



AMERICAN SOCIETY FOR  
HISTOCOMPATIBILITY AND IMMUNOGENETICS

ACCREDITATION REVIEW PROGRAM

# INTERIM APPLICATION INSTRUCTIONS

Revision 8/1/2009

# INTERIM REPORT - GENERAL INSTRUCTIONS

## PLEASE READ CAREFULLY

1. **IMMEDIATELY UPON RECEIPT:** please read all instructions carefully, before completing the application.
2. This application should require no paperwork to be submitted except the following items:
  - a. The Declaration of Intent and the Attestation Statement signed by the Laboratory Director or authorized individual.
  - b. Any proficiency testing corrective action required, that is, failure to reach 80% consensus with any proficiency testing challenge. \*\*  
\*\*Please submit all proficiency testing results for the July 1, 2010 deadline. Unfortunately, the electronic operation for PT submission is not available at this time.
  - c. Any deficiencies noted during the self-inspection together with appropriate corrective actions.
  - d. Validation materials for new areas of accreditation or new methods/technologies.
  - e. Laboratory Accreditation Fees.
3. All documentation must be in English and typed.
4. Accreditation in Hematopoietic Stem Cell/Bone Marrow (HSC/BM) Transplantation requires that the laboratory provide final compatibility service to a bone marrow transplant program.
5. 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.
6. CFR Sec. 493.51 requires that CMS be notified within 30 days of any change in ownership, name, location, director or technical supervisor and general supervisor.
7. Be sure to complete the cover page with the name of the individual who performed the self-inspection and date of the self-inspection in Section A.
8. 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 INTERIM REPORT

When your interim report is complete and ready for submission, complete the [report online](#) or send the completed Word document file to the ASHI Accreditation Manager, Melissa McElroy, [melissa@cmehelp.com](mailto:melissa@cmehelp.com).

Send the original and **TWO** copies of the following original documents listed below to:

### Additional Documentation Required:

- a. The Declaration of Intent and the Attestation Statement signed by the Laboratory Director or authorized individual.
- b. Any proficiency testing corrective action required, that is, failure to reach 80% concordance with any proficiency testing survey or 100% with an ABO proficiency testing survey. \*\*  
**\*\*Please submit all proficiency testing results for the July 1, 2010 deadline. Unfortunately, the electronic operation for PT submission is not available at this time.\*\***
- c. Any deficiencies noted during the self-inspection together with appropriate corrective actions.
- d. Validation materials for new areas of accreditation or new methods/technologies.
- e. Laboratory Accreditation Fees\*\*

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

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

**THE ACCREDITATION MANAGER PERFORMS AN INITIAL REVIEW OF THE INTERIM REPORT. INCOMPLETE INTERIM REPORTS 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 ONLINE FILING OF THE INTERIM REPORT

## PLEASE READ CAREFULLY

The Accreditation Review Board has instituted a new database that will provide superior tracking of individual laboratory activities and the review process. One of the features of the new database is the ability to upload the data that is supplied by laboratories. You may [file this report online](#) or use the Application Packet supplied as a Microsoft Word document with this notification. At this time we do not have the ability to accept other word processing software. The format of the packet has changed, however you will notice that the areas that require information are shaded in gray. Each of the gray areas will expand if you are supplying more than one line of documentation. To easily navigate between online fields, simply hit the TAB key (hitting enter or return saves your data and takes you to the next page.)

Upon receipt of the electronic notification:

### Online Submission:

1. Go to the website [www.gotomylist.com/jeffco/ashi/interimreport/index.cfm](http://www.gotomylist.com/jeffco/ashi/interimreport/index.cfm)
2. Enter unique inspection ID number
3. Enter the laboratory ASHI number
4. Follow filing instructions – hit save & continue after each section
5. Be sure to hit the finalize button when the report is complete and print out a copy for your records.
6. Mail required signature pages (Section B) and supporting documentation (PT) as needed.
7. The data supplied will be uploaded to the database. In subsequent years, your application will be returned with the previous years' information already completed. Only revisions and updates to the laboratory activities will be required.

### Microsoft Word Document Submission:

*(If you do not wish to complete the interim report online, please contact the Accreditation Office and the MS Word document will be sent to you via email.)*

1. Open the document in MS Word.
2. Fill in the gray areas with the proper laboratory information. Tab to each of the gray sections. Don't attempt to reformat or change the template, as only the data appearing in the shaded areas will be transferred.
3. Once the Application is complete, Save a copy for your records and Send the original file back with any supplemental documentation required. You can save the file on a disk to be mailed with your packet, OR you may email the file to [Melissa@cmehelp.com](mailto:Melissa@cmehelp.com).
4. Mail required signature pages (Section B) and supporting documentation as needed.
5. The data supplied will be uploaded to the database. In subsequent years, your application will be returned with the previous years' information already completed. Only revisions and updates to the laboratory activities will be required.

# DIRECTIONS FOR FILING THE INTERIM REPORT

## A. COVER PAGE

Provide the names of the laboratory, director(s), department and institution, **as they should appear in the ASHI Directory (+)**.

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.

### Areas of Accreditation

Put an "X" in all areas for which you wish to be evaluated for accreditation and record "**NEW**" for those areas you are adding and want ASHI to evaluate. **Note:** If adding a new area of accreditation, please remember a portfolio review of the Laboratory Director 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 '**Discontinued/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. Additionally, a portfolio review of the Laboratory Director may be required, if the Laboratory Director is not currently qualified by the Director Training Review Committee in that method/technology. Please refer to attached Validation guidelines (**Section M and Appendix 2**), validation checklist (**Appendix 3**) and/or Documentation of Director(s)/Technical Supervisor(s) Qualifications (**Appendix 1**).

