Accreditation Review Board

APPLICATION

INSTRUCTIONS

Revision May 2022
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I. GENERAL INSTRUCTIONS

Please read these instructions carefully. If you have any questions throughout the process please email your Accreditation Manager, Melissa Weeks: MWeeks@ashi-hla.org

1. IMMEDIATELY UPON RECEIPT: Please read all instructions carefully, before completing the application.

2. The application must be submitted using the online application. If internet access is not available for completing the application please notify the accreditation manager. If your laboratory is applying for reaccreditation, some sections of your current application will be duplicated from previous applications, so you will not have to reenter most of the application data from scratch. These sections include: Key Personnel, Areas of Accreditation, Subcontracted Laboratories, and Personnel.

3. Some sections of the application will require you to attach documents by browsing through files on your computer. To make this clear, these sections are identified with the following: “ATTACH:” Review these requirements ahead of time, so you will know what you need to have scanned and ready for uploading into the application.

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 or its designee be notified within 30 days of any change in ownership, name, location, director or technical supervisor and general supervisor.

7. The ASHI Standards & Guidance is available online at the ASHI Website and will also be emailed to you with these instructions. This document is NOT required to be completed and submitted with your application, but may help in preparation for your laboratory inspection.

8. If you fail to meet the submission deadline, your packet will be accepted by accreditation 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.

SUBMISSION OF THE APPLICATION – now completely online!

When your application is complete and ready for submission, follow the instructions on the online application to submit entirely online. Instructions are provided electronically throughout the online application, by clicking on the question mark icons or instructions links in each section.

If you need to send any part of the application in hard copy form, send an original and FOUR copies (total of five), to the following:

<table>
<thead>
<tr>
<th>USPS, FedEx, UPS, DHL Delivery address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHI Accreditation Office</td>
</tr>
<tr>
<td>453 Annapolis Street W</td>
</tr>
<tr>
<td>St. Paul, MN 55118</td>
</tr>
<tr>
<td>856-335-3299 x 7004</td>
</tr>
</tbody>
</table>
II. THE INSPECTION PROCESS

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 ARB Executive Board 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.

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.

You will be able to respond to deficiencies cited (if any) in the application itself; so that the laboratory’s electronic records will all be in one place. More instructions on this feature will be provided to you at the time of your inspection.
**III. APPLICATION BREAKDOWN – Section by Section**

**A. Registration & Demographics – NEW LABS ONLY!**

*For Laboratories applying for reaccreditation, enter the same login information that you used in previous years (**NEW IN 2019: the login ID is your laboratory’s ASHI number!)*

There is a link to click if you forgot your password, or you can contact the accreditation manager to have it reset.

**STEP 1:** To begin a new ASHI application online, you must first register in the system. The Accreditation Manager will provide you a link via email that you will click on to start the registration process. On the LearningBuilder homepage, click on “register as an applicant” on the left hand side. Enter your email address and a password. *(NOTE: this will be the one and only login for your ASHI application, which means that you may be sharing the login email & password with someone else.)*

Enter the name of the laboratory contact person and address. This step creates your account, but it must be confirmed by email. See step 2.

**STEP 2:** Check your email for the confirmation message & link, click on it and it will bring you back to the LearningBuilder system. *(NOTE: if you don’t see the confirmation email immediately, check your spam/junk folder.) You will have one application listed, click on the orange “Start your ASHI Application” button.

**STEP 3:** In the pop up window, enter your laboratory’s demographic information (address, etc.) Click on the green “save” button.

EXAMPLE REGISTRATION SCREEN:
B. Key Personnel

Provide the names of the laboratory, director(s), technical supervisor(s), clinical consultant(s), general supervisor(s) and director(s) in training, board certifications (if applicable) and upload CVs for each.

NOTE: If the director also serves the role of technical supervisor or clinical consultant, those corresponding sections do NOT need to be filled out in the online application. In addition, all key personnel must be included in section G: PERSONNEL, below.

Click the blue save button to save each record if you need to revisit this section later. Click the green “Add/Confirm Person” button to complete a record.

ATTACH: CVs for director, technical supervisor, clinical consultant, and general supervisor
ATTACH: credentialing licensure (if applicable)

NOTE: CFR 493 requires that the laboratory have a director (493.1441), technical supervisor (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.

DIRECTOR/TECHNICAL SUPERVISOR SPECIFIC QUALIFICATIONS
(ASHI Standard E.2 and E.3)

(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 ACHI, 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.

