



AMERICAN SOCIETY FOR
HISTOCOMPATIBILITY AND IMMUNOGENETICS

ACCREDITATION REVIEW PROGRAM

ON-SITE APPLICATION
INSTRUCTIONS

Revision 8/1/2009

ASHI ACCREDITATION PROGRAM APPLICATION INSTRUCTIONS

This Application is used for the following:

LABORATORIES RENEWING ACCREDITATION DURING THE ON-SITE INSPECTION YEAR

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GLOSSARY OF ABBREVIATIONS

ABB	American Board of Bioanalysis
ABCC	American Board of Clinical Chemistry
ABHI	American Board of Histocompatibility and Immunogenetics
ABMLI	American Board of Medical Laboratory Immunology
ABMM	American Board of Medical Microbiology
Ab	antibody
Ag	antigen
AHG	antihuman globulin
AP	Accreditation Program
ARB	Accreditation Review Board
CDC	complement-dependent cytotoxicity
CE	continuing education
CFR	Code of Federal Regulation
CLIA	Clinical Laboratory Improvement Act (Amendments)
CMS	Centers for Medicare and Medicaid Services
DHHS	Department of Health and Human Services
DNA	deoxyribonucleic acid
ELISA	enzyme-linked immuno-sorbent assay
FTE	full time equivalent
HHT	human histocompatibility testing
HLA	human leukocyte antigen
HSC/BM	hematopoietic stem cells/bone marrow
JC	Joint Commission (formerly JCAHO)
MLC	mixed lymphocyte culture
NMDP	National Marrow Donor Program
PCR	polymerase chain reaction
PRA	panel reactive antibody
SEOPF	South Eastern Organ Procurement Foundation
SSOP	sequence specific oligonucleotide probe
SSP	sequence specific primer
TAT	turn around time
TX	transplant
UNOS	United Network for Organ Sharing
XM	crossmatch

GENERAL INSTRUCTIONS

PLEASE READ CAREFULLY

1. **IMMEDIATELY UPON RECEIPT:** Please read all instructions carefully, before completing the application.
2. All documentation must be in English and typed. The application must be submitted using the online application. If internet access is not available for completing the application please notify the accreditation manager.
3. Accreditation in Hematopoietic Stem Cell/Bone Marrow (HSC/BM) Transplantation requires that the laboratory provide final compatibility service to a bone marrow transplant program.
4. Accreditation in Deceased Donor Solid Organ Transplantation requires that the laboratory provide 24-hour on call coverage for deceased donor workups and be the laboratory of record for the final crossmatch with the recipient.
5. CFR Sec. 493.51 requires that CMS or its designee be notified within 30 days of any change in ownership, name, location, director or technical supervisor and general supervisor.
6. The Inspector's Checklist is available online at the ASHI Website and will also be emailed to you with these instructions. This checklist is NOT required to be completed and submitted with your packet, but may help in preparation for your laboratory inspection.
7. If you fail to meet the submission deadline, your packet will be accepted by central office, but not processed until the following cycle, with a reinstatement fee which will at a minimum cover the cost of administrative processing for the various regulatory agencies. The reinstatement fee is \$1000.

Please contact the accreditation office or your commissioner if clarification of these instructions is needed. Review all materials before submission.

SUBMISSION OF THE APPLICATION

When your application is complete and ready for submission, follow the instructions on the online application to submit online.

To send the additional paper documentation required (see below: **SECTION N, PAGE 25**), send an original and **FOUR** copies (*total of five*), to the following:

Overnight Mailing:
ASHI Accreditation Office
90 County Rd C West
Suite 300
St. Paul, MN 55117
651/487-2806

Processing of the application **will not begin if the ASHI Executive Office has not received payment of the laboratory's accreditation fees.

Retain these instructions to help you prepare for the inspection.

THE ACCREDITATION MANAGER PERFORMS AN INITIAL REVIEW OF THE APPLICATION. INCOMPLETE APPLICATIONS WILL NOT BE PROCESSED FURTHER UNTIL THEY ARE COMPLETE AND DEADLINES CANNOT BE EXTENDED; FAILURE TO SUBMIT COMPLETE MATERIALS ON TIME COULD RESULT IN EXPIRATION OF YOUR ASHI ACCREDITATION.

SPECIFIC INSTRUCTIONS RELATING TO ELECTRONIC FILING OF THE APPLICATION

PLEASE READ CAREFULLY

The Accreditation Review Board has instituted a new online version of the on-site application. Follow the link provided by the Accreditation Manager. Enter your laboratory ID and password provided to the laboratory Director or contact person. These instructions, detailing the specific information required in each field are included on the web site. This application together with the required documentation can be submitted through the actual application online and the attachment of documents. We encourage you to print out a final version of the application for your records. Instructions are provided electronically throughout the application, by clicking on the question mark icon.

INSPECTION

Inspectors are appointed on the basis of their expertise, objectivity, integrity, experience, and by geographic location to minimize expenses born by the applicant or the Society. If you believe an appointed inspector has a conflict of interest that will interfere with his/her objectivity, please petition in writing for a different inspector. You will have one right of refusal. The commissioner will evaluate the situation and take appropriate action.

The inspection may take one or more days, depending upon the areas in which accreditation is sought and size of the laboratory. To facilitate a thorough evaluation, please have all records readily available and, if possible, designate at least one individual to assist the inspector in accessing the necessary information. The manual, or a separate protocol manual, should provide instructions for the appropriate use of each technique and specify testing for the various clinical applications.

At the end of the inspection, an exit interview will be conducted and the inspector will inform you if deficiencies were found. The inspection is only one part of an extensive evaluation process and any comments made by the inspector must not be construed as judgment for or against approval of the laboratory. After the inspection has been performed, complete the inspection evaluation online (you will be sent a link). It will immediately be sent to the Inspector Training Chair for the continued evaluation of the inspection process. The on-site review of the laboratory is not complete until this evaluation is received.

RESPONSE TO DEFICIENCIES

Following the inspection, responses to the deficiencies, cited by the inspector and any other deficiencies identified by the commissioner, must be submitted within 30 days of the notification of the deficiency. Responses must include supporting documentation and may be submitted via email to your commissioner.

A. COVER PAGE

Provide the names of the laboratory, director(s), department and institution, **as they should appear on the accreditation certificate (+)**.

CFR 493 requires that the laboratory have a director (493.1441), technical specialist (493.1447), clinical consultant (493.1453) and general supervisor (493.1459). ASHI requires that all U.S. and International labs have all four positions. Provide the appropriate name(s) for each position.

***There must be a name entered for all positions listed above. The online application will not allow the application to be submitted if left blank.*

Areas of Accreditation

Mark “current” in all areas in which you wish to be evaluated for accreditation and mark “New” for those in which your lab is not currently accredited. **Note:** If adding a new area of accreditation, please remember a portfolio review of the Laboratory Directory may be required, if the Laboratory Director is not currently qualified by the Director Training Review Committee in that area of accreditation. Please refer to attached Documentation of Director(s)/Technical Supervisor(s) Qualifications (**Appendix 1**).

Methods/Technologies

The methods and technologies currently accredited for the laboratory by ASHI are noted in the ‘**Current**’ column. If you are adding a new method/technology, put an ‘**X**’ in the ‘**New**’ column. If the laboratory has discontinued a method/technology or the method/technology does not apply to current laboratory practice, put an ‘**X**’ in the ‘**NA**’ column. List the **Vendor and Kit** for each Method/Technology in the last column.

Note: If adding a new method/technology, please remember that validation of the new method/technology must be provided. Please refer to attached Validation guidelines (**Section M and Appendix 2**), validation checklist (**Appendix 3**).

