

In-House Quality Assurance Accreditation for Kendrick Laboratories, Inc.

Kendrick Laboratories, Inc. is a Contract Research Organization specializing in protein analysis services. Mainly, we perform analytical 1D and 2D gel electrophoresis for food, biotech and pharmaceutical companies. Kendrick Labs is registered with the FDA through December 2020 (registration number FEI 3001238747) and subject to regular FDA inspections.

A strong infrastructure of SOPs, developed and refined over many years, is maintained by QA personnel. A list of regulatory SOPs is provided below; credentials of QA personnel are provided on the following pages. A copy of our QA Manual is available on demand.

Index - Standard Operating Procedures (SOPs)

G-SERIES	GENERAL
G-1100 v002	Writing SOPs
G-1101 v004	Duties of the QA Manager
G-1102 v003	Quality Manual
G-1103 v005	QA Auditing of SOP compliance
G-1104 v001	Investigation of Deviations
G-1105 v004	Data Checking and Control of Changes
G-1106 v004	Investigation of Out-of-Specification Results
G-1107 v001	Determining R _f Values for 1D and 2D Gels
G-1108 v005	Policy on SOP Deviation and Change Control
G-1109 v000	Corrective and Preventative Action (CAPA)
G-1110 v005	Distribution and archival of SOP's
G-1111 v000	Good Documentation Practices
G-1112 v001	Vendor Selection and Qualification
G-1113 v000	Handling Complaints
G-1114 v000	Laboratory Notebook Procedures
G-1115 v005	Receipt of GLP/GMP Materials
G-1118 v008	Receipt, Storage, and Tracking of GLP/GMP Samples
G-1120 v015	Master Equipment List
G-1130 v003	Archival of GLP/GMP Raw data, Calibration Records and Reports
G-1135 v001	Maintenance of GLP/GMP Data Integrity
G-1140 v001	Reporting of GLP results
G-1145 v009	GLP/GMP Orientation and Training Program for Employees
G-1200 v012	Adjustable Pipettor Calibration
G-1205 v002	Melles Griot Filter Calibration
G-1210 v013	Freezer Log and maintenance
G-1211 v009	Refrigerator Log and maintenance
G-1212 v011	Automatic Monitoring of Temperature in Refrigerators and Freezers
G-1220 v008	Balance Calibration
G-1230 v003	Thermometer Calibration
G-1231 v002	Data Logger and Sensor Calibration
G-1240 v001	Timer Calibration
G-1245 v000	NIST Calibrated Ruler Use
G-1252 v003	ChroMate 4300 Microplate Reader Use and Calibration
G-1260 v006	Water System Meter Calibration and Maintenance
G-1270 v005	pH Meter Calibration
G-1276 v000	Power Supply Calibration
G-1278 v000	83 Multimeter Calibration

In addition, Kendrick Labs has seven Protocol SOPs for in-house testing, fifteen Protocol SOPs custom written for various companies, and 105 Laboratory SOPs. Credentials of Quality Assurance Personnel and the Lab Manager are below.

Curriculum Vitae of Quality Assurance Personnel

Christina Rose - Quality Assurance Manager

Education and Training:

Part time 2D Analyst, (2002 - May 2010); part time QA Assistant (2009 - May 2010)
B.S. in Anthropology and Zoology, University of Wisconsin-Madison (May 2010)
2D Analyst June 2010 - present
QA Assistant June 2010 - Feb 2011
QA Associate Feb. 2011 – Sept 2016
Senior Quality Assurance Associate Oct 2016 - April 2018
Quality Assurance Manager April 2018 - present

Training Certification-Excel Spreadsheets (March, 2010)
Training Certification-Method Validation (July, 2010)
Training Certification-Quality Assurance Duties and Archiving (February, 2011)
Training Certification-Comparison of GCP, GLP, and GMP (June, 2014)
Training Certification-Rees Scientific Software and Alarm Response (August, 2016)
Training Certification-Checking for changes after SameSpots Applied (November, 2016)
Seminar: FDA Enforcement in 2017 (June, 2017)
Training Certification-CASSS Midwest Discussion Group: Challenges or Special Considerations When Developing ADCs and Bi-specifics (June, 2017)
Training Certification-Receiving Materials
GLP/GMP Ongoing Training: complete through March 2019

Nancy Kendrick – Senior Quality Assurance Associate, CEO

Education and Training:

B.S. in Biology, Chemistry minor, Illinois State University, Normal, IL (1967)
Ph.D. in Neurobiology, Washington University at St. Louis, MO (1973)
Postdoctoral fellowship at Washington University, Physiology Dept (1974-1976)
Postdoctoral fellowship at Univ. Wisconsin-Madison, Biochemistry Dept (1977-1981)
President of QuantiGel Corp, (software development company, 1986-1995)
President/CEO of Kendrick Labs Inc. (1981-present)
QA Manager (1997-2018)
Sr QA Associate (2018-present)

