

AMERICAN BOARD OF HISTOCOMPATIBILITY AND IMMUNOGENETICS
Laboratory Director
Content Outline

1. Administration and Management (40 Items)

A. Quality Assurance (16 items)

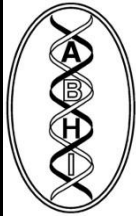
1. Determine if technical staff has received training and continuing education
2. Select external laboratory proficiency testing programs or develop alternatives
3. Develop quality assurance programs (e.g., appropriateness of work, timeliness of work)
4. Monitor quality assurance program (e.g., monitor quality indicators)
5. Evaluate competency of laboratories used for referral testing
6. Monitor test utilization
7. Review test results for accuracy and completeness
8. Review safety requirement procedures followed when hazardous conditions occur (e.g., biological, chemical, fire, disaster)

B. Fiscal Management (8 items)

1. Allocate staff and resources
2. Justify new and existing staff positions
3. Consult with administrative personnel on laboratory procedures (e.g., accounting, billing, purchasing)
4. Develop laboratory budget
5. Develop fee structure for laboratory services
6. Develop laboratory cost containment measures
7. Evaluate testing procedures considering cost/benefit criteria
8. Monitor laboratory budget
9. Negotiate contracts
10. Negotiate personnel salaries and benefits
11. Negotiate for laboratory equipment and facilities
12. Negotiate resources for laboratory programs
13. Develop fee structure for research testing

C. Personnel Management (8 items)

1. Assign all duties and responsibilities of consultants, supervisors, and technologists
2. Authorize or conduct personnel actions:
 - a. classification decisions
 - b. employee selection (e.g., interview, application review, reference checks)
 - c. grievance procedures
 - d. performance evaluations
 - e. performance feedback
 - f. promotions
 - g. qualification determination
 - h. salary determination
 - i. transfers
 - j. terminations
3. Follow institutional guidelines on counseling personnel on personal or interpersonal problems

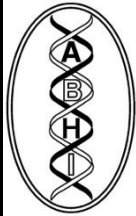


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4. Determine administrative actions to be taken from proficiency testing results
5. Develop standards of performance for laboratory personnel
6. Develop job descriptions
7. Develop workload indicators
8. Direct staff compliance with all federal, state, and local safety laws and regulations
9. Evaluate competency of laboratory personnel:
 - a. assess performance of duplicate testing
 - b. assess performance of blind testing
 - c. assess performance of equipment maintenance procedures
 - d. assess problem solving skills
 - e. monitor recording of test results
 - f. observe test performance
 - g. review worksheets
10. Evaluate staff knowledge of all federal, state, and local safety laws and regulations
11. Monitor workload indicators
12. Prevent unauthorized deviations from established laboratory procedures
13. Monitor internal and external work standards and regulations

D. Laboratory Operations (8 items)

1. Approve source of all reagents
2. Authorize a staff member to approve test reports
3. Authorize a staff member to release (sign) test reports
4. Determine if established protocols are being followed
5. Authorize deviations from established procedures, processes, and protocols when clinically indicated
6. Develop protocols for specimen collection and handling (including rejection criteria)
7. Develop protocols for collection, organization, and systematic retrieval of all test results
8. Develop or implement protocols and systems for safe handling, storage, and disposal of biological, chemical, and radioactive materials in compliance with governmental safety requirements
9. Develop procedures for laboratory test reporting to establish information to include on reports
10. Develop procedures for laboratory test reporting to determine when interpretive notes are necessary
11. Develop and maintain policy/protocol manual
12. Direct the implementation of necessary remedial actions when test results do not meet established limits of accuracy
13. Monitor remedial actions for effectiveness
14. Direct laboratory compliance with regulatory agencies
15. Evaluate equipment, personnel, and space requirements for reliable test performance



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16. Direct implementation of institutional policy and programs
17. Maintain effective working relationships (e.g., interact with accrediting agencies, administrative officials, citizens groups, medical community, organ procurement organizations, regulatory agencies)
18. Maintain knowledge of professional liability and risk management issues
19. Participate in meetings with clinical teams
20. Plan short-term and long-term laboratory objectives
21. Investigate and resolve client complaints
22. Serve as managerial resource
23. Supervise laboratory equipment maintenance
24. Supervise laboratory staff
25. Supervise the reporting of all laboratory results
26. Ensure laboratory compliance with laws regarding protected health information

2. Clinical Functions (65 Items)

A. Interpretation of Results (22 items)

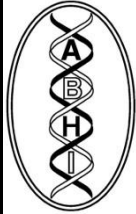
1. Analyze immunologic risk factors for transplantation
2. Interpret and evaluate test results according to the clinical application
3. Interpret individual test results for correlation with clinical outcome
4. Define appropriate resolution of HLA type for clinical application
5. Provide interpretive notes for laboratory test reports
6. Review and sign test reports

B. Provide Consultation (22 items)

1. Consult with medical services regarding testing needs
2. Provide consultation to clinical teams in the areas of:
 - a. histocompatibility (including donor selection)
 - b. immunogenetics (including disease association, pharmacogenomics)
 - c. transplantation (including post-transplant monitoring)
3. Provide consultation to clinical teams on the interpretation of test results
4. Provide consultation on appropriateness of tests and results to interested parties (e.g., attorneys, parents, patients, other clients)
5. Provide consultation on alloantibody amelioration or avoidance
6. Serve as clinical resource

