Westchester gov.com

George Latimer
County Executive

WHEREAS, a vacancy exists in the membership of the Westchester County Laboratories and Research Board of Managers:

NOW, THEREFORE, I, George Latimer, County Executive of Westchester County, in accordance with the terms and provisions of the Westchester County Charter, appoint Dr. Renée M. Howell, 184 Dante Avenue, Tuckahoe, New York as a member of the Westchester County Laboratories and Research Board of Managers, for the term January 1, 2021 to December 31, 2025.

Given under my hand
and seal this 1st day
of January, 2021.

George Latimer
County Executive

Office of the County Executive

Michaelian Office Building
148 Martine Avenue
White Plains, New York 10601

Email: CE@westchestergov.com
Telephone: (914)995-2900

westchestergov.com

Westchester gov.com

George Latimer
County Executive

December 31, 2020

Dr. Renée M. Howell
184 Dante Avenue
Tuckahoe, NY 10707

Dear Dr. Howell,

It is my pleasure to appoint you to serve as a member of the Westchester County Laboratories and Research Board of Managers, pursuant to the Laws of Westchester County §261.91. This appointment is for a term to commence on January 1, 2021 and expire on December 31, 2025.

Your appointment is subject to confirmation by the Westchester County Board of Legislators, but your service begins immediately. You must complete the attached Oath of Office and file it with the County Clerk prior to the next Laboratories and Research Board of Managers meeting, and provide this office with a copy within 30 days. Please contact the Westchester County Department of Laboratories and Research at (914) 231-1715 for the date, place, and time of the upcoming Laboratories and Research Board of Managers meeting for your participation.

When you have filed your Oath of Office, a Resolution to confirm your appointment will be submitted to the County Board of Legislators. As part of the confirmation process, you may be called before the Board to be interviewed.

Pursuant to Local Law, as a member of a Westchester County Board and/or Commission, you are responsible for adhering to the requirements of our Code of Ethics, which includes the annual filing of a financial disclosure statement with the County Board of Ethics. A financial disclosure form is attached.

Warmest wishes for a successful tenure.

Very Truly Yours,

George Latimer
Westchester County Executive

GL/wm

cc: Honorable Board of Legislators
Dr. Aleksandar Milovanovic, Acting Westchester County Pathologist/Medical Examiner
Joan McDonald, Director of Operations

Office of the County Executive

Michaelian Office Building
148 Martine Avenue
White Plains, New York 10601

Email: ce@westchestergov.com
Telephone: (914)995-2900

westchestergov.com

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

SUMMARY

Executive leader with strong operational skills. Known for ability to conceptualize and successfully execute business strategy. Successful track record launching life science and IVD products (PMA approval, 510K clearance, self-filed) at multiple companies. Experienced at directing highly matrixed teams. Passion for team building and organizational development, creating transparent communication processes, creating innovative solutions, and negotiating across functional areas.

EXPERIENCE

Siemens Healthineers, Tarrytown, NY

Senior Director, Clinical Affairs **April 2019 - present**
Manage a team of 40 scientists responsible for clinical affairs and operations supporting clinical trials for ADVIA Centaur® and Dimension Vista® immunoassay *in-vitro* diagnostics.

- Responsible for clinical study design to support global product regulatory submissions that have led to successful *de novo*, EUA, 510K, PMA, IVD clearances/approvals from FDA and CE Mark and IVD EU approvals. Team received two breakthrough status designations from FDA for Alzheimer biomarkers in 2020.
- Responsible for engagement of key opinion leaders (KOL) as part of clinical trial design
- Responsible for all aspects of clinical operations including technical, compliance-related, and contractual/financial.
- Leading department through conversion from paper to digital eTMF.
- Provide day to day leadership to clinical staff who sit on product development core teams.
- Influence development of standards and guidelines through participation in external boards, and engagement of professional societies or agencies.
- Establish clinical research-related policies, processes, and procedures in alignment with Quality organization.
- Provide support for other business lines (Point of Care, Molecular, Hematology/Hemostasis, and Veterinary products) as needed.

Principal, Design Quality, Medical, Scientific and Statistical Affairs **Jan 2015 - April 2019**

Position responsible for driving product quality across Laboratory Diagnostics. Collaborated across R&D, Technical Operations, Medical Affairs and Manufacturing during product development to create quality control systems ensuring that products meet customer, regulatory, proficiency, and manufacturing requirements over the life of the product. Coordinated quality control systems for assays across Chemistry, Immunoassay, Hematology/Hemostasis, POC, and Molecular product lines.