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## 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 gives 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.

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## 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 to the ASHI Accreditation office.**

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## 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'. (Do not enter CE hours for ABHI certified individuals.)

**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

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

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## 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.
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## 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 (CMS) 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.
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## J. PROFICIENCY TEST RESULTS

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 single 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 time frame 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 events the laboratory has received for which results are available prior to submission of the packet, regardless of the number of send-outs in a calendar year.** . In other words, if a PT program has 2 send-outs per year, the laboratory must submit the summary reports from the last 3 that have been graded with results returned to the laboratory.
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 (send-out) of each analyte. **One hundred percent** 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.**

## 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 the Test Data required for the addition of new Technologies or new Categories of Accreditation (see above).
- Must submit complete Validation materials.
- The validation material may be used to partially fulfill Test Data requirements.
- 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. The step-by-step procedure;
- c. The protocol for use of the procedure;
- d. The program for personnel training;
- e. Documentation of the competency of personnel who will be performing the test and reviewing the test results;
- f. Performance specifications to include accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, limitations, and any other relevant characteristics;
- g. Quality control procedures;
- h. Calibration data for necessary equipment (from Commissioner's Checklist);
- i. Parallel Testing with Reference Samples or samples tested with approved method\*;  
A minimum of 20 parallel testing results – include worksheets if not blinded  
Include a variety of test results (different antigens, antibody specificities, etc.)
- j. Parallel testing with another approved method in-house is acceptable if the new methodology does not represent a new Technology.
- k. For new Technology, a blinded parallel test must be submitted. Blinded parallel testing results from the reference laboratory and the validating laboratory must be reported independently to the Commissioner.
- l. The laboratory must be enrolled in PT program.

## 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.

<b>Technology</b>	<b>Methods included under Technology</b>
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**
- **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.

## INTERIM REPORT CHECKLIST OF REQUESTED DOCUMENTS

PLEASE NOTE THOSE ITEMS IN 'BOLD' MUST BE SENT TO THE ACCREDITATION OFFICE:

- Cover page (Section A)
  - Contact Information
  - Individual performing self inspection and self inspection date
  - Areas of Accreditation
    - **Validation documentation, if adding new areas of accreditation**
    - **Director portfolio, if adding new areas of accreditation**
  - Methods and Technologies
    - **Validation documentation, if adding new methods/technologies**
    - **Director portfolio, if adding new methods/technologies**
- **Declaration of Intent - Attestation Statement (Original and 2 copies to the Accreditation Office) (Section B)**
- Personnel List (Section F)
  - Be sure On-call (OC), Technical Competency (TC) and Continuing Education (CE) are included for all clinical testing personnel.
- Laboratory Activities (Section H)
- Laboratory Test Data for CMS (Section I)
- Proficiency Result Summary Form (Section J)
- **Proficiency testing corrective actions, if applicable (Original and 2 copies to the Accreditation Office)\*\***

**\*\*Please submit ALL proficiency testing results for the July 1, 2010 deadline. Unfortunately, the electronic operation for PT submission is not available at this time.**

- **Any deficiencies noted during the self-inspection together with appropriate corrective actions.**
- **Laboratory Accreditation Fees**

**Reminder: All the information submitted for the Interim application must be available for review during the next on-site inspection of the laboratory.**

# APPENDIX 1

## SUPPLEMENTARY DOCUMENTATION OF DIRECTORS(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.

<b>Technologies:</b>	<b>Testing Categories:</b>	<b>Methods included under Technology:</b>
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	<b>2 weeks</b>
Review of portfolio by DTR with summary and recommendations sent to designated ARB Co-Chair	<b>2 months</b>
Telephone interview of applicant by ARB Co-Chair and DTR reviewer	<b>2 weeks</b>
Recommendation of certification to ARB Program Director	
Certification letter to applicant from ARB program director and DTR Chair	<b>2 weeks</b>

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

## APPENDIX 4: Policy for Enhanced Proficiency Testing

**POLICY NAME:** Enhanced Proficiency Testing Requirements  
**POLICY NO.:** O-13-01, M-1-02, M-2-04, M-3-04, M-4-06  
**DATE APPROVED:** 05-07-01, 04-05-02, 09-21-04, 11-01-04, 08-06-06

### RATIONALE

Enhanced Proficiency Testing requirements are the same as the requirements for a new method approval.

### POLICY

Laboratories will be required to submit enhanced proficiency testing results when the consecutive proficiency testing challenges for 12 months preceding the application do not reach 80% concordance with the consensus.

Enhanced Proficiency Testing requirements are equal to the number of samples in the laboratory's designated yearly proficiency testing survey or 8 samples; whichever is less.

**When Enhanced Proficiency Testing is required, the lab may use blinded, parallel testing with another ASHI Accredited laboratory or equivalent (check with the laboratory's Commissioner.) If the laboratory has been performing successfully in a second approved Proficiency survey (refer to ARB policy R-36-06) of the same analyte, those results may be submitted to satisfy the requirement for Enhanced Proficiency Testing. These results must cover the same 12-month period as the designated Proficiency Testing survey and conform to all other proficiency testing requirements.**

For ABO/Rh grouping, failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory performance. Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. ABO/Rh testing must be outsourced to another CLIA certified laboratory until successful performance in proficiency testing for ABO/Rh has been completed. Results of the proficiency testing in ABO/Rh will be reviewed and approved by the ARB before routine testing may be resumed.

**Enhanced Proficiency Testing for ABO/RH must be provided by a CMS-approved PT provider. There are several CMS approved PT programs for ABO/Rh.**

Laboratories outside of North America may substitute and include local proficiency exchange programs.