CLINICAL CONSULTANT SPECIFIC 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.

EXAMPLE KEY PERSONNEL SCREEN:

C. Subcontracted Laboratories

List the laboratories subcontracted and the testing they provide. For example: Laboratory XYZ, provided 2-plus field resolution DNA Class I typing. Scan and attach evidence of their certification, such as their ASHI certificate. Click the Record/Confirm Lab button to complete this step.

ATTACH: ASHI certificates for the subcontracted laboratories
D. Areas of Accreditation

For each area of accreditation listed, click on the orange “edit/confirm area” button to enter the information. Record the percentage of clinical effort of each area of accreditation and upload an example transplant center agreement and case report for each area of accreditation.

**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 ACHI Portfolio Committee in that area of accreditation. Please send a separate email to the accreditation office explaining the addition of a new area of accreditation.

**ATTACH:** A patient case report from the last 6 months for each clinical application. **Please remember to redact all patient identifiers.** A case report is defined as the final report you would send out/what the physician would see (DO NOT SEND RAW DATA).

-AND-

**ATTACH:** For each area in which you are seeking re-accreditation, submit an example of a signed/dated (lab reviewed) transplant center agreement that relates to each particular area of accreditation. We understand that laboratories sometimes have multiple agreements, simply choose one example to upload per area of accreditation. **NOTE:** for the area of “Histocompatibility Testing for Other Clinical Purposes” and “Transfusion Support” we understand this would not be affiliated with a transplant center, so simply upload a brief protocol on how the testing is done in your laboratory in place of an agreement.

**EXAMPLE AREA OF ACCREDITATION SCREEN:**
E. Testing Categories

HLA Typing
For each of the subcategories under HLA Typing, distinguished by class I & class II, enter test number data and proficiency testing information by clicking on the orange “Enter PT Info and Volume” button.

Record the test volume for each method/technology (under 1,000; 1,000-2,000; 2,000-3,000; or over 3,000.)

Enter up to 4 methods for each subcategory. Click on the orange “submit and move to method PT” button.

For the Proficiency Testing data, identify if the method is primary or not and report the 3 most recent surveys/challenges from your laboratory. If your laboratory performed Proficiency Testing on only 2 surveys in the past year, the 3 most recent must still be provided to meet the CMS requirement of the rolling time-frame. Record the proficiency testing vendor and the name of survey (sendout). See Appendix 2 below, for specific instructions for Proficiency Testing reporting. All uploaded PT must be reviewed/signed by the laboratory director or director designee.

ATTACH: Corrective action for PT, if applicable.

Hit the green “FINISH” button

Crossmatch
For each of the subcategories under Crossmatch, distinguished by T Cell & B Cell, enter test number data and proficiency testing information by clicking on the orange “Enter PT Info and Volume” button.

Record the test volume for each method/technology (under 1,000; 1,000-2,000; 2,000-3,000; or over 3,000.)

Enter up to 4 methods for each subcategory. Click on the orange “submit and move to method PT” button.

For the Proficiency Testing data, identify if the method is primary or not and report the 3 most recent surveys/challenges from your laboratory. If your laboratory performed Proficiency Testing on only 2 surveys in the past year, the 3 most recent must still be provided to meet the CMS requirement of the rolling time-frame. Record the proficiency testing vendor and the name of survey (sendout). See Appendix 2 below, for specific instructions for Proficiency Testing reporting. All uploaded PT must be reviewed/signed by the laboratory director or director designee.
ATTACH: Corrective action for PT, if applicable.

Hit the green “FINISH” button

**Antibody Detection (Screen)**

For each of the subcategories under Antibody Detection (Screen), distinguished by Class I & Class II, enter test number data and proficiency testing information by clicking on the orange “Enter PT Info and Volume” button.

Record the test volume for each method/technology (under 1,000; 1,000-2,000; 2,000-3,000; or over 3,000.)

Enter up to 4 methods for each subcategory. Click on the orange “submit and move to method PT” button.

For the Proficiency Testing data, identify if the method is primary or not and report the 3 most recent surveys/challenges from your laboratory. If your laboratory performed Proficiency Testing on only 2 surveys in the past year, the 3 most recent must still be provided to meet the CMS requirement of the rolling time-frame. Record the proficiency testing vendor and the name of survey (sendout). See Appendix 2 below, for specific instructions for Proficiency Testing reporting. All uploaded PT must be reviewed/signed by the laboratory director or director designee.