B. DECLARATION OF INTENT

Several agencies and organizations recognize ASHI accreditation as meeting their performance requirements for histocompatibility laboratories. These organizations include the following:

Centers for Medicare and Medicaid Services (“CMS”)

Centers for Medicare and Medicaid Services for ABO/Rh Testing (“CMS”)

Centers for Medicare and Medicaid Services for General Immunology Testing (“CMS”)

National Marrow Donor Program (“NMDP”)

United Network for Organ Sharing (“UNOS”)

Agency for Health Care Administration – State of Florida

Each organization requires that ASHI immediately notify the agency of any action that would limit, revoke, or deny ASHI accreditation. Your declaration of intent to do so give ASHI the right to perform on-site inspections and to provide required information to such deemed organizations/agencies.

Check the “YES” box for the organizations that you intend to utilize ASHI accreditation to fulfill that organization’s requirements. **Do not leave any portion blank, mark either “YES” or “NO”.**
The director or other authorized individual must sign this section.

ATTESTATION STATEMENT

Fill in the attestation statement. Section B requires the signature of the Laboratory Director or other authorized individual.

The original copy of the Declaration of Intent and the Attestation Statement must be returned SIGNED, hard copy, to the ASHI Accreditation office. (see below: SECTION N, PAGE 25)

C. PERSONNEL
DIRECTOR/TECHNICAL SUPERVISOR QUALIFICATIONS
ASHI Standard E.2 and E.3

The individual identified as director/technical supervisor must complete this section. If two or more individuals share the director/technical supervisor's responsibilities, use a copy of the forms for each individual. Scan and attach a current copy of the director's state licensure if required.

(CFR 493.1443) For lab directors, MDs must be licensed to practice medicine in the state in which the lab is located or deemed qualified as of 2-28-92. If not an MD, they must have an earned doctoral degree (Ph.D.) in a biological, chemical, or physical science and, by 12-31-02 be certified by ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.

(CFR 493.1449) Technical supervisors must be either an MD licensed to practice medicine in the state in which the lab is located (no grandfather clause) or a PhD (as above) and (for either degree) have 4 years post doctoral training and/or experience in histocompatibility or 2 years training and/or experience in the laboratory specialty of general immunology plus 2 years training and/or experience in histocompatibility.

In most cases, one person fills both positions.

Complete all sections and scan and attach a copy of current licensure if a state requirement (required for all MDs).

- C1. Areas of Accreditation / Technologies: Currently accredited Areas of Accreditation and Technologies are noted in the first column (and cannot be changed). Put an "X" in all of Accreditation and Technologies in which you wish to be evaluated for accreditation "NEW". For all new of Areas of Accreditation, please put an "X" if the Director portfolio requirements have been submitted to the Director Training Review and Credentialing Committee (DTRC). **(Appendix 1)**
- C2. Laboratory Involvement: Please supply appropriate information for each section.

D. PERSONNEL
CLINICAL CONSULTANT QUALIFICATIONS
ASHI Standard E.4

If the clinical consultant is not the director or technical supervisor, **submit a copy of the curriculum vitae (abridged/updated for the last 2 years), current certification and current licensure if a state requirement.**

(CFR Sec. 493.1455) The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must (a) be qualified as a laboratory director under Sec. 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, Sec. 493.1443(b)(6); or (b) be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

If the Director/Technical Supervisor serves as the Clinical Consultant, it must be stated on this form.

E. PERSONNEL
GENERAL SUPERVISOR QUALIFICATIONS
ASHI Standard E.5

This section should be completed by **all** personnel with authority to sign out final reports and/or function as a general supervisor. If the director serves as general supervisor, indicate this in Section C2, Laboratory Operations, and leave the remainder of this section blank.

F. PERSONNEL LIST

List all personnel who perform work related to **Histocompatibility and Immunogenetics** activities of the laboratory, including the director(s), co-director(s), associate director(s), director(s)-in-training, scientist(s), fellow(s), supervisor(s), technologist(s), technician(s), lab aide(s) and assistant(s), support staff (clerical, secretarial), administrative personnel (information technology, business manager, etc.).

Supply the following information under each heading on the Personnel List.

- Start date M/YY:** Enter the month/year the staff member began work in this laboratory
- Name:** Enter the Name of the Individual
- Position:** Enter the position the staff member holds in the laboratory
- Degrees:** Enter the highest degree this staff member has attained (i.e. PhD, MS, BS,)
- Certifications:** Enter any certification this staff member has attained (i.e. D(ABHI), CHS, CHT, MT, MLA)
- Years HHT:** Enter the number of years of working experience in human histocompatibility testing (HHT)
- C:** Mark 'X' if they are involved in the **clinical testing** area of the laboratory
- R:** Mark 'X' if they are strictly involved in **research-only** areas of the laboratory
- A:** Mark 'X' if they are involved in only **administrative/support** staff functions of the laboratory (i.e. clerical, secretarial, information technology, business manager)
- OC:** Mark 'X' if the individual participates in **on-call** activities for deceased donor testing
- TC:** Mark 'X' certifying that **Technologist Competency Assessment** for this individual was completed for the time period covered by this interim application.
- Note:** This information must be available for review during any on-site inspection of the laboratory.
- Total CE:** Include total number of **continuing education** hours for each staff member of the clinical staff.
Note: If staff members are currently ABHI certified enter 'ABHI'.

Note: This information must be available for review during any on-site inspection of the laboratory. The minimum number of continuing education hours per year required by ASHI is:

Director/Technical Supervisor	50 hours
Clinical Consultant	12 hours
Director-in-Training	27 hours
Technologist	12 hours
Supervisor	27 hours

*****Please double check that you have included the Laboratory Director and Director-in-Training on the Personnel List.***

G. CONTINUING EDUCATION SUMMARY

For the lab director and each member of the technical staff, submit a summary of participation in continuing education during the previous year (calendar year or fiscal year). Note programs which are Histocompatibility and/or Immunogenetics related and ASHI approved. Briefly describe the program content. Include safety training, technical meetings, clinical meetings, technical competency assessment and review of proficiency testing, quality control and lab manuals. Note the number of hours of actual participation and the level of participation (lecturer, presenter, participant or attendee).

The minimum hours of continuing education will be met if the individual is ABHI certified and has maintained continued certification. ABHI certified individuals are **not** required to submit a continuing education summary form. For directors/technical supervisors **not** maintaining continued certification, a minimum of 50 hours/year is required. For general supervisors **not** maintaining continued certification as a CHS, a minimum of 27 hours/year is required. For those clinical consultants, testing personnel and Directors-in-Training **not** maintaining continued certification, a minimum of 12 hours/year is required.

Supply the following information either in the following format or on the Continuing Education Summary Form:

Name

Position

Brief job description (i.e. supervises serologic testing and performs molecular testing)

Program

Participation hours

Participation level

Approved by ABHI

Content

Summary of contact hours by type and total

****If your laboratory has institutional forms that are used to track CE hours, you may attach those documents to each individual's CE record in Section G.***

H. LABORATORY ACTIVITIES

There are seven (7) sections of laboratory activities to complete.

