

**American Board of
Histocompatibility
and Immunogenetics**

**Candidate
Handbook**

Effective January 2009

CHA

Certified Histocompatibility Associate

CHT

Certified Histocompatibility Technologist

CHS

Certified Histocompatibility Specialist

Diplomate

Histocompatibility Laboratory Director

**THE HISTOCOMPATIBILITY LABORATORY DIRECTOR EXAM WILL BE
OFFERED IN 2009.**

American Board of Histocompatibility
and Immunogenetics
P.O. Box 19173
Lenexa, KS 66285-9173
913/895-4602
Fax: 913/895-4652
www.ASHI-HLA.org/ABHI



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All questions and requests for information about the ABHI examination program should be directed to:

American Board of Histocompatibility and Immunogenetics
P.O. Box 19173
Lenexa, KS 66285-9173
913/895-4602
www.ASHI-HLA.org/ABHI

All questions and requests for information about examination scheduling should be directed to:

Applied Measurement Professionals, Inc.
18000 W. 105th Street
Olathe, KS 66061-7543
Voice: 913/895-4600
Fax: 913/895-4650
Website: www.goAMP.com



INTRODUCTION

The American Board of Histocompatibility and Immunogenetics (ABHI) is a certifying board offering voluntary credentialing examinations in the field of histocompatibility and immunogenetics.

This Candidate Handbook was developed to assist you in preparing for the Certified Histocompatibility Associate (CHA), Technologist (CHT), Specialist (CHS) and Histocompatibility Laboratory Director examinations. These examinations are based on the content outlines developed from a national job analysis that identified tasks that are significant to the practice of histocompatibility associates, technologists, specialists and laboratory directors nationwide.

This handbook provides information about the examination and application process for the ABHI Examinations. It outlines the design and content of the examination and guides candidates throughout the entire examination process from application through test taking. For your convenience, this handbook may also be downloaded from ABHI's website, located at www.ashi.hla.org/abhi.

INDEPENDENT TESTING AGENCY

ABHI has contracted with Applied Measurement Professionals, Inc. (AMP) to assist in the administration and scoring of the examinations. AMP, located in the greater Kansas City area, is a leading provider of licensing and certification examinations for professional organizations.

NONDISCRIMINATION POLICY

ABHI and AMP do not discriminate among candidates on the basis of race, color, creed, gender, religion, national origin, disability or marital status.

ELIGIBILITY REQUIREMENTS

Applicants must meet the eligibility requirements and provide all supporting documentation for the requested examination as stated in the ABHI application form to gain admission to an examination.

■ Eligibility Requirements for Certified Histocompatibility Associate (CHA)

1. Completion of 24 hours of college level coursework from an accredited college or university in chemical, physical, biological or clinical laboratory science courses (qualifying courses can include general biology, immunology, zoology, genetics, biochemistry, physiology and clinical laboratory science). A minimum

of 6 semester hours of chemistry and 6 semester hours of biology will be required within the 24 hours. Official transcripts will be required to document completed coursework.

2. In addition to the education requirements, the applicant must have a least two year's documented* relevant full-time work experience in an approved ** laboratory performing histocompatibility testing. The two years of experience must be completed within five years of the application date and by the last day of the month in which the examination is given.

* Documentation of histocompatibility work experience must be in the form of a statement of competency or a letter from the laboratory director verifying length of time in histocompatibility testing and detailing actual work performed with a brief description of the procedures used. This letter must be signed by the lab director.

** An approved histocompatibility laboratory must be an ASHI/UNOS- or EFI -accredited laboratory. An applicant with insufficient work experience in an ASHI/UNOS or EFI-accredited laboratory can petition to sit for the examination through the SPONSORSHIP route. However, a minimum of two year's of relevant work experience is still required.

■ Eligibility Requirements for Certified Histocompatibility Technologist (CHT)

1. A baccalaureate degree in chemical, physical, biological or clinical laboratory science from an accredited college or university or possess a baccalaureate degree with at least 24 semester hours of science courses that include – (i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination. Please submit official transcripts documenting completed coursework.

2. In addition to the education requirements, the applicant must have at least one year's documented* relevant full-time work experience in an approved** laboratory performing histocompatibility testing. This year of experience must be completed within five years of the application date and by the last day of the month in which the examination is given.

* Documentation of histocompatibility work experience must be in the form of a statement of competency or a letter from the laboratory director verifying length of time in histocompatibility testing and detailing actual work performed with a brief description of the procedures used. This statement or letter must be signed by the lab director.

** An approved histocompatibility laboratory must be an ASHI/UNOS- or EFI-accredited laboratory. An applicant with insufficient work experience in an ASHI/UNOS- or EFI-accredited laboratory can petition to sit for the examination through the SPONSORSHIP route. However, a minimum of one year of relevant work experience is still required.



■ Eligibility Requirements for Certified Histocompatibility Specialist (CHS)

1. A baccalaureate degree in chemical, physical, biological or clinical laboratory science from an accredited college or university or possess a baccalaureate degree with at least 24 semester hours of science courses that include – (i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination. Please submit official transcripts documenting completed coursework.
2. At least five year's documented,* relevant full-time work experience in an approved** laboratory performing histocompatibility testing. This experience must be completed within 10 years of the application date and prior to the date of examination.

*Documentation of histocompatibility work experience must be in the form of a statement of competency or a letter from the laboratory director verifying length of time in histocompatibility testing and detailing actual work performed with a brief description of the procedures used. This letter must be signed by the lab director.

**An approved histocompatibility laboratory must be an ASHI/UNOS- or EFI-accredited laboratory. An applicant with insufficient work experience in an ASHI/UNOS- or EFI-accredited laboratory can petition to sit for the examination through the SPONSORSHIP route. However, a minimum of five years relevant work experience is still required.

OFFICIAL DOCUMENTS: CHA, CHT AND CHS

1. An **OFFICIAL TRANSCRIPT(S)** bearing the seal and signature of the registrar from the college or university conferring degree(s)*. If your transcript is being sent directly to ABHI, please indicate this in the appropriate box in section 1. All transcripts **MUST** be received prior to the completion deadline. All applicants will be required to submit official transcripts whether or not they have previously attempted the examination.
2. Documentation of histocompatibility work experience with a Laboratory Director's signature.
3. **APPLICATION STATEMENT:** The statement at the end of this application must be completed and submitted for the application to be valid. Any application submitted without the completed statement will be returned without evaluation.
4. Detailed sponsorship letter, if appropriate.

*Foreign Education: If a candidate is basing his/her eligibility on a degree or courses from a foreign university, the official transcript or copy must first be evaluated by the International Education Research Foundation, Inc., P.O. Box 3665, Los Angeles, California 90231-3665, (310) 258-9451, FAX (310) 342-7086. The detailed course by course evaluation must be submitted with the application for the certification examination.

■ Eligibility Requirements for Histocompatibility Laboratory Director

Earned doctoral degree (PhD) in a biological science or have a medical degree (MD, DO).

In addition to the education requirements, the applicant must have:

1. Have at least 2 years full-time post-doctoral laboratory training or experience in immunology, histocompatibility, immunogenetics, or a related field or a residency in clinical and/or anatomic pathology or other related medical specialty and have at least 2 years full-time post-doctoral training in directing or supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory. **Reference letters documenting the level of clinical involvement are required.**
2. If the applicant has relevant pre-doctoral experience supervising high complexity testing in human histocompatibility and immunogenetics in an ASHI-accredited or approved laboratory, this may be credited at a rate of 0.5 years of post-doctoral training per each year of appropriate pre-doctoral experience up to a total of 2 of 4 years of post-doctoral experience. **Reference letters documenting the level of clinical involvement are required.**

Candidates who have received medical postdoctoral training may substitute training in certain specialties to offset a portion of the postdoctoral experience in immunology. For example:

- a. One year equivalent to training received in transfusion medicine/blood bank and clinical immunology/infectious disease serology.
- b. Six months equivalent to training in allergy/immunology and rheumatology and other clinical sub-specialties.

Official documentation of clinical training and experience in histocompatibility and immunogenetics as well as general laboratory management must be submitted.

The degree and experience requirements to sit for the ABHI Board exam for Diplomates are similar to the ASHI requirements for a Laboratory Director. Thus, if one passes the ABHI board, he/she will usually be qualified to serve as an ASHI Director for at least one of the categories of testing. The difference may lie in the type of experience that is approved and accepted by ASHI. Eligibility to sit for the ABHI Diplomate exam does not guarantee that the individual will be qualified as an ASHI Director upon passing the exam and becoming board-certified. The credentials, training, and experience must be examined and approved by the ASHI Director Training Review and Credentialing Committee Board.



The training curriculum and work experience must appropriately prepare the candidate to fulfill the requirements of a Histocompatibility Laboratory Director. The candidate must provide documentation detailing his/her experience in histocompatibility and immunogenetics as well as general laboratory management. All documentation will be reviewed by the ABHI Credentials Committee.

Official Documents: Histocompatibility Laboratory Director

1. An official transcript(s) bearing the seal and signature of the registrar from the college or university conferring doctoral degree in a biological science. If your transcript is being sent directly to ABHI, please indicate this in the appropriate box in section 1.
2. Documentation of equivalent work experience, as appropriate (see eligibility requirements).

Foreign education: If a candidate is basing his/her eligibility on a degree or courses from a foreign university, the official transcript or copy must first be evaluated by the International Education Research Foundation, Inc., P.O. Box 3665, Los Angeles, CA, 90231-3665, (310) 258-9451, Fax (310) 342-7086. The evaluation must be submitted with the application for the Laboratory Director Examination.

Application Statement: The statement at the end of the application must be completed and submitted for the application to be valid. Any application submitted with the completed statement will be returned without evaluation.

EXAMINATION ADMINISTRATION

The CHA, CHS, and CHT examinations will be offered twice a year in March and September. The application deadlines will be January 1 and June 1 respectively.

The Histocompatibility Laboratory Director Examination will be offered in September 2009. The deadline for submitting applications is June 1, 2009.

The examination is delivered by computer at over 150 AMP Assessment Centers geographically located throughout the United States. The examination is administered by appointment only Monday through Saturday at 9:00 a.m. and 1:30 p.m. during the month of **September**. Available dates will be indicated when scheduling your examination. Candidates are scheduled on a first-come, first-served basis.

Associates, Technologists and Specialists will be given 3.5 hours of testing time. Candidates for the Laboratory Directors examination will be given a total of 5 hours to complete the examination. Computer based testing allows 4 hour testing sessions, therefore 2 sessions of testing will be required for the directors, e.g. a morning session and an afternoon session.

The content area of the Histocompatibility Laboratory Directors examination will be divided as follows:

Part 1: Content categories 2 and 5; 110 scored items to be administered in 3 hours.

Part 2: Content categories 1, 3, and 4; 90 score items to be administered in 2 hours.

Please be aware that you will be required to complete both sessions to obtain a final score for testing.

The examinations are not offered on the first Monday in September, in observance of the Labor Day holiday.

REGISTERING FOR AN EXAMINATION

Candidates should ensure that the ABHI Examination Registration Form has been properly completed and that the information provided is accurate. Your careful attention will enable prompt and efficient processing. Candidates will not be able to schedule an examination appointment with AMP until the ABHI Registration Form has been processed. AMP will send written notification to registered candidates with examination scheduling procedures.

■ Fees and Refund Policy (New fees for 2009)

The examination fees are:
CHA/CHT – \$195 USD
CHS – \$225 USD
Histocompatibility Laboratory
Director – \$890 USD
Examination fees are subject to change.

EXAMINATION FEES

Candidates must submit the appropriate fee made payable to ABHI with a complete examination application. Payment may be made by credit card (American Express, Visa or MasterCard), personal check, cashier's check or money order. A \$25 fee will be charged for any payment returned unpaid by the bank for any reason. Cashing of your check DOES NOT confirm acceptance to sit for the examination. In the event a candidate's application is rejected by ABHI, a \$75 non-refundable processing fee will be withheld, and the remainder will be returned to the candidate.

FORFEITURE OF FEE

A candidate who:

1. does not schedule an examination within the 30-day eligibility period;



2. fails to reschedule an examination within four business days prior to the scheduled testing session;
3. fails to report for an examination appointment;
4. arrives more than 15 minutes late for the examination appointment; or
5. fails to provide proper ID at the Assessment Center will forfeit the examination fee and must reapply for the examination by submitting a new application, documentation and full examination fee.

