Journal of Molecular Diagnostics, Vol. 2, No. 4, November 2000

Special Article

The Development of a Post-Baccalaureate Certificate Program in Molecular Diagnostics

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A post-baccalaureate certificate program in diagnostic molecular sciences was created in 1995 by the Diagnostic Genetic Sciences Program in the School of Allied Health at the University of Connecticut. The required on-campus lecture and laboratory courses include basic laboratory techniques, health care issues, cell biology, immunology, human genetics, research, management, and molecular diagnostic techniques and laboratory in molecular diagnostics. These courses precede a 6-month, full-time practicum at an affiliated full-service molecular laboratory. The practicum includes amplification and blotting methods, a research project, and a choice of specialized electives including DNA sequencing, mutagenesis, *in situ* hybridization methods, or molecular diagnostic applications in microbiology. Graduates of the program are immediately eligible to sit for the National Credentialing Agency examination in molecular biology to obtain the credential Clinical Laboratory Specialist in Molecular Biology (CLSp(MB). This description of the University of Connecticut program may assist other laboratory science programs in creating similar curricula. *(J Mol Diag 2000, 2:174–177)*

The need for qualified entry-level technologists to fill positions opening in molecular diagnostics has been apparent since the mid-1980s. The Human Genome Project has characterized several thousand human genes, and genomic sequencing has also been completed for several organisms that cause human disease. Probes and primers for diagnostic testing of infectious disease, inherited disease, and cancer as well as identity determination and transplantation matching have become available as genes are identified and sequenced. There are at least 32 Food and Drug Administration (FDA)-approved/cleared tests for infectious disease and ten FDA approved/cleared tests for human genes.[1,2]

As increasing numbers of molecular tests have become available, demand for technologists with skills in this expanding discipline has followed. Most of the technologists currently performing these tests have been trained on the job, which is both expensive and time-consuming.

In the early 1990s, laboratory science programs began incorporating some molecular lectures or courses into their curriculum; however, formal molecular diagnostics programs were lacking. A task force was created in January 2000 by the National Accrediting Agency for Clinical Laboratory Sciences to study the existing programs with molecular science components to determine essential elements for an accredited program. The task force compiled a list of laboratory science programs with varying degrees of emphasis on molecular science. Of 17 programs in the United States, two in addition to the University of Connecticut's appear to have a sufficient practicum component to qualify students to sit for the credentialing examination. Three laboratory science programs have expanded their curricula to include molecular diagnostics as a separate major or track, but they do not offer 6-month laboratory practica. Australia has two programs with emphasis in molecular methods,[3] and two cytogenetics programs in Canada recently changed their curricula to include substantial coursework in molecular diagnostics, including a practicum of less than 6 months.[4]

The University of Connecticut Program

History

Since the mid-1980s, laboratory professionals have shown interest in becoming proficient in the rapidly expanding field of molecular diagnostics. In response, the Program Director of the Diagnostic Genetic Sciences (DGS) Program at the University of Connecticut recruited a faculty member to create the first post-baccalaureate

Funded in part by the Yankee Ingenuity Initiative/Elias Howe Grant through Connecticut Innovations, Inc.

Accepted for publication September 6, 2000.

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certificate program in molecular diagnostics to include a required full-time, 6-month practicum component.

To be sure that needs of potential employers were met, a questionnaire was sent in 1994 to 50 laboratories in the Northeast that performed molecular tests. The survey listed topics and skills in molecular diagnostics and asked recipients to indicate whether or not an entry level technologist should know each of them. The topics and skills most frequently identified as important included *in situ* hybridization, polymerase chain reaction (PCR), reverse transcriptase PCR, restriction fragment length polymorphism, DNA isolation, Southern blot, Northern blot, B and T lymphocyte gene rearrangement analysis, Fragile X detection, infectious disease hybridization assays, recombinant DNA procedures, and sister chromatid exchange assay. The range of testing offered by the laboratories varied tremendously. Some performed exclusively forensic science, others exclusively cancer research; some did primarily infectious disease testing, others genetic pre- and/or post-natal testing. Some content areas were identified as common to most of the laboratories, however. The on-campus didactic and laboratory courses and the required practicum developed by the DGS faculty were designed to meet these more general needs. Other, more specific content was performed by a minority of laboratories. The elective practicum courses were designed to meet these more particular needs and to allow students to pursue specific areas of interest.