ATTACH: Corrective action for PT, if applicable.

Hit the green “FINISH” button

**Antibody Identification**

For each of the subcategories under Antibody Identification, distinguished by Class I & Class II, enter test number data and proficiency testing information by clicking on the orange “Enter PT Info and Volume” button.

Record the test volume for each method/technology (under 1,000; 1,000-2,000; 2,000-3,000; or over 3,000.)

Enter up to 4 methods for each subcategory. Click on the orange “submit and move to method PT” button.

For the Proficiency Testing data, identify if the method is primary or not and report the 3 most recent surveys/challenges from your laboratory. If your laboratory performed Proficiency Testing on only 2 surveys in the past year, the 3 most recent must still be provided to meet the CMS requirement of the rolling time-frame. Record the proficiency testing vendor and the name of survey (sendout). See Appendix 2 below, for specific instructions for Proficiency Testing reporting. All uploaded PT must be reviewed/signed by the laboratory director or director designee.
ATTACH: Corrective action for PT, if applicable.
Hit the green “FINISH” button

Other Testing Categories
For each of the subcategories under Other Testing Categories, including Immunophenotyping, Cellular testing, ABO, Other, Donor Serology, NAT, and other, enter test number data and proficiency testing information by clicking on the orange “Enter PT Info and Volume” button.

Record the test volume for each method/technology (under 1,000; 1,000-2,000; 2,000-3,000; or over 3,000.)

Enter up to 4 methods for each subcategory. Click on the orange “submit and move to method PT” button.

For the Proficiency Testing data, identify if the method is primary or not and report the 3 most recent surveys/challenges from your laboratory. If your laboratory performed Proficiency Testing on only 2 surveys in the past year, the 3 most recent must still be provided to meet the CMS requirement of the rolling time-frame. Record the proficiency testing vendor and the name of survey (sendout). See Appendix 2 below, for specific instructions for Proficiency Testing reporting. All uploaded PT must be reviewed/signed by the laboratory director or director designee.

ATTACH: Corrective action for PT, if applicable.

Hit the green “FINISH” button

NOTE: If any Category or System is new, validation materials must be provided to your commissioner for review. Review the validation instructions and fill out and submit the validation checklist (APPENDIX 1) with the validation materials, and send directly to your commissioner. For a current listing of ARB commissioners and contact information, please visit www.ashi-hla.org, click on Lab Center, then click on Accreditation, then click on Review Board.

EXAMPLE TESTING CATEGORY SCREEN:
F. CLIA Laboratory Activities

THIS SECTION IS TO BE COMPLETED ONLY BY THOSE LABORATORIES USING ASHI FOR CLIA PURPOSES, AS INDICATED ON THE DECLARATION OF INTENT. 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 A PART OF ITS ROLE AS A DEEMING AGENT FOR CMS.

✓ ATTACH: current CLIA certificate

Add activities by clicking the blue “add activity” button. Use the orange “Select” buttons to pick the applicable areas of testing for your laboratory – including: Transplant, Non-Transplant and General Immunology.

Once the applicable areas are added to your application, you can enter specific test data, including: 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.

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.

EXAMPLE CLIA LABORATORY ACTIVITIES SCREEN:
G. Personnel

Enter individual records for 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.).

Click on the orange “Add/Confirm Personnel” button to add a new record (person) OR confirm an existing record. Follow the steps in the pop up window based on the chart below.

New in 2019: **ATTACH:** for all testing personnel, attach a transcript of the highest degree earned. This can be official or unofficial. If the transcript is from an educational institution outside of the United States, foreign equivalency evaluation must also be included. States that require licensure (list below) are exempt from this section and do NOT have to upload transcripts.

**ATTACH:** State licensure for personnel, if applicable. The following US states & territories require licensure for clinical laboratory practitioners:

i. California  
ii. Florida  
iii. Hawaii  
iv. Louisiana  
v. Montana  
vi. Nevada  
vii. New York  
viii. North Dakota  
ix. Rhode Island  
x. Tennessee  
xi. West Virginia  
-xii. Puerto Rico  

Click the blue save button to save each record if you need to revisit this section later. Click the green “Add/Confirm Person” button to complete a record. Key personnel must be listed in this section as well.