- Led teams in assessing product and process controls using a variety of quality management tools such as value stream mapping, process mapping, FMEA, Kepner-Tregoe analysis, DOE, surface response mapping, statistical process control, etc.
- Participated in resolution of field issues related to quality control performance.
- Led company-wide council to communicate control system best practice.
- Developed and tracked metrics to assess system effectiveness and reported to executive management.
- Developed relationships with key opinion leaders (KOLs) in Laboratory Diagnostics Standardization and Harmonization and organized education sessions across multiple company sites which featured KOLs.

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

People Solutions, Richmond VA **Oct 2014 -Dec 2014**
Senior Consultant
Advised companies on assay development strategy, CLIA lab set-up and documentation, assay risk assessment, assay control and calibrator design, and Design Control in compliance with ISO 13485 and FDA 21CFR820 for IVD.

Canon US Life Sciences, Rockville, MD **Feb 2010 - July 2014**
Director, Research and Development
Provided technical and business strategy leadership for internal entrepreneurial effort which established a new business unit focused on molecular diagnostics. Direct oversight for chemistry, molecular biology, engineering and software. Advised senior executive management on technology development and market opportunity. Responsible for departmental budgets. Responsibilities included collaboration with R&D engineering and software teams at other company sites in US and Asia.

- Oversaw design concept through field testing of first instrument with integrated chemistry for detection of human heritable diseases and oncology using PCR and DNA high resolution melting in a unique microfluidics consumable. Guided team through product development documentation practices to support FDA/ISO 13485 compliance.
- Grew assay development and engineering team from small separate teams to a single integrated functional department of 50 scientists, engineers, software developers, and project management. Initiated project management for company.
- Hired Reagent Manufacturing team and oversaw building of ISO 13485/FDA compliant-ready laboratory manufacturing space
- Helped create the company strategic vision for commercial launch of instrument and assays, as well as long range (5-10 year) strategic vision for business unit.
- Established relationships with KOLs in Human Genetics and Infectious Disease resulted in scientific publications.
- Doubled size of company intellectual property pipeline.

SeraCare Life Sciences (formerly Boston Biomedica),
Gaithersburg, MD **2008-2010**
Director, Product Development

Provided leadership for new product development, life cycle management of commercialized FDA and CE labeled products, and Maryland manufacturing operations. Product lines included ACCURUN® and SeraCon™ controls for serology, DNA, and cell-based immunology reagents used in IVD, vaccine development, and toxicology testing. Direct oversight for technical project management. Direct reports included project managers and tech transfer/bulk manufacture group. Responsible for departmental budget.

- Led company through earned value budget management system for finance and project tracking.
- Architect of company Product Development Process which covered technology assessment/ portfolio management through to product commercialization.
- Created company Design Control Process.

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

- Led efforts for VOCR and product definition with Marketing.
- Assisted Business Development in assessing new business opportunities which produced several partnering agreements.
- Led product development teams to create and release seven new products in initial year of tenure including first line of controls focused on human genetic testing and cellular immunology.
- Awarded CDC Contract 2009-N-11292 "Preparation of Performance Evaluation Samples in Support of the CDC Model Performance Evaluation Program (MPEP) for HIV-1 Rapid Testing".

QIAGEN Inc (formerly Digene Corporation), Gaithersburg, Maryland **2001-2008**

Director, Assay Transfer **Feb 2007 - June 2008**
Provided leadership for several technical teams that developed *in vitro* diagnostic assays. Led technical direction for late-stage product development. Mentored scientists on experimental design and data interpretation. Led product requirements definition using customer assessments, competitor evaluations, and clinical studies. Responsible for conducting clinical studies to support verification and validation of 510K and PMA FDA clearance/approval. Led activities for product transfer to manufacturing and support to regulatory for clinical trials. Responsible for group budget.

- Collaborated on creation of the company IVD Product Development Process
- Collaborated with researchers in academics and CLIA labs on several epidemiology studies looking at HPV genotypes from various geographic and clinical populations resulting in several publications
- Chosen by Executive Management to participate in a training program for Global Leadership
- Created a BioBank for the R&D department that sourced clinical samples and characterized them for use in R&D studies

Director, Product Development **July 2004-Feb. 2007**
Provided leadership for several technical teams that developed nucleic acid-based *in vitro* diagnostic assays for HPV genotyping and screening. Product lines included digene HC2 High Risk HPV Test, Sample Conversion kit, *care*HPV test(China) and HPV 16/18/45 probe. Mentored scientists on experimental design and data interpretation. Responsible for assisting with technical evaluation of intellectual property as part of business development. Responsible for conducting clinical studies related to product development, verification, and validation for 510K, PMA FDA clearance/approvals and CE mark.

