

CURRICULUM VITAE

R. Neill Carey, Ph.D., F.A.C.B.

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Clinical Chemist
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EDUCATION:

<u>Degree</u>	<u>Institution Conferring</u>	<u>Year</u>
B.S., Chemistry	University of Richmond	1967
M.A., Chemistry	Duke University	1970
Ph.D., Chemistry	Duke University	1972

SOCIETIES AND PROFESSIONAL ORGANIZATIONS:

Phi Beta Kappa
American Association for Clinical Chemistry
American Society for Quality

MAJOR RESEARCH INTEREST:

Application of Statistical Methods to Clinical Laboratory Quality Control and Method Evaluation

APPOINTMENTS:

Philip Morris Company, Richmond, VA: Technician, summer 1966
Reynolds Metals Company, Richmond, VA: Technician, summer 1967
Duke University Department of Chemistry: NDEA Title IV Fellow, 1967-68, 1969-71
Duke University Medical Center: Medical Technologist II, 1969
University of Wisconsin-Madison
 Department of Medical Technology: Teaching Assistant, 1971
 Department of Medicine: Project Associate, 1972
 Department of Pathology: Instructor 1972-1974, Assistant Professor 1974-1977
 Clinical Chemistry Laboratory: Assistant Director 1972-1974, Associate Director 1974-1976, Director 1976-1977
Peninsula Regional Medical Center, Salisbury, MD
 Clinical Chemist, 1977-present
 Acting Laboratory Manager, 1981-1982
Salisbury State University, Salisbury, MD
 Adjunct Faculty, Department of Medical Technology, 1977-1979
 Associate Clinical Professor, Department of Medical Technology, 1980-1992

AWARDS

American Association for Clinical Chemistry: Outstanding Speaker Award, 1992, 1993, 1997
Capital Section, American Association for Clinical Chemistry: Joseph H. Roe Award for Contribution in
the Field of Clinical Chemistry, 1996
National Academy of Clinical Biochemistry: Fellow, 2002

MEMBERSHIP ON PROFESSIONAL COMMITTEES AND PROFESSIONAL ACTIVITIES:

American Association for Clinical Chemistry, Uric Acid Reference Method Study Group, Standards
Committee, 1976-1977
American Association for Clinical Chemistry, Capital Section, Secretary, 1991, 1995, Chairman,
Nominating Committee, 2003
American Association for Clinical Chemistry, Contributed Papers Committee, 1984 National Meeting,
1982-1984
Clinical Ligand Assay Society, Contributed Papers Chairman, 1990, 1991 National Meetings
College of American Pathologists, Laboratory Accreditation Program Inspector 1003836
NCCLS Subcommittees on User Evaluation of Precision and Comparison of Methods, National
Committee for Clinical Laboratory Standards 1979-1999
NCCLS Area Committee on User Evaluation Protocols, National Committee for Clinical Laboratory
Standards, member 1982-1991, advisor 1991-present
NCCLS Subcommittee on User Demonstration of Performance for Precision and Accuracy of Quantitative
In Vitro Diagnostic Products, chairman, 1995-2002, will chair revisions in 2004

CONSULTING:

Dade, Division American Hospital Supply, Miami, FL, 1976-1985
Drs. Tymkiw and Boolukos, Nanticoke Memorial Hospital, Seaford, DE, 1977-1981
Clinical Products Division, E.I. DuPont DeNemours & Co., Wilmington, DE, 1981-1989
Clinical Assays, Cambridge, MA 1983-1984
Community Health Computing, Houston, TX, 1987-1989
Paramax Systems Division, Baxter Healthcare Corp., Irvine, CA, 1988-1994
Ventrex Laboratories, Inc., Portland, ME, 1989-1990
Sunquest Information Systems, Tucson, AZ, 1993
Ortho Diagnostic Systems, Raritan, NJ, 1993-2003
First Medical, Inc., Mountain View, CA, 1995-1996
Dade International, Miami, FL, 1995-1996
Bio-Rad Laboratories, Irvine, CA 2002

MILITARY EXPERIENCE:

Enlisted 1968-1974: Virginia, North Carolina, Wisconsin Army National Guard, honorably discharged

CIVIC ACTIVITIES:

Newtown Association, Salisbury, MD, Board of Directors 1977-1980, 1984-1987, 1990-1992, President 1984-1985, 1990-1992
City of Salisbury, MD, Newtown Historic District Commission, 1982-1988, Vice-Chairman 1984-1985, Board of Housing Appeals and Adjustments, 1990-present

PUBLICATIONS:

PH.D. THESIS:

Carey RN: I. LABTRAN - A language and system for programming chemical experiments. II. Polarographic behavior of some group IVB derivatives of naphthalene. Duke University, 1972.

