





Histocompatibility Fellowship Histocompatibility & Immunogenetics Laboratory Department of Pathology and Laboratory Medicine

Director Training Program

<u>GOALS</u>

- 1. To provide intensive didactic and technical training in the field of histocompatibility testing and transplant immunology.
- 2. To provide the fellow with the knowledge and skills to assume an HLA Laboratory Director position.
- 3. To prepare the fellow for certification examination by the American College of Histocompatibility and Immunogenetics (ACHI).
- 4. To prepare the fellow for certification by the American Society of Histocompatibility and Immunogenetics (ASHI) Director Training Review Committee (DTR).
- 5. To involve the fellow in research projects relevant to clinical applications of Immunogenetics and histocompatibility.

DURATION

This is a two year ASHI certified training program.

ELIGIBILITY

The fellow must have earned an MD or a PhD in immunology, genetics or related biological science from an accredited institution. Two years post-doctoral fellowship in immunology is preferable.

CURRICULUM

First Year

The first year will emphasize the technical aspects of histocompatibility testing and transplant immunology. On-the-bench training will be provided in each area of the laboratory testing. The fellow will be expected to keep a log of all testing performed and will be certified as competent to perform a task through the Alberta Precision Laboratories, HIL Master Training System when training is successfully completed. Monthly reports will be made to document short-term goals and accomplishments.

The fellow will meet monthly for one hour with the laboratory director to review the training progress, address any concerns and allow time for feedback.

The training will consists of the following components for each rotation:

- 1. **Didactic** Reading and discussing principles and concepts of procedures; mini tutorials with the laboratory director and supervisor; attending journal clubs, seminars, conferences.
- 2. **Practical** Performing the procedures, documentation of tests performed, successful mastery of all tasks outlined in the manual.
- Quality Assurance (QA) Understanding what quality control (QC) is necessary for each test performed, why it is done and actual performance of the QC when possible. Understanding the measures instituted by the laboratory to monitor QA.
- 4. Interpretation and Application Interpretation of results, troubleshooting and uses for the tests.

Orientation and Clinical Rotations

- Meet with the Department Head Administrative Assistant
- Meet with the Histocompatibility and Immunogenetics Laboratory (HIL) Administrative Assistant
- Meet with the Laboratory Director and Supervisor (review of training plan)
- Meet with the Section Manager & Supervisor
- APL HR general rotation (confidentiality, corporate, etc.)
- APL Safety Training
- LIS Training (HistoTrac, Millennium, Connect Care and CBS CTR)
- Receiving and Accessioning 2 weeks
- Luminex Antibody bench
- Flow based assays (Flow Crossmatch)
- Molecular assays (DNA/SSO/SSP/NGS)
- 1 month (during quarterly renal testing)
- 1 month 4 months

Research and Development Projects – Two years

The fellow may take on special clinical laboratory projects as assigned by the clinical director. These can include conducting a demo of a new test, correlation of two tests, generating QA trends, etc.

Rotations in affiliated transplant programs

- BMT transplant (MUD Searches)
- Molecular hematology

- 1 day 1 week
- Extra renal rotation (Edmonton Lab), pending funding 2 weeks

<u>Note</u>: The above training components are not necessarily received sequentially. Additional training is available during the second year. The time allocated for each bench may be extended or shortened at the discretion of the laboratory supervisor and laboratory director. The fellow will be put on rotations that accommodate the different components of the training.

Second Year

The second year of training will concentrate more on the director's responsibilities and management skills. At this time, the trainee may be placed on the On-Call schedule for donor workups. The following components will be stressed during the second year of training:

- 1. Review of worksheets and co-signing reports
- 2. Review of proficiency testing results; documentation of corrective actions
- 3. Analysis of HLA antibody screens and antibody identification
- 4. Review and analysis of tray QC; using information obtained in interpretation of results
- 5. Research and development projects
- 6. Developing management skills and nurturing "team spirit" within the laboratory
- 7. Completion of portfolio for documentation of training
- 8. Preparing for ASHI DTR oral examination
- 9. Preparing for ACHI Director's examination
- 10. Training in newly added method or technology as needed
- 11. Special projects

DOCUMENTATION OF TRAINING EXPERIENCE

The fellow will be required to document his/her training as per ASHI DTR requirement (<u>www.ashi-hla.org</u>), by maintaining a case book of personally studied patient work-ups and follow-up studies that include demographic, pre- and post-transplant clinical information, serum screening analysis, crossmatching evaluations, HLA typing and antigen/haplotype matching, any other patient data (i.e. transplant biopsy data), appropriate literature references, and the program director's signature. The case book will also include retrospective review of previously transplanted deceased and living donors. The fellow's case book is expected to include review of the following:

- Deceased renal transplants, including as many recipients of different ethnic groups as possible
- Living related renal transplants of different ethnicity (with haplotype analysis)
- HSC/BM transplantation: Related donor
- HSC/BM transplantation: Unrelated donor

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 Cases of Non-transplant clinical purposes (i.e. HLA Disease Association and Pharmacogenetics)

Test performance will be documented for:

Provide a listing of cases reviewed by the applicant for each technology using the ASHI template. Include a brief description of the case or reference the case from a category of testing where the technology is used:

- Solid phase methods
- Molecular methods
- Flow cytometry

<u>Note</u>: At least 5 of the cases will be completed in the first year of training. The confidentiality of the patients must be protected.