On the day of your examination appointment, report to the Assessment Center no later than your scheduled exam time. Once you enter the office, look for the sign indicating AMP Assessment Center Check-In. A CANDIDATE WHO ARRIVES MORE THAN 15 MINUTES AFTER THE SCHEDULED TESTING TIME WILL NOT BE ADMITTED. To gain admission to the Assessment Center, a candidate must present two forms of identification, one containing a current photograph. Both forms of identification must be valid and include the candidate's current name and signature. The candidate also will be required to sign a roster for verification of identity.

■ Scheduling an Examination

After the candidate has received written confirmation from AMP, there are two ways to schedule an appointment for the examination.

1. Schedule Online: The candidate may schedule an examination appointment online at any time by using AMP's online application/scheduling service. To use this service, follow these easy steps:
 - Go to www.goAMP.com and select "Candidates."
 - Follow the simple, step-by-step instructions to select your examination program and register for an examination.

OR

2. Telephone Scheduling: Call AMP at 888/519-9901 to schedule an examination appointment. This toll-free number is answered from 7:00 a.m. to 7:00 p.m. (Central Time) Monday through Thursday, 7:00 a.m. to 5:00 p.m. on Friday and 8:30 a.m. to 5:00 on Saturday.

When scheduling an examination, be prepared to confirm a location, a preferred date and time for testing, and to provide your Social Security number as a unique identification number. AMP will use your Social Security number only as an identification number in maintaining your record. When you contact AMP to schedule an examination appointment, you will be notified of the time to report to the Assessment Center. Please make a note of it because you will NOT receive an admission letter.

If you call AMP by 3:00 p.m. Central Time on...	Depending on availability, your examination may be scheduled beginning...
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday/Saturday
Thursday	Monday
Friday	Tuesday

■ Assessment Center Locations

AMP Assessment Centers have been selected to provide accessibility to the most candidates in all states and major metropolitan areas. AMP Assessment Centers are typically located in H&R Block offices. A current listing of AMP Assessment Centers, including addresses and driving directions, may be viewed at AMP's website located at www.goAMP.com. Specific address information will be provided when a candidate schedules an examination appointment.

■ Request for International Test Center

Requests may be made for international test centers. Reservations for these special sites will require an additional test center fee of \$225. The ABHI examinations will be offered in computerized format.

International test centers may be arranged for candidates living outside of the United States. Candidates may elect to have the ABHI examination administered by computer at an international AMP Assessment Center. For a complete list of international AMP Assessment Centers please visit AMP's Web site (www.goAMP.com). AMP is working toward continued expansion of the Assessment Center Network and ABHI recommends that you continue to check the available list for additional sites.

■ Special Arrangements for Candidates with Disabilities

ABHI and AMP comply with the Americans with Disabilities Act and strive to ensure that no individual with a disability is deprived of the opportunity to take the examination solely by reason of that disability. ABHI and AMP will provide reasonable accommodations for candidates with disabilities.

Wheelchair access is available at all Assessment Centers. Candidates with visual, sensory or physical disabilities that would prevent them from taking the examination under standard conditions may request special accommodations and arrangements. Candidates testing with approved special accommodations should schedule their test via AMP's toll-free number to ensure their accommodations



are confirmed. Be sure to inform AMP of your need for special accommodations when calling to schedule your examination.

■ Telecommunication Devices for the Deaf

AMP is equipped with Telecommunication Devices for the Deaf (TDD) to assist deaf and hearing-impaired candidates. TDD calling is available 8:30 a.m. to 5:00 p.m. (Central Time) Monday-Friday at 913/495-4437. This TDD phone option is for individuals equipped with compatible TDD machinery.

■ Examination Appointment Changes

A candidate may reschedule an examination appointment at no charge **once** by calling AMP at 888/519-9901 at least four business days prior to the scheduled testing session. (See table below.)

If the examination is scheduled on...	AMP must be contacted by 3:00 p.m. Central Time to reschedule the examination by the previous...
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday
Thursday	Monday
Friday	Tuesday

■ Missed Appointments and Cancellations

A candidate will forfeit the examination registration and all fees paid to take the examination under the following circumstances.

- The candidate wishes to reschedule an examination but fails to contact AMP at least four business days prior to the scheduled testing session,
- The candidate wishes to reschedule a second time,
- The candidate appears more than 15 minutes late for an examination, or
- The candidate fails to report for an examination appointment.

A complete ABHI Examination Registration Form and examination fee are required to re-register for the examination.

■ Inclement Weather, Power Failure or Emergency

In the event of inclement weather or unforeseen emergencies on the day of an examination, AMP will determine whether circumstances warrant the cancellation, and subsequent rescheduling, of an examination. The examination will usually not be rescheduled if the Assessment Center personnel are able to open the Assessment Center. If power to an Assessment Center is temporarily interrupted during an administration, your examination will restart where you left off and you may continue the examination.

Candidates may visit AMP’s website at www.goAMP.com prior to the examination to determine if AMP has been advised that any Assessment Centers are closed. Every attempt is made to administer the examination as scheduled; however, should an examination be canceled at an Assessment Center, all scheduled candidates will receive notification following the examination regarding rescheduling or reapplication procedures.

EXAMINATION CONTENT

To begin your preparation in an informed and organized manner, you should know what to expect in terms of examination content. Information regarding the content of the examination is presented in this handbook. The content outlines will give you a general impression of the examination and, with closer inspection, can give you specific study direction by revealing the relative importance given to each category on the examination.



ABHI Certified Histocompatibility Associate (CHA) and Technologist (CHT) Detailed Content Outline

I. General Laboratory Skills and Specimen Requirements (10 questions)

- A. Specimen Requirements (6 questions)
 - 1. Provide information to outside sources on specimen requirements, including, but not limited to, proper labeling, collection specifics, preservation, and verification of requests from appropriate source
 - 2. Follow time, temperature, and biosafety guidelines for proper packaging and labeling for transport
 - 3. Establish criteria for specimen acceptability and inspect specimens received for testing
 - a. Verify completeness and accuracy of test requisitions in accordance with laboratory accrediting and regulatory agencies
 - b. Check for proper patient identification, volume, use of appropriate anticoagulant, and date of collection
 - c. Assess quality of specimens submitted (e.g., clotting, hemolysis, age of specimen, adverse storage or shipping conditions) and appropriateness of type of specimen for test requested
 - d. Identify, label, and log specimens into laboratory records
 - e. Prioritize testing to be performed, including emergency situations
 - f. Follow legal and institutional requirements regarding security and confidentiality of patient/client records
 - 4. Perform venipuncture to collect blood samples for testing
 - a. Determine appropriate anticoagulant and volume to be collected
 - b. Label specimen(s) as required
 - 5. Request new samples when original specimens are unacceptable
- B. Laboratory Safety (2 questions)
 - 1. Identify and minimize laboratory hazards
 - a. Identify sources of biohazards and use Standard Precautions
 - b. Correctly handle, store, and dispose of flammables, volatiles, toxic chemicals, liquid nitrogen, and gas cylinders according to OSHA guidelines
 - c. Dispose of glass, syringes, sharps, and needles in appropriately labeled and structured containers
 - 2. Use established general laboratory safety procedures for determining the location and utilization of fire extinguishers, eye wash, fire blanket, fire alarm, evacuation plans, power failure procedures, etc.

- C. Laboratory Maintenance (2 questions)
 - 1. Use established guidelines for cleaning, decontamination, and sterilization procedures for glassware, instruments, and work areas
 - 2. Maintain an accurate inventory of supplies and reagents; utilize supplies and reagents effectively while considering shelf life and expiration dates
 - 3. Validate, utilize, and maintain computer databases of patient information

II. Reagent Preparation (15 questions)

- A. Prepare Solutions, Stains, and Gradients (2 questions)
 - 1. Choose and prepare appropriate solutions and reagents (e.g., buffered saline solutions, media, cryopreservation solutions, vital stains, and radioisotopes), with required additives and supplements
 - 2. Prepare and standardize blood cell isolation gradients (e.g., ficoll-hypaque/isopaque and percoll)
- B. Prepare Serological Reagents (8 questions)
 - 1. Prepare control serum reagents utilizing established methods of collection, screening, pooling, heat-inactivation, storage conditions and methods of plasma conversion
 - 2. Use complement according to established guidelines
 - a. Determine for each lot/batch number the optimum titer and strength of reactions with each type of target cells to be tested
 - b. Follow established procedures for handling and storage of complement: aliquot size, maintenance temperature, thawing, dispensing, lability
 - 3. Handle antiglobulin reagent according to established guidelines
 - a. Determine for each lot/batch number the optimum titer and strength of reactions with each type of target cells to be tested
 - b. Follow established procedures for handling and storage of antiglobulin reagent: aliquot size, maintenance temperature, thawing, dispensing, lability
 - 4. Type sufficient numbers of volunteer cell donors to have necessary HLA types available for reagent testing and controls for HLA testing
 - a. Select appropriate cells for QC of reagents
 - b. Select a panel of cells for antibody screening
 - 5. Identify, characterize, and maintain serological reagents for HLA typing
 - a. Determine methods to obtain, preserve, and inventory HLA reagents
 - b. Perform platelet or cellular adsorption if indicated (e.g., autoadsorption, removal of Class I antibody)



- c. Develop a well defined panel of cells, taking into account racial distribution, crossreactive antigens, antigen frequency, and linkage disequilibrium
 - d. Characterize serum against defined panel
 - e. Utilize methods for the identification of reagent grade sera using methods of serum analysis (e.g., chi square, tail analysis, correlation coefficient), with or without computer assistance
 - f. Select appropriate Class I and Class II trays for patient typing
6. Select and prepare reagents appropriate for flow cytometry
 - a. Select and validate negative control serum/ reagents
 - b. Select and validate positive control sera (pool of high PRA sera) and positive control reagents
 - c. Verify specificity of monoclonal antibodies
 - d. Select appropriate reagents/fluorescent stains specific for anti-human immunoglobulin isotypes and for cell surface markers
 - e. Determine volumes and titers of reagents to be used for each test sample
 7. Select and validate reagents for ELISA
 - a. Prepare positive, negative, and reagent controls
 - b. Mix, dilute, and store assay reagents according to manufacturer's instructions
- C. Prepare Reagents for Molecular Assays (5 questions)
1. Type sufficient numbers of volunteer cell donors to have necessary HLA types available for reagent testing and controls for HLA testing – Select a reference panel of cells to be used for DNA typing
 2. Prepare and standardize reagents for nucleic acid extraction
 3. Use primers and probes of known specificity and sequence
 4. Prepare and standardize primer mixtures to achieve the defined specificity for template used in testing; store under conditions that maintain specificity and sensitivity
 5. Test each set of primers and probes periodically for specificity, using reference nucleic acid material
 6. Prepare appropriate controls to detect technical failure and contamination with previously amplified products
 7. Use standardized size markers that reflect range of expected fragment sizes

III. Methodology (40 questions)

- A. Cell and Serum Preparation (10 questions)
1. Prepare and/or store specimens for testing according to established guidelines
 2. Cell Preparation
 - a. Select an isolation technique for the type of specimen (e.g., blood, spleen, lymph node) considering the properties of cells which influence isolation (e.g., cell density, surface immunoglobulin, adherence, cell surface receptors)
 - b. Recognize and eliminate components which may interfere with the assay (e.g., RBC, platelets, PMNs)
 - c. Determine acceptability of target cell preparations (e.g., viability and purity)
 - d. Perform accurate cell counts and calculations
 - e. Cryopreserve cells to ensure adequacy for future use
 - f. Select and prepare target cells used in an assay based on physical, functional or phenotypic properties
3. Serum Preparation
- a. Obtain, aliquot, and store serum for maintenance of biologic activity
 - b. Select appropriate patient specimens for testing considering current and historical PRA information, sensitizing events
 - c. Prepare serum for testing (e.g., use of reducing reagents, cell adsorption or concentration)
 - d. Prepare crossmatch and patient serum screening trays, including appropriate test samples and controls
- B. Serological Assays (15 questions)
1. Cytotoxicity
 - a. Determine HLA phenotype
 - 1) Select trays
 - 2) Perform test according to established procedures regarding cell purity, addition of reagents, complement, wash steps, incubation times, temperature, vital staining
 - 3) Read and record HLA typing results, utilizing consistent scoring per ASHI standards
 - b. Detect presence of lymphocytotoxic antibodies
 - 1) Select appropriate screening or crossmatch method (e.g., to detect HLA vs. non-HLA antibodies, IgG vs. IgM isotype, T- vs. B-cell specific) and perform test according to established procedures regarding target cell selection and addition of reagents, complement, wash steps, incubation times, temperature, vital staining
 - 2) For patients awaiting solid organ transplantation, determine frequency of antibody screening
 - 3) For crossmatch, select appropriate patient specimens and target cells, taking into account historical PRA information, sensitizing events, type of antibody to be detected
 - 4) Read and record results, utilizing consistent scoring per ASHI standards
 2. ELISA
 - a. Perform testing for antibody screening or crossmatching according to established procedures and with adequate controls regarding reagent and serum concentrations, control sera, wash steps, incubation times, pH, temperature
 - b. Use dilute or adsorbed sera when indicated