BOOKS:

Cembrowski GS, Carey RN: Laboratory Quality Management: QC & QA, American Society of Clinical Pathologists Press, Chicago, IL, 1989.

TEXTBOOK CHAPTERS:

Garber CC, Carey RN: Evaluation of methods. In Kaplan LA, Pesce AJ, eds., Clinical Chemistry: Theory, Analysis, and Correlation, C.V. Mosby, St. Louis, MO, 1984. Second edition, 1989, Third edition, 1996, Fourth edition, 2003.

Garber CC, Carey RN: Laboratory statistics. In Kaplan LA, Pesce AJ, eds., Clinical Chemistry: Theory, Analysis, and Correlation, C.V. Mosby, St. Louis, MO, 1984. Second edition, 1989.

BOOK CHAPTERS:

Garber CC, Carey RN: Automation in the clinical laboratory. I. Concepts. In Automated Stream Analysis for Process Control, Vol. 1. Manka DP, ed., Academic Press, New York, 1982.

Garber CC, Carey RN: Automation in the clinical laboratory. II. Classification and examples. In Automated Stream Analysis for Process Control, Vol. 1. Manka DP, ed., Academic Press, New York, 1982.

JOURNAL ARTICLES:

Toren EC, Carey RN, Sherry AE, Davis JE: LABTRAN - A language and system for programming chemical experiments. *Anal Chem*, 44:339, 1972.

Pitt CG, Carey RN, Toren EC Jr: The electronic properties of aryl substituted polysilanes. *J Am Chem Soc*, 92:3806, 1972.

Toren EC Jr, Davis JE, Nutt SK, Carey RN: The electrochemistry of benzo(b)quinolizinium ion. *Z Anal Chem*, 264, 1973.

Carey RN, Feldbruegge D, Westgard JO: Evaluation of the Technicon adaptation of the glucose oxidase - peroxidase MBTH-DMA procedure to the SMA 12/60 and comparison to other automated methods. Clin Chem 20:595, 1974.

Carey RN, Wold S, Westgard JO: Principal component analysis: An alternative to referee methods in method comparison studies. Anal Chem 47:1825, 1975.

Toren EC Jr, Carey RN, Cembrowski GS, Shirmer JA: Computer controlled instrument system for sequential chemistry testing. I Description of instrumentation and system features. Clin Chem 19:1114, 1973.

Westgard JO, Carey RN, Wold S: Criteria for judging precision and accuracy in method development and evaluation. Clin Chem 20:825, 1974.

Kudirka PJ, Busby MG, Carey RN, Toren EC Jr: Separation of creatine kinase isoenzymes by high pressure liquid chromatography. Clin Chem 21:450, 1975.

Westgard JO, Carey RN, Feldbruegge DH, Jenkins LM: Performance studies on the Technicon SMAC analyzer: Precision and comparison of values with methods in routine laboratory service. Clin Chem 22:489, 1976.

Busby MD, Kudirka PJ, Carey RN, Toren EC Jr: Automated separation of lactate dehydrogenase isoenzymes. Clin Chem 22:468, 1976.

Laessig RH, Westgard JO, Carey RN, Hassemer D, Schwartz T, Feldbruegge DH: Assessment of a serum separator device for obtaining specimens suitable for clinical analyses. Clin Chem 22:35, 1976.

Laessig RH, Westgard JO, Carey RN, Hassemer D, Schwartz T, Feldbruegge DH: Assessment of the serum separator tube (SST) as an intermediate storage device within the laboratory. Am J Clin Pathol 66:653, 1976.

Laessig RH, Carey RN, Westgard JO, Hassemer D, Habig R: Field evaluation of the Becton-Dickinson serum separator tube. Health Laboratory Science 13:209, 1976.

Westgard JO, deVos DJ, Hunt MR, Quam EF, Carey RN, Garber CC: Concepts and practices in the evaluation of laboratory methods. I. Background and approach. II. Experimental procedures. III. Statistics. IV. Decisions on acceptability. V. Applications. Am J Med Technol 44: 290, 420, 552, 727, 803, 1978. Also published as a monograph by American Society for Medical Technology.

Garber CC, Carey RN: Albumin activation of urinary amylase as determined with the DuPont ACA. Clin Chem 24:702, 1978.

