



BioTECHNICA DIAGNOSTICS

61 Moulton St., Cambridge, Massachusetts 02138 (617) 576-1966

030-29657

July 20, 1988

United States Nuclear Regulatory Commission  
Region I  
631 Park Avenue  
King of Prussia, PA 19406

RECEIVED

'88 AUG -8 11:23

re: License number 20-27930-01

Dear Sir or Madam:

We would like to amend our NRC license to reflect recent changes in technical personnel here at BioTechnica Diagnostics. Ms. Deborah Grabbe and Dr. Karen K. Vaccaro should be deleted from our license since they are no longer employed by BID. Ms. Mary Keville, our Reference Laboratory Supervisor has recently been named the Radiation Safety Officer. Both she and Dr. Donna Taylor, Sr. Research Scientist, are responsible for the supervision of employees using radioisotopes, along with Dr. Cynthia K. French who is currently listed on our license. I have enclosed statements regarding the training and experience of Ms. Keville and Dr. Taylor, along with copies of their curriculum vitae.

Ms. Keville and Dr. Taylor should replace Ms. Grabbe and Dr. Vaccaro under the conditions of our license. Ms. Keville will henceforth be the contact person regarding NRC licensing issues. Please contact me if you require any further information.

Very truly yours,

*Mary Keville*

Mary Keville, MT(ASCP)MPH  
Reference Laboratory Supervisor

Log	Aug 7
Remitter	
Check No.	2606
Amount	\$120
Fee Category	3M
Type of Fee	AMD
Date of Fee	8/31/88
Date of Payment	8/31/88
By:	<i>M. Keville</i>

Attachments

14 2 11 92 707 0061  
RECEIVED-REGION 1

"OFFICIAL RECORD COPY"

ML10 109305

9001190023 8B1112  
REG1 LIC30 PDR  
20-27930-01

26 JUL 1988

Mary Keville

Statement of Training, Education and Responsibilities:

Ms. Keville has a B.S. in Medical Laboratory Science from Northeastern University, Boston, 1974 and a Masters Degree in Public Health from Boston University, 1979. She has been employed as a Microbiologist and Laboratory Supervisor in several hospitals since 1974. From 1980 - 1987 she supervised the Clinical Microbiology Laboratory at University of Massachusetts Medical Center in Worcester where she was responsible for the technical and administrative supervision of twenty-three medical technologists and technicians, involved in providing Microbiology and Serology services for a 380 bed teaching hospital. Since January, 1987 she has functioned as our Reference Laboratory Supervisor, responsible for the overall technical and administrative functions of an independent clinical laboratory which performs DNA probe assays using <sup>32</sup>P labeled DNA probes. She has been responsible for supervising the medical technologists who synthesize and use these probes.

Ms. Keville's primary training in Radiation Safety occurred at Northeastern University and the New England Baptist/ New England Deaconness Hospital School of Medical Technology. In the past she has performed diagnostic in vitro assays using <sup>125</sup>I. Over the past 18 months she has worked extensively with <sup>32</sup>P in quantities of 1mCi per assay or probe synthesis. She has worked closely with Ms. Grabbe to execute our Radiation Safety Program and has been responsible for the documentation of radioactive waste since April, 1987. She plans to attend a one week course in September, 1988 on Occupational and Environmental Radiation Safety at the Harvard University School of Public Health.

Ms. Keville's current responsibilities include conducting the safety training for all employees, including radiation safety, biosafety, chemical, fire and occupational safety. She is also responsible for obtaining and maintaining all federal, state and local licenses in conjunction with our Research and Development effort and our licensed independent laboratory.

Enclosed please find Ms. Keville's curriculum vitae and documentation of her experience as a clinical laboratory supervisor.