3. Flow cytometry
 - a. Test for lymphocyte subsets by immunophenotyping
 - b. Screen for antibodies
 - c. Perform crossmatching
 - d. Perform testing using appropriate reagents and controls (e.g., monoclonal antibodies, secondary antibodies, fluorochromes, positive and negative controls) and according to established procedures (e.g., cell concentration, serum/cell ratio, wash steps, incubation times)
 - C. Molecular Biology Assays (15 questions)
 1. Determine the level of molecular typing required (low, medium or high resolution)
 2. Verify specificity of test reagents
 3. Extract nucleic acid material using methods that have been referenced in scientific literature and validated in the laboratory
 - a. Select an isolation technique to provide sample of adequate quantity and quality for testing
 - b. Assess DNA sample for integrity, quantity, and quality
 - c. Prepare and store purified nucleic acid material appropriately; develop methods to validate integrity of DNA sample under short- and long-term storage conditions
 - d. Ensure that unamplified DNA specimens are isolated from post-amplification work areas
 - e. Understand effect of anticoagulants on extraction of nucleic acid material
 4. Perform nucleic acid amplification according to established methods
 - a. Follow established guidelines for physical/biochemical barriers to prevent DNA contamination (e.g., dedicated work areas, supplies and equipment for pre- and post-amplification procedures)
 - b. Monitor nucleic acid contamination within each amplification study
 - c. Monitor quality of specific amplification products by gel electrophoresis, hybridization with consensus probe, etc.
 - d. Include controls to detect amplification failure in every amplification mixture if presence of amplified product is used as end result (e.g., SSP method)
 - e. Optimize the PCR reaction to produce desired sensitivity and specificity required for testing
 5. Perform gel electrophoresis of nucleic acid material using established procedures
 - a. Select markers of known sequences that give discrete electrophoretic bands that span and flank entire range of system being tested
 - b. Include known human control DNA when restriction endonucleases have been used
 - c. Dispense equal amounts (mg/ml) of nucleic acid material into each lane
 - d. Optimize concentration of materials in gels used for detection of PCR products
 6. Perform procedure(s) necessary for allele or antigen identification utilizing appropriate controls and considering specificity of primers and probes, temperature, hybridization conditions, specificity and sensitivity of labeling and detection methods
 - a. Perform typing by SSP
 - b. Perform typing by SSOP
 7. Read and record results according to established guidelines
- #### IV. Test Results Interpretation (40 questions)
- A. Serological Results (22 questions)
 1. Cytotoxicity
 - a. Interpret results of HLA Class I and Class II serological typing
 - 1) Review controls (e.g., positive, negative cell viability complement) to evaluate validity of data; recognize the need to repeat an assay based on inappropriate control results
 - 2) Determine antigen assignments based on patterns of serologic reactivity from manual or computer generated data
 - a) identify HLA antigens using monospecific and multispecific antisera
 - b) recognize cross reactive groups for Class I and Class II HLA antigens
 - c) identify splits of broad specificities
 - d) recognize common antigen combinations possible due to linkage disequilibrium
 - e) interpret reactivity patterns of "public determinants" which are shared among the "private" specificities (e.g., Bw4, Bw6, DR51, DR52, DR53)
 - 3) Evaluate the validity of antigen assignments and assess the need to perform additional testing; resolve any ambiguities
 - 4) Assign haplotypes/genotypes, as appropriate in family studies; consider possibility of recombination
 - 5) Consider DNA typing results when available
 - 6) Identify potential bone marrow donors based on HLA typing
 - b. Interpret crossmatch results
 - 1) Review controls to evaluate validity of data
 - 2) Evaluate need for further testing when appropriate (e.g., poor viability, autoantibody, weak reactivity)
 - 3) Review donor/recipient match and patient's PRA and sensitization history in light of crossmatch results; resolve any ambiguities
 - c. Interpret results of patient antibody screening
 - 1) Evaluate antibody screening data from manual or computer generated data considering linkage disequilibrium, crossreactivity of antigens and racial distribution of the panel used for testing
 - 2) Calculate panel reactive antibody (PRA)
 - 3) Evaluate antibody specificity using statistical indices (e.g., chi square, correlation coefficient, tait analysis)



- 4) Review patient's sensitization history in light of positive results
 - 5) Identify platelet donors based on patient HLA type, antibody screening results and knowledge of crossreactive antigen groups and "public" determinants
 2. Flow Cytometry Assays
 - a. Review controls to evaluate validity of data
 - b. Establish criteria for reporting and evaluating test results based on laboratory's established threshold for positive reactions
 - c. Distinguish between calculations of linear vs. log amplification in determining fluorescence intensity
 - d. Evaluate need for further testing when appropriate
 - e. For crossmatching, review donor/recipient match, and patient PRA and sensitization history, in light of crossmatch results
 3. ELISA
 - a. Review controls to evaluate validity of data
 - b. Define criteria for reporting and evaluating of test results based on laboratory's established threshold for positive reactions
 - c. Evaluate need for further testing when appropriate
 4. Interpret compatibility of ABO test results
 - B. Molecular Biology Assays (16 questions)
 1. Establish criteria for accepting or rejecting an amplification assay
 2. Establish criteria for identification of contamination of amplified nucleic acid material
 3. Establish acceptable limits of signal intensity for each primer mixture, probe and positive and negative controls; initiate corrective actions when these criteria are not met
 4. Evaluate controls and size markers, and determine if repeat testing is required
 5. Recognize primer-dimer products and differentiate bands based on size
 6. Determine allele assignments based on reactivity patterns of primers/probes using two independent interpretations of primary data whenever possible
 7. Establish procedures for assignment of types; be able to recognize reaction patterns that may have more than one possible interpretation
 8. Establish procedures for incorporating criteria for assignment of new alleles
 9. Determine appropriate high resolution testing to be performed based on low resolution results and clinical relevance
 10. Identify and address discrepancies between molecular and serological testing results
 11. Recognize unusual antigen association patterns and initiate additional testing if needed
 12. Assign haplotypes/genotypes, as appropriate, in family studies; consider possibility of recombination
 - C. Results Reporting (2 questions)
 1. Using all required information and WHO nomenclature, prepare results for director review and signature
 2. Establish guidelines for reporting results in emergency situations
 3. Issue reports to appropriate personnel; follow regulatory guidelines for inclusion of minimum required information
- V. General Histocompatibility Testing Principles and Theory (30 questions)**
- A. Major Histocompatibility Complex (MHC) Immunogenetics (10 questions)
 1. Utilize knowledge of biological and chemical principles behind serological, cellular, flow cytometric, molecular, and ELISA assays
 2. Describe the basic structure and function of MHC molecules and genes
 3. Identify variations in HLA allele and haplotype frequency resulting from geographical and racial differences
 4. Describe HLA association with disease susceptibility and resistance¹
 5. Differentiate between phenotype and genotype
 - B. Molecular Genetics (8 questions)
 1. Differentiate between primer and probe design for HLA allele detection
 2. Describe the process of polymerase chain reaction (PCR) and its application to molecular typing
 3. Describe the molecular typing methods utilized for the identification of the major histocompatibility alleles (e.g., RFLP, SSP, SSOP, Sequencing)
 - C. Basic Immunology and Serology (12 questions)
 1. Describe the essential features of the immune system
 - a. Identify the cellular components of the immune system (e.g., T cell, B cell, APCs)
 - b. Describe the function of HLA molecules in antigen presentation
 - c. Distinguish between cellular and humoral (antibody) response
 - d. Explain the complement pathway of immune mediated injury
 - e. Differentiate the classes of immunoglobulin, including functional differences between classes that may affect reactivity in assay systems and in vivo
 2. Apply basic immunological principles to graft rejection/acceptance and graft vs. host disease
 3. Describe the principles of the complement dependent cytotoxicity assay
 4. Explain the serologic concepts of CYNAP, antibody avidity, specificity and sensitivity, crossreactivity, and antigenic determinants (epitopes)



VI. Quality Assurance (15 questions)

A. Reagents (7 questions)

1. Develop quality control procedures on reagents and products, and plan corrective action to be taken
2. Maintain quality control procedures on reagents and products, taking corrective action when necessary
3. Choose and standardize controls appropriate to the requirements of the assay in use, and maintain records in accordance with regulations
4. Maintain a reagent log and control system
 - a. Record data on purchased chemicals, biologicals, and radionucleotides
 - b. Label reagents with name, concentration, dates prepared/received/opened, storage requirements, expiration dates, and NFPA codes
 - c. Store and dispose of reagents properly
 - d. Maintain log of Material Safety Data Sheets (MSDS) and product inserts
5. Evaluate and choose biologicals and chemicals conforming to purity, specificity, sterility, and stability required for the intended assays
6. Assess the quality of reagents by reproducibility, parallel studies, titration studies, pH check, etc.
7. Perform appropriate tests for nucleic acid, radioisotope, chemical, and microbial contamination

B. Instrumentation/Equipment (2 questions)

1. Calibrate, validate, and operate instruments and equipment by applying criteria established by the laboratory, manufacturer and/or accrediting and regulatory agencies
2. Adjust and/or repair simple instruments and equipment; obtain external services when appropriate
3. Initiate contingency plan when malfunctions occur (e.g., power or equipment failure)
4. Monitor and document operating conditions (e.g., temperature, CO₂ levels, liquid nitrogen levels)

C. Documentation (4 questions)

1. Validate changes in testing methods by parallel or confirmatory testing
2. Maintain identity of specimen throughout testing and reporting of results, meeting processing time deadlines; address delays in result reporting
3. Establish and implement policies to reject specimens when criteria of acceptability for testing are not met and to ensure that unacceptable specimens are not tested
4. Document incidents related to quality of testing
5. Establish a system to maintain records of testing results for all subjects tested according to regulatory guidelines
6. Establish and implement a system to report testing results in a timely, accurate and reliable manner
7. Establish and implement policy to perform periodic antibody screening of patients awaiting solid organ transplantation
8. Maintain records of potentially sensitizing events for each patient awaiting solid organ transplantation
9. Establish and implement policy for repeat testing to be performed when necessary
10. Establish, implement and document corrective action procedures to deal with any inconsistency or errors in reporting of test results or problems with communication with laboratory
11. Develop and implement program to regularly assess abilities of laboratory personnel to reproduce test results of previously characterized specimens
12. Validate prior to use any automated systems and computer programs used to assist in the interpretation of reaction patterns; test routinely for accuracy and reproducibility

D. Compliance (2 questions)

1. Maintain testing guidelines set by regulatory agencies (e.g., ASHI, UNOS, CLIA, OSHA) for procedures being performed in the laboratory
2. Participate in internal and external (e.g., ASHI/CAP surveys) quality assurance and proficiency testing programs
3. Implement program to monitor compliance to laboratory policies