- Section 1: Enter the **dates** of the time period (twelve [12] month period preceding the application date) covered by this application.
- Section 2: Enter the approximate **percent** of the laboratory's total clinical effort for each Area of Accreditation. The total should equal 100%. Also, enter the number of patients on the UNOS renal waiting list(s).
- Section 3: Enter the **number of individuals** (not the number of tests) for which your laboratory provided services in the past twelve (12) month period preceding the application date.
- Section 4: Enter the **number of typings** performed for each methodology. Put zero (0) if there were no tests performed.
- Section 5: Enter the **number of crossmatch tests** performed for each methodology. Put zero (0) if there were no tests performed. Do not include preliminary crossmatch (ROP) trays in this number.
- Section 6: Enter the **number of antibody screens** performed for each methodology. Note that there are separate categories for antibody screening and antibody identification. Put zero (0) if there were no tests performed.
- Section 7: Enter the **number of tests** performed for each methodology. Put zero (0) if there were no tests performed. If a certain test performed in the laboratory is not listed add the number of tests and the name of the test in the 'Other' section.
-

I. LABORATORY ACTIVITIES: CMS LABORATORY TEST DATA

THIS SECTION IS ONLY TO BE COMPLETED BY THOSE LABS INDICATING ON THEIR DECLARATION OF INTENT THAT THEY USE ASHI FOR CLIA PURPOSES.

The Centers for Medicare and Medicaid Services has based its fee structure on laboratory test volume. ASHI is required to submit this information as part of its role as a deeming agent for CMS. The information needed from each laboratory is: number of subjects typed, number of serum specimens screened for antibody (regardless of the number of different techniques used or the number of times a specimen was screened), and number of donor-recipient pairs crossmatch tested. These should be further divided into transplant and non-transplant studies. Typing of potential donors for Bone Marrow registries is considered Histocompatibility Testing for Other Clinical Purposes. Note that these numbers will be different from those submitted above. They will be used ONLY to determine CMS fees.

CMS has provided the following guidelines for determining test volume:

- Waived tests are not counted in the total test volume.
 - The specialty of Histocompatibility has subspecialties Transplant and Non-transplant. (HLA typing for disease association is an example of a non-transplant test)
 - In the specialty of Histocompatibility and its subspecialties, each HLA typing, HLA antibody screen or HLA crossmatch is counted as one test.
 - The specialty of Immunohematology has subspecialties ABO/Rh group, Antibody transfusion, Antibody non-transfusion, Antibody identification and Compatibility.
 - For Immunohematology, each ABO group, Rh type, antibody screen, antibody identification or crossmatch is counted as one test.
 - Do not count calculations, quality control, quality assurance or proficiency testing assays.
-

J. PROFICIENCY TEST RESULTS

NOTE: Hard copy PT results and summary forms are still required to be sent to the Accreditation Office with your packet. Refer to Section N, page 25 of the application instructions.

Laboratory accreditation requires successful participation in approved external proficiency testing (PT) programs, when available, for all clinical tests performed by the laboratory in the testing categories for which they are seeking accreditation. Laboratories must designate a single provider for each analyte tested or type of test with a specific method, e.g. low resolution class I using SSOP etc **or**, if each locus is tested by a different method, specify each locus and a corresponding method. Laboratories may use more than one PT survey provider, but must designate the primary survey provider for each analyte tested. Proficiency tests must be rotated among all technologists performing clinical tests and must be processed and tested in the same manner as patient specimens.

Review of Proficiency Testing

1. Laboratories must designate a PT provider for each analyte (type of test with a specific method, e.g., HLA-A typing using SSP) tested. If a laboratory has multiple methods and uses more than one PT provider, the laboratory must make it clear on the PT summary report which PT exchange is used with each method.
2. In accordance with CMS , a rolling timeframe is used to determine PT performance wherein 3 consecutive PT results are assessed. The rolling time frame is continuous and does not reset annually. Laboratories must submit the three most recent proficiency testing results the laboratory has received prior to submission of the packet.
3. Successful PT participation is defined as satisfactory performance on 2 of 3 consecutive send-outs (challenges) of PT. **Satisfactory** PT performance requires a minimum of 80% concordance (agreement with the consensus, graded result) for each challenge of each analyte (100% concordance is required for ABO/RH). A single miss on any specimen is considered to be an incorrect phenotype/result.
4. **Unsuccessful** participation in a PT program is defined as any of the following:
 - **Unsatisfactory** performance on 2 consecutive send-outs; or
 - **Unsatisfactory** performance on 2 out of 3 send-outs; or
5. The ARB will review all cases of unsuccessful PT and determine appropriate action. In all cases, additional PT submission (which may include enhanced PT- see below) will be required. If patient care is ascertained to be in immediate jeopardy, the certification will be suspended for the method under review. **CMS will be notified of a suspension within 10 days** in cases of immediate jeopardy. **CMS will be notified within 30 days for all other suspensions or limitations of ASHI certification.**
6. If a laboratory's certificate is suspended, the laboratory must then demonstrate sustained **satisfactory** performance on two consecutive proficiency testing events, one of which may be enhanced proficiency on site, before the ARB will consider it for reinstatement for certification.
7. If PT performance is unsuccessful for ABO/Rh testing, the ABO/Rh testing must be outsourced to another CLIA certified laboratory until there has been satisfactory performance on two consecutive exchanges. Currently there are no CMS-approved providers of enhanced proficiency testing for ABO/Rh.
8. Proficiency testing must be submitted for all methods used in the laboratory at least twice per year (for example, for Antibody Screening by ELISA, Luminex, Serology AHG, Serology CDC and/or Flow Beads)

- The laboratory must have a written policy that describes how the PT will be used to assess performance of each of the methods used in the laboratory. This policy must be established prior to testing the PT samples. All PT testing must be submitted according to the pre-established schedule of testing.
 - The laboratory must participate in at least two separate send-outs for each method.
 - The laboratory must perform testing for a minimum of 8 samples for each method.
9. Failure to enroll, perform or report results for a PT event by the providers' deadline for submission is **unsatisfactory** and results in a score of 0% for that send-out or analyte.
10. A laboratory may choose to include samples that did not reach consensus in the evaluation of proficiency testing (ex. when the number of graded samples is very small). If non-graded samples are included, the laboratory must submit and count all ungraded samples as well as the graded samples for the last twelve months. The correct response will be the majority response. The Commissioner will review cases on an individual basis when there is no clear consensus, taking into account how close the majority response is to 80% and any trends noted in the overall results submitted by the laboratory.
11. Proficiency testing results must be reported at the same resolution that is reported clinically.
12. **DNA typing – “low resolution”** will be granted if serologic resolution (antigen-level) is reported predominantly. Serologic equivalent resolution results must conform to the latest list of antigens and alleles as published in the appropriate WHO nomenclature (generally one year prior to application submission).
13. **DNA Typing – “high resolution”**
- Laboratories performing high resolution DNA typing must report a single 4 digit allele for those alleles that have unique sequence within exon 2 and 3 for Class I loci, and exon 2 for Class II loci, as designated in the currently observed IMGT/HLA database release. If there are alleles present whose differences lie outside of these exons, the laboratory may report these alleles as a group. These allele groups must match those reported in the currently observed IMGT/HLA database ambiguous allele combination table.
 - Laboratories must achieve high resolution typing for at least 80% of the alleles typed by high resolution method(s).
 - The database used for defining high resolution should be updated at least every 6 months and must not be older than 12 months.
14. The laboratory may choose to perform high resolution typing on a reduced number of the PT challenges. This is allowed under the following conditions:
- The laboratory must have a written policy that describes how the PT will be used to assess performance of each of the methods used in the laboratory. This policy must be established prior to testing the PT samples. All PT testing must be submitted according to the pre-established schedule of testing.
 - The written policy must be submitted along with the PT summary report when applying for ASHI re-accreditation.
 - The laboratory must participate in at least two separate send-outs for each method.
 - The laboratory must perform testing for a minimum of 8 samples for each method.