CURRICULUM VITAE  
Mary Wolkovich Keville

Education:

- 1965-1969 Hudson Catholic High School, Hudson, Massachusetts
- 1969-1974 Northeastern University, Boston, Massachusetts;  
B.S., Medical Technology, June, 1974
- 1973-1974 New England Baptist Hospital School of Medical  
Tehnology, Boston, Massachusetts (Internship)
- 1976-1979 Boston University School of Medicine, Boston,  
Massachusetts; Master in Public Health,  
Concentration: Health Care Research,  
Epidemiology; M.P.H., May 1979

Certification: M.T. (ASCP) 098180, August, 1974

Experience:

1987-Present

BioTechnica Diagnostics, Inc., Cambridge, MA;  
Supervisor, Reference Laboratory, Manufacturing  
and Quality Assurance. Duties include:  
Responsible for day to day operation of the  
Reference laboratory and manufacture and quality  
control of reagents for a company which markets a  
DNA Probe Test Service for several species of  
bacteria known to be etiological agents of  
periodontal disease. Specific responsibilities  
include: supervision of technologists in all  
three areas; preparation and quality control of  
all reagents; performance of DNA probe assays,  
data evaluation; production, planning and  
scheduling of tests and manufacturing; initiation  
of documentation for new procedures and  
improvements to present procedures; general  
administrative responsibilities for personnel and  
budget.

1980-1987

University of Massachusetts Medical Center,  
Worcester, Massachusetts; Supervisor, Microbiology  
Laboratory, 380 bed university teaching hospital.  
Duties included: Technical supervision of all  
areas of Microbiology and Serology, including  
review of daily work, development of new  
procedures, review of quality control, and  
training of new employees. Administrative duties  
included hiring, employee performance review and  
scheduling for 23 employees, preparation and  
administration of the annual budget, (non-payroll



Experience (continued)

budget of \$300,000) and communication with other hospital departments. Other activities included coordination of laboratory inservice education programs for technologists and medical students, and teaching of laboratory procedures and administration to clinical pathology residents and infectious disease fellows.

1981-1987

Associate Professor, Department of Molecular Genetics and Microbiology, University of Massachusetts Medical School. Duties included: Responsibility for Medical School Microbiology Course Student Lab including development of content of laboratory sessions, preparation of written handout for students, supervision of laboratory preparation, and orientation and supervision of laboratory instructors.

1982-1984

Worcester State College, Worcester, Massachusetts. Lecturer: Biology Department, Microbiology Course for Nurses.

1980-1982

Northeastern University, Boston, Massachusetts  
Faculty: Department of Medical Laboratory Science  
Lecturer: Clinical Microbiology courses,  
Epidemiology courses.

1978-1980

Bon Secours Hospital, Methuen, Massachusetts  
Supervisor, Microbiology Laboratory, 300 bed community hospital. Duties included: Supervision of technologists and technicians in the Microbiology Section including: Bacteriology, Parasitology, Mycology, Mycobacteriology, and Fluorescent Studies. Responsible for all technical procedures and quality control. Administrative responsibilities include: Employee review, schedules, ordering of supplies, and preparation of annual budget.

1976-1977

New England Baptist Hospital, Boston, Massachusetts. Senior Technologist, Bacteriology. Duties included: Routine Bacteriology, Serology, Parasitology. Supervision of Medical Technology Internship students. Procedure writing, Quality Control.

Experience (continued)

- 1976-1977 Acting Supervisor, Bacteriology, August-September, 1976.  
Acting Supervisor, Bacteriology, June-October, 1977.  
Faculty, Northeastern University, Department of Medical Laboratory Science.
- 1975 Arlington Hospital, Arlington, Virginia. Staff Medical Technologist, Bacteriology. Duties included: Routine Bacteriology, Parasitology, Mycology, Mycobacteriology, and Fluorescent Microscopy.
- 1974 Centre Community Hospital, State College, Pennsylvania Staff Medical Technologist, Rotating Departments.
- 1973-1974 New England Baptist Hospital, Boston, Massachusetts. Internship as Medical Technologist.
- 1971-1974 New England Baptist Hospital, Boston, Massachusetts Laboratory Technician, Bacteriology and Hematology. 18 months full-time as co-op student; 12 months part-time.

Publications:

1. Keville, M.W., G.V. Doern. 1982. Comparison of the API 20S Streptococcus Identification System with an Immunorheophoresis Procedure and Two Commercial Latex Agglutination Tests for Identifying Beta-Hemolytic. Streptococci. J. Clin. Microbiol. 16:92-95.
2. Cheeseman, S.H., G.V. Doern, R.A. Ferriani, M.W. Keville, B.R. McGra and J.A. Stewart. 1984. Detection of Cytomegalovirus Antibody with Two Commercially Available Assays, an Indirect Hemagglutination Test and an Enzyme Immunosorbent Assay. J. Clin. Microbiol. 20:9-11.
3. Keville, M.W., and G.V. Doern, 1984. Evaluation of the DMS Rapid E System for Identification of Clinical Isolates of the family Enterobacteriaceae. J. Clin. Microbiol. 20:1010-1011.
4. Keville, M.W., G.V. Doern, M. Sauboulle, and D. Sewell. 1984. Evaluation of Chemstrip LN Alone and in Combination with the Bac T Screen for Detection of Bacteriuria. Abstract; Fourth International Symposium on Rapid Methods and Automation in Microbiology and Immunology.