- Built new capabilities in R&D by creating and hiring scientists for protein engineering and purification, analytic chemistry, and process statistics
- Created strong relationship with global product marketing group and helped architect VOCR and competitor analysis for business case assessment
- Selected as lead R&D member of "Digene University", a technical training program used for sales and marketing employees and developed cell biology, molecular biology and infectious disease modules
- Developed and mentored several key scientist-managers who were strategically placed across the R&D management group
- Introduced capabilities of protein engineering, protein purification, and analytical chemistry to R&D department
- Completed research phases for a novel HPV genotyping assay
- Led re-engineering of several key reagents of the hybrid capture technology

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

Director, Quality Control **Feb. 2001-July 2004**
Established operating policies and metrics for QC laboratory testing 510K and PMA diagnostic kits, historical product data analysis/trending system, and product specification revision process. Provided guidance to QC manager and scientists as needed in day-to-day operations, product transfer, experimental design/data interpretation and resolution of customer complaints. Participated on late-stage product development teams as a Manufacturing representative. Led Shop Floor Control module on company ERP effort. Led project management of custom database for QC assay results. Responsible for department budget.

- Reduced QC related non-conformities by 75% within the first year of taking position and by 95%
- within a three year period.
- Reduced QC test turn-around time by 75% within first two years by streamlining testing and broadening technician training.
- Worked with manufacturing management to install accurate MRP planning data and transferred inventory from yearly physical system to cycle count system.
- Reduced QC failure rate by 50% by completing statistical review of manufacturing data and revising product specifications to include specification funnels as products moved from raw material through bulk, vialing, and packaging.

Life Technologies, Inc.(now Thermo Fisher) **1997-2001**
Frederick, Maryland

Group Leader and Senior Scientist, Technical Manufacturing **2000-2001**
Managed assay development of technical support team. Team supported established line of molecular biology reagents. Led assay re-development for problematic QC assays, and assisted process scientists with developing assays required to monitor manufacturing processes. Served as technical liaison between R&D and Operations during new product transfer, primarily with QC assay development and validation.

Group Leader, Molecular and Cell Biology **1998-2000**
Managed Molecular Biology production and QC groups. Groups responsible for large scale production of plasmids, genomic DNAs and RNA for catalog product, as well as QC of all nucleic acid products and molecular biology reagent kits (cloning, gene expression, sequencing, etc.). Coordinated lab work, analyzed group metrics, led technical direction for day-to-day troubleshooting, led new product introduction, managed department budget, investigated customer complaints, and maintained product planning data system.

Staff Scientist, Technical Manufacturing **1997-1998**

Boston Biomedica, Rockville, Maryland **1994-1997**
Senior Scientist and Manager, Molecular Biology

National Institutes of Health, Bethesda, Maryland **1992-1994**
Institute of Diabetes and Digestive and Kidney Diseases
Intramural Research Training Award

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

ADDITIONAL EXPERIENCE

American Association for Clinical Chemistry
Chair Industry Division 2020
Chair-Elect Industry Division 2019
Treasurer Industry Division 2018
Responsible for coordinating Industry Division Meeting at AACC Annual Meeting 2018 -2020

Clinical Laboratory Standards Institute(CLSI). Sub-Committee Advisor (2003-present)
M53-2nd edition Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection (member) *in progress*
M53-1st edition Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection (advisor)
MM20-1st edition Quality Management for Molecular Genetic Testing (advisor)
MM01-3rd edition Molecular Methods for Clinical Genetics and Oncology Testing (member)
Association for Molecular Pathology (AMP) Industry Task Force 2012-2015
Member Maryland Tech Council BioAlliance Program Committee (2008-2011)

EDUCATION

Executive Certificate in Management and Leadership,
Sloan School of Management, MIT, Cambridge, MA.

Ph.D., Department of Microbiology, Rutgers -- The State University of New Jersey and Department of Molecular Genetics and Microbiology, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ.
Dissertation Title: *In vivo* sequence heterogeneity of human immunodeficiency virus type 1 (HIV-1) *env* and *pol* gene regions: Evidence for recombination.

M.S., Department of Microbiology, Rutgers -- The State University of New Jersey and University of Medicine and Dentistry of New Jersey, New Brunswick, NJ.

B.S., Douglass College, Rutgers -- The State University of New Jersey, New Brunswick, NJ.
Major in Medical Technology. Certified by American Society of Clinical Pathologists.

PATENTS/APPLICATIONS

US 9,447,458 Detection of Neighboring Variants
US 9,840,737 Methods and Systems for Sequential Determination of Genetic Mutations and/or Variants
US 20120178077 Thermal Calibration filed 7/2012

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

PUBLICATIONS (partial list)

Sundberg, S.O., CT Wittwer, **R.M. Howell**, J.J. Huuskonen, R.J. Pryor, J.S. Farrar, H.M.Stiles, R.A. Palais, and I.T. Knight. 2014. Microfluidic Genotyping by Rapid Serial PCR and High Speed Melt Analysis. *Clin Chem*. 60:10 1306-1313 . http://www.clinchem.org/content/early/2014/08/11/clinchem.2014.223768

Wilkinson, D.E., *et. al.* on the behalf of the Collaborative Study Group (**RM Howell** member of the Collaborative Study Group). Establishment of the 1st world health organization international standards for human papillomavirus type 16 DNA and type 18 DNA.
International Journal of Cancer. 2010. 15;126(12):2969-83.