15. A **corrective action** report must be submitted for all PT errors and outliers. The corrective action report must include:
- The analyte identified as discrepant with consensus result;
 - The PT provider summary report. Include documentation of unsatisfactory sample or attempt for re-shipment, if applicable;
 - Documentation of satisfactory results on 2 prior challenges and 2 subsequent challenges, if possible;
 - Director's review of results and description of possible problem;
 - Evidence of thorough investigation, conclusions, and corrective action to prevent similar error in future. Indicate if error was due to pre-analytical, analytical, or post-analytical problems.
 - Actions taken to ensure the ongoing quality and accuracy of patient test results. (Ex. Split sampling or inter-laboratory comparison, testing by alternate method, or change in reagents, procedure, etc.)
 - Review of reported patient results may be appropriate and necessary depending on the cause of the error (PT errors may detect reagent failures and may reflect patient testing done at the same time).

Specific Instructions:

1. **Tabulate the results on the Proficiency Result Summary Form**
2. **Calculate the concordance (# of successful analytes/ total # of analytes)**
3. **Submit a copy of all PT provider Summary Reports.**
4. **Submit a copy of corrective actions for any errors in any category submitted.**
5. **If proficiency testing is not available for a test your laboratory performs, validate accuracy and reproducibility of the test at least twice each year and submit a summary of these results (e.g. MLC).**
6. **Unsuccessful participation in proficiency testing requires remedial action as detailed in CFR 493.1701. Failure to take remedial action can result in HCFA imposed sanctions as specified in CFR 493, subpart R.**

K. QUALITY ASSURANCE

K1: Submit a list of Quality Assurance Monitors used in the laboratory together with a one-year summary of the results of those monitored events. For example: Turn-around-time, specimen rejection logs, reporting errors, complaints. A Quality Assurance Summary Report Form is provided in the packet.

JCAHO requires that all laboratories report sentinel events occurring in the laboratory. Answer the question and if yes, provide a summary of the event including the accrediting agencies notified and the corrective action to prevent the event from occurring again.

K2: For previously accredited laboratories, briefly describe performance improvement programs initiated.

K3: List laboratories subcontracted and the testing they provide. For example: Laboratory XYZ, provided high resolution DNA Class I typing. Scan and attach evidence of their certification, such as their ASHI certificate.

L. TEST PROCEDURES AND PROTOCOLS

ALL LABORATORIES ARE REQUIRED TO SUBMIT THE FOLLOWING:

Submit a complete case file from the last month for each clinical application. (Ref. ARB Policy R-05-99) These case files can be scanned and attached to the online application. Please remember to redact all patient identifiers.

A case file consists of: A requisition of the orders and a report;

-AND-

For each area in which you are seeking re-accreditation, submit a one-page summary of the testing.

For the application of Hematopoietic Stem Cell/Bone Marrow Transplantation: Related Donor, describe the testing process, including the procedures (tests) used in the initial patient work-up, initial donor work-up, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing, etc.. Accreditation in HSC/BM Transplantation requires that the laboratory provide final compatibility service to a HSC/BM transplant program.

For the application of Hematopoietic Stem Cell/Bone Marrow Transplantation: Unrelated Donor, describe the testing process, including the procedures (tests) used in the initial patient work-up, initial donor work-up, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing, etc.. Accreditation in HSC/BM Transplantation requires that the laboratory provide final compatibility service to a HSC/BM transplant program.

For the application of Solid Organ Transplantation: Deceased Donor, describe the testing process including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), deceased donor work-up, pre-TX work-up, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Accreditation in this area requires that the laboratory provide 24-hour on call coverage and meets the requirements of the UNOS Standards (US Laboratories only).

For the application of Solid Organ Transplantation: Live Donor, describe the testing process, including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), initial donor work-up, all additional pre-TX testing, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Include variations for different organ types. Accreditation in this area requires that the laboratory meet the requirements of the UNOS Standards (US Laboratories Only).

For the application of Parentage Testing, describe what purposes tests for genetic identity are done (e.g. parentage testing, other genetic relationships, zygosity determination, sample switch, etc.). Describe the testing process including the procedures (tests) used, what antigens/alleles are tested, what protocols are employed to assure specificity, and, if probabilities or likelihoods are calculated, provide references for the algorithms.

For the application of Histocompatibility Testing for Non-Transplant Clinical Purposes, describe the testing process, including the procedures (tests) used for each different clinical application (e.g. disease association studies, donor drives, testing for clinical trials, etc.). Typing of potential donors for Bone Marrow registries is considered Histocompatibility Testing for Other Clinical Purposes.

For the application of Transfusion Support, (e.g. platelet support) describe the testing process, including the procedures (tests) used (typing, antibody screening, crossmatching, etc.), specimen selection criteria, requirements for specific testing, etc.

M. VALIDATION REQUIREMENTS FOR USING A NEW PROCEDURE OR TEST

Among the most critical aspects of laboratory evaluation are the assessment of test performance and outcome. This evaluation process includes a review of results of not only proficiency test surveys but also of tests performed during the various situations found in the laboratory and of internal proficiency tests. These situations include the tests performed on subjects in varying states of health and tests performed using various types of material (blood, lymph nodes, spleen, etc.). The purpose of these guidelines is to describe the minimum data that must be submitted by all laboratories.

Prior to reporting test results of a new procedure or test, the laboratory must establish performance specifications and demonstrate that it can obtain these performance specifications or, for FDA-approved kits, the specifications of the manufacturer. Performance specifications include accuracy, precision, analytical sensitivity and analytical specificity to include interfering substances, reportable range of patient test results, reference range(s) (normal values) and any other performance characteristics required for test performance. Calibration and calibration verification procedures must be performed and documented. Control and quality assurance procedures must be routinely performed. Personnel must be trained, qualified and have appropriate technical supervision available. For further information, refer to CFR 493.1201b, 493.1205a, 493.1205c, 493.1213, 493.1217, 493.1218, 493.1701, 493.1705 and 493.1709.

Minimally, these sections require the lab to do the following:

1. Establish specification requirements for test performance
2. Evaluate the test system to assure that it meets the specification requirements
3. Identify and establish ongoing quality control measures
4. Train personnel and take measures to evaluate and ensure their ongoing competency

VALIDATION STUDIES – for any new Testing Method

- A. New Laboratories must submit the validation data for each of the methods used in the laboratory. This material may also be used to partially fulfill the requirements for Test Data Submission required from new laboratories.
- B. Accredited laboratories
Addition of new method in Technology for which laboratory is already approved:
- Must submit complete validation materials to the Commissioner for review.
 - Upon approval by the Commissioner and co-Chair, the new methodology will be added to the accreditation letter.

Addition of method that falls under Technology for which laboratory has **not** been previously approved:

- Must submit complete Validation materials
- Must submit Blind Parallel Testing – the number must be at least equal to the number of challenges in a full year of Proficiency testing
- A focused on-site inspection will be required if not done with regular on-site inspection.

C. Requirements for Validation of new Methods

Clinical test results can be reported out once the validation packet is completed by the laboratory. The following materials must be submitted to the Commissioner for review and approval prior to the methodology/technology being added to the accreditation letter:

- a. Summary of the internal validation data and interpretation of data by the Director;
- b. Testing protocol – how test is to be used; purpose of test
- c. The step-by-step procedure;
- d. Performance specifications to include accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, limitations, and any other relevant characteristics
- e. Quality control procedures
- f. Equipment Calibration data
- g. Training checklist
- h. Documentation of the competency of personnel who will be performing the test and reviewing the test results;
- i. Parallel Testing for new method under a Technology for which the laboratory is already approved:
 - Reference Samples or samples tested in parallel with approved in-house
 - A minimum of 20 parallel testing results or equal to 1 year proficiency testing– include worksheets if not blinded
 - Include a variety of test results (different antigens, antibody specificities, etc.)

