*

- Had five direct reports, including Managers/Supervisors of four groups of 28 people, and a Clinical Affairs Scientist
- Lead cross-functional team in IVD Product Development from concept through commercialization for multiple platforms, including:
 - Automated chemiluminescent immunoassays on the BIO-FLASH platform;
 - NOVA View automated fluorescent microscope: software and reagent development
- Responsible for all Design Control activities, such as: risk management, design planning, verification, validation and design transfer to manufacturing
- Prepared, filed and managed regulatory (FDA) submissions, established and maintained successful communication with FDA

Director of Research & Development, *TheraTest Laboratories, Inc.*, Lombard, IL, 2006 - 2011

- Planned, managed and executed projects for the development of ELISA assays for the measurement of autoantibodies in a cross-functional team environment
 - Developed and commercialized immunoassays for the diagnosis and management of celiac disease and autoimmune thyroid diseases; completed assay development project for thyroid stimulating hormone (TSH) ELISA
- Independently prepared, filed and successfully managed/negotiated several 510(k) submissions until clearance
- Improved communication with costumers by launching and editing the company's quarterly Newsletter

Associate Director of CLIA Reference Laboratory, *TheraTest Laboratories, Inc.*, Lombard, IL, 2008 to 2011

- Supervised diagnostic testing, method evaluation and implementation, quality assurance and proficiency testing and documentation
- Ensured CLIA compliance
- Troubleshoot technical problems, provided consultation and interpretation for results

Assistant Professor and Associate Lab Director, *Clinical Immunology Laboratory, University of Debrecen Medical School, Hungary*, 1994-2006

- Directed and managed daily activity of laboratory with 20+ personnel, gained expertise with a broad range of diagnostic platforms, including solid phase immunoassays, indirect immunofluorescence, nephelometry, electrophoresis, flow cytometry
- Mentored PhD students and pathology residents

Director of Clinical Immunology Laboratory, *Department of Infectious Diseases and Pediatric Immunology, University of Debrecen Medical School, Hungary*, 2000 to 2002 and 2004 to 2006 (part-time job)

- Established and headed the diagnostic laboratory for the evaluation of immunodeficiency and pediatric autoimmune disorders

Postdoctoral Fellow, *University of Illinois at Chicago, Section of Rheumatology and Northwestern University, Chicago, IL* 2002 to 2004

- Investigated the pathomechanism of experimental mouse scleroderma model (bleomycin-induced skin fibrosis)

Resident and fellow, *Blood Transfusion Center, Kenezy Gyula County Hospital, Debrecen, Hungary*, 1988 to 1994

EDUCATION

Board Certifications: American Board of Medical Laboratory Immunology (ABMLI), 2008

Hungarian Board of Clinical Pathology (Laboratory Medicine) 2000

Hungarian Board of Transfusion Medicine, 1994

Ph.D. in Clinical Immunology (Thesis: Autoantibodies against phospholipid-binding plasma proteins: Detection, characterization and clinical significance)

Medical Doctor, University Medical School of Debrecen, Hungary

PROFESSIONAL AFFILIATIONS

International Society for Laboratory Hematology

Association of Medical Laboratory Immunologists (AMLI)

American Association for Clinical Chemistry (AACC)

Past Chair of the Clinical and Diagnostic Immunology Division of the AACC, 2018-present

SELECTED PUBLICATIONS (complete publication list is available upon request)

1. Bentow C, **Lakos G**, Martis P, Wahi E, Garcia M, Viñas O, Espinosa G, Cervera R, Sjöwall C, Carmona-Fernandes D, Santos MJ, Hanly JG, Mahler M. International multi-center evaluation of a novel chemiluminescence assay for the detection of anti-dsDNA antibodies. *Lupus*. 2016 Jul;25(8):864-72.
2. **Lakos G**, Gonzalez M, Flaherty D, Bentow C, Ibarra C, Stimson D, Nacario L, Hiemann R, Dervieux T. Detection of anti-dsDNA antibodies by computer-aided automated immunofluorescence analysis. *J Immunol Methods*. 2016 Feb 24. doi: 10.1016/j.jim.2016.02.019.
3. Bertolaccini ML, Amengual O, Andreoli L, Atsumi T, Chighizola CB, Forastiero R, de Groot P, **Lakos G**, Lambert M, Meroni P, Ortel TL, Petri M, Rahman A, Roubey R, Sciascia S, Snyder M, Tebo AE, Tincani A, Willis R. 14th International Congress on Antiphospholipid Antibodies Task Force. Report on antiphospholipid syndrome laboratory diagnostics and trends. *Autoimmun Rev*. 2014 Sep;13(9):917-30.
4. **Lakos G**, Norman GL, Mahler M, Martis P, Bentow C, Santora D, Fasano A. Analytical and clinical comparison of two fully automated immunoassay systems for the diagnosis of celiac disease. *J Immunol Res*. 2014;2014:371263.
5. **Lakos G**. Interference in antiphospholipid antibody assays. *Semin Thromb Hemost*. 2012 Jun;38(4):353-9.
6. **Lakos G**, Favaloro EJ, Harris EN, Meroni PL, Tincani A, Wong RC, Pierangeli SS. International consensus guidelines on anticardiolipin and anti- β 2-glycoprotein I testing: report from the 13th International Congress on Antiphospholipid Antibodies. *Arthritis Rheum*. 2012 Jan;64(1):1-10.
7. Gyetvai A, Szekanecz Z, Soós L, Szabó Z, Fekete A, Kapitány A, Teodorescu M, Sipka S, Szegedi G, **Lakos G**. New classification of the shared epitope in rheumatoid arthritis: impact on the production of various anti-citrullinated protein antibodies. *Rheumatology (Oxford)*. 2010;49:25-33.
8. Fekete A, Soos L, Szekanecz Z, Szabo Z, Szodoray P, Barath S, **Lakos G**. Disturbances in B- and T-cell homeostasis in rheumatoid arthritis: Suggested relationships with antigen-driven immune responses. *J Autoimmun*. 2007;29:154-63.
9. **Lakos G**, Takagawa S, Chen SJ, Ferreira AM, Han G, Masuda K, Wang XJ, DiPietro LA, Varga J. Targeted Disruption of TGF-beta/Smad3 Signaling Modulates Skin Fibrosis in a Mouse Model of Scleroderma. *Am J Pathol*. 2004;165:203-17.
10. **Lakos G**, Melichian D, Wu M1, Glimcher L, Varga J. Increased bleomycin induced skin fibrosis in mice lacking the Th1-specific transcription factor T-bet. *Pathobiology*. 2006;73:224-37.