Quest Diagnostics Nichols Institute

14225 Newbrook Drive
Post Office Box 10841
Chantilly, Virginia 20153-0841
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800.336.3718

Br. 2

Quest Diagnostics

September 30, 2008

Dennis R. Lawyer
U.S. Nuclear Regulatory Commission
Region I
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

03003366

RE: License No. 45-13936-01
Quest Diagnostics Nichols Institute

Dear Mr. Lawyer:

Attached are the Curriculum Vitae for Dr. Lu Song and Dr. Kenneth Sisco, who we would like to have listed as additional users on the above license.

Any questions regarding the above matter may be directed to Mr. Christopher Bartos, consultant, Krueger-Gilbert Health Physics, Inc. at (410) 665-5447 or Mr. John Praither, Radiation Safety Officer, at (703) 802-6900, Ext. 5921.

Sincerely,

John D. Praither
Radiation Safety Officer

Kenneth L. Sisco, M.D., Ph.D.
14225 Newbrook Drive
Chantilly, VA 20151
Tel. (703) 802-7007
kenneth.l.sisco@questdiagnostics.com

Professional and Educational Experience:

2008-Present

Medical Director, Nichols Institute, Quest Diagnostics, Chantilly, VA

* This position, as Director of the Laboratory (CLIA), requires medical supervision of various departments in appropriating and/or developing and implementing cutting edge technologies for esoteric diagnostic assays, as well as approval of procedures, validations and quality assurance. Medical consultations to physicians and hospital clients are also provided.

2003-2008

Medical Director, Clinical Laboratory, Quest Diagnostics, West Hills, CA

* This position required medical direction of one of the largest commercial laboratories in the United States which processed up to 45,000 requisitions per day. Supervision of personnel, testing and quality assurance, as well as providing consultation to physicians concerning laboratory results characterized my responsibilities.
* This position was part of the management team which supervised the largest merger in US history of three commercial laboratories into one (2006) with over 90% client retention.
* Retirement of the Anatomic Pathology Medical Director, required also my acting as interim AP Medical Director during a search (10/06-01/07).
* Client satisfaction improved with growth of market share after the merger during my tenure accompanied by improvement in all quality assurance metrics.

2001-2003

Investigative Molecular/Anatomic Pathologist, LifeSpan Biosciences, Ltd., Seattle, WA

* This position involved utilizing anatomic pathology and teaching skills in the analyses of neoplastic, diseased and normal tissue. Mapped areas of the central nervous system as well as fifty different peripheral tissues involving all organ systems were analyzed for the expression of 320 G-protein coupled receptors.
* Immunohistochemistry, in-situ hybridization, Northern blot analysis and transfection studies were used to provide valuable information through my lectures at their facilities and our reports to pharmaceutical companies (BMS, Merck, Novartis, Pfizer, P&G, Aventis, Schering-Plough, and others) concerning G-protein coupled receptor related drug targets, their distribution and relevance to etiologies of selected diseases. Several new drug projects were generated at the drug companies as a result of these data.

1997-2001

Medical Director, Clinical Laboratory Services, Christiana Care Health System, Newark, DE

Adjunct Associate Professor, University of Delaware, Newark, DE

*This position was responsible for supervision of the clinical laboratories of two (600 bed and 200 bed) hospitals, being Medical Director of the Medical Technology Department of the University of Delaware and providing clinical pathology consultation for the medical staff, including participating in the weekly teaching rounds in the MICU.

*Our hospital laboratories added new instrumentation, molecular techniques, and established a partnership with a national commercial laboratory expanding our market to outpatient testing.

1994-1997
Chairman, Pathology Department, Holy Cross Hospital, Silver Spring, MD
Adjunct Assistant Professor, Pathology Department, Uniformed Services University of Health Sciences (USUHS), Bethesda, MD

*My responsibilities included anatomic pathology rotation (surgical pathology, cytology, and bone marrow analyses) and supervision of four pathologists and laboratory personnel in a 400 bed hospital affiliated with George Washington University and Children's National Medical Center, as well as lectures to medical students at USUHS, the medical school for active duty military and U.S. Public Health Service officers.
*New cytologic techniques, and laboratory testing were introduced including off-site (surgery center) frozen sections, increased pediatric infectious disease testing, improved automation in hematology, and chemistry.