Cathro, H.P., T. Loya, F. Dominguez, S. Howe, **R. Howell**, K. Orndorff, E. Mendez , P.C. Fung , N.L. Beer, P. Allen, M.H. Stoler,and H.F. Frierson, Jr.. 2009. HPV Profile of Women in Belize City, Belize: Correlation with Cervical Cytopathologic Findings. *Human Pathology*. 40:942-9.

LaMere, B.J. **R. Howell**, B. Fetterman, J. Shieh, and P.E. Castle. 2008. Impact of Six-Month Frozen Storage of Cervical Specimens in Alkaline Buffer Conditions on Human Papillomavirus Genotyping. *J Virol Methods*. 151:298-300.

Howell, R.M. 2005. Tools for Molecular Diagnostics. *IVD Technology* 11 :76-79.

Howell, R.., and K. Usdin. 1997. The ability to form intrastrand tetraplexes is an evolutionarily conserved feature of the 3' end of L1 retrotransposons. *Mol. Biol. Evol.* 14 (2):144-55.

Howell, R.M., K.J. Woodford, M.N. Weitzmann, and K. Usdin. 1996. The chicken β-globin gene promoter forms a novel "cinched" tetrahelical structure. *J. Biol. Chem.* 271:5208-5214.

Howell, R.M., J.E. Fitzgibbon, A. Noe, Z. Ren, T.A. Schwartzer, D. Gocke, and D.T. Dubin, 1991. *In vivo* sequence variation of the human immunodeficiency virus type 1 *env* gene: Evidence for recombination among variants found in a single individual. *AIDS Res. Hum. Retroviruses*. 7:869-876.

ABSTRACTS/POSTERS (partial list)

Payne,R., L.Halik, C. DiPasquale, J. Ma, H.Zhang, J. Conklin, M. Foltz, E. May, **R. Howell**, K. Yokoyama, A. Natrajan. Development of a High Sensitivity Cardiac Troponin I Assay on the Siemens ADVIA Centaur® Immunoassay Systems.2016. American Association for Clinical Chemistry.

Moll, J.R., H. Shandilya, N. Eisenach, JJ Huuskonen, and **RM Howell**. Design of Experiment (DOE) studies to identify a general reaction chemistry for use in a microfluidic fast PCR/High Resolution Melt (HRM) analysis. 2013. Annual Association for Molecular Pathology Meeting

Xu, L., Yancy, JA, C. Armstrong, L. Jiang, and **R.M. Howell**. Rapid genotyping of 23 CF mutations using High Resolution Melt Analysis. 2011. Annual Association for Molecular Pathology Meeting

RENÉE M. HOWELL, PhD, MT(ASCP)
cell: 301-830-3409
email : renee.howell@siemens-healthineers.com
LinkedIn : www.linkedin.com/in/reneemhowell

Jiang, L, S. Buszczak, A. Millson, E. Lyon, C. Armstrong, and R. Howell. High Resolution Melting Analysis Combining Scanning and Genotyping for Rapid detection of MCAD Deficiency. 2010. Annual Association for Molecular Pathology Meeting

Moen, Jr., PT, Anekella, B, Huang, CE, Wong, K, Manak, M, and Howell, RM. Platform specific Quality Controls for Nucleic Acid Tests for *Chlamydia trachomatis* (CT) and *Neisseria gonorrheae* (NG). 2009. 23rd Annual Clinical Virology Symposium, Daytona Beach, FL

L. Kobayashi, J. Giles, C. Fishman, C. Cornetta, A. Patterson, A. Virmani, P. Rosenelli, L. Bell, P. Eder, J. Ray, and R. Howell. A Novel, Rapid Magnetic Particle Based Method for Purification of DNA from PreservCyt Cytology Samples for the Next Generation Hybrid Capture HPV Screening Assay. 2008. Annual Association for Molecular Pathology Meeting.

COUNTY OF WESTCHESTER
OATH OF OFFICE

STATE OF NEW YORK)
) ss.:
COUNTY OF WESTCHESTER)

I, Renee Howell do solemnly swear (or affirm) that I will support
(Print or Type Name)

the constitution of the United States, and the constitution of the State of New York, and that I will faithfully discharge the duties of the office of Labs & Research Bd of Mgr in and for the County of Westchester, according to the best of my ability.

Date: January 5, 2021

(Signature)

Sworn to and subscribed before me this 5th day of January, 2021.

(Signature)

John J. Allen
(Print or Type Name)

Deputy County Clerk
(Title of Official Administering Oath)