For a **new Technology**, a blinded parallel test must be submitted.

Results from parallel testing with another ASHI-accredited laboratory must be submitted independently to the Commissioner. Parallel testing for a new Technology may include the following:

- Blinded samples tested in parallel with another ASHI-accredited laboratory
 - Well-characterized reference materials that were blinded prior to testing (ASHI repository, commercial panels, etc)
 - A complete set (one year) of proficiency testing with graded results
 - A combination of the above
- j. The laboratory must be enrolled in an approved PT program.
 - k. On-site inspection required if **New Technology**

AREAS of ACCREDITATION and MAJOR TECHNOLOGIES

The information below is to be used to determine if additional Test Data Submission or a Director Portfolio is needed.

For a new laboratory, Validation packets must be submitted for all methods used in the laboratory. In addition, the Test Data Submission requirements must be met for each new Testing Category (see below)

For new Directors, a portfolio must be submitted for all Areas of Accreditation and Major Technologies for which they are seeking approval.

For established laboratories that wish to add a new Testing Category (see below), the Test Data submission requirements as well as the validation packet must be submitted. Validation samples and cases used in Director portfolio may be used to at least partially meet this requirement.

For established laboratories that wish to add a new Method under a Technology for which the laboratory already has accreditation, only the Validation Packet needs to be submitted.

For ASHI-approved Directors who wish to add a new Area of Accreditation or Major technology for which they have not been previously approved, a portfolio will need to be submitted to the DTR. A portfolio is not needed if adding a method under a previously approved technology.

Areas of Accreditation are:

HSC/BM Transplantation: Related Donor
 HSC/BM Transplantation: Unrelated Donor
 Solid Organ Transplantation: Deceased Donor
 Solid Organ Transplantation: Live Donor
 Parentage Testing
 Histocompatibility Testing for Non-Transplant Clinical Purposes
 Transfusion Support*

* For accreditation in the area of Transfusion Support, the laboratory must:

- Perform HLA typing, antibody screening/identification for patients (HLA/Platelet/or granulocyte antibody testing for patients)
- Provide interpretive notes on results of testing
- Make recommendations for selection of donors for platelet or granulocyte transfusion
- Monitor outcome of platelet or granulocyte transfusions

Technologies are:

Serology
 Molecular –Polymorphism analysis
 Sequencing/ Fragment Analysis
 Flow Cytometry
 Cellular

ABO.Rh *

* ABO testing requires validation, but not a separate portfolio.

Technology	Methods included under Technology
Serology/Solid Phase	Cytotoxicity assay for HLA typing, PRA, XM; ELISA PRA, XM, cytokines; Microarray or Bead PRA analysis
Molecular- Polymorphism analysis	SSOP, revSSOP, SSP, RFLP, Microarray or Bead array typing
SBT / Fragment Analysis	Sequencing, Engraftment, RSCA, STR, VNTR, Heteroduplex
Flow Cytometry	Crossmatch, HLA Antibody, Immunophenotyping, CD34, Stimulation assays
Cellular	MLC, PLT, Mitogen or Ag stimulation, and Immune Cell Function (ex. e.g., by measuring thymidine incorporation or ATP production)

Other methods not listed above will be reviewed for determination of appropriate Technology area.

ADDING A NEW METHOD under a PREVIOUSLY APPROVED TECHNOLOGY

1. Adding a new method that is included under a previously approved Technology will not require a focused inspection.
2. The laboratory must submit a Validation Packet to the Commissioner as described in “Validation Studies” above. Parallel testing with the laboratory’s previous method can be submitted. Blind parallel testing is not needed unless the level of resolution for HLA typing or antibody sensitivity for PRA testing makes parallel testing with the previous method unsatisfactory.
3. The Commissioner will review the Validation packet for completeness and discuss results of the parallel study with the co-Chair. If the Commissioner and co-Chair approve the Validation Packet, the Accreditation Manager will be notified.
4. The Commissioner will fill out a Checklist to verify that the all components of the Validation Packet were received, reviewed, and approved. The Commissioner will discuss and resolve any issues concerning the validation packet with the co-Chair. The completed Checklist is sent to the full ARB for an e-mail vote.
5. Upon approval by the ARB, the laboratory’s letter will be modified to include the new method and the effective date for the approval of the new method.

DATA SUBMISSION REQUIREMENTS for TESTING CATEGORIES

New laboratories or Laboratories adding the following Testing Categories:

- **HLA Typing results**
- **Crossmatch Testing**
- **Antibody Testing**
- **Cellular Assays**
- **Engraftment Studies**
- **Immunophenotyping by Flow Cytometry**
- **Parentage Testing**

Laboratories must submit the testing data described in **Appendix 2** if the method being validated falls into a testing category for which the laboratory has not previously been accredited. If the Director is also submitting a portfolio, the same cases may be used to fulfill the Director Review Requirements and the laboratory testing requirements, when appropriate for both.

N. ACCREDITATION APPLICATION CHECKLIST – PAPER DOCUMENTATION TO BE SENT*

**send the paper copies only if you cannot scan and attach the documents to the online application*

FIVE copies of:

- Declaration of Intent – Attestation Statement (**Section B**)
- Director/Technical Supervisor(s) current state license, if applicable (**Section C**)
- Clinical Consultant(s) current state license, if applicable (**Section D**)
- Copy of state license for each of the technical personnel, if applicable (**Sections C, D, E, and F**)
- Proficiency testing reports (**Section J**)
- Proficiency testing corrective actions, if applicable (**Section J**)
- Certificates of subcontracted laboratories (**Section K**)
- Description of testing process and a complete file for appropriate application(s) (**Section L**)
- (Submit the overview of the lab protocol together with a report or reports which reflect the testing methodologies used in the laboratory to support that particular area. Please remember to redact all patient identifiers. No worksheets, please!)
 - ❑ HSC/BM Transplantation: Related Donor
 - ❑ HSC/BM Transplantation: Unrelated Donor
 - ❑ Solid Organ Transplantation: Deceased Donor (Include serum screening protocol)
 - ❑ Solid Organ Transplantation: Live Donor (Include serum screening protocol)
 - ❑ Genetic Identification= Parentage Testing
 - ❑ Histocompatibility Testing For Non-Transplant Clinical Purposes
 - ❑ Transfusion Support

- Validation documentation for new procedures or tests (Adjust order to coincide with packet) (**Section M**)
 - ❑ Summary of the internal validation data and interpretation of the data
 - ❑ Step by step procedure
 - ❑ Protocol for use of the procedure
 - ❑ Program for personnel training
 - ❑ Documentation of staff competency
 - ❑ Performance specifications
 - ❑ Quality control procedures
 - ❑ Calibration data
 - ❑ Parallel testing with reference samples summary
 - ❑ Proficiency testing program for which laboratory is enrolled

- Laboratory Accreditation Fees

APPENDIX 1:

SUPPLEMENTARY DOCUMENTATION OF DIRECTOR(S)/TECHNICAL SUPERVISOR(S) QUALIFICATION

New Directors:

The Director Training & Credentialing Review Committee will perform the review of new Director qualifications and experience as follows for new Areas of Accreditation.