Garber CC, Feldbruegge DF, Miller RC, Carey RN: Evaluation of the co-immobilized hexokinase/glucose-6-phosphate dehydrogenase method for glucose, as adapted to the Technicon SMAC. Clin Chem 24:1186, 1978.

Laessig RH, Hoffman GL, Westgard JO, Carey RN, Feldbruegge DH, Hassemer D: A comparison of hard and soft glass blood drawing tubes. Am J Clin Pathol 72:952, 1979.

Davis TE, Kahan L, Tormey DC, Larson FC, Anderson SA, Crowley JJ, Carey RN: Clinical studies of a fast, homoarginine-sensitive alkaline phosphatase (FHAP) in patients with cancer. Cancer 41:1110, 1981.

Duncan P, Gochman N, Bayse D, Burnett R, Carey N, Carter R, Fellows WD, Garber C, Kessler G, McComb R, Miller W, Nast P, Ryan W, Schaffer R, Tajeda B, Vanderlinde R, Widdowson G: A candidate reference method for uric acid in serum. II. Interlaboratory testing. *Clin Chem* 28:291, 1982.

Carey RN, Tyvoll JL, Plaut DS, Hancock MS, Barry PL, Westgard JO: Performance characteristics of some statistical quality control rules for radioimmunoassay. *J Clin Immunoassay* 8:245-252, 1985.

Cembrowski GS, Hackney JR, Carey RN: The detection of problem analytes in a single proficiency test challenge in the absence of health care financing administration rule violations. *Arch Pathol Lab Med* 117:437-443, 1993.

Green GA IV, Carey RN, Westgard JO, Carten T, Shablesky L, Achord D, Page E, Le AV: Quality control for qualitative assays: design of a quantitative QC procedure to assure the analytical quality required for an ELISA for hepatitis B surface antigen. *Clin Chem* 43:1618-1621, 1997.

MANUSCRIPTS IN PREPARATION:

Green GA IV, Maiore T, Shablesky L, Achord D, Page E, Le AV, Carey RN: Quality control of qualitative immunosorbent assays to detect hepatitis b surface antigen: determining optimal concentrations for positive quality control materials, 2003.

Carey RN, Cembrowski GS, Zaki Z, Garber CC. Performance characteristics of several "rules" for self-interpretation of proficiency testing (PT) data, 2003.

NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS) PROTOCOLS:

Subcommittee on user evaluation of precision: EP5, User evaluation of precision performance of clinical chemistry devices. Proposed guideline, 1981, Tentative guideline, 1982, 1992, Approved guideline, 1999.

Subcommittee on user comparison of methods: EP9, User comparison of quantitative clinical laboratory methods using patient samples. Proposed guideline, 1984, Tentative guideline, 1992, Approved guideline, 1995, Second edition, 2002.

Subcommittee on user demonstration of performance: EP15, User demonstration of performance for precision and accuracy. Proposed guideline, 1998, Approved guideline, 2001, will revise to A2 in 2004.

LETTERS:

Westgard JO, Carey RN, Wold S: Comments on the judgment of the acceptability of new clinical methods (Reply). *Clin Chem* 23:776, 1977.

Carey RN, Harris EK: Proposed changes to "Information for Authors." *Clin Chem* 33:2323, 1987.

Carey RN, Frye RM, Cook JD, Koch TR, Harris EK: Between-lot/between-instrument variations of the Abbott IMx method for prostate-specific antigen. *Clin Chem* 38:2341-2343, 1992.

INVITED PAPERS:

Quam EF, Westgard JO, Carey RN: Selecting glucose methods that meet your laboratory glucose requirements. *Lab Med* 6:35, 1975.

Westgard JO, Carey RN, Huntington RW, Joiner BL: Medical usefulness requirements for judging acceptability of precision and accuracy in clinical chemical analyses. *Organisation Des Laboratoires - Biologie Prospective, III Colloque de Pont-a-Mousson*, 59-62, 1975.

Jenkins LM, Hunt MR, Carey RN, Westgard JO: Workload recording: A tool for optimizing laboratory efficiency. *Lab Med* 7:36, 1976.

Westgard JO, Carey RN, Hewitt TE, Wold S, Joiner B: Design considerations in testing aspartate aminotransferase (AST) methods. *Proceedings of the First InterAmerican Symposium on Quality Control in Laboratory Medicine*, Key Biscayne, FL, April 7-9, 1976, pp 141-148.

Carey RN, Westgard JO, Dial MD: Evaluation of analytical methods which measure the activity of aspartate aminotransferase; results of testing AST methods. *Proceedings of the First InterAmerican Symposium on Quality Control in Laboratory Medicine*, Key Biscayne, FL, April 7-9, 1976, pp 149-156.