Quality Regulations and Standards for Biotechnology: GMPs at MATC (Spring, 1999)
Training Certification: Excel Spreadsheets (March, 2010); Method Validation (July, 2010)
Training Certification-Comparison of GCP, GLP, and GMP (June, 2014)
Seminar: FDA Enforcement in 2017 (June, 2017)
Training Certification-CASSS Midwest Discussion Group: Challenges or Special Considerations When Developing ADCs and Bispecifics (June, 2017)
Wrote, supervised writing, or gave final approval to SOPs at Kendrick Labs, Inc
GLP/GMP Ongoing Training: complete through March, 2019

Societies

Member of AES, ASBMB, and AAAS
Councilor of American Electrophoresis Society (AES), 1996-1998
Vice President AES, 2000-2002; President AES, 2002-2004

Nancy Kendrick continued:

American Electrophoresis Society - Abstracts for talks

Kendrick, N., Hoelter, M., Koll, A., Powers, G., and Johansen, J. "Tyrosine phosphorylation of Src versus keratin proteins in human lung tumors" AES Annual Meeting, Nov 2017, Minneapolis, MN

Kendrick, N., Hoelter M., Koll, A., Powers, G. and Johansen, J. "Refinement of an Internal Standard for Phosphotyrosine Western Blotting" AES Annual Meeting, Nov 2016, San Francisco, CA

Kendrick, N., Hoelter, M., Koll, A. and Johansen, J. "Preparation of a phosphotyrosinylated protein standard for 2D gel western blotting" AES Annual Meeting, Nov 2015, Salt Lake City, UT

Kendrick, N., Hoelter, M. and Johansen, J. "Identification of Receptor Tyrosine Kinases using Western blot image overlays from 2D gels." AES 30th Annual Meeting, Nov 2013, San Francisco, CA

Johansen, J and Hoelter, M and **Kendrick, N.**, "Optimization of 2D Gel Transblotting for HCP Antibody Analysis", AES 26th Annual Meeting, Nov 2009, Nashville, TN

In addition, Dr. Kendrick has 29 publications, 3 white papers, and 22 abstracts.

Isaac O'Malley-Laursen - Quality Assurance Associate

Education and Training:

B.S. in Biochemistry at the University of Wisconsin-Madison (May 2011)

Part time Laboratory Assistant at Kendrick Labs (Aug 2010 - May 2011)

Biochemist at Kendrick Labs (June 2011 - present)

Quality Assurance Assistant at Kendrick Labs (March 2013 - April 2016)

Quality Assurance Associate at Kendrick Labs (April 2016-present)

Senior 2D Analyst at Kendrick Labs (April 2016-present)

Training Certification-Progenesis PG240 software and report writing (September, 2011)

Training Certification-GMP analysis and reports (February, 2012)

Training Certification-1D Gel Loading (March, 2012)

Training Certification-Host Cell Protein Analysis (September, 2012)

Training Certification-Wet Gel Handling (February, 2013)

Training Certification-Quality Assurance Checking of Fish Speciation Reports (March, 2013)

Training-Certification-Quality Assurance Duties and Archiving (November, 2014)

Training Certification-Comparison of GCP, GLP, and GMP (November, 2014)

Training-Certification-Quality Assurance Checking of GMP Reports (July, 2015)

Training Certification-Rees Scientific Software and Alarm Response (August, 2016)

Training Certification-Checking for and Correcting data changes after SameSpots Applied (November, 2016)

Seminar: FDA Enforcement in 2017 (June, 2017)

GLP/GMP Ongoing Training: complete through March, 2019

Jon Johansen - Laboratory Manager

Education and Training:

B.S. in Biochemistry from University of Wisconsin-Madison (1985)

Biochemist at Kendrick Labs (1985-1992)

Laboratory Manager at Kendrick Labs 1992 – present

Training Certification-CASSS Midwest Discussion Group: Challenges or Special Considerations When Developing ADCs and Bispecifics (June, 2017)

Wrote or supervised writing of most SOPs at Kendrick Labs, Inc

GLP/GMP Ongoing Training: complete through March, 2019

Jon Johansen continued:

American Electrophoresis Society - Abstracts for talks

Kendrick, N., Hoelter, M., Koll, A., Powers, G., and **Johansen, J.** "Tyrosine phosphorylation of Src versus keratin proteins in human lung tumors" AES Annual Meeting, Nov 2017, Minneapolis, MN
 Kendrick, N., Hoelter M., Koll, A., Powers, G. and **Johansen, J.** "Refinement of an Internal Standard for Phosphotyrosine Western Blotting" AES Annual Meeting, Nov 2016, San Francisco, CA
 Kendrick, N., Hoelter, M., Koll, A., and **Johansen, J.** "Preparation of a phosphotyrosinylated protein standard for 2D gel western blotting" AES Annual Meeting, Nov 2015, Salt Lake City, UT
 Kendrick, N., Hoelter, M., Koll, A., and **Johansen, J.** "Quantification of 2D Gel anti-pTyrosine Western Blots from Human Tumor Samples" AES 31th Annual Meeting, Nov 2014, Atlanta, GA
 Kendrick, N., Hoelter, M. and **Johansen, J.** "Identification of Receptor Tyrosine Kinases using Western blot image overlays from 2D gels." AES 30th Annual Meeting, Nov 2013, San Francisco, CA
Johansen, J and Hoelter, M and Kendrick, N, "Optimization of 2D Gel Transblotting for HCP Antibody Analysis", AES 26th Annual Meeting, Nov 2009, Nashville, TN

Publications

Kendrick, NC., **Johansen, JJ**, Lee, PR and Santek, DA. "Optimization of an HP Scanjet for Quantification of Protein Electrophoresis Gels" *Anal. Biochem.* 219: 297-304, 1994
 Burgess-Cassler, A, **Johansen, J**, Santek, D, Ide J and Kendrick N. Computerized quantitative Analysis of Coomassie-Blue Stained Serum Proteins Separated by 2D Electrophoresis. *Clin. Chem.* 35: 2297, 1989.

In addition, Jon has two publications, two white papers and 9 abstracts.

Matt Hoelter - Western Blot Manager, Senior Biochemist, 2D Analyst

Education and Training:

B.S. in Biochemistry from University of Wisconsin-Madison (May 2004)
 Laboratory Assistant at Kendrick Labs (March 2002 – May 2003)
 Biochemist at Kendrick Labs (May 2004 – April 2010)
 2D Analyst at Kendrick Labs (May 2004 – present)
 Senior Biochemist (May 2010 – present)
 Western Blotting Manager (May 2013 – present)

Training Certification-Quality Assurance for Fish Analyses for the FDA (August, 2006)
 Training Certification-Silver staining (August, 2007)
 Training Certification-2D Gel Loading (July, 2009)
 Training Certification-Progenesis PG240 and SameSpots (February, 2013)
 Training Certification-IEF Tube Gel Pouring and Extrusion (February, 2013)
 Training Certification-Fish Sample Preparation for FDA reports (February, 2013)
 Training Certification-Wet Gel Handling (February, 2013)
 Training Certification-Rees Scientific Software and Alarm Response (August, 2016)
 Training Certification-Checking for and Correcting data changes after SS Applied (Nov, 2016)
 Training Certification-Receiving Materials (May, 2017)
 Training Certification-CASSS Midwest Discussion Group: Challenges or Special Considerations When Developing ADCs and Bispecifics (June, 2017)
 Training Certification-Receiving Samples (August, 2018)
 GLP/GMP Ongoing Training: complete through March, 2019

Executive Director of the American Electrophoresis Society 2006 - present

Matt Hoelter continued:

American Electrophoresis Society - Abstracts for talks

Kendrick, N., **Hoelter, M.**, Koll, A., Powers, G., and Johansen, J. "Tyrosine phosphorylation of Src versus keratin proteins in human lung tumors" AES Annual Meeting, Nov 2017, Minneapolis, MN

Kendrick, N., **Hoelter M.**, Koll, A., Powers, G. and Johansen, J. "Refinement of an Internal Standard for Phosphotyrosine Western Blotting" AES Annual Meeting, Nov 2016, San Francisco, CA

Kendrick, N., **Hoelter, M.**, Koll, A., and Johansen, J. "Preparation of a phosphotyrosinylated protein standard for 2D gel western blotting" AES Annual Meeting, Nov 2015, Salt Lake City, UT

Kendrick, N., **Hoelter, M.**, Koll, A., and Johansen, J. "Quantification of 2D Gel anti-pTyrosine Western Blots from Human Tumor Samples " AES 31th Annual Meeting, Nov 2014, Atlanta, GA

Kendrick, N., **Hoelter, M.** and Johansen, J. "Identification of Receptor Tyrosine Kinases using Western blot image overlays from 2D gels." American Electrophoresis Society 30th Annual Meeting, Nov 2013, San Francisco, CA

In addition, Matt has two white papers and 12 abstracts.

Additional Trained Employees

In addition, Kendrick Labs employs a Senior Biochemist, two Associate Biochemists, four Biochemists, two Lab Technicians and one part-time 2D Analyst, all trained appropriately according to SOP G-1145.