AREAS of ACCREDITATION are:

HSC/BM Transplantation: Related Donor
HSC/BM Transplantation: Unrelated Donor
Solid Organ Transplantation: Deceased Donor
Solid Organ Transplantation: Live Donor
Parentage Testing
Histocompatibility Testing for Other Clinical Purposes
Transfusion Support

1. The candidate's CV – credentials will be evaluated by the DTRC chairperson and Reviewer(s) and the ARB member participating in the oral interview, all of whom will serve on the oral exam committee.
2. The ASHI Director serving as mentor will oversee the review of cases and document on a notarized Director Training Verification document that the following have been successfully completed by the candidate:
 - a. Log of cases reviewed for each Area of Accreditation for which approval is sought;
 - b. 10 cases for each Area of Accreditation must be written up with worksheets, interpretations, comments, further testing needed, etc. (1-2 case studies for each Area of Accreditation must be submitted along with the application. See #5)

By signing the Director Training Verification Document, the mentor is attesting that the candidate has gained the necessary experience to be deemed "competent" in the Areas of Accreditation indicated on the checklist.

The mentor must be an ASHI-approved laboratory director.

3. The mentor must provide a summary of training program and letter of support for the applicant.
4. The candidate must meet all of the educational, certification, and training requirements as stated in the current version of the ASHI standards.
5. The DTRC may request that the candidate submit an additional complete case study that he/she has personally reviewed for each Area of Accreditation.
6. For each Area of Accreditation, the candidate must submit a protocol for testing, which includes a list of the tests that could be used in a typical case and provide the reasoning and justification for each test in terms of optimizing patient care in a cost-efficient manner. The list does not necessarily have to be what is actually done in the candidate's laboratory. The purpose of this

exercise is to show that the candidate is knowledgeable about the methods available to an HLA laboratory and how to use them in a clinical setting.

7. Upon receipt of above materials, the DTRC will send the candidate 1-2 of its own case studies for each Area of Accreditation that is being requested for approval. The applicant will review the case studies and send the DTRC a written 1-3 page summary for each case study.

Note: This exercise may be waived by the DTRC for applicants who have successfully passed the Diplomate (ABHI) exam.

8. Oral examination by the DTRC: After successful completion of the case study reviews, the DTRC Chair will contact the candidate to arrange an interview.
 - a. The interview committee will consist of the DTRC reviewer(s) an ARB representative (co-chair or program director), and the DTRC chair.
 - b. The Accreditation Manager will transcribe comments concerning the interview.
 - c. The interview will be an opportunity for the applicant to respond to open-ended questions about laboratory practice and to discuss these with the interviewers. The interview usually takes 1-2 hours.
 - d. The role of the ARB during the oral interview is ensure the candidate is questioned fairly and extensively.

The interview can be conducted via a conference call or in-person at an ASHI regional or national meeting.

9. The DTRC Committee will vote on whether to approve the Director for the specified Areas of Accreditation. If approved, the Chair of the DTRC will notify the Accreditation Manager of the decision and the Database will be updated to reflect ASHI approval for the Director in the specified Areas of Accreditation.
10. The letter of approval for new Directors will be signed by both the DTRC Chair and the ARB Program Director.
11. If not approved, the DTRC will work with the applicant to determine the course of action needed to obtain approval. This may include documentation of additional training and experience, additional case file reviews, etc.
12. The Appeal process will consist of the candidate stating in a letter the reason why he/she is appealing the decision of the DTRC. The appeal letter will be reviewed by a panel consisting of the DTRC reviewer(s), the Chair of the DTRC, and representative(s) from the ARB. The appeal process will be concluded within 60 days of receipt of the appeal letter. The decision of the Appeal Committee will be issued in a letter to the candidate.

Adding new Area of Accreditation for previously ASHI-approved Director

ASHI-approved directors who wish to add a new Area of Accreditation must submit to the DTRC the following materials:

1. Outline/ Summary of Training

2. Log of Cases reviewed (refer to Director Training Verification document)

3. An example of a complete case file with detailed analysis, including worksheets, interpretations, comments, further testing needed, etc.

4. For each new Area of Accreditation, the candidate must submit a protocol for testing, which includes a list of the tests that could be used in a typical case and provide the reasoning and justification for each test in terms of optimizing patient care in a cost-efficient manner. The list does not necessarily have to be what is actually done in the candidate's laboratory. The purpose of this exercise is to show that the candidate is knowledgeable about the methods available to an HLA laboratory and how to use them in a clinical setting.

5. Written analysis of case studies provided by the DTRC.

 Note: This exercise may be waived for applicants who have successfully passed the Diplomate (ABHI) exam.

6. Oral examination at the discretion of the DTRC after review of submitted materials.

 Note: In the case of an established Director/Technical Supervisor who is adding an Area of Accreditation, the oral interview may be waived, depending on the experience of the applicant.

7. Validation materials for any new Technologies or Methods that were established for the new Area of Accreditation must be submitted to the ARB Commissioner.

Adding new Technology or Testing Category for previously ASHI-approved Director

The Accreditation Review Board (ARB) will process the validation for new Technologies or Testing Categories and will no longer require separate DTRC approval.

1. If the Director was involved in the validation of a new Technology or Testing Category, then the validation packet submitted to the Commissioner is sufficient documentation of training and review.
2. If the Director moves to a laboratory that does a Technology or Testing Category for which he/she was not previously approved, the Director must submit a log of case reviews to the Commissioner. (Including 1-2 case studies with data for each Technology or Testing Category.) This should be completed prior to the on-site inspection for a New Director.

For new Technologies and Testing Categories the minimum number of cases required for review is:

50 HLA typings	10 Cellular assays
20 HLA crossmatch tests	10 Engraftment studies
50 HLA antibody screens/IDs	10 Flow Phenotype cases
50 Parentage testing cases	

3. The Director/Technical Supervisor must demonstrate sufficient experience with the Technologies or Testing Category employed in order to know their strengths and limitations. The following documents must be submitted to ensure that the test is working properly, that the Director/Technical Supervisor is able to interpret results correctly and troubleshoot when necessary. The QC and QA program must be in place and functioning for the new Technology or Testing Category.
 - Signed copies of QC data
 - Signed copies of proficiency testing reports
 - Signed copies of procedures and protocols in use in the laboratory
 - Evidence of review of worksheets by applicant with recognition of potential or actual problems
 - Description of action taken to address problems with testing

New Method - For established laboratories that wish to add a new Method under a Technology or Testing Category for which the laboratory already has Accreditation, only the Validation Packet needs to be submitted to the Commissioner. This can be done at any time and does not have to coincide with an on-site inspection. Once the validation has been reviewed by the Commissioner and approved by the co-Chair, a new Accreditation letter indicating the new Method will be issued to the laboratory.

Technologies:	Testing Categories:	Methods included under Technology:
Serology/Solid Phase	HLA Typing Crossmatching HLA Antibody Screen/ID Parentage Testing	Cytotoxicity, ELISA, Microarray
Molecular- Polymorphism analysis	HLA Typing Parentage Testing	SSO, rSSO, SSP, RFLP
SBT / Fragment Analysis	HLA Typing Chimerism Parentage Testing	Sequencing, Engraftment, STR, VNTR, Heteroduplex
Flow Cytometry	Crossmatching HLA Antibody Screen/ID Immunophenotyping	Methods for Quantitation, Direct Labeling, Indirect Labeling, Internal Labeling, External Labeling
Cellular		MLC, PLT, CTL, Mitogen or Antigen stimulation, and Immune Cell Function (ex. e.g., by measuring thymidine incorporation or ATP production)
ABO/Rh		ABO grouping, Rh typing, anti-A1 titers

Other methods not listed above will be reviewed for determination of appropriate Technology area.

DIRECTOR PORTFOLIO REQUIREMENTS

The complete Director portfolio will no longer be required to be sent to the DTRC Committee, but will be reviewed by the mentor and signed off (see Director Training Verification document above) when the mentor is confident that the applicant is fully trained. The DTRC may request the applicant to submit one or more of the case study analyses for each Area of Accreditation for which approval is being sought. In addition, the ARB will have the Inspector document that the portfolio was complete during the next on-site inspection. (Retain cases for a minimum of two years.)