ABHI Certified Histocompatibility Specialist (CHS) Detailed Content Outline

I. General Laboratory Skills and Specimen Requirements (9 questions)

- A. Specimen Requirements (4 questions)
 - 1. Provide information to outside sources on specimen requirements, including, but not limited to, proper labeling, collection specifics, preservation, and verification of requests from appropriate source
 - 2. Follow time, temperature, and biosafety guidelines for proper packaging and labeling for transport
 - 3. Establish criteria for specimen acceptability and inspect specimens received for testing
 - a. Verify completeness and accuracy of test requisitions in accordance with laboratory accrediting and regulatory agencies
 - b. Check for proper patient identification, volume, use of appropriate anticoagulant, and date of collection
 - c. Assess quality of specimens submitted (e.g., clotting, hemolysis, age of specimen, adverse storage or shipping conditions) and appropriateness of type of specimen for test requested
 - d. Identify, label, and log specimens into laboratory records
 - e. Prioritize testing to be performed, including emergency situations
 - f. Follow legal and institutional requirements regarding security and confidentiality of patient/client records
 - 4. Request new samples when original specimens are unacceptable
- B. Laboratory Safety (3 questions)
 - 1. Identify and minimize laboratory hazards
 - a. Identify sources of biohazards and use Standard Precautions
 - b. Correctly handle, document, store, and dispose of radioactive materials per mandated laboratory guidelines and as dictated by the isotope's characteristics
 - c. Correctly handle, store, and dispose of flammables, volatiles, toxic chemicals, liquid nitrogen, and gas cylinders according to OSHA guidelines
 - d. Dispose of glass, syringes, sharps, and needles in appropriately labeled and structured containers
 - e. Establish guidelines for action in case of chemical spills
 - 2. Use established general laboratory safety procedures
 - a. Determine location and utilization of fire extinguishers, eye wash, fire blanket, fire alarm, evacuation plans, power failure procedures, etc.
 - b. Maintain list of personnel to be notified regarding emergencies

- c. Establish guidelines for action in case of personnel or patient accident or injury
- d. Document and report personal injuries to appropriate personnel

- C. Laboratory Maintenance (2 questions)
 - 1. Maintain an accurate inventory of supplies and reagents; utilize supplies and reagents effectively while considering shelf life and expiration dates
 - 2. Validate, utilize, and maintain computer databases of patient information

II. Reagent Preparation (16 questions)

- A. Prepare Solutions, Stains, and Gradients (2 questions)
 - 1. Choose and prepare appropriate solutions and reagents (e.g., buffered saline solutions, media, cryopreservation solutions, vital stains, and radioisotopes), with required additives and supplements
 - 2. Prepare and standardize blood cell isolation gradients (e.g., ficoll-hypaque/isopaque and percoll)
- B. Prepare Serological Reagents (9 questions)
 - 1. Prepare control serum reagents utilizing established methods of collection, screening, pooling, heat-inactivation, storage conditions and methods of plasma conversion
 - 2. Use complement according to established guidelines
 - a. Determine for each lot/batch number the optimum titer and strength of reactions with each type of target cells to be tested
 - b. Follow established procedures for handling and storage of complement: aliquot size, maintenance temperature, thawing, dispensing, lability
 - 3. Handle antiglobulin reagent according to established guidelines
 - a. Determine for each lot/batch number the optimum titer and strength of reactions with each type of target cells to be tested
 - b. Follow established procedures for handling and storage of antiglobulin reagent: aliquot size, maintenance temperature, thawing, dispensing, lability
 - 4. Type sufficient numbers of volunteer cell donors to have necessary HLA types available for reagent testing and controls for HLA testing
 - a. Select appropriate cells for QC of reagents
 - b. Select a panel of cells for antibody screening
 - 5. Identify, characterize, and maintain serological reagents for HLA typing
 - a. Determine methods to obtain, preserve, and inventory HLA reagents
 - b. Perform platelet or cellular adsorption if indicated (e.g., autoadsorption, removal of Class I antibody)

¹ Task edited by committee



- c. Develop a well defined panel of cells, taking into account racial distribution, crossreactive antigens, antigen frequency, and linkage disequilibrium
 - d. Characterize serum against defined panel
 - e. Utilize methods for the identification of reagent grade sera using methods of serum analysis (e.g., chi square, tail analysis, correlation coefficient), with or without computer assistance
 - f. Perform testing to confirm specificity of serum reagents procured from other laboratories
 - g. Prepare trays of Class I and Class II reagent antisera to be used for HLA typing
 - h. Select appropriate Class I and Class II trays for patient typing
6. Select and prepare reagents appropriate for flow cytometry
- a. Select and validate negative control serum/reagents
 - b. Select and validate positive control sera (pool of high PRA sera) and positive control reagents
 - c. Verify specificity of monoclonal antibodies
 - d. Select appropriate reagents/fluorescent stains specific for anti-human immunoglobulin isotypes and for cell surface markers
 - e. Determine volumes and titers of reagents to be used for each test sample
7. Select and validate reagents for ELISA
- a. Prepare positive, negative, and reagent controls
 - b. Mix, dilute, and store assay reagents according to manufacturer's instructions
- C. Prepare Reagents for Molecular Assays (5 questions)
1. Type sufficient numbers of volunteer cell donors to have necessary HLA types available for reagent testing and controls for HLA testing – Select a reference panel of cells to be used for DNA typing
 2. Prepare and standardize reagents for nucleic acid extraction
 3. Use primers and probes of known specificity and sequence
 4. Prepare and standardize primer mixtures to achieve the defined specificity for template used in testing; store under conditions that maintain specificity and sensitivity
 5. Test each set of primers and probes periodically for specificity, using reference nucleic acid material
 6. Prepare appropriate controls to detect technical failure and contamination with previously amplified products
 7. Use standardized size markers that reflect range of expected fragment sizes

III. Methodology (29 questions)

- A. Cell and Serum Preparation (5 questions)
1. Prepare and/or store specimens for testing according to established guidelines
 2. Cell Preparation
 - a. Select an isolation technique for the type of specimen (e.g., blood, spleen, lymph node) considering the properties of cells which influence isolation (e.g., cell density, surface immunoglobulin, adherence, cell surface receptors)
 - b. Recognize and eliminate components which may interfere with the assay (e.g., RBC, platelets, PMNs)
 - c. Determine acceptability of target cell preparations (e.g., viability and purity)
 - d. Perform accurate cell counts and calculations
 - e. Cryopreserve cells to ensure adequacy for future use
 - f. Select and prepare target cells used in an assay based on physical, functional or phenotypic properties
 3. Serum Preparation
 - a. Obtain, aliquot, and store serum for maintenance of biologic activity
 - b. Select appropriate patient specimens for testing considering current and historical PRA information, sensitizing events
 - c. Prepare serum for testing (e.g., use of reducing reagents, cell adsorption or concentration)
 - d. Prepare crossmatch and patient serum screening trays, including appropriate test samples and controls
- B. Serological Assays (12 questions)
1. Cytotoxicity
 - a. Determine HLA phenotype
 - 1) Select trays
 - 2) Perform test according to established procedures regarding cell purity, addition of reagents, complement, wash steps, incubation times, temperature, vital staining
 - 3) Read and record HLA typing results, utilizing consistent scoring per ASHI standards
 - b. Detect presence of lymphocytotoxic antibodies
 - 1) Select appropriate screening or crossmatch method (e.g., to detect HLA vs. non-HLA antibodies, IgG vs. IgM isotype, T- vs. B-cell specific) and perform test according to established procedures regarding target cell selection and addition of reagents, complement, wash steps, incubation times, temperature, vital staining
 - 2) For patients awaiting solid organ transplantation, determine frequency of antibody screening



- 3) For crossmatch, select appropriate patient specimens and target cells, taking into account historical PRA information, sensitizing events, type of antibody to be detected
 - 4) Read and record results, utilizing consistent scoring per ASHI standards
2. ELISA
- a. Perform testing for antibody screening or crossmatching according to established procedures and with adequate controls regarding reagent and serum concentrations, control sera, wash steps, incubation times, pH, temperature
 - b. Use dilute or adsorbed sera when indicated
3. Flow cytometry
- a. Screen for antibodies
 - b. Perform crossmatching
 - c. Perform testing using appropriate reagents and controls (e.g., monoclonal antibodies, secondary antibodies, fluorochromes, positive and negative controls) and according to established procedures (e.g., cell concentration, serum/cell ratio, wash steps, incubation times)
- C. Molecular Biology Assays (12 questions)
1. Determine the level of molecular typing required (low, medium or high resolution)
 2. Verify specificity of test reagents
 3. Extract nucleic acid material using methods that have been referenced in scientific literature and validated in the laboratory
 - a. Select an isolation technique to provide sample of adequate quantity and quality for testing
 - b. Assess DNA sample for integrity, quantity, and quality
 - c. Prepare and store purified nucleic acid material appropriately; develop methods to validate integrity of DNA sample under short- and long-term storage conditions
 - d. Ensure that unamplified DNA specimens are isolated from post-amplification work areas
 - e. Understand effect of anticoagulants on extraction of nucleic acid material
 4. Perform nucleic acid amplification according to established methods
 - a. Follow established guidelines for physical/biochemical barriers to prevent DNA contamination (e.g., dedicated work areas, supplies and equipment for pre- and post-amplification procedures)
 - b. Monitor nucleic acid contamination within each amplification study
 - c. Monitor quality of specific amplification products by gel electrophoresis, hybridization with consensus probe, etc.
 - d. Include controls to detect amplification failure in every amplification mixture if presence of amplified product is used as end result (e.g., SSP method)
 - e. Optimize the PCR reaction to produce desired sensitivity and specificity required for testing
 5. Perform gel electrophoresis of nucleic acid material using established procedures
 - a. Select markers of known sequences that give discrete electrophoretic bands that span and flank entire range of system being tested
 - b. Dispense equal amounts (mg/ml) of nucleic acid material into each lane
 - c. Optimize concentration of materials in gels used for detection of PCR products
 6. Perform procedure(s) necessary for allele or antigen identification utilizing appropriate controls and considering specificity of primers and probes, temperature, hybridization conditions, specificity and sensitivity of labeling and detection methods
 - a. Perform typing by SSP
 - b. Perform typing by SSOP
 7. Read and record results according to established guidelines
- IV. Test Results Interpretation (37 questions)**
- A. Serological Results (20 questions)
1. Cytotoxicity
 - a. Interpret results of HLA Class I and Class II serological typing
 - 1) Review controls (e.g., positive, negative cell viability complement) to evaluate validity of data; recognize the need to repeat an assay based on inappropriate control results
 - 2) Determine antigen assignments based on patterns of serologic reactivity from manual or computer generated data
 - a) identify HLA antigens using monospecific and multispecific antisera
 - b) recognize cross reactive groups for Class I and Class II HLA antigens
 - c) identify splits of broad specificities
 - d) recognize common antigen combinations possible due to linkage disequilibrium
 - e) interpret reactivity patterns of "public determinants" which are shared among the "private" specificities (e.g., Bw4, Bw6, DR51, DR52, DR53)
 - 3) Evaluate the validity of antigen assignments and assess the need to perform additional testing; resolve any ambiguities
 - 4) Assign haplotypes/genotypes, as appropriate in family studies; consider possibility of recombination
 - 5) Consider DNA typing results when available
 - 6) Identify potential bone marrow donors based on HLA typing
 - b. Interpret crossmatch results
 - 1) Review controls to evaluate validity of data
 - 2) Evaluate need for further testing when appropriate (e.g., poor viability, autoantibody, weak reactivity)
 - 3) Review donor/recipient match and patient's PRA and sensitization history in light of crossmatch results; resolve any ambiguities



- c. Interpret results of patient antibody screening
 - 1) Evaluate antibody screening data from manual or computer generated data considering linkage disequilibrium, crossreactivity of antigens and racial distribution of the panel used for testing
 - 2) Calculate panel reactive antibody (PRA)
 - 3) Evaluate antibody specificity using statistical indices (e.g., chi square, correlation coefficient, tail analysis)
 - 4) Review patient's sensitization history in light of positive results
 - 5) Identify platelet donors based on patient HLA type, antibody screening results and knowledge of crossreactive antigen groups and "public" determinants
2. Flow Cytometry Assays
 - a. Review controls to evaluate validity of data
 - b. Establish criteria for reporting and evaluating test results based on laboratory's established threshold for positive reactions
 - c. Distinguish between calculations of linear vs. log amplification in determining fluorescence intensity
 - d. Evaluate need for further testing when appropriate
 - e. For crossmatching, review donor/recipient match, and patient PRA and sensitization history, in light of crossmatch results
3. ELISA
 - a. Review controls to evaluate validity of data
 - b. Define criteria for reporting and evaluating of test results based on laboratory's established threshold for positive reactions
 - c. Evaluate need for further testing when appropriate
4. Interpret compatibility of ABO test results
- B. Molecular Biology Assays (15 questions)
 1. Establish criteria for accepting or rejecting an amplification assay
 2. Establish criteria for identification of contamination of amplified nucleic acid material
 3. Establish acceptable limits of signal intensity for each primer mixture, probe and positive and negative controls; initiate corrective actions when these criteria are not met
 4. Evaluate controls and size markers, and determine if repeat testing is required
 5. Recognize primer-dimer products and differentiate bands based on size
 6. Determine allele assignments based on reactivity patterns of primers/probes using two independent interpretations of primary data whenever possible
 7. Establish procedures for assignment of types; be able to recognize reaction patterns that may have more than one possible interpretation
 8. Establish procedures for incorporating criteria for assignment of new alleles