Publications (continued)

5. Doern, G.W., A. Dascal, and M. Keville, 1985. Susceptibility Testing with the Sensititer Breakpoint Broth Microdilution System. *Diagn. Microbiol. Infect. Dis.* 3:185-191.

Continuing Education:

- 1975           Arlington Hospital, Series of sixteen lectures on current laboratory methods
- 1975           A.P.I. Workshop on Yeast, Lanha Maryland
- 1975           A.P.I. Workshop on Anaerobes, Lanha Maryland
- 1976           A.P.I. Workshop on Infection Control, Burlington, Massachusetts
- 1977           Massachusetts Association of Public Health, Seminar on Hospital Epidemiology, State Laboratory, Boston, Massachusetts (one day)
- 1978-Sept.    Clinical Microbiology Reviews, Mayo Clinic, Rochester, Minnesota
- 1978-Sept.    American Society for Microbiology Workshop: Rare Gram Negative Rods, Sturbridge, Massachusetts (one day)
- 1978-Dec.     American Society for Microbiology Workshop: Dermatophytes; Boston, Massachusetts (2 days)
- 1979-May      American Society of Clinical Pathologists Simultaneous Identification and Antimicrobial Susceptibility Testing, Chicago, Illinois (4 days)
- 1980           American Society for Microbiology Annual Meeting, Miami, Florida
- 1981           International Symposium of Rapid Methods and Automation in Microbiology, Washington, D.C.
- 1983           ASM Workshop on Miscellaneous Gram Negative Bacilli
- 1983           Mycology Course - Mayo Clinic, Rochester, Mn. (one week)
- 1984           International Symposium on Rapid Methods in Clinical Microbiology and Immunology. Berlin, West Germany
- 1984           NACMID Annual Meeting, Worcester, Massachusetts



Continuing Education (continued)

- 1984 NACMID Workshop on Actinomycetales, State  
Laboratory, Boston, Massachusetts
- 1985 NACMID Annual Meeting, Danvers, Massachusetts
- 1986 NACMID Annual Meeting, Hartford, CT.
- 1980-1987 Regular attendance at Infectious Disease Rounds at  
the University of Massachusetts Medical Center,  
Worcester, Massachusetts
- 1987 ASM workshop: DNA Probes, Atlanta, Georgia
- 1987 ASM workshop: DNA Probe Applications, Atlanta,  
Georgia
- 1987 ASM workshop: Quality Assurance of Diagnostic  
Products
- 1987 ASM Annual Meeting, Atlanta, Georgia

Professional Affiliations:

American Society of Clinical Pathologists

American Society for Microbiology

Northeast Branch, American Society for Microbiology

Northeast Association for Clinical Microbiology and  
Infectious Disease

Treasurer; 1983-1984

Secretary; 1985

President-Elect; 1986

President; 1987

Greater Boston Microbiology Supervisors Group  
Chairman; 1983

References:

H. Richard Hinrichs, M.D.  
Pathology Department  
Presbyterian Hospital  
Albuquerque, N.M.

Other references furnished upon request

Address:

38 Finn Road  
Harvard, MA 01451  
(617) 456-8906

Donna Taylor

Statement of Training, Education and Responsibilities

Dr. Taylor received a B.A. degree in Chemistry from ELME College in 1981 and a Ph.D. degree in Biochemistry from Brown University in 1985. Immediately after receiving her Ph.D. she began a one year Postdoctoral Fellowship program in Immunology at the Massachusetts Institute of Technology under the direction of Dr. Susumu Tonegawa. She has been employed by BioTechnica Diagnostics as a Research Scientist since December 1, 1986. At BioTechnica, she has been involved in research and development as well as technical support of DNA probe assays using <sup>32</sup>P labeled DNA probes. She has also been responsible for supervising lab personnel who work with or around radioactivity.