1. The purpose of this portfolio is to provide documentation of the applicant's ability to review and interpret test results obtained in various clinical situations; to provide insight into probable causes of and appropriate solutions for test failure; to recommend additional follow-up tests as needed; and to provide appropriate commentary for use by clinicians.
2. **Portfolio materials should include:**
 - a. **Log of all cases reviewed** for each Area of Accreditation of testing. Include a brief description for each case.
 - 50 related HSC/BM cases
 - 50 unrelated HSC/BM cases
 - 50 deceased donor Solid Organ cases
 - 50 living donor Solid Organ cases
 - 50 cases of Parentage Testing
 - 20 cases of Transfusion Support
 - 20 cases of Histocompatibility Testing for Non-Transplant Clinical Purposes
 - b. The log should list:
 - the type of case;
 - a short description of the testing performed. No interpretative comments need to be included in the Log portion of the portfolio. (See Complete Case Files to be submitted below in section c).
 - Indicate if work was done in applicant's laboratory or reviewed at another lab.

Ex.1 Solid organ transplantation

CASE #1 – Deceased donor renal transplant recipient.

- Initial workup including Class I HLA typing by serology, Class II typing by DNA and 3 months PRA screening by flow beads, including specificity, and AHG.
- Log of HLA Antibody data from workup to transplantation.
- Final crossmatch results by cytotoxicity and flow cytometry, including auto crossmatch.
- Donor typing result.

Ex.2 Typing for Other Clinical Purposes.

Case #2. Disease association.

- Class II typing for narcolepsy patient.
- Low resolution molecular testing for DRB1 (DRB1*15)

- High resolution molecular DQB1 typing to determine the presence of DQB1*0602

c. **Complete Case Files**

At least 10 (ten) complete cases for each Area of Accreditation must be reviewed and approved by the mentor. The DTR may request that one or more of these cases be submitted for each Area of Accreditation. These case files should include:

- All testing performed including raw data with interpretation of result, signed and dated by applicant and ASHI approved Director.
- The final report provided to the physician.
- Correlation of results from the different tests.
- A Cover Sheet must be included for each complete case submitted.

Please make sure that all names and other identifiers are removed.

d. **Cover Sheet requirements for Complete Case Reviews**

A cover sheet for each case should discuss the thought process involved in reaching the conclusions presented and how the interpretations of data were made. Cover sheets should be detailed. They should address the testing performed in the case and make technical as well as interpretive comments regarding that testing.

The cover sheet for the case files should reflect the applicant's expertise in:

1. **Test selection:** The Director/Technical Supervisor/Clinical Consultant must be capable of determining what tests are necessary for various clinical applications and must be able to develop new tests and test strategies as dictated by changes in individual patient status.
2. **Interpretation/Consultation:** The Director/Clinical Consultant must have adequate expertise to know what information is needed to evaluate individual clinical cases and be capable of utilizing the collective body of information to assess risk level, identify possible clinical strategies, and make scientific evaluations of the immune state of the patient. Further, the Director/Clinical Consultant should be capable of supporting clinical studies and of using clinical data in the ongoing development of test interpretation of results when appropriate.

3. **Selection of Appropriate Case Files**

- a. If cases are selected from the Applicant Director's laboratory, several routine cases may be included in the portfolio. At least 5 cases should be selected to demonstrate problem solving of difficult or interesting cases.
- b. Case files may be derived from other laboratories. These cases should have a more detailed cover sheet, since the Applicant Director did not do the initial review. The coversheet should include how the Applicant Director would handle these cases, particularly where it might differ from the actual case. This may be based on newer technology or on differences in approach.
- c. The DTRC will have test case files that will be sent to the Applicant for review, written interpretation, and comments. After review of the Applicant's response to the written case reviews, the DTRC may request submission of additional case studies if there is concern that the Applicant is not yet ready for the oral examination.

Submission of Director Application Material

The case logs, complete case files, training verification documentation and checklist, and supportive letters must be submitted to the ASHI Accreditation Office in order to ascertain completeness. It will then be forwarded to the Director's Training Review and Credentialing Committee for review.

A fee of \$150 per new Area of Accreditation, or \$700 for review of qualifications to direct a full service laboratory must be submitted to the ASHI Accreditation Office Manager.

Applicant process timelines:

Review of CV of applicant by ARB-Co-Chairs and DTR Chair and Vice-Chair	2 weeks
Review of portfolio by DTR with summary and recommendations sent to designated ARB Co-Chair	2 months
Telephone interview of applicant by ARB Co-Chair and DTR reviewer Recommendation of certification to ARB Program Director	2 weeks
Certification letter to applicant from ARB program director and DTR Chair	2 weeks

Decisions will reflect the joint evaluation of the DTR subcommittee and the ARB. **The ASHI Accreditation Office will retain all submitted portfolio material.**

Director Training Verification Documentation

Name of Director-in-Training: _____

Board Certification Yes / No

Board: _____

Number: _____

Training Institution: _____

Mentor: _____

Dates of Training _____

Place an "x" to indicate each **Area of Accreditation** for which the applicant has completed training.

Place an "x" to indicate that the log of cases reviewed and in-depth analysis of clinically interesting case studies have been completed.

____ I. **HSC/BM Transplantation: Related Donor**

____ Log of 50 Case Reviews completed

____ Analysis of 10 interesting cases completed

____ II. **HSC/BM Transplantation: Unrelated Donor**

____ Log of 50 Case Reviews completed

____ Analysis of 10 interesting cases completed

____ III. **Solid Organ Transplantation: Deceased Donor**

____ Log of 50 Case Reviews completed

____ Analysis of 10 interesting cases completed

____ IV: **Solid Organ Transplantation: Live Donor**

____ Log of 50 Case Reviews completed

____ Analysis of 10 interesting cases completed

____ V. **Parentage Testing**

____ Log of 50 Case Reviews completed

____ Analysis of 10 interesting cases completed

____ VI. **Histocompatibility Testing for Non-Transplant Clinical Purposes**

____ Log of 20 Case Reviews completed

____ Analysis of 5 interesting cases completed

____ VII. **Transfusion Support**

____ Log of 20 Case Reviews completed

____ Analysis of 5 interesting cases completed

I, _____, attest that the Director-in-training,

_____ has completed adequate training and has gained the necessary experience for the areas checked above.

Signature of Mentor

Date

(Please have signature notarized)

Notary signature

ID #

Date of expiration

Date

APPENDIX 2:

SUPPLEMENTARY DOCUMENTATION FOR LABORATORIES ADDING NEW TESTING CATEGORIES

DATA SUBMISSION REQUIREMENTS for TESTING CATEGORIES

New laboratories or Laboratories adding the following Testing Categories:

- **HLA Typing results**
- **Crossmatch Testing**
- **Antibody Testing**
- **Cellular Assays**
- **Engraftment Studies**
- **Immunophenotyping by Flow Cytometry**
- **Parentage Testing**

Laboratories must submit the testing data described below if the method being validated falls into a testing category for which the laboratory has not previously been accredited. If the Director is also submitting a portfolio, the same cases may be used to fulfill the Director Review Requirements and the laboratory testing requirements, when appropriate for both.