SPECIFIC CURRICULUM

I. Flow Cytometry

- A. Practical
 - 1. Instrument set-up and calibration
 - 2. Source, type and use of reagent antibodies (monoclonals)
 - 3. Data acquisition
 - Test methodologies
 - Analysis on the flow cytometer
 - Proper gating parameters
 - 4. Data analysis
 - Proper interpretation
 - Clinical correlation
 - Troubleshooting
- B. Quality Control
 - 1. Machine maintenance and operation
 - 2. Reagent QC
- C. Application
 - 1. Flow cytometric crossmatch
 - Selection of positive and negative controls
 - Interpretation of negative control values
 - Establishment of "cut-off"
 - Interpretation of positive crossmatch T and/or B cell reactions

II. DNA Technology

- A. Practical
 - 1. SSO method
 - 2. SSP method
 - 3. NGS Method
- B. Quality Control (QC)
 - 1. Reagent QC
 - 2. Equipment QC and maintenance
 - 3. Wipe test
- C. Application
 - 1. Use of DNA typing in bone marrow transplantation
 - 2. Use of DNA typing in solid organ transplantation
 - 3. Disease associations with HLA Class I and Class II alleles
 - 4. Pharmacogenetics

IV. Management

The fellow will be given basic management principles together with specific skills unique to histocompatibility and transplantation laboratories. These skills will be learned by a combination of the following means:

- Attending selected management meeting
- Participating in daily problem solving in laboratory
- Attend and participate in weekly laboratory meeting with technologists, supervisor, lab manager and director.
- Reading of training manuals
- Attending management seminars and workshops (APL, ASHI, AFDT, UofC)
- Rotating in pertinent APL departments (i.e. purchasing, finance, HR)

The following topics are incorporated in the training via reading and by attending workshops:

- A. Regulations and standards governing histocompatibility laboratories in Canada and US.
 - 1. Inspections and accreditations (CPSA, ASHI)
 - 2. WHMIS standards
 - 3. CBS LDPE and HSP protocols
 - 4. HIPPA and OSHA standards
 - 5. ESRD regulations, fee schedules, cost reports
 - 6. Federal and Provincial regulations (HOPE, CST, CBS)
 - 7. Legal/professional liability
- B. Accounting principles applied to the laboratory
 - 1. Budget preparation and monitoring
 - 2. Developing charges, cost accounting, billing
 - 3. Computer break-even point (BEP)

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- C. Personnel Management
 - 1. Recruitment, salaries and fringe benefits
 - 2. Defining job descriptions, objectives, responsibilities
 - 3. Training and continuing education
 - 4. Personnel evaluations
- D. Laboratory organization and management principles
 - 1. Developing structure and lines of authority
 - 2. Logistics of laboratory operation-laboratory organization
 - 3. Inventory and ordering
 - 4. Evaluation of laboratory efficiency, distribution of workload
 - 5. Evaluation of workload and turnaround time

V. Research

The fellow is supposed to engage in research projects throughout the training period. The research activities should not interfere with bench training and should be conducted after 3:30 pm and on weekends. These projects are related to transplant immunology, immunogenetics and histocompatibility. The fellow is encouraged to present his/her data in national and international meetings. There will be APL allowance to cover the cost of one meeting per year.

REGULARLY SCHEDULED LECTURE AND MEETINGS

Transplant Rounds- Weekly (1½ hrs). Review of cases by transplant surgeons, nurses, pathologists, social workers and other transplant professionals. These cases consist of kidney and/or pancreas recipients.

Bone Marrow Meeting – Once weekly (1hr). Review of potential autologous and allogenic peripheral stem transplant patients by the transplant team at the Tom Baker Cancer Centre. These patients include individuals with CML, ALL, MM, NHL, PLL.

Lab Weekly Meeting – Once weekly (1hr). Review of lab business on a weekly basis.

QA/QI Monthly Meeting- Once monthly (1 ½ hrs). Review of monthly QA variances, approve initiation of QI programs, follow trends and update QA indicators.

Test Results Review – Daily (45 mins). The fellow will discuss the results of clinical typing with the laboratory director and/or laboratory supervisor.

Research Meeting – Once a week (1hr). The fellow will meet with the director to discuss the progress of the research projects.

Quarterly Research and Development Progress Meeting – Once every three months (2hrs). Fellow meets with the director to review participation in research projects, scientific presentations, publications, and grant proposal writing.

Alberta Transplant Institute - Once weekly (1hr). Seminar covering different aspects of transplantation.

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CONTINUING EDUCATION

Georgetown Histocompatibility Teleconference CST Annual Meetings ASHI Annual Meetings ASHI Regional Workshops AFDT Courses American Transplant Congress ASH Annual Meetings ARSHI Webinars

PROGRAM DIRECTOR AND OTHER PERSONNEL

Noureddine Berka, PhD., D(ABHI) is the Clinical Director of the Alberta Precision Laboratories Histocompatibility and Immunogenetics Laboratory and is the head of the Histocompatibility and Immunogenetics Training Program. Dr. Berka will supervise the progress of the fellow and provide didactic instruction. He will work with the fellow in developing interpretative skills and troubleshooting problems. He will also serve together with other scientists as a scientific mentor for the fellow.

Faisal Khan, Ph.D., D(ABHI), will co-train the fellow and serve as a co-scientific mentor, providing guidance on specific histocompatibility research projects and help him sharpen his/her writing and publication skills. Dr. Khan will also provide the fellow with a rotation in STR chimerism.