9. Determine appropriate high resolution testing to be performed based on low resolution results and clinical relevance
10. Identify and address discrepancies between molecular and serological testing results
11. Recognize unusual antigen association patterns and initiate additional testing if needed
12. Assign haplotypes/genotypes, as appropriate, in family studies; consider possibility of recombination
- C. Results Reporting (2 questions)
 1. Using all required information and WHO nomenclature, prepare results for director review and signature
 2. Establish guidelines for reporting results in emergency situations
 3. Issue reports to appropriate personnel; follow regulatory guidelines for inclusion of minimum required information

V. General Histocompatibility Testing Principles and Theory (25 questions)

- A. Major Histocompatibility Complex (MHC) Immunogenetics (8 questions)
 1. Utilize knowledge of biological and chemical principles behind serological, cellular, flow cytometric, molecular, and ELISA assays
 2. Describe the basic structure and function of MHC molecules and genes
 3. Identify variations in HLA allele and haplotype frequency resulting from geographical and racial differences
 4. Describe HLA association with disease susceptibility and resistance, association vs. linkage and relative risk
 5. Differentiate between phenotype and genotype
- B. Molecular Genetics (7 questions)
 1. Describe the structural components of nucleic acids and the organization of genes within chromosomes
 2. Describe gene expression accounting for mutations and null alleles
 3. Differentiate between primer and probe design for HLA allele detection
 4. Describe the process of polymerase chain reaction (PCR) and its application to molecular typing
 5. Describe the molecular typing methods utilized for the identification of the major histocompatibility alleles (e.g., RFLP, SSP, SSOP, Sequencing)
- C. Basic Immunology and Serology (10 questions)
 1. Describe the essential features of the immune system
 - a. Identify the cellular components of the immune system (e.g., T cell, B cell, APCs)
 - b. Describe the function of HLA molecules in antigen presentation
 - c. Explain MHC restriction and the principle of self-recognition
 - d. Distinguish between cellular and humoral (antibody) response
 - e. Explain the complement pathway of immune mediated injury



- f. Differentiate the classes of immunoglobulin, including functional differences between classes that may affect reactivity in assay systems and *in vivo*
2. Apply basic immunological principles to graft rejection/acceptance and graft vs. host disease
3. Explain the general concept of tolerance and immunological effects of immunosuppression
4. Describe the principles of the complement dependent cytotoxicity assay
5. Explain the serologic concepts of CYNAP, antibody avidity, specificity and sensitivity, crossreactivity, and antigenic determinants (epitopes)

VI. Quality Assurance (19 questions)

A. Reagents (8 questions)

1. Develop quality control procedures on reagents and products, and plan corrective action to be taken
2. Maintain quality control procedures on reagents and products, taking corrective action when necessary
3. Choose and standardize controls appropriate to the requirements of the assay in use, and maintain records in accordance with regulations
4. Maintain a reagent log and control system
 - a. Record data on purchased chemicals, biologicals, and radionucleotides
 - b. Label reagents with name, concentration, dates prepared/received/opened, storage requirements, expiration dates, and NFPA codes
 - c. Store and dispose of reagents properly
 - d. Maintain log of Material Safety Data Sheets (MSDS) and product inserts
5. Evaluate and choose biologicals and chemicals conforming to purity, specificity, sterility, and stability required for the intended assays
6. Assess the quality of reagents by reproducibility, parallel studies, titration studies, pH check, etc.
7. Perform appropriate tests for nucleic acid, radioisotope, chemical, and microbial contamination

B. Instrumentation/Equipment (3 questions)

1. Calibrate, validate, and operate instruments and equipment by applying criteria established by the laboratory, manufacturer and/or accrediting and regulatory agencies
2. Adjust and/or repair simple instruments and equipment; obtain external services when appropriate
3. Initiate contingency plan when malfunctions occur (e.g., power or equipment failure)
4. Monitor and document operating conditions (e.g., temperature, CO₂ levels, liquid nitrogen levels)

C. Documentation (5 questions)

1. Validate changes in testing methods by parallel or confirmatory testing
2. Maintain identity of specimen throughout testing and reporting of results, meeting processing time deadlines; address delays in result reporting

3. Establish and implement policies to reject specimens when criteria of acceptability for testing are not met and to ensure that unacceptable specimens are not tested
4. Document incidents related to quality of testing
5. Establish a system to maintain records of testing results for all subjects tested according to regulatory guidelines
6. Establish and implement a system to report testing results in a timely, accurate and reliable manner
7. Establish and implement policy to perform periodic antibody screening of patients awaiting solid organ transplantation
8. Maintain records of potentially sensitizing events for each patient awaiting solid organ transplantation
9. Establish and implement policy for repeat testing to be performed when necessary
10. Establish, implement and document corrective action procedures to deal with any inconsistency or errors in reporting of test results or problems with communication with laboratory
11. Develop and implement program to regularly assess abilities of laboratory personnel to reproduce test results of previously characterized specimens
12. Validate prior to use any automated systems and computer programs used to assist in the interpretation of reaction patterns; test routinely for accuracy and reproducibility

D. Compliance (3 questions)

1. Maintain testing guidelines set by regulatory agencies (e.g., ASHI, UNOS, CLIA, OSHA) for procedures being performed in the laboratory
2. Participate in internal and external (e.g., ASHI/CAP surveys) quality assurance and proficiency testing programs
3. Implement program to monitor compliance to laboratory policies

VII. Supervisory Functions/Management (15 questions)

A. Staffing (4 questions)

1. Determine levels and types of personnel necessary to perform tasks
2. Utilize institutional and regulatory policies regarding employee selection, job descriptions, performance evaluations, benefits, counseling, and grievance procedures
3. Schedule and supervise personnel to optimize efficiency in providing necessary level of service
4. Conduct training of laboratory technologists, students, and physicians in techniques and procedures used in the laboratory
5. Provide education regarding history and principles of histocompatibility to new technologists, students, physicians, and others
6. Provide and participate in continuing education for technical personnel
7. Review appropriate literature



8. Monitor and document competency of testing personnel by job function and ensure performance improvement
 9. Facilitate a means of communication between laboratory staff concerning new procedures, proficiency results, etc.
- B. Cost Management (3 questions)
1. Determine and choose cost-effective methodologies, reagents, and equipment for laboratory operation
 2. Assist in determination of laboratory budgets, considering costs and revenues
 3. Prepare technical reports reflecting volume of work performed, procedures utilized, and testing results
 4. Prepare reports and analyses identifying progress or adverse trends
 5. Indicate tests performed for billing purposes
- C. Laboratory Operations (8 questions)
1. Implement appropriate federal, state, local, institutional and accreditation agency laws, regulations, standards, policies, and ensure compliance
 2. Establish communications to interact effectively with patients and medical personnel at all levels within and outside of the laboratory
 3. Participate in department goal setting and/or mission statement
 4. Assist in laboratory space allocation and design when applicable
 5. Prepare and update laboratory manuals or procedures and policies
 6. Assist in preparation of laboratory certification/ accreditation applications
 7. Prepare reports of quality assurance and proficiency testing results
 8. Store all relevant worksheets, records, and results in such a manner that they are easily accessible to personnel
 9. Develop and validate new procedures and technologies
 10. Develop an appropriate inventory system to manage laboratory reagents and supplies
 11. Validate commercial software packages for data analysis, data management, and inventory systems
 12. Maintain appropriate security measures for computer systems
 13. Participate in institution wide planning and quality assurance programs



ABHI Histocompatibility Laboratory Director Detailed Content Outlinex

	<u>Number of Items</u>	<u>Number of Items</u>	
I. Administrative/Management	20		
A. Quality Assurance	8		
1. Determine if technical staff has received training and continuing education		5. Determine administrative action(s) to be taken from proficiency testing results	
2. Develop/Design laboratory proficiency testing programs		6. Develop/Design standards of performance for technologists	
3. Develop/Design quality assurance programs (e.g., appropriateness of work, timeliness of work)		7. Develop job descriptions	
4. Develop "Quality Assessment of Improvement Programs"		8. Develop workload indicators	
5. Evaluate competency of laboratories used for referral testing		9. Direct staff compliance with all federal, state, and local safety laws/regulations	
6. Monitor test utilization		10. Evaluate competency of laboratory personnel:	
7. Monitor quality assurance program (e.g., appropriateness of work, timeliness of work)		a. assess performance of duplicate testing	
8. Review test results for accuracy and completeness		b. assess performance of blind testing	
9. Review safety requirement procedures followed when hazardous conditions occur:		c. assess performance of equipment maintenance procedures	
a. biological specimen		d. assess problem solving skills	
b. chemical		e. monitor recording of test results	
c. fire		f. observe test performance	
B. Fiscal Management	4	g. review worksheets	
1. Allocate budget		11. Evaluate staff knowledge of all federal, state, and local safety laws/regulations	
2. Consult with administrative personnel on laboratory procedures (e.g., accounting, billing, purchasing)		12. Monitor workload indicators	
3. Develop laboratory budget		13. Monitor laboratory output to prevent unauthorized deviations from established laboratory procedures	
4. Develop fee structure for laboratory services		14. Monitor internal/external work standards and regulations	
5. Develop laboratory cost containment measures			
6. Evaluate testing procedures considering cost/benefit criteria		D. Laboratory Operations	4
7. Monitor laboratory budget		1. Approve source of all reagents	
8. Negotiate contracts		2. Authorize a staff member to release (sign) test reports	
9. Negotiate personnel salaries and benefits		3. Determine if established protocols are being followed	
10. Negotiate for laboratory equipment and facilities		4. Develop/Design protocols for collection, organization, and systematic retrieval of all test results	
11. Negotiate resources for laboratory programs		5. Develop/Design protocols/systems for handling, storage, and disposal of biological, chemical, and radioactive materials	
C. Personnel Management	4	6. Develop/Design procedures for laboratory test reporting to establish information to include on reports	
1. Assign all duties/responsibilities of consultants, supervisors, and technologists		7. Develop/Design procedures for laboratory test reporting to determine when interpretive notes are necessary	
2. Authorize a staff member to approve test reports		8. Implement safety requirements (e.g., fire, chemical, biological specimen)	
3. Authorize or conduct personnel actions:		9. Develop and maintain policy/protocol manual	
a. classification decisions		10. Direct the implementation of necessary remedial action(s) when test results do not meet established limits of accuracy	
b. employee selection		11. Direct laboratory compliance with regulatory agencies	
c. grievance procedures		12. Direct laboratory compliance with governmental safety requirements	
d. performance evaluations		13. Evaluate equipment, personnel, and space requirements for reliable test performance	
e. performance feedback			
f. promotions			
g. qualification determination			
h. salary determination			
i. transfers			
j. terminations			
4. Counsel personnel on personal/interpersonal problems			