HLA Typing Data

1. HLA Typing data must be submitted on a minimum of **50 typings**, with all patient identifiers removed from each document. Such data should also include all worksheets and interpretations. (A minimum of 20 typings must be submitted for each typing method used in the laboratory) Ten of these typings must be submitted as Case studies (see #5 below).
2. Sufficient data must be submitted so that each of the major antigens is represented.
3. Submitted data must include tests that were performed by each technologist involved in clinical testing.
4. Procedures and reagents used to perform typings must be described in the applicant laboratory's procedure manual.
5. Case Studies:

A minimum of ten case studies must be submitted. These should include interesting cases, if possible, that show the laboratory's ability to accurately type, troubleshoot, interpret, and correlate results with other testing information.

The Case Studies must include each of the major types of patients for which the laboratory will perform tests (i.e. hemodialysis patients, potential heart transplant recipients, deceased donors, bone marrow patients, etc.).

The Case Studies must include test results on each of the various typing materials that will be used by the laboratory (e.g. peripheral blood, pre-recovery deceased donor blood, lymph nodes, spleen, etc.). Laboratories without access to a particular type of sample may request that it be supplied by another ASHI-accredited laboratory.

6. Blinded Parallel Testing:

As partial fulfillment of the requisite number of typings for accreditation, the applicant center must submit external blinded parallel validation tests. The number of blinded samples required must be equivalent to the number provided by the PT program in which the laboratory is subscribed. The phenotypic identity of these reference samples must not be revealed to the applicant laboratories prior to submission of their results.

The blinded parallel testing results are submitted independently to the Commissioner for review and may include the following:

- a. Specimens tested in parallel with another ASHI-accredited laboratory
- b. Well-characterized reference materials (ASHI repository, commercial panels, etc)
- c. A complete set (one year) of proficiency testing with graded results
- d. A combination of the above (if c is partial)

Crossmatch Testing Data

1. For each crossmatch method used, the applicant laboratory must submit results from a **minimum of 20 tests** collectively performed on the various types of material it will be receiving for crossmatch testing as follows:

- a. 5 subjects tested using lymph nodes*
- b. 5 subjects tested using spleen*
- c. 5 subjects tested using pre-recovery deceased donor blood*
- d. 5 subjects tested using living donor blood
- e. 5 subjects tested using autologous blood

*May be omitted if not part of the laboratory's protocol.

Multiple materials from the same subject (ex. Blood, lymph nodes, spleen) may be used for crossmatch comparisons.

- 2. Submitted data must include tests that were performed by each technologist involved in clinical testing.
- 3. Procedures and reagents used to perform typings must be described in the applicant laboratory's procedure manual
- 4. Data to be submitted:
 - a. Crossmatch reading sheets and/or worksheets
 - b. List of fluorochromes used by the laboratory (Flow crossmatch)
 - c. Donor and recipient HLA typing results
 - d. Results of antibody screen of serum samples

5. Blinded Parallel Testing

The number of blinded samples required must be equivalent to the number provided by the PT program in which the laboratory is subscribed. The results must not be revealed to the applicant laboratories prior to submission of their results.

The blinded parallel testing results are submitted independently to the Commissioner for review and may include the following:

- a. Specimens tested in parallel with another ASHI-accredited laboratory
- b. A complete set (one year) of proficiency testing with graded results
- c. A combination of the above (if b is partial)

HLA Antibody Screen and Antibody Identification Tests

1. HLA antibody testing results must be submitted on a minimum of **50 samples**, with all patient identifiers removed from each document. Such data should include all worksheets and interpretations. (A minimum of 20 testing analyses must be submitted for each antibody screen/identification method used in the laboratory.)
2. Data to be submitted:
 - a. Number of subjects in cell/bead/ELISA panel or number of antigens in single antigen panels
 - b. Number of subjects yielding a positive result
 - c. Antibody specificities identified
 - d. Patient self antigens
 - e. Interpretive comments as appropriate.
3. Sufficient data must be submitted so that specificities to each of the major CREG groups are represented.
4. Submitted data must include tests that were performed by each technologist involved in clinical testing.
5. Procedures and reagents used to perform testing must be described in the applicant laboratory's procedure manual.
6. Blinded Parallel Testing
The number of blinded samples required must be equivalent to the number provided by the PT program in which the laboratory is subscribed. The results must not be revealed to the applicant laboratories prior to submission of their results.

The blinded parallel testing results are submitted independently to the Commissioner for review and may include the following:

- a. Specimens tested in parallel with another ASHI-accredited laboratory
- b. A complete set (one year) of proficiency testing with graded results
- c. A combination of the above (if b is partial)

Cellular Assays

MLC Tests

1. Results of MLC tests for 10 donor-recipient pairs.
2. Data to be submitted:
 - a. HLA phenotypes of subjects tested and controls
 - b. All raw data including tapes from scintillation counters, data on replicates and calculations.
 - c. Report of results along with an interpretation.

Other Cellular Assays – 10 case studies

ENGRAFTMENT/CHIMERISM ANALYSIS TESTS

1. Results for 10 Post-Transplant Engraftment/Chimerism Analyses for at least 5 different donor/recipient pairs
2. Data to be included:
 - a. Alleles/phenotypes used for analysis for the recipient pre-transplant, the donor and the recipient's post-transplant sample.
 - b. All raw data including computer printouts and calculations
 - c. Reports of results including interpretative comments
3. Blinded parallel testing
The number of blinded samples required must be equivalent to the number provided by the PT program in which the laboratory is subscribed. The results must not be revealed to the applicant laboratories prior to submission of their results.

IMMUNOPHENOTYPING BY FLOW CYTOMETRY

1. Results for 10 phenotype tests for different patients
2. Data to be included
 - a. Cell Surface Markers tested for and reagents used
 - a. All raw data including computer print-outs and calculations
 - b. Reports of results including interpretative comments
3. Blinded Parallel Testing
 - The number of blinded samples required must be equivalent to the number provided by the PT program in which the laboratory is subscribed.
 - The results must not be revealed to the applicant laboratories prior to submission of their results.

Parentage Testing

1. 50 Cases
2. 1 year PT results or equivalent blinded parallel testing

APPENDIX 3:

VALIDATION CHECKLIST

Laboratory Name: _____

ASHI # _____ CLIA # _____ UNOS # _____

Director/Technical Supervisor: _____

Commissioner: _____ Date of Review: _____

New Addition: _____

- ___ Director previously approved for **Area of Accreditation**
If not: ___ Director approved by DTRC
- ___ Director previously approved for **Technology** (see table on page 2)
If not: ___ Log of case reviews submitted
- ___ Laboratory previously approved for **Testing Category** (see table on page 2)
If not:
Log of cases reviewed and 1-2 cases with data included:
 - ___ 50 HLA typings, ___ 10 Cellular assays
 - ___ 20 HLA crossmatch tests, ___ 10 Engraftment studies
 - ___ 50 HLA Ab screens/IDs, ___ 10 Flow Phenotype cases
 - ___ 50 Parentage Testing cases
 - ___ Test data included different types of testing material if applicable (PB, LN, Spleen)

Validation Checklist (required for all additions)

- ___ Summary and Interpretation of Validation - signed by Director
- ___ Testing protocol – how test is to be used; purpose of test
- ___ Step-by-step procedure
- ___ Performance Specifications – summary of accuracy, precision, sensitivity, specificity, range of results, normal values, limitations of assay
- ___ QC procedures
- ___ Equipment Calibration data
- ___ Parallel Study – for new Method, may be with previously approved method; Include worksheets if not blinded parallel study;
Minimum of 20 tests or equal to 1 yr PT
(Blinded parallel testing required if New Technology or Testing Category)
- ___ Training checklist
- ___ Competence documentation for those trained to perform test
- ___ Enrolled in PT program
- ___ **On-site inspection required if New Technology or Testing Category**

- ___ Validation approved ___ Additional data requested

COMMISSIONER

CO-CHAIR