1991-1994
Medical Director, Nichols Institute, and MetPath Laboratories, Dallas, TX

*My job involved medical direction of laboratory personnel during mergers in the Dallas-Ft. Worth market. Now the labs are part of Quest Diagnostics.
*During my tenure, net income improved ten-fold and quality assurance measures were revised and improved, clinical pathology consultation was provided to Baylor, Presbyterian and Harris hospital systems as well as surgical pathology and cytology consultation.

1987-1991
Chairman, Pathology Department, St. Elizabeth Hospital, Beaumont, TX

*This position required anatomic pathology rotation and oversight of four pathologists in a 500 bed tertiary care hospital and cancer treatment center.
*My tenure saw the introduction of immunohistochemical testing, flow cytometry, CT guided fine needle aspiration cytology, and two additional subspecialties to this pathology group.

1985-1987
Staff Pathologist and **Director**, Clinical Chemistry, Naval Hospital, San Diego

*Clinical chemistry consultation was provided to the largest teaching hospital in the Navy as well as participation in the surgical pathology rotation.

1981-1985
Resident, Clinical and Anatomic Pathology, National Naval Medical Center, Bethesda, MD and
Laboratory Instructor, Uniformed Services University of Health Sciences (USUHS)

*This 450 bed teaching hospital was also affiliated with the National Institutes of Health, Armed Forces Institute of Pathology and USUHS.

1979-1981
Assistant Research Scientist, Department of Human Genetics, University of Michigan, Ann Arbor, MI

*Our work in the laboratory of Dr. D. Rucknagel resulted in a new DNA hybridization technique and elucidation of certain hemoglobin genetic abnormalities resulting in my promotion from Postdoctoral Fellow to Assistant Research Scientist.

1974-1979
Ph.D., Molecular Biology, Johns Hopkins University School of Medicine, Baltimore, MD
*My thesis research discovered a new mechanism of genetic transformation.
Advisor: Dr. H.O. Smith (Nobel Laureate in Medicine, 1978)

1972-1974
Research Associate, Laboratory of Neurobiology, National Institute of Mental Health, Bethesda, MD
*Our research found new membrane structures involved in nerve conduction.
Advisor: Dr. I. Tasaki (discoverer of saltatory conduction).

1971-1972
Intern, Straight Internal Medicine, University of Alabama, Birmingham, AL
*Attending staff included Drs. Tinsley Harrison (Professor Emeritus and former Editor-in-Chief of *Harrison's Principles of Internal Medicine*) and T.J. Reeves (Chairman of Internal Medicine).

1967-1971
M.D. with Honors and **M.S.** in Physiology and Biophysics, University of Arkansas School of Medicine (UAMS), Little Rock, AR
*My Master's thesis research discovered new information about calcium and smooth muscle contraction. Advisor: Dr. R. Sandberg (cardiologist and biophysicist)

1963-1967
A.B., Chemistry, Washington University, St. Louis, MO
*Special interests included mathematics, physical chemistry and biology. Summer research in embryology was performed under the guidance of Dr. Anderson Nettleship (former Chairman of Pathology, UAMS; former Research Fellow, Rockefeller Institute, Manhattan Project; and former student under Dr. William Welch of Johns Hopkins School of Medicine).

Honors:

Military:

Captain, U. S. Naval Reserve Retired
Meritorious Service Medal
Navy Commendation Medals (2)
Letter of Commendation

Medals were awarded for work performed as ***Ancillary Directors*** for Fleet Hospitals 21 and 22, ***Coordinator for the Inspection*** of Fleet Hospital 22, and ***Head, Outpatient Clinic*** for our Naval Reserve Unit in the National Naval Medical Center, Bethesda, MD. The Fleet Hospitals were 500 bed mobile field hospitals having medical and surgical capabilities in support of U.S. Marine combat units. The Letter of Commendation was awarded for my work as a ***staff pathologist*** at Camp Pendleton Hospital (during a brief staff shortage).

Medical School:

M.D. with Honors
Upjohn Award
Lange Award

Medical school honors and awards were for academic achievement and excellence in research performed during the summers in medical school for the completion of a M.S. degree in Physiology and Biophysics.

Licensure:
Arkansas, Maryland, California, Texas, Delaware, Washington, and Virginia are active. New York Certificate of Qualification (Anatomic and Clinical Pathology categories) is active.