Laboratory space and equipment to perform molecular testing was obtained via funding from Victoria C. and Henry W. Nozko, Sr. and a Yankee Ingenuity Initiative/Elias Howe Grant funded by the State of Connecticut (Strasbaugh L, Williams GS: Establishment of a DNA identification diagnosis training facility. Grant 95H034, Connecticut Innovations, Inc., 1995). These funds provided for the construction of two student laboratories in the School of Allied Health: a PCR laboratory and a chromosome imaging laboratory that includes a darkroom and space for fluorescence *in situ* hybridization (FISH). The grant provided equipment and supplies for two new student laboratory courses in molecular genetics: an introductory human genetics laboratory course offered by the Department of Molecular and Cell Biology and an advanced laboratory course in molecular diagnostics offered by the Diagnostic Genetic Sciences Program in the School of Allied Health.

The Faculty

The Diagnostic Genetic Sciences Program faculty consists of three individuals: the Program Director, who is certified in cytogenetics Clinical Laboratory Specialist in Cytogenetics (CLSpCG) and cytology (CT American Society of Clinical Pathology (ASCP)), a half-time faculty member certified in medical technology (MT(ASCP)) and specialty in blood bank (SBB(ASCP)), and a full-time faculty member certified in cytogenetics (CLSpCG) and molecular biology (CLSpMB). Faculty are prepared at the master's or doctorate level.

Table 1. Plan of Study

- First semester (15 credit hours of required courses)
  - Human Genetics (3 credits)
  - Basic Laboratory Techniques in Medical Laboratory Sciences (3 credits)
  - Health Care Issues for the Health Professional (3 credits)
  - Management for the Health Professional (3 credits)
  - Cell Biology (3 credits)
- Second semester (15 credit hours of required courses)
  - Research for the Health Professional (3 credits)
  - Immunology for the Medical Laboratory Sciences (3 credits)
  - Diagnostic Molecular Technologies (3 credits)
  - Laboratory in Molecular Diagnostics (2 credits)
- Recommended electives:
  - Medical Cytogenetics (4 credits)
  - Developmental Biology (3 credits)
  - Biochemistry (4 or 5 credits)
  - DNA Identification (2 credits)
- Third semester (practicum; 15 credit hours of required courses)
  - Blotting Methods (6 credits)
  - Amplification Methods (6 credits)
  - Research in Molecular Genetics (1 credit)
- One of the following electives:
  - Topics in Molecular Genetics (2 credits)
  - Mutagenesis (2 credits)
  - DNA Sequencing (2 credits)
  - Molecular Diagnostic Applications in Microbiology (2 credits)
  - *In Situ* Hybridization Methods (2 credits)

Admission Requirements

Applicants to the Molecular Diagnostic Sciences (MDS) certificate program must have earned a baccalaureate degree in biology, cytogenetics, medical technology/clinical laboratory science, or a related area with prerequisite coursework in microbiology, biochemistry, and statistics.

Curriculum

The curriculum consists of various courses currently available in the School of Allied Health or elsewhere at the University of Connecticut, plus newly developed courses in molecular diagnostics. Table 1 shows the typical plan of study for the MDS Certificate Program. The former includes Allied Health core courses, required of all students in the School of Allied Health (Research for the Health Professional, Health Care Issues for the Health Professional, and Management for the Health Professional). Specific core medical laboratory sciences courses are required of all students in the laboratory disciplines offered at University of Connecticut (Basic Laboratory Techniques for the Medical Laboratory Sciences and Immunology for the Medical Laboratory Sciences). Also required are courses in Human Genetics and Cell Biology, both offered by the Department of Molecular and Cell Biology.

Survey responses were used to help develop the on-campus and practicum courses in molecular diagnostics. Additional topics were added as the field of molecular

medicine evolved and more sites offering a broader range of tests became available for our practicum students. The on-campus lecture courses cover molecular methods of diagnosing infectious disease, hematological malignancy, solid tumors, inherited genetic disease and human identification used in forensics and tissue typing for transplantation medicine. The specific methods covered are DNA and RNA extraction methods, *in situ* hybridization (ISH) protocols including FISH, mutation scanning and screening methods, PCR, reverse transcriptase PCR, ligase chain reaction, transcription mediated amplification, branched DNA, and mutagenesis techniques.

The following procedures are completed in the on-campus student laboratory: DNA extraction using organic solvents, salt precipitation, and chelation methods; mononuclear cell enrichment by density gradient centrifugation; FISH with three types of probes; B and T lymphocyte gene rearrangement by Southern analysis; PCR for D1S80; and restriction fragment length polymorphism (RFLP) analysis of mock crime scene evidence.