	<u>Number of Items</u>		<u>Number of Items</u>
14. Direct implementation of institutional policy and programs		2. Evaluate potential of hyperacute rejection	
15. Maintain effective working relationships (liaison) (e.g., accrediting agencies, administrative officials, citizens groups, medical community, organ procurement organizations, regulatory agencies)		3. Evaluate donor and recipient histocompatibility	
16. Maintain knowledge of professional liability and risk management issues		4. Evaluate prior sensitization of transplant recipient for clinical relevance	
17. Organize meetings with transplant physicians and coordinators		5. Evaluate biological clinical significance of pre-existing tissue specific antibodies prior to transplant	
18. Plan long-term (strategic) laboratory objectives		6. Correlate histocompatibility data with other laboratory tests, and clinical and pathologic findings (e.g., biophysical results, clinical chemistry, HLA typing, physical findings)	
19. Plan short-term laboratory objectives		7. Verify test validity and accuracy of interpretation by establishing parameters for test results	
20. Resolve client complaints		D. Protocol Development	10
21. Review laboratory procedure/protocol manuals annually		1. Determine patient information to be provided to laboratory	
22. Serve as managerial resource		2. Determine the appropriate selection of tests with client for various clinical applications	
23. Supervise laboratory equipment maintenance		3. Determine pre/post graft testing protocols	
24. Supervise laboratory staff		4. Select tests to best meet clinical needs of patient population served by laboratory	
25. Supervise the reporting of all laboratory results		III. Technology Development and Implementation	<u>50</u>
II. Clinical Functions	<u>60</u>	A. Development of Tests	13
A. Interpretation of Results	20	1. Determine technical action(s) to be taken from proficiency testing results	
1. Analyze immunologic risk factors for transplantation		2. Develop/Design testing procedures for special conditions/samples (e.g., abnormal blood profiles)	
2. Interpret individual test results for correlation with clinical outcome		3. Develop/Design follow-up procedures when test failure occurs	
3. Sign test reports		4. Determine specimen requirements for specific tests	
4. Define HLA phenotype/genotype for clinical application		5. Develop appropriate controls for each test	
5. Develop/Design procedures for laboratory test reporting by providing interpretive notes		6. Develop laboratory programs to accommodate changing clinical needs	
6. Interpret/Evaluate test results considering the type of organ		7. Initiate innovative laboratory procedures	
7. Review all test reports		8. Select methods for test performance	
B. Provide Consultation	20	9. Serve as technical resource	
1. Attend clinical transplant meetings/rounds		B. Implementation of Tests	13
2. Consult with medical services regarding testing needs		1. Approve all technical procedures	
3. Provide consultation to clinicians in the areas of:		2. Approve changes in technical procedures	
a. histocompatibility		3. Develop/Design procedures for equipment operation	
b. immunogenetics		4. Develop and maintain technical procedure manual	
c. transplantation		5. Establish normal ranges for test results	
4. Provide consultation to physicians and other medical staff on the interpretation of test results		6. Select equipment for test performance	
5. Provide consultation on appropriateness of tests and results to interested parties (e.g., attorneys, parents, patients, other clients)		7. Select test reagents	
6. Provide consultation on alloantibody removal methods		C. Verification of Tests	12
7. Serve as clinical resource		1. Determine action(s) to be taken from quality control data review	
C. Correlative Functions	10	2. Determine action(s) to be taken from equipment verification data	
1. Evaluate impact of patient condition, including but not limited to pre-existing disease, therapy and immune status related to:		3. Develop/Design procedures that ensure reported test results are within established limits of accuracy	
a. HLA phenotyping/genotyping			
b. histocompatibility testing			



	<u>Number of Items</u>		<u>Number of Items</u>
4. Develop/Design quality control procedures for laboratory tests (e.g., accuracy of reported tests)		B. Teaching: Non-medical Groups	4
5. Develop/Design equipment performance verification procedures		1. Conduct general education seminars with the public	
6. Monitor quality control procedures for laboratory tests (e.g., accuracy of reported tests)		2. Develop outreach programs and increase awareness of histocompatibility testing	
7. Review all QC testing of reagents		3. Provide instruction to administrative personnel regarding billing and reimbursement	
8. Review quality control data		C. Personal Growth	10
9. Review equipment performance verification data		1. Attend national/international histocompatibility meetings/workshops	
10. Verify test validity and accuracy of interpretation to:		2. Evaluate training and continuing education needs of self	
a. establish controls for test procedure(s)		3. Maintain current knowledge of MHC structure and function	
b. establish controls for test application(s)		4. Participate in immunology, immunogenetics, and transplantation continuing education	
c. establish parameters for reliable test outcome		5. Review (read) professional journals and books	
D. Evaluation of Tests	12	6. Review (read) current federal and state regulations	
1. Analyze clinical testing data to evaluate test methods (e.g., graft outcome for transplantation, efficiency of drug protocols)		V. Scientific Principles	50
2. Evaluate the typing reagents		A. Application of Basic Science	25
3. Identify limitations of the tests employed in the laboratory		1. Authorize deviations from written procedure manual given a specific population regarding technical procedures	
4. Monitor all laboratory results by checking raw data for test outcome trends		2. Evaluate basic science research as to its clinical relevance	
5. Review all technical work		3. Serve as scientific resource	
IV. Educational Activities/Personal Growth	20	4. Apply basic science to the solution of clinical problems in organ transplantations	
A. Teaching: Medical Personnel	6	5. Evaluate non-HLA antigens for their potential to act as histocompatibility antigens	
1. Conduct seminars in histocompatibility for clinicians and transplant coordinators		B. Clinical Ramifications	13
2. Conduct general education seminars with medical personnel		1. Analyze outcome of:	
3. Conduct general education seminars with physicians		a. solid organ transplants	
4. Develop/Design personnel orientation/training programs (e.g., histocompatibility testing, quality control of tests and reagents, preventative maintenance of equipment, safety measures, waste disposal)		b. bone marrow transplants	
5. Develop in-service education program for laboratory staff		c. disease association	
6. Direct personnel training programs		d. transfusion	
7. Direct training of residents and fellows		2. Authorize deviations from written procedure manual given a specific population regarding policy and protocol	
8. Evaluate training and continuing education needs of clinical staff		3. Evaluate diagnostic performance of new technology	
9. Evaluate training and continuing education needs of technical staff		C. Research	12
10. Organize meetings with technical staff regarding:		1. Conduct clinical and basic research projects	
a. application of laboratory techniques in clinical medicine		2. Develop clinically oriented research programs (e.g., HLA and disease associations, immune phenotyping of lymphocytes by FACS, development of new methodologies)	
b. scientific basis of laboratory techniques		3. Develop/Design laboratory test performance characteristics	
11. Provide instruction to laboratory supervisor regarding general knowledge		4. Direct research and development programs in the laboratory	
12. Provide instruction to laboratory supervisor regarding laboratory policies		5. Identify new testing methodologies	
13. Select learning aids for use by laboratory staff (e.g., books, journals, videos)		6. Participate at national/international histocompatibility meetings/workshops (e.g., present research findings)	
14. Train doctoral and medical personnel in HLA and histocompatibility testing		7. Write scholarly articles	



Sample Examination Questions

The ABHI Examinations have been developed to objectively measure the knowledge and skills required for histocompatibility technologists and specialists. The CHA, CHS and CHT examinations contain 150 multiple-choice questions plus 20 non-scored questions. The Histocompatibility Laboratory Director examination will contain 200 multiple-choice questions plus a determined amount of non-scored questions. The examinations are developed by an examination committee of experts in the field who are appointed by ABHI.

The following are examples of multiple-choice questions:

- Which specimen type usually provides the highest yield of B lymphocytes?
 - serum
 - peripheral blood
 - lymph node
 - spleen
- The build-up of residue will interfere with the performance of the Hamilton repeating syringe. Which of the following procedures is most appropriate for cleaning the syringe?
 - Soak in a strong acid solution.
 - Rinse with detergent and water.
 - Autoclave for 20 minutes.
 - Soak in a clorox solution.
- In a family study, the following typing is obtained:

Mother HLA –A1, 2, B7, 8
 Child HLA –A2, B7, 8

The biological father of the child could have contributed all of the following HLA haplotypes **EXCEPT**

 - Ax, Bx.
 - A2, B7.
 - A2, B8.
 - Ax, B7.
- Antigen presentation to helper T cells is primarily a function of which of the following MHC classes?
 - Class I
 - Class II
 - Class III
 - II only
 - I and III only
 - II and III only
 - I, II, and III

Answer Key		
Item #	Content	
	Category	Key
1.	3A	D
2.	4B	B
3.	4A	A
4.	5C	A

SUGGESTED STUDY MATERIALS

As a certifying agency, ABHI is not directly involved in assisting individuals to prepare for examinations. Applicants may wish to consult some of the following sources for background and specific information in the various content areas to be covered by the CHA, CHT, CHS, or Histocompatibility Laboratory Director examinations. Alternate materials are also available in most medical libraries.

Content Areas

- ABHI Statements of Competence for Histocompatibility Personnel, 1998
- ASHI Standards for Histocompatibility Testing, 2005
- UNOS Standards for Histocompatibility, 2005
- ASHI Laboratory Accreditation Inspection Checklist, 2005
- CAP Laboratory General Checklist, 2005
- CAP Histocompatibility Checklist, 2005

General Laboratory Skills and Safety

- OSHA Guidelines, Federal Register, 56 (No235): pp 64175-64182, 1991
- CMS CLIA Regulations, Federal Register, 68 (No16): pp 3639-3714, 2003
- Laboratory Safety: Principles and Practices* (1995) Am Society Micro, Washington, DC
- ASHI Laboratory Manual*, 4th Ed. 2001, updates 2005

Laboratory Management

- Clinical Laboratory Medicine*, K. McClatchey (ed), Lippincott, Williams & Wilkins, 2001
- Management: Theory, Process and Practice*, RM Hodgetts
- Clinical Laboratory Management Review*. Bi-monthly from CLMA, Williams & Wilkins

Basic Immunology

- Cellular and Molecular Immunology*, 5th Ed. A. Abbas (ed). Saunders 2005
- Essential Immunology*, 6th Ed. Roitt, Brostoff & Male. Mosby 2001



Immunology: The Immune System in Health and Disease, 6th Ed. C. Janeway (ed) Garland Publishing, 2004

The Immune System. P. Parham, Garland Publishing, Elsevier Science, 2004

Illustrated Dictionary of Immunology, JM Cruse & RE Lewis. CRC Press, 2002

Histocompatibility and Immunogenetics

HLA Facts Book, Marsh, Parham, & Barber, Academic Press, 2005

HLA in Health and Disease 2nd Ed., Academic Press, 2000

HLA Beyond Tears, 2nd Ed. GE Rodey DeNovo, Inc. 2000

The HLA Dictionary 2004, Schreuder, Hurley, Marsh, etal: Tissue Antigens (2005) 65,1-55; or Human Immunology (2005) 66,170-210; or International Journal of Immunogenetics (2005) 32,19-69.

Transplantation

Primer on Transplantation, 2nd Ed. Norman & Suki, AST, 2001

Clinical Transplants, published yearly 1988-present, Cecka & Terasaki, (eds) UCLA Tissue Typing Laboratory, Los Angeles, CA

Hemopoietic Cell Transplantation, 3rd Ed. Thomas, Blume & Forman, Blackwell Science

Cord Blood Characteristics: Role in Stem Cell Transplantation. Cohen, Gluckman, Rubinstein & Madrigal (eds). Blackwell Science, Inc. 2000

Flow Cytometry

Immunophenotyping, Stewart & Nicholson (eds) Wiley-Liss, Inc, 2000

Flow Cytometry in Clinical Diagnosis. Keren (ed) ASCP Press 3rd Ed, 2001

Practical Flow Cytometry, 4th Ed. Shapiro (ed) Wiley-Liss, Inc. 2003

Molecular Biology

DNA: The Secret of Life. Barry & Watson, Knopf Publishing, 2003.

Genes VIII. Lewin, 8th Ed, Wiley & Sons, 2003.

PCR Technology: Current Innovations, Library of Congress, Cataloging-in-Publication Data, 2nd Ed, 2003.

Molecular Biology of the Cell, 4th Ed. Alberts, Garland Publishing, 2002.

Human Molecular Genetics, 3rd Ed. Strachan, AP Read, 2003.

Molecular Typing 2000: A Technical Manual for Histocompatibility Laboratories, SEOPF

Seminars & Courses

Georgetown Teleconferences offered by the Georgetown University Medical Center via interactive seminars

covering many topics in histocompatibility and immunogenetics. Contact Georgetown University Medical Center at 202/784-2909.

AFDT basic and advanced workshops offered biannually. Topics covered are histocompatibility and immunology and genetics. Contact AFDT at 804/323-9890 for more information.

ASHI Regional meetings are usually offered in the spring and the ASHI Annual Meeting is usually held in the fall. Contact ASHI Executive Office at 856/638-0428 for more information.

ASHI Quarterly Quizzes, contact ASHI Executive Office at 856/638-0428.

TAKING THE EXAMINATION

Your examination will be given by computer at an AMP Assessment Center. You do not need any computer experience or typing skills to take your examination. On the day of your examination appointment, report to the Assessment Center no later than your scheduled testing time. Look for the signs indicating AMP Assessment Center Check-in. A CANDIDATE WHO ARRIVES MORE THAN 15 MINUTES AFTER THE SCHEDULED TESTING TIME WILL NOT BE ADMITTED.