Board Examinations:
Diplomate, American Board of Pathology in ***Anatomic and Clinical Pathology.***
Diplomate, National Board of Medical Examiners

Organizational Memberships:

College of American Pathologists	*(Fellow/Inspector)*
National Academy of Clinical Biochemists	*(Fellow Emeritus)*
American Society for Clinical Pathology	*(Fellow)*
Naval Reserve Association	*(Life Member)*
Military Officer Association of America	*(Life Member)*
American Mensa, Ltd.	*(Life Member)*
National Eagle Scout Association	*(Life Member)*

Publications:
1. Sisco, K. The role of external calcium in the contractions of vascular smooth muscle. *Clinical Research* 19: 83 (1971) (abstract)

2. Sisco, K., Warashina, A., Tasaki, I. Solvent sensitivity of fluorescence of aminonaphthalene sulfonates and usefulness as probes for nerve excitation. *The Biological Bulletin* 145: 457 (1973) (abstract)

3. Tasaki, I., Carbone, E., Sisco, K., Singer, I. Spectral analyses of extrinsic fluorescence of the nerve membrane labeled with aminonaphthalene derivatives. *Biochem. Biophys. Acta* 323: 220-233 (1973).

4. Gainer, H., Carbone, E., Singer, I., Sisco, K., Tasaki, I. Identification of some membrane protein subunits obtained from squid giant axon. *Comp. Biochem. Physiol.* [A] 47: 477-484 (1974).

5. Carbone, E., Sisco, K., Warashina, A. Physico-chemical properties of 2,6-ANS binding sites in squid giant axons: Involvement of water molecules in the excitation process. *J. Membrane Biology* 18: 263-276 (1974).

6. Tasaki, I., Sisco, K., Warashina, A. Alignment of anilinonaphthalene-sulfonate and related fluorescent probe molecules in squid axon membrane and in synthetic polymers. *Biophy. Chem.* 2: 316-326 (1974).

7. Tasaki, I., Sisco, K. Electrophysical and optic methods for studying the excitability of the nerve membrane. *Methods of Membrane Biology*, Korn, E. D., ed., Plenum Publishing Corporation, Volume 5: 163-194 (1975).

8. Davis, R. H., Sisco, K. L., Sharp, F. R. Protein synthetic activity in nervous tissue from different anatomical regions of lobster. *Comp. Biochem. Physiol.* [B] 57(1): 65-71 (1977).

9. Sisco, K., Smith, H. O. Sequence specific DNA uptake in *Haemophilus* transformation. *Proc. Natl. Acad. Sci. U.S.A.* 76: 972-976 (1979).

10. Danner, D. B., Deich, R. A., Sisco, K. L. and Smith, H. O. An eleven base pair sequence determines the specificity of DNA update in *Haemophilus* transformation. *Gene* 11: 311-318 (1980).

11. Frossard, P., Sisco, K. and Rucknagel, D. Improvement of the transfer of small plasmid DNA fragments from acrylamide gel onto nitrocellulose paper.
Analytical Biochemistry 134(2): 265-268 (1983).

12. Bruzdzinski, C., Sisco, K., Ferucci, S., and Rucknagel, D. The occurrence of alpha (G-Philadelphia) globin allele on a double locus chromosome.
Am. J. Human Genetics 36(1): 101-109 (1984).

13. Sisco, K., Kouns, D. and Garvin, D. CSF monoclonal gammopathy in multiple sclerosis.
Proceedings of SAFMLS 17(3): 18-20 (1988).

14. Sisco, K. Is RNA in serum bound to nucleoprotein complexes? *Clinical Chemistry* 47(9): 1744-1745 (2001).

15. Chow, J.M., Guo, J., Barbosa, S., Sisco, K., Mueller, K., Blackburn, P., Mikanda, J., Bolan, G. Incident and repeat chlamydia and gonorrhea infection among females seeking care in a large family planning program in California, 2003-2004 *ISSTDR 2005* 839 July 12, 2005 1600-1800, (abstract).

16. Chow, J.M., Guo, J., Gilson, D., Samuel, M., Barbosa, S., Sisco, K., Mueller, K., Thiel, H., Steinberg, S., Bolan, G. Repeat Chlamydia and gonorrhea infection using case-based surveillance reports and laboratory-based prevalence monitoring data, California, 2003-2004 *2006 National STD Prevention Conference* (abstract).

17. Chow, J.M., Guo, J., Samuel, M.C., Sisco, K., Mueller, K., Steinberg, S., Bolan, G., Chlamydia and gonorrhea infection among female family planning clients diagnosed with pelvic inflammatory disease in California, 2003-2006. *17th International Society for STD Research (ISSTDR)*, Seattle, WA (abstract).