Dr. Taylor's primary training in Radiation Safety occurred at Brown University in Providence Rhode Island. At Brown University she learned to work with <sup>32</sup>P, <sup>3</sup>H, and <sup>35</sup>S. One year after her training at Brown, she attended a two day seminar at Marian Hospital in Providence on Radiation Safety in the Laboratory. At BioTechnica Diagnostics she has worked with <sup>3</sup>H and <sup>32</sup>P, with <sup>32</sup>P being the major isotope she uses. Generally, she uses 1 mCi or less per experiment and a maximum of 4 mCi per week.

Enclosed please find Dr. Taylor's resume.



DONNA A. TAYLOR

17 Otis St.  
Watertown, MA 02172

Home (617)926-3581

Work (617)576-1966

EDUCATION

Ph.D., Biochemistry, December 1985  
Brown University, Providence, RI

B.A., Chemistry (minor, Biology), May 1981  
College of Our Lady of the Elms, Chicopee, MA

EXPERIENCE

Research Scientist, December 1986 - present  
BioTechnica Diagnostics, Cambridge, MA  
Supervisor: Dr. Cynthia French  
-Evaluated model systems for nonisotopic user-friendly DNA probe kits  
-Developed and tested DNA probes to suspected periodontal pathogens  
-Acted as technical liaison between R&D and reference lab  
-Evaluated antibodies in latex agglutination assays  
-Trained and supervised one asst. scientist and two lab assistants  
-Transcribed molecular biology procedures into manufacturing documents

Postdoctoral Fellow, November 1985 - December 1986  
Massachusetts Institute of Technology, Cambridge, MA  
Principal Investigator: Dr. Susumu Tonegawa  
Studied the organization of the T cell receptor gamma gene family.  
Techniques used: Maxam-Gilbert sequencing, genomic and plasmid DNA purification, oligo purification, gel electrophoresis, cloning (plasmids, phage, and cosmids), Southern blotting, restriction mapping, DNA labeling, and hybridization.

Research Assistant, December 1981 - November 1985  
Brown University, Providence, RI  
Thesis Advisor: Dr. William Suggs  
Thesis: Conformational Studies of Poly (dA-dT) and its Phosphorothioate Analogs  
Techniques used: organic synthesis, DNA modification, enzyme assays, protein isolation and purification, DNA purification, gel electrophoresis, multinuclear NMR, UV spectroscopy, DNA-drug binding constant determinations, DNA melting studies, and DNA labeling.

Teaching Assistant and Tutor, 1981 - 1985  
Brown University, Providence, RI  
For courses in organic chemistry and general chemistry

Summer Research Intern, June 1980 - August 1980  
State University of New York at Brockport  
Advisor: Dr. Ingo Peterson  
Synthesis and rearrangement reactions of fluoranthene derivatives

## PUBLICATIONS

DNA Probe Detection of *Eikenella corrodens*, *Wolinella recta*, and *Fusobacterium nucleatum* in Subgingival Plaque, J. Lippke, W. Peros, D. Taylor, M. Keville, F. Raia, and C. French, submitted 1988

Evidence for Sequence-Specific Conformational Changes in DNA from the Melting Temperatures of DNA Phosphorothioate Derivatives, J.W. Suggs and D.A. Taylor, *Nuc. Acids Res.* 1985. 13:5707.

Studies on the Interaction of 3 $\beta$ ,17 $\beta$ -Dipyrandium and DNA Phosphorothioate Derivatives, J.W. Suggs and D.A. Taylor, *FEBS Lett.* 1985, 180:77

## REFERENCES

available upon request

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: 03620  
STATUS CODE: 0  
FEE CATEGORY: 3M  
EXP. DATE: 19920131  
FEE COMMENTS: .....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSER: BIOTECHNICA DIAGNOSTICS, INC.  
RECEIVED DATE: 880726  
DOCKET NO: 3029657  
CONTROL NO.: 109305  
LICENSE NO.: 20-27930-01  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT:                       
CHECK NO.:                     

3. COMMENTS

SIGNED [Signature]  
DATE 8/24/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1.47)

1. FEE CATEGORY AND AMOUNT: 3M \$ 120

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT                       
RENEWAL                       
LICENSE                     

3. OTHER                     

SIGNED [Signature]  
DATE 8/24/88