<table>
<thead>
<tr>
<th>Start date M/D/Y:</th>
<th>Enter the month/day/year the staff member began work in this laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Enter the Name of the Individual</td>
</tr>
<tr>
<td>Position:</td>
<td>Enter the position the staff member holds in the laboratory</td>
</tr>
<tr>
<td>Degrees:</td>
<td>Enter the highest degree this staff member has attained (i.e. PhD, MS, BS,)</td>
</tr>
<tr>
<td>Certifications:</td>
<td>Enter any certification this staff member has attained (i.e. ACHI Fellow or Associate, CHS, CHT, MT, MLA)</td>
</tr>
<tr>
<td>Years HHT:</td>
<td>Enter the number of years of working experience in human histocompatibility testing (HHT)</td>
</tr>
<tr>
<td>OC:</td>
<td>Mark YES or NO if the individual participates in on-call activities for deceased donor testing</td>
</tr>
<tr>
<td>Competency Assessment</td>
<td>Mark YES or NO certifying that Technologist Competency Assessment for this individual was completed for the time period covered by this interim</td>
</tr>
</tbody>
</table>
**Performed:** 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 ACHI certified enter ‘0’ and then record the ACHI certification number in the field below. CE record 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

**EXAMPLE PERSONNEL SCREEN:**

![Personnel Record: Add Personnel](image)

- **Start Date:** 12/22/2011
- **Name:** Jane Doe
- **Position:** General Supervisor
- **Degrees:**
- **Certifications:** OCH
- **HRT Years:** 8
- **On Call:** No
- **Technically Competent:** Yes
- **Total CE Hours:** 27
- **ACHI Certification #:** 123456

- [Save](#)  -  [Cancel](#)  -  [Record Person](#)
H. General Questions

- Under the Application Questions section, click on the orange “Answer Questions” button.
- For Interim laboratories only: **ATTACH:** the self-inspection form.
- List any other accreditation that your laboratory holds (i.e. CAP, AABB, etc.)
- List any discontinued test in your laboratory, from the last year.
- Enter your CLIA certificate expiration date & name of the director listed on the certificate, if applicable.
- If you have any new tests, you can upload the validation right into the application (not mandatory). If there is more than one file simply mail/email the validation separately to your commissioner.
- Click on the green “Record Answers” button.

**EXAMPLE GENERAL QUESTIONS (APPLICATION QUESTIONS) SCREEN:**

![Application Questions: Answer Questions](image)
I. Declaration of Intent/Attestation Statement

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

- Centers for Medicare and Medicaid Services (“CMS”)
- Centers for Medicare and Medicaid Services for ABO/Rh Testing
- Centers for Medicare and Medicaid Services for General Immunology Testing
- National Marrow Donor Program (“NMDP”)
- The Joint Commission (“TJC”)
- United Network for Organ Sharing (“UNOS”)
- Agency for Health Care Administration – State of Florida

SPECIFIC INSTRUCTIONS FOR THE APPLICATION:

This section is to be completed by the Laboratory Director or other individual with appropriate authority. Under the General Questions section of the application, click on the sub category, orange button “Add Declarations”.

Select YES from the drop down menu for the organizations that you intend to utilize ASHI accreditation to fulfill that organization’s requirements. Do not leave any portion blank; select either “YES” or “NO”. Click the save button, or click the green “record attestation” button.

ATTACH: signed Attestation Statement form. A blank template is provided.

I understand it is my laboratory’s responsibility to 1). Obtain a CLIA Certificate of Accreditation; 2). Pay any applicable fees; and 3). Meet the proficiency testing (PT) requirements for ABO/Rh typing, if applicable.

By checking “yes”, I authorize: 1). My PT organization to furnish to ASHI the results of the laboratory’s participation in an approved PT program for the purpose of monitoring the laboratory’s PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person; 2). ASHI to release to CMS or a CMS agent the laboratory’s PT results that constitute unsuccessful participation in an approved PT program; 3). ASHI to release to CMS notification of the actions taken by ASHI as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action; 4). CMS or a CMS agent to conduct a validation inspection after the laboratory has been issued a certificate of accreditation by ASHI or in response to a substantial allegation of non-compliance. 5) By checking “yes” to ABO/Rh, General Immunology, I authorize all PT results for regulated analytes to be released to CMS or other organizations as applicable.

In addition, I have indicated by checking “yes”, my laboratory’s intent to use ASHI accreditation to fulfill the requirements of other organizations. By checking “yes,” I grant to ASHI, on behalf of my laboratory, permission to perform on-site inspections and provide information required to the indicated organization.
I understand that if my laboratory wishes to change any of these arrangements, it is the laboratory’s obligation to inform ASHI in writing of its intent to do so.