C. Correlative Functions (11 items)

1. Evaluate impact of HLA typing and histocompatibility testing on:
 - a. disease diagnosis
 - b. therapeutic regimens
 - c. immune status (including graft versus host disease, chimerism, etc.)
 - d. familial relationships
2. Evaluate impact of patient disease status, therapy, and immune status on laboratory test results
3. Evaluate potential for hyperacute and accelerated rejection
4. Evaluate donor and recipient histocompatibility



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5. Evaluate prior sensitization of transplant recipient for clinical relevance
6. Evaluate clinical significance of pre-existing and de novo auto- and allo-antibodies
7. Correlate histocompatibility data with other laboratory tests, and clinical and pathologic findings (e.g., cytogenetics, hematology, histology of biopsies)
8. Verify test validity and accuracy of interpretation by establishing parameters for test results

D. Development of Clinical Testing Protocols (10 items)

1. Establish a process for developing and maintaining clinical testing protocols
2. Determine patient information to be provided to laboratory
3. Determine the appropriate selection of tests with clinical teams for various clinical applications
4. Determine appropriate specimen source and frequency of collection and testing
5. Develop pre- and post-transplant testing protocols
6. Select tests to best meet clinical needs of patient population served by laboratory

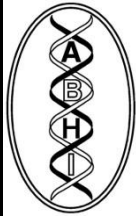
3. Technology Development and Implementation (48 Items)

A. Development of Tests (16 items)

1. Evaluate new laboratory procedures for clinical utility
2. Select methods for test performance
3. Determine specimen requirements for specific tests
4. Select equipment for test performance
5. Select test reagents
6. Develop appropriate controls for each test
7. Develop testing procedures for special conditions/samples (e.g., abnormal blood profiles)
8. Establish criteria for acceptance of a test run
9. Develop follow-up procedures for test failures
10. Modify laboratory processes to accommodate changing clinical needs
11. Serve as a technical resource

B. Verification of Tests (17 items)

1. Develop quality control procedures to ensure reported test results are within established limits of accuracy
2. Develop equipment performance verification procedures
3. Review quality control data (e.g., reagents, equipment function and calibration)
4. Monitor test results for effectiveness of quality control procedures
5. Analyze clinical data to evaluate utility of test methods (e.g., graft outcome for transplantation, efficiency of drug protocols)
6. Determine actions to be taken after review of equipment verification, quality control data, and test results
7. Identify limitations of the tests employed in the laboratory



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C. Implementation of Tests (15 items)

1. Develop, approve, and maintain all technical procedures
2. Validate and approve changes in technical procedures
3. Develop procedures for equipment operation
4. Establish normal ranges for test results
5. Monitor clinical data for ongoing evaluation of the utility of test methods

4. Educational Activities and Professional Growth (14 Items)

A. Education of Healthcare Professionals (5 items)

1. Conduct seminars in histocompatibility and immunogenetics for healthcare professionals
2. Develop and implement training programs for practicing and in-training healthcare professionals (e.g., laboratory staff, coordinators, students, residents, fellows)
3. Develop and implement orientation and training programs for laboratory personnel (e.g., histocompatibility testing, quality control of tests and reagents, preventative maintenance of equipment, safety measures, waste disposal)
4. Develop in-service education program for laboratory staff
 - a. general knowledge
 - b. application of laboratory techniques in clinical medicine
 - c. scientific basis of laboratory techniques
 - d. laboratory policies
5. Evaluate training and continuing education needs of clinical and technical staff
6. Select educational materials for use by laboratory staff (e.g., books, journals, web sites, teleconferences, podcasts)
7. Provide instruction to administrative personnel regarding billing and reimbursement

B. Education of General Public (4 items)

1. Develop educational materials for the public
2. Develop outreach programs and increase awareness of histocompatibility testing

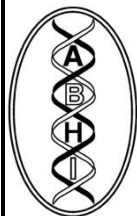
C. Professional Growth (5 items)

1. Evaluate training and continuing education needs of self
2. Participate in immunology, immunogenetics, and transplantation continuing education (e.g., meetings, workshops, teleconferences, online resources)
3. Maintain currency with HLA nomenclature
4. Maintain currency with professional literature
5. Maintain currency with federal and state regulations

5. Scientific Principles (33 Items)

A. Application of Basic Science (17 items)

1. Evaluate basic science research as to its clinical relevance
2. Serve as scientific resource
3. Apply basic science to the solution of clinical problems
4. Evaluate non-HLA antigens for their potential to act as histocompatibility antigens



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B. Clinical Ramifications (9 items)

1. Analyze histocompatibility and immunogenetics testing in the context of:
 - a. solid organ transplants
 - b. bone marrow transplants
 - c. disease association
 - d. platelet transfusion support
 - e. antibody amelioration
 - f. TRALI
 - g. Pharmacogenomics
2. Evaluate diagnostic performance of new technology

C. Research 7 items)

1. Develop or collaborate on clinical, basic, and translational research projects (e.g., HLA and disease associations, immune phenotyping, development of new methodologies)
2. Develop innovative laboratory tests
3. Enhance performance characteristics of current laboratory tests
4. Identify and adapt methodologies from other disciplines to histocompatibility and immunogenetics testing applications
5. Participate at national or international histocompatibility meetings and workshops (e.g., present research findings)
6. Write scholarly articles, book chapters, grant proposals, etc.