Identification

To gain admission to the Assessment Center, you must present two forms of identification, one with a current photograph. Both forms of identification must be current and include the candidate's current name and signature. The candidate will be required to sign a roster for verification of identity.

Acceptable forms of photo identification include a current driver's license with photograph, a current state identification card with photograph, a current passport, or a current military identification card with photograph. Employment ID cards, student ID cards and any type of temporary identification are NOT acceptable as the primary form of identification.

You must have proper identification to gain admission to the Assessment Center. Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of your examination fee.

Security

ABHI and AMP maintain examination administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their abilities. The Assessment Center is continuously monitored by audio and video surveillance equipment for security purposes.



The following security procedures apply during the examination:

- Examinations are proprietary. No cameras, notes, tape recorders, Personal Digital Assistants (PDAs), pagers or cellular phones are allowed in the testing room.
- No programmable calculators are permitted. Only silent, hand-held, solar-or battery-operated calculators without paper tape-printing capabilities or alphabetic keypads, may be used.
- No guests, visitors or family members are allowed in the testing room or reception areas.
- No personal items, valuables, or weapons should be brought to the Assessment Center. Only keys and wallets may be taken into the testing room and AMP is not responsible for items left in the reception area.

■ Examination Restrictions

- No personal belongings will be allowed in the Assessment Center. Pencils will be provided during check-in.
- You will be provided with scratch paper to use during the examination. You must return the scratch paper to the supervisor at the completion of testing, or you will not receive a score report. No documents or notes of any kind may be removed from the examination room.
- No questions concerning the content of the examination may be asked during the examination.
- Eating, drinking or smoking will not be permitted in the Assessment Center.
- You may take a break whenever you wish, but you will not be allowed additional time to make up for time lost during breaks.

■ Misconduct

Individuals who engage in any of the following conduct may be dismissed from the examination, their scores will not be reported and examination fees will not be refunded. Examples of misconduct are when a candidate:

- creates a disturbance, is abusive, or otherwise uncooperative;
- displays and/or uses electronic communications equipment such as pagers, cellular phones, PDAs;
- gives or receives help or is suspected of doing so;
- attempts to record examination questions or make notes;
- attempts to take the examination for someone else; or
- is observed with notes, books or other aids.

■ Copyrighted Examination Questions

All examination questions are the copyrighted property of ABHI. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may subject you to severe civil and criminal penalties.

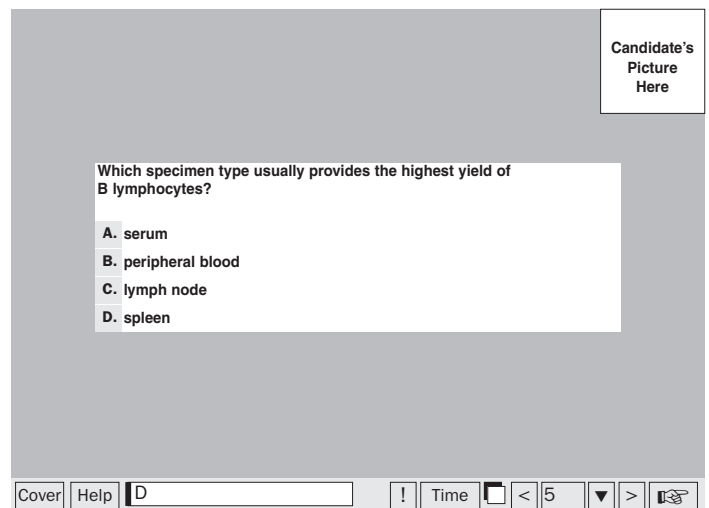
■ Practice Examination

After your identification has been confirmed, you will be directed to a testing carrel. You will be instructed on-screen to enter your Social Security number. You will take your photograph which will remain on screen throughout your examination session. This photograph will also print on your score report.

Prior to attempting the examination, you will be given the opportunity to practice taking an examination on the computer. The time you use for this practice examination is NOT counted as part of your examination time or score. When you are comfortable with the computer testing process, you may quit the practice session and begin the timed examination.

■ Timed Examination Multiple-choice Software

Following the practice examination, you will begin the timed examination. Before beginning, instructions for taking the examination are provided on-screen.



The computer monitors the time you spend on the examination. The examination will terminate if you exceed the time allowed. You may click on the "Time" box in the lower right-hand corner of the screen or select the Time key to monitor your time. A digital clock indicates the time remaining for you to complete the examination. The Time feature may be turned off during the examination.



All items on the ABHI examinations are multiple-choice and have equal weight for scoring, excluding the nonscored items used for pretesting purposes. Pretesting is accomplished by interspersing new untried items throughout the examination. These items are not scored as part of the candidate's credentialing examination, and they do not affect an individual's pass/fail status. Pretesting is used to collect meaningful statistics about new items that may appear as scored items on future examinations.

The 20 nonscored items are in addition to the 150 scored items on the CHT, CHA and CHS examination. Testing time for the previously mentioned examinations will be 3.5 hours to allow ample time to complete the examinations.

The Histocompatibility Laboratory Director Examination has 30 nonscored items in addition to the 200 scored item test as in the past. Candidates will be given five hours to complete the examination in two testing sessions.

Only one examination question is presented at a time. The question number appears in the lower right hand corner of the screen. Choices of answers to the examination question are identified as A, B, C, or D. You must indicate your choice by either typing in the letter in the response box in the lower left hand of the computer screen or clicking in the option using the mouse. To change your answer, enter a different option by pressing the A, B, C, or D key or by clicking on the option using the mouse. You may change your answer as many times as you wish during the examination time limit.

To move to the next question, click on the forward arrow (>) in the lower right portion of the screen or select the NEXT key. This action will move you forward through the examination question by question. If you wish to review any question or questions, click the backward arrow (<) or use the left arrow key to move backward through the examination.

An examination question may be left unanswered for return later in the examination session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the Time button. Click on the hand icon or select the NEXT key to advance to the next unanswered or bookmarked question on the examination. To identify all unanswered and bookmarked questions, repeatedly click on the hand icon or press the NEXT key. When the examination is completed, the number of examination questions answered is reported. If not all questions have been answered and there is time remaining, return to the examination and answer those questions. Be sure to provide an answer for each examination question before ending the examination. There is no penalty for guessing.

■ Candidate Comments

During the examination, online comments may be provided for any question by clicking on the button displaying an exclamation point (!) to the left of the Time button. This opens a dialogue box where comments may be entered. Comments will be reviewed, but individual responses will not be provided.

FOLLOWING THE EXAMINATION

After completing the examination, candidates are asked to complete a short evaluation of their examination experience. Then, candidates are instructed to report to the examination proctor to receive their score report. Scores are reported in written form only, in person or by U.S. mail. Scores are not reported over the telephone, by electronic mail or by facsimile.

Your score report will indicate a "pass" or "fail." Your pass/fail status is determined by your raw score. Additional detail is provided in the form of raw scores by major content category. A raw score is the number of questions you answered correctly.

■ Pass/Fail Score Determination

The methodology used to set the minimum passing score is the Angoff Method; this is a criterion-referenced process in which expert judges estimate the passing probability of each question on the examination. These judgments are averaged to determine the minimum passing score (i.e., the number of correctly answered questions required to pass the examination), to ensure that those who pass the examination have demonstrated a sufficient level of knowledge of histocompatibility to warrant certification. Statistical equating procedures are used to ensure that each examination form that is developed will be of a consistent level of difficulty, based on the average difficulty of the questions being scored.

■ Scores Cancelled by ABHI or AMP

ABHI and AMP are responsible for the validity and integrity of the scores they report. On occasion, occurrences, such as computer malfunction or misconduct by a candidate, may cause a score to be suspect. ABHI and AMP reserve the right to void or withhold examination results if, upon investigation, violation of its regulations is discovered.



■ If You Pass the Examination

When you pass either ABHI certification examination for the first time, you will be awarded either the Certified Histocompatibility Associate (CHA), Certified Histocompatibility Technologist (CHT) Certified Histocompatibility Specialist (CHS) or the Diplomate (D)ABHI credential. You will receive a certificate acknowledging your achievement.

■ If You Do Not Pass the Examination

You will be given the opportunity to apply for a future examination.

FAILING TO REPORT FOR AN EXAMINATION

A candidate who fails to report for an examination forfeits the registration and all fees paid to take the examination. A completed ABHI Registration Form and examination fee are required to reapply for examination.

CONFIDENTIALITY

Information about candidates for testing and their examination results are considered confidential. Studies and reports concerning candidates will contain no information identifiable with any candidate, unless authorized by the candidate.



Candidate Handbook



**American Board of
Histocompatibility
and Immunogenetics**
P.O. Box 19173
Lenexa, KS 66285-9173
(913) 895-4602

Sponsored by:

*The American Society for
Histocompatibility and Immunogenetics*

APPLICATION INSTRUCTIONS

American Board of Histocompatibility and Immunogenetics Certification Examination
Certified Histocompatibility Associate (CHA)
Certified Histocompatibility Technologist (CHT)
Certified Histocompatibility Specialist (CHS)
Histocompatibility Laboratory Director D(ABHI)

APPLICATION DEADLINE: January 1 for March Testing; June 1 for September Testing

APPLICATION SUBMISSION: Your application and all verifying documents (i.e., transcripts and statements of competency or letters of competency) and fees must be received in our office postmarked no later than the application deadline indicated on the cover page of this packet. If there is information lacking on your application, you will be given the opportunity to submit the documentation by a specific date, but will be required to pay an additional \$25 processing fee. The Board strictly adheres to this completion deadline. Individuals whose applications are incomplete will be notified in writing and given the opportunity to submit the supporting documentation along with the \$25 processing fee by a specified deadline.

APPLICATION FEES: CHA – \$195 U.S. Dollars – 2009
CHT – \$195 U.S. Dollars – 2009
CHS – \$225 U.S. Dollars – 2009
ABHI Diplomate – \$890 U.S. Dollars
(Fees for exams listed above are subject to change.)

No application will be processed unless accompanied by the appropriate application fees.

IMPORTANT NOTE:

To prevent a delay in processing your application, answer all information blanks carefully and completely. If the requested information does not apply to you, **enter N/A (not applicable)** where appropriate. Any blanks may cause your application to be perceived as incomplete and require further documentation and an additional \$25 processing fee.

MAIL ORIGINAL TO:

American Board of Histocompatibility and Immunogenetics
P.O. Box 19173
Lenexa, KS 66285-9173
Overnight Mail Only:
18000 W. 105th Street
Olathe, KS 66061-7543



**American Board of
Histocompatibility
and Immunogenetics**
P.O. Box 19173
Lenexa, KS 66285-9173
(913) 895-4602

Sponsored by:

*The American Society for
Histocompatibility and Immunogenetics*

EXAMINATION APPLICATION

TYPE OR PRINT CLEARLY

I wish to take the examination for CHA CHT CHS Histocompatibility Laboratory Director recertification.

Have you ever applied/sat for an ABHI examination before? Yes No

Which examination? _____ When? _____ Cert. # _____

I have a disability and may require some accommodation in taking this examination. I understand if an accommodation is not requested in advance, ABHI cannot guarantee the availability of such accommodation.

MR. CIN or
NAME MS. SS# _____
LAST FIRST MIDDLE

HAVE YOU EVER USED ANOTHER NAME? Yes No If so, list _____

PREFERRED MAILING ADDRESS WORK HOME

WORK MAILING _____ HOME MAILING _____
ADDRESS _____ ADDRESS _____

WORK PHONE (_____) _____ HOME PHONE (_____) _____
FAX _____ E-MAIL _____

NOTE: Please line through or put "N/A" for "not applicable" in all areas of the application that do not pertain to you. Any areas not filled out or noted as "not applicable" will be assumed to be incomplete. ALL DOCUMENTATION MUST BE SUBMITTED AT THE TIME OF APPLICATION.

Section I – Education

INSTITUTION/ADDRESS	MAJOR	DEGREE	GRAD DATE	OFFICIAL TRANSCRIPTS ENCLOSED/ORDERED
		/		
		/		
		/		
		/		
		/		

If you are applying for the Histocompatibility Laboratory Directors Examination complete only pages 28, 32 and 33 and submit appropriate documentation. (Next Histocompatibility Laboratory Director examination will be September 2009.)