**ATTESTATION STATEMENT:** The director or other authorized individual must sign the attestation statement and upload the signed form to the application. A blank template is provided in the online application.

**EXAMPLE DECLARATION OF INTENT/ATTESTATION STATEMENT SCREENS:**

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**J. Inspection**

More instructions for this section will be provided at the time of your laboratory’s inspection.
APPENDIX 1

VALIDATION GUIDELINE

Laboratory Name: _______________________________________________________

ASHI # ___________________ CLIA # ______________ UNOS # _____________

Director/Technical Supervisor: _____________________________________________

Commissioner:___________________________ Date of Review: _______________

New Addition: _____________________________________________________________________

___ Director or Technical Supervisor previously approved for **Area of Accreditation**
   If not: ___ Director or Technical Supervisor approved by ACHI PORTFOLIO COMMITTEE

___ Laboratory previously approved for **Area of Accreditation**
   If not: ___ Submit Laboratory Validation Packet

___ Director or Technical Supervisor previously approved for **Test Category** (see table)
   If not: ___ Director or Technical Supervisor approved by ACHI PORTFOLIO COMMITTEE; or,
   ___ Participation in Laboratory’s Validation Documented

___ Laboratory previously approved for **Testing Category** (see table)
   If not: ___ Log of cases reviewed and 1-2 cases with data included:

**Validation Checklist**

___ Summary and Interpretation of Validation - signed by Director or Technical Supervisor
___ 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
___ Training checklist
___ Competence documentation for those trained to perform test
___ Enrolled in PT program
___ Parallel Testing – for new Method, may be with previously approved method; Include worksheets if not
   blinded parallel study; Minimum of 20 tests or equal to 1 year PT
   (Blinded parallel testing required if New Testing Category or System. Acceptable performance is 80% or
   greater concordance.)

___ Validation approved ___ Additional data requested

___________________________  ____________________________
Commissioner           Co-Chair
<table>
<thead>
<tr>
<th>CLIA Specialties/ Subspecialties</th>
<th>Category</th>
<th>Analyte*</th>
<th>System</th>
<th>Method**</th>
<th>Submitted validation required</th>
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</thead>
<tbody>
<tr>
<td>Histocompatibility</td>
<td>Immunogenetics – HLA Typing</td>
<td>HLA</td>
<td>Molecular</td>
<td>SSP, SSOP, Real-Time PCR, Sanger Sequencing, NGS</td>
<td>Internal validation – labs are required to notify the commissioner</td>
</tr>
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<td></td>
<td>Serology</td>
<td>Microcytotoxicity</td>
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<tr>
<td></td>
<td>Immunogenetics – Non-HLA Typing</td>
<td>Cytokine</td>
<td>Molecular</td>
<td>SSP, SSOP, Real-Time PCR, Sanger Sequencing, NGS</td>
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<td>HNA, HPA, KIR, MICA</td>
<td>Serology</td>
<td>Microcytotoxicity</td>
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<td>Serology</td>
<td>Microcytotoxicity</td>
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<td>Endothelial Cell, Platelet</td>
<td>Flow Cytometry</td>
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<td>Antibody Testing – HLA Detection</td>
<td>Detection</td>
<td>Serology</td>
<td>Microcytotoxicity</td>
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<td>Complement Fixation</td>
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<td>Solid Phase</td>
<td>ELISA, Microarray</td>
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<td></td>
<td>Antibody Testing – Non-HLA Autoantibody</td>
<td>AT1R, ETAR, HPA, KIR, MICA</td>
<td>Serology</td>
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<td>ABO, RhD, A Subgrouping</td>
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<td>Phenotyping</td>
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<td>Cellular</td>
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*This list includes only the common analytes in clinical histocompatibility laboratories and is not intended to be exhaustive.

**Novel, emerging technologies and methods may require validation submitted at the discretion of the ARB.
APPENDIX 2

SPECIFIC INSTRUCTIONS FOR LABORATORY PROFICIENCY TESTING:

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 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.

1. Laboratories must designate a PT provider for each analyte tested by a primary method, e.g., single field resolution HLAClass I typing using SSP or 2-plus field resolution HLA Class II using combined SBT and SSOP. If a laboratory has multiple primary 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 analyte and each primary method. Laboratories must only designate one primary method per analyte and testing for each analyte must be limited to the primary method designated.

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. 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;
   - 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).