Carey RN, Eggert AA, Quam EF, Feldbruegge DH, Westgard JO: Evaluation, data handling, and quality control of a SMAC analyzer in a university hospital laboratory. In Advances in Automated Analysis, Proceedings of the Technicon Congress, 1976. Mediad, Tarrytown, NY, 1977, pp 223-228.

Westgard JO, Carey RN, Feldbruegge DH, Jenkins LJ, Hunzicker JJ, Quam EF, Loftin LA, Burmeister BJ, Hunt MR: Experiences with a SMAC analyzer. *Lab Med* 8:16, 1977.

Eckert GH, Carey RN: Application of statistical control rules to quality control in radioimmunoassay. *J Clin Immunoassay* 8:107-111, 1985.

Cembrowski GS, Carey RN: Quality control in the 1990s. *Lab Med* 20:375, 1989.

Carey RN: Implementation of multirule quality control procedures. *Lab Med* 20:393-399, 1989.

Cembrowski GS, Carey RN: Considerations for the implementation of clinically derived quality control procedures. *Lab Med* 20:400-405, 1989.

Carey RN: Multirule quality control procedures. *Ann Ist Super Sanita* 27:419-426, 1991.

Carey RN: Quality control rules for immunoassay. ENDO Division, AACC Press, 1992.

Cembrowski GS, Engebretson MJ, Hackney JR, Carey RN: A systems approach to assure optimal proficiency testing in the hematology laboratory. *Clinics in Laboratory Medicine* 13:973-985, 1993.

Cembrowski GS, Crampton C, Byrd J, Carey RN: Detection and classification of proficiency testing errors in HCFA regulated analytes: application to ligand assays. *J. Clin. Immunoassay* 1994;17:210-215.

Cembrowski GS, Anderson PA, Crampton CA, Coupland R, Carey RN: Pumping up your PT: an efficient method for inspecting PT results. *Medical Laboratory Observer*, January, 1996, 46-51.

Carey RN: Tips on managing the quality of immunoassays. *Westgard Quality Corporation Guest Essay*, March, 1997. <http://westgard.com>.

INVITED EDITORIAL:

Cembrowski GS, Carey RN: Adding value to proficiency testing programs. Clin Chem 46:7-8, 2000.

WORKSHOP PRESENTATIONS AT NATIONAL MEETINGS:

Carey RN, Garber CC, Koch DD (co-presenters vary): Concepts and practices in the evaluation of laboratory methods.

American Association for Clinical Chemistry: 1977, 1978, 1979, 1980, 1981, 1982, 1983, 1984, 1985, 1986, 1987, 1988, 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002

Canadian Society for Laboratory Technology: 1984, 1992

Canadian Association of Clinical Chemists: 1987

Carey RN, Tyvoll JL: Statistical quality control. Clinical Ligand Assay Society: 1983.

Perlstein M, Carey RN: Quality control for immunoassays. Clinical Ligand Assay Society: 1984.

Cembrowski GS, Carey RN, Kurtycz DFI (co-presenters vary): Improving statistical quality control. American Society of Clinical Pathologists/College of American Pathologists: 1985, 1986, 1988.

INVITED SYMPOSIA AND TALKS NOT PUBLISHED ELSEWHERE:

Carey RN: Selection and evaluation of analytical instruments and methods. Robert First Conference: Clinical Laboratory Testing in the United States, Chicago, IL January 22-23, 1979.

Carey RN: Statistics applied to selection and evaluation of analytical methods. Foundations Fund for Research in Psychiatry: Workshop on Clinical Pharmacology in Psychiatry. American College of Neuropsychiatry Meeting, San Juan, Puerto Rico, December 13-14, 1980.

Carey RN: Clinical evaluation of instruments. Clinical Ligand Assay Society, National Meeting, Detroit, MI, May 4-8, 1982.

Carey RN: On-line computer based quality control in the clinical laboratory. Johns Hopkins Hospital, Annual Laboratory Medicine Symposium, Baltimore, MD, September 21-23, 1982.

Carey RN: How many controls do you need? Ohio Valley Section of American Association for Clinical Chemistry, Columbus, Ohio, October 15, 1983.

Carey RN: Quality control of endocrinology assays. Hospital of the University of Pennsylvania, Annual Pepper Laboratory Symposium, Philadelphia, PA, April 18, 1985.

Carey RN: Implementation of statistical control systems in the chemistry laboratory. Quality Control in the 1990s, Park Nicollet Laboratory Symposium, Minneapolis, MN, September 22, 1988.