The required practicum courses are Amplification Methods, Blotting Methods, and Research in Molecular Genetics. All students are encouraged to submit their research for the Association of Genetic Technologists (AGT) Annual Student Research Award Competition. In 1999, a Molecular Diagnostic Sciences student from the University of Connecticut became the first molecular student to win that competition with a paper titled "Detecting Aneuploidy: Comparison of Primed *in situ* Labeling (PRINS), Fluorescence *in situ* Hybridization (FISH) and Chromosome Analysis."

All MDS students must also take one elective course while on practicum. Current electives courses include *In Situ* Hybridization Methods, Mutagenesis, Microbiology Applications of Molecular Diagnostics, DNA Sequencing, and Topics in Molecular Genetics.

To meet these curricular requirements, students typically complete two semesters on campus followed by a 6-month practicum in one or more molecular laboratories, gaining extensive hands-on experience. The program matriculates students twice a year, in September and January. Upon completion of the program, students are qualified to take the National Credentialing Agency (NCA) certification examination in Molecular Biology. The NCA examination has been taken by 13 of the 16 eligible graduates and 12 (92%) of University of Connecticut graduates have passed on the first try; the national pass rate is 72%.[5–7]

The Student Population

Students enter the MDS certificate program after having earned a baccalaureate degree in a laboratory science, biology, or a related subject area. Though it had been expected that most students would be biology majors with limited job opportunities, this proved not to be the case. Eighteen of the 27 total students enrolled in the program since its inception were graduates of the undergraduate or certificate programs in Diagnostic Genetic Sciences at the University of Connecticut. Although the DGS curriculum emphasizes classical cytogenetics, it also includes all of the required on-campus coursework of the MDS curriculum. Therefore, DGS students are able to complete the MDS program by completing the 6-month practicum in molecular diagnostics. These students can become dual-certified in cytogenetics and molecular biology, increasing their job flexiblity. Two additional students have degrees in Medical Technology, and one is a medical laboratory technician who was also graduated from the DGS undergraduate program. These students are able to become dual- or even triple-certified.

The first student matriculated into the MDS certificate program at the University of Connecticut in the Fall of 1995. Since then, 22 additional students have completed the program. The class size has increased from one in the first class to five in the class that matriculated in the Fall of 1999. Class size was initially limited to four students each semester, based on the availability of affiliation sites. With the addition of new practicum sites, the class capacity is now eight per semester. The number of affiliated practicum sites remains a limiting factor for enrollment.

The Practicum Sites

Practicum sites are all in the United States; most are in the Northeast (one in Colorado, five in Connecticut, and two each in Massachusetts, Montana, New York, Ohio, Pennsylvania, and Virginia). Each site conducts a different battery of tests with emphasis on different disciplines. Affiliated laboratory sites must perform at least Southern blot analysis and standard PCR, and must be prepared to offer the student a hands-on research project, in order to be a full-service practicum site. Two sites currently offer elective courses only.

New Directions

This academic year the DGS faculty, with the assistance of its advisory board, will be developing an undergraduate individualized major with a plan of study in molecular diagnostics. Students choosing this major will graduate from the University of Connecticut with a Bachelor of Science degree with an Individualized Major in Molecular Diagnostics. The upper division plan of study will include all courses required for the MDS certificate program, with additional courses from the DGS program and Molecular and Cell Biology Department or other units on campus. Graduates will be eligible to take the NCA examination in Molecular Biology immediately upon graduation.

Conclusion

Beginning in the Fall of 1995, students with baccalaureate degrees in the medical laboratory sciences, biology, or related fields and who have strong science backgrounds have had an opportunity to enroll in a post-baccalaureate certificate program in molecular diagnostics that includes a full-time, 6-month practicum

experience. During the subsequent four years, 23 students have completed the program, and two more will be entering in the Spring of 2000. Fifteen graduates work as technologists in molecular laboratories or perform molecular-related work in clinical laboratory settings or at biotechnology companies. Five of the dual-certified graduates are working in cytogenetics laboratories where they perform FISH or design DNA probes for FISH. A few of the graduates have chosen to seek graduate degrees or work in research laboratories. It is hoped that the University of Connecticut program will serve as a model for others wishing to establish programs of study in molecular diagnostics.

References

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