Curriculum Vita

Name: **Lu Song**
Phone: (703) 802-7122
E-mail: lu.x.song@questdiagnostics.com

Certification

Diplomate, American Board of Clinical Chemistry

Education

Postdoctoral Fellow:	Mayo Clinic, Clinical Chemistry Postdoctoral Training Program, Department of Laboratory Medicine and Pathology, Rochester, Minnesota. 1996-1998
Postdoctoral Fellow:	University of Miami, Department of Physiology and Biophysics. 1991-1996.
Postdoctoral Fellow:	Lawrence Berkeley Laboratory, Cell and Molecular Biology, Berkeley, California. 1989-1991.
Ph. D.	Biophysical Chemistry, University of Washington, Seattle, Washington, USA. 1989.
B. S.	Analytical Chemistry, University of Science and Technology of China, Hefei, China. 1982.

Clinical Laboratory Experience:

Technical Director, Quest Diagnostics, Nichols Institute, Chantilly, Virginia. 2006-Present.
Technical Director, Quest Diagnostics, Pittsburgh, Pennsylvania. 2004-2006.
Technical Director, Central Pennsylvania Alliance Laboratory, York, Pennsylvania. 2001-2004.
Radiation Safety Committee Member, York Hospital, York, Pennsylvania, 2001-2004.
Assistant Professor, Clinical Chemistry Program, Cleveland State University, Cleveland, Ohio. 1998-1999.
Postdoctoral Fellow in Clinical Chemistry, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN. 1996-1998

Responsibilities include: technical performance and clinical utility of all tests, clinical consultation, quality control and quality improvement programs and compliance with regulations. Evaluated, validated and implemented new chemistry, immunochemistry, and molecular testing platforms or instruments. Validated and implemented new tests to serve our clinicians and to improve the clinical sensitivity and specificity of certain tests. Consulted with health care providers at all levels regarding matters related to laboratory services. Provided assistance in test interpretation and utilization. Provided interpretations for serum and urine protein electrophoresis and immunofixation electrophoresis. Maintained and updated the database for maternal serum triple and quad markers. Updated and calculated MOMs based on patient testing data. Initiated and facilitated a quality improvement program for the laboratory. Developed a quality metrics to monitor lab quality. Monitor monthly statistics of testing data to evaluate the prevalence of disease, percentage of immunity for certain virus in the population served and to spot trends of

problems. Assisted with troubleshooting problems related to instruments, QC problems, and test performance. Participated in the management of the laboratory. Assisted with development of administrative policies to increase efficiency and productivity. Assisted with training of technologists in new procedures. Assisted in the preparation for lab inspections by CAP and FDA. Added, modified or changed the standard operation procedures in order to meet the regulations. Assisted with continuing education programs by giving lectures on new tests and organizing seminars or teleconference on various new topics in clinical chemistry.

Research Accomplishment:

Studied clinical utilities of urinary type IV collagen as an early marker for diabetes nephropathy by developing an immunoassay for the marker. Developed an automated method for the screen of DNA mutations using novel nucleic acid based technology (US Patent 6451526). Developed a method for sampling and analyzing insulin-like growth factor-I (IGF-I) from dry spot. I have also identified and reported a novel urinary protein electrophoresis pattern during my practice of clinical chemistry. My research accomplishment includes both clinical chemistry and basic research.

Teaching Experience:

1998-1999: Assistant Professor, Clinical Chemistry Division, Chemistry Department, Cleveland State University, Cleveland, Ohio.

Gave lectures related to clinical chemistry, protein electrophoresis and molecular testing to postdoctoral fellows and pathology residents. Participated in the development of new courses in molecular testing. Gave various lectures related to chemistry and chemistry laboratory to undergraduate and graduate students.

Honors And Awards:

1998 First-Place Award, Student Research Awards, American Association for Clinical Chemistry Annual Meeting, Chicago.
1990 Travel Award by the 10th International Biophysical Congress.
1981 Chemistry Graduate Program (CGP) Fellowship (China-USA)
1980 Outstanding Student Award, University of Science and Technology of China.

Professional Society Membership

National Academy of Clinical Biochemistry
American Association for Clinical Chemistry
Mayo Clinic Alumni Association

This is to acknowledge the receipt of your letter/application dated 9/30/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment C45-1936-01)

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

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You may call us on (610) 337-5398, or 337-5260.

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(6-96)

Sincerely,
Licensing Assistance Team Leader