Carey RN: Glucose methods: evaluation and comparison. Diabetes and the Clinical Laboratory, Park Nicollet Laboratory Symposium, Minneapolis, MN, September 14, 1989.

Carey RN, Cembrowski GS: Statistical quality control. Johns Hopkins University Department of Laboratory Medicine, Baltimore, MD, May 15, 1990.

Carey RN: Statistics and quality control. Osler Institute Pathology Review Course, Hagerstown, MD, May 19-26, 1990.

Carey RN: I. Continuous Quality Improvement Rollout. II. Proficiency Testing and Quality Control. Cochrane Region Laboratory Program Summer Symposium, Cochrane, Ontario, June 10-13, 1994.

Carey RN: User validation of analytical performance - a cookbook. Capital Section of American Association for Clinical Chemistry, Greenbelt, MD, February 21, 1996.

Carey RN: NCCLS Protocols for Method Evaluation. There's more than pass/fail in PT scores. Proficiency testing breakout. Total Quality Management Symposium. Michener Institute, Toronto, Ontario, Canada, May 24 – 26, 2001.

Carey RN: Use of optimized control rules for proficiency testing evaluation. Edutrak 3304, Reshaping proficiency testing: Lessons for laboratorians, providers & regulators. American Association for Clinical Chemistry National Meeting, Chicago, IL, July 31, 2001.

Carey RN: I. NCCLS protocols for method evaluation. II. Using proficiency testing for self-improvement. Quality Control Symposium, University of Medicine and Dentistry of New Jersey, Scotch Plains, NJ, March 22 – 23, 2002.

Carey RN: Implementing Six Sigma Analytical Quality in the Laboratory: Method Evaluation and Quality Control. Dade Days, Washington, D.C., October 2, 2003.

Carey RN: Quality Control Charts for Discrete Variables: Tools for Improving Laboratory Processes. Dade Days, Washington, D.C., October 2, 2003.

MANAGEMENT WORKSHOP:

Wilson D, Carey RN: SPC Toolbox: Statistics and Quality Control Charts for Quality Assurance and Quality Improvement. Peninsula Regional Medical Center. Presented 4 times annually.

TELECONFERENCE PRESENTATION:

Cembrowski GC, Carey RN: Application of Westgard rules to immunoassay and hematology labs. Telemedicine Canada, Toronto, Canada, December 7, 1989.

ABSTRACTS - NOT PUBLISHED ELSEWHERE:

Carey RN, Eggert AA, Toren EC Jr: Least squares fitting and plotting of polyacrylamide-gel-immobilized antibody radioimmunoassay data by use of a LINC computer. Clin Chem 18:576, 1972.

Carey RN, Miller RC, Westgard JO: Response of two ratio-reporting techniques to systematic errors of enzyme methods. Clin Chem 21:906, 1975.

Polutanovich TA, Carey RN: Adaptation of an immunochemical method for CK-MB to the centrifugal analyzer. Clin Chem 25:1142, 1979.

Carey RN, Beebe S, Barry PL, Westgard JO: Assessment of performance characteristics of some quality control rules for retrospective analysis of control data from the IL 508. Clin Chem 31:1017, 1985.

Green G, Maiore T, Shablesky LA, Achord D, Page E, Korte L, Anson M, Fosdick M, Carey RN, Le AV: Quality control procedures for qualitative assays: determining optimal concentrations for positive controls

for an enzyme linked immunosorbent assay (ELISA) for hepatitis B surface antigen (HBsAg). Clin Chem 41:S212, 1995.

Zaki Z, Carey RN, Cembrowski GS, Hackney JR: Simulation studies of Alberta warning notifications; more specific rules needed? Canadian Society of Clinical Chemists, June 14-18, Ottawa, Ontario, Abstract #43.

Zaki Z, Carey RN, Cembrowski GS, Kazmierczak SC: Self-improvement by participant interpretation of proficiency testing data from events with 2 to 5 samples. Clin Chem 46:A70, 2000.

Cembrowski GS, Douville P, Carey RN: Nomogram to select optimal length of break-in period for new control lots. Clin Chem 46:A71, 2000.

Carey RN, Cembrowski GS, Zaki Z, Garber CC. Performance characteristics of several "rules" for self-interpretation of proficiency testing (PT) data. Clin Chem 48:A175, 2002.

ABSTRACT SUBMITTED:

Carey RN, Kearney M, Meney BM, Miller SR: Delta check limits updated. Submitted for AACC National Meeting, Los Angeles, CA, July 2004.