Section II – Experience

Employment experience in HISTOCOMPATIBILITY TESTING. Please give exact dates.

HLA EXPERIENCE	YOUR CAPACITY	DATES OF EMPLOYMENT
INSTITUTION		/ / TO / /
ADDRESS		
DIRECTOR		

Was this laboratory ASHI/UNOS- or EFI-accredited during dates of employment? Yes No If no, please see SPONSORSHIP route of application.

HLA EXPERIENCE	YOUR CAPACITY	DATES OF EMPLOYMENT
INSTITUTION		/ / TO / /
ADDRESS		
DIRECTOR		

Was this laboratory ASHI/UNOS- or EFI-accredited during dates of employment? Yes No If no, please see SPONSORSHIP route of application.

HLA EXPERIENCE	YOUR CAPACITY	DATES OF EMPLOYMENT
INSTITUTION		/ / TO / /
ADDRESS		
DIRECTOR		

Was this laboratory ASHI/UNOS- or EFI-accredited during dates of employment? Yes No If no, please see SPONSORSHIP route of application.

NOTE: For those individuals requiring sponsorship:

I will be sponsored for HLA experience. My sponsors will be:

1. _____
 NAME TITLE INSTITUTION

2. _____
 NAME TITLE INSTITUTION

Please check the areas in which your laboratory is ASHI accredited below and indicate which tests your laboratory performs.

AREAS OF ACCREDITATION

- General Immunology
- HSC/BM Transplantation: Related Donor
- HSC/BM Transplantation: Unrelated Donor
- Solid Organ Transplantation: Deceased Donor
- Solid Organ Transplantation: Live Donor
- Parentage Testing
- Typing for Non-TX Clinical Purposes
- Transfusion Support

LABORATORY TESTING

- KIR Typing
- Serologic Typing
- DNA typing by SSP
- DNA typing by SSOP
- DNA typing by reverse SSOP (including strips, microbead array and chips)
- DNA typing by SBT
- DNA typing by RFLP
- Antibody screen/ID by cytotoxicity
- Antibody screen/ID by ELISA
- Antibody screen/ID by microbead array
- Antibody screen/ID by flow cytometry

- Crossmatch by cytotoxicity
- Crossmatch by flow cytometry
- Crossmatch by solid phase
- STR/VNTR for monitoring engraftment
- STR/VNTR for parentage/genetic ID
- MLC
- Cellular Assays
- Immune Function testing
- T cell Immunoassays (including Cylex ImmuKnow)
- ABO/Rh Testing
- Anti-A titers
- Immunophenotyping

HLA WORK EXPERIENCE STATEMENT OF COMPETENCY FROM LABORATORY DIRECTOR

Applicant's Name _____ CIN or SS# _____

Please give the approximate percent of time working in each area and techniques/responsibility.

	CLINICAL		RESEARCH	
	Description	% Time	Description	% Time
SEROLOGICAL TYPING CLASS I				
CLASS II				
ANTIBODY SCREENING				
CROSSMATCHING				
CELLULAR TESTING				
MOLECULAR				
FLOW CYTOMETRY				

Additional information (attach additional sheet if needed): _____

*The above named individual has worked in my laboratory for / in a full-time part-time status
Year Months
 (if part-time: % FTE) and has performed the above responsibilities.

I hereby certify that _____ is qualified to sit for the
 CHA CHT CHS examination according to the ABHI eligibility requirements.

I am the director of an ASHI/UNOS-or EFI-accredited laboratory. I _____
(PRINT NAME)

DO SOLEMNLY SWEAR (AFFIRM) THAT I HAVE MADE OR READ THE CONTENTS HEREOF, AND TO THE BEST OF MY KNOWLEDGE AND BELIEF, THE FOREGOING STATEMENTS AND ANSWERS ARE TRUE IN SUBSTANCE AND EFFECT, AND ARE MADE IN GOOD FAITH.

 Signature of Laboratory Director

***Laboratory Directors are permitted to verify previous HLA work experience of employee, in the event prior experience was a consideration for hiring. Please indicate in the "Additional Information" area if you are verifying previous experience.**

NOTE: This page may be photocopied and used for additional laboratory directors to document previous experience.

SPONSORSHIP PROGRAM DOCUMENTATION OF WORK EXPERIENCE

Individuals applying for examination through the Sponsorship route must complete this portion of the application.

NOTE: This page may be photocopied and used for additional sponsors.

Applicant's Name _____ CIN or SS# _____

APPLICANTS:

Individuals lacking relevant work experience in an approved histocompatibility laboratory must fulfill the requirement by sponsorship. Each applicant must have this form completed by two sponsors. The sponsor forms should be completed and the signature of the sponsor must be notarized.

Additional supporting documentation of participation in the field of HLA such as ABHI-approved workshops and SEOPF courses should be included with the application. Individuals who are pursuing eligibility through the sponsorship route may contact the Credentials Committee Chair (or committee member) or ABHI executive office for assistance.

CHA – Must have forms submitted by one CHS with current ABHI certification and one laboratory director (director of ASHI/UNOS or EFI-accredited laboratories) or two CHS's with current ABHI certification.

CHT – Must have forms submitted by one CHS with current ABHI certification and one laboratory director (director of ASHI/UNOS- or EFI-accredited laboratories) or two CHS's with current ABHI membership.

CHS – Must have forms submitted by two sponsors. The sponsors are to include one CHS with current ABHI certification and a laboratory director (laboratory directors must be from ASHI/UNOS or EFI-accredited laboratories) or two laboratory directors.

SPONSORS:

The sponsorship route for applying to sit for the ABHI CHA, CHT and CHS examination is designed to allow applicants who meet both the requirement for education and time working in the field of histocompatibility testing, but whose working experience was not obtained in an ASHI/UNOS- or EFI-accredited laboratory.

Please answer the following questions and have your signature notarized before returning to the applicant.

1. Describe in detail your working relationship with the applicant.

2. List the laboratory skills that are unique to histocompatibility testing that the applicant has been trained to perform and has successfully mastered.

3. List relevant professional activities that you have shared with the applicant such as workshops, publications or other mutual associations.

4. Explain why you as a histocompatibility professional believe the applicant is qualified to sit for the ABHI credentialing examination.

SIGNATURE OF SPONSOR _____

Complete this page if you are applying for the Histocompatibility Laboratory Directors Examination.

The next administration of the Histocompatibility Laboratory Directors Exam will be September 2009

Section II – Training

POSTDOCTORAL TRAINING IN IMMUNOLOGY, IMMUNOGENETICS, OR CELL BIOLOGY:

DATES OF TRAINING

INSTITUTION	
ADDRESS	
MENTOR	

DOCUMENTATION ENCLOSED ____ OR BEING SENT UNDER SEPARATE COVER ____.

Section III – Experience

FORMAL TRAINING IN HUMAN HISTOCOMPATIBILITY TESTING

YOUR CAPACITY

DATES OF EMPLOYMENT

INSTITUTION		
ADDRESS		
DIRECTOR		

DOCUMENTATION ENCLOSED ____ OR BEING SENT UNDER SEPARATE COVER ____.

PROFESSIONAL EXPERIENCE IN THE HISTOCOMPATIBILITY LAB AT THE EQUIVALENT OF AN
ASSOCIATE/ASSISTANT DIRECTOR OR OTHER SUPERVISORY LEVEL

YOUR CAPACITY

DATES OF EMPLOYMENT

INSTITUTION		
ADDRESS		
DIRECTOR		

DOCUMENTATION ENCLOSED ____ OR BEING SENT UNDER SEPARATE COVER ____.

If you have special circumstances or need clarification of qualification contact:

Lorita Rebellato-deVente, PhD, dip.ABHI, Credentials Committee Chair at rebellatol@ecu.edu

Important Notice: The candidates should be advised of the low passing rate of applicants lacking the appropriate clinical experience.

Based on a survey disseminated among active HLA laboratory directors, and their actual time allocation to the different topics, the exam was designed to include the following:

<u>Task</u>	<u>% of Questions</u>
Administrative	10%
Clinical	30%
Technical	25%
Educational	10%
Scientific	25%

All tasks are clinically oriented, and require substantial hands-on experience in the daily routine of an HLA laboratory to pass successfully.

APPLICATION STATEMENT

I hereby make application to the American Board of Histocompatibility and Immunogenetics (ABHI) for admission to the examination leading to the issuance to me of the appropriate Certificate, all in accordance with and subject to the ABHI's Rules and Regulations. I agree to accept and abide by disqualification from the examination or from the issuance of a Certificate, and to return to the Board any such Certificate in the event that the Board shall determine that any of the statements made by me in connection with this application for examination are false in any material respect, or that I violated any of the rules governing such examinations.

In consideration of the acceptance of this application for examination, I hereby release the Board, its members, examiners, officers, and agents from any and all liability to me which, but for this release, may arise out of or in connection with this application, the related examinations, the score or scores given with respect to such examination, or any failure of the Board to issue me a Certificate. I agree to indemnify the Board, its members, examiners, officers and agents and hold them harmless from any loss, damage, cost or expense (including attorney's fees), in any suite or complaint, threatened or filed, in law or in equity and arising out of or in connection with this application, the related examinations, the score or scores given with respect to such examinations, the issuance to me of a Certificate, or any failure of the Board to issue me a Certificate.

I, _____, DO SOLEMNLY SWEAR (AFFIRM) THAT I AM THE APPLICANT
(PRINT NAME)

NAMED IN THIS APPLICATION, THAT I HAVE MADE OR READ THE CONTENTS HEREOF, AND TO THE BEST OF MY KNOWLEDGE AND BELIEF, THE FOREGOING STATEMENTS AND ANSWERS ARE TRUE IN SUBSTANCE AND EFFECT, AND ARE MADE IN GOOD FAITH.

CHECKLIST: (To be completed by applicant)

- CHECK OR MONEY ORDER FOR APPLICATION FEE PAYABLE TO ABHI
- COMPLETED APPLICATION
- APPLICATION STATEMENT
TRANSCRIPTS
 - ORDERED
 - ENCLOSED
- DOCUMENTATION

REMEMBER: IT IS THE APPLICANT'S RESPONSIBILITY TO MAKE SURE THE APPLICATION(S), TRANSCRIPT(S) AND ALL NECESSARY DOCUMENTATION IS RECEIVED AT THE ABHI EXECUTIVE OFFICE BY THE STATED DEADLINE. IF YOU HAVE ANY QUESTIONS, PLEASE CALL THE EXECUTIVE OFFICE.

METHOD OF PAYMENT:

- CHECK
- CREDIT CARD: MasterCard/VISA
 American Express

Card Number

Expiration Date

Cardholder Signature

Cardholder Name

REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS

If you have a disability covered by the Americans with Disabilities Act, please complete this form and the Documentation of Disability-Related Needs on the reverse side so your accommodations for testing can be processed efficiently. The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality.

Candidate Information

Social Security/CIN Number _____ - _____ - _____

Requested Exam Date: _____

Name (Last, First, Middle)

Street Address

City State Zip Code/Postal Code Country

Daytime Telephone Number

Special Accommodations

I request special accommodations for the _____ examination.

Please provide (check all that apply):

- Special seating or other physical accommodation
- Large print examination
- Reader
- Extended examination time (time and a half)
- Separate testing area
- Other special accommodations (Please specify.)

Comments: _____

Signed: _____ **Date:** _____

**Return this form with your examination application and fee to:
Examination Services Department, AMP, 18000 W. 105th Street, Olathe, KS 66061-7543.
If you have questions, call the Examination Services Department at 913/895-4600.**

DOCUMENTATION OF DISABILITY-RELATED NEEDS

Please have this section completed by an appropriate professional (education professional, physician, psychologist, psychiatrist) to ensure that AMP is able to provide the required test accommodations.

Professional Documentation

I have known _____ since ____ / ____ / ____ in my capacity as a
Examination Candidate Date

Professional Title

The candidate discussed with me the nature of the examination to be administered. It is my opinion that, because of this candidate's disability described below, he/she should be accommodated by providing the special arrangements listed on the reverse side.

Description of Disability: _____

Signed: _____ **Title:** _____

Printed Name: _____

Address: _____

Telephone Number: _____

Date: _____ **License # (if applicable):** _____

**Return this form with your examination application and fee to:
Examination Services Department, AMP, 18000 W. 105th Street, Olathe, KS 66061-7543.
If you have questions, call the Examination Services Department at 913/895-4600.**