



## Accreditation Review Board

# APPLICATION INSTRUCTIONS

Revision 8/31/2017

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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@ahredchair.com](mailto:MWeeks@ahredchair.com) or call 651-202-3637.

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:

<b>USPS, FedEx, UPS, DHL Delivery address:</b>
ASHI Accreditation Office
1716 Field Avenue
St. Paul, MN 55116
651-202-3637

## 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. 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:

The screenshot shows a web form titled "Register for an Account" on the LearningBuilder platform. The form is divided into two main sections: "Account Information" and "Contact Information".

**Account Information:**

- Email\*:
- Confirm Email\*:
- Password\*:
- Confirm Password\*:

**Contact Information:**

- Title:
- Address\*:
- Line 1\*:
- Line 2\*:
- Line 3\*:
- City\*:
- State/Province:
- Postal Code:
- Country\*: USA (dropdown menu)
- First Name\*:
- Middle Name\*:
- Last Name\*:
- Suffix:
- Phone Number\*:

At the bottom left of the form, there are two buttons: "Save" (in orange) and "Cancel".

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## 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 ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.

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

In most cases, one person fills both positions.

### **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:

The screenshot shows the LearningBUILDER web application interface. A modal dialog box titled "Director: Add Key Personnel" is open. The dialog box contains the following fields and buttons:

- First Name\*:
- Last Name\*:
- Curriculum Vitae\*:
- Certification Board:
- Certification Board - Other:
- Credential Documentation:
- Please add any comments about this person here:
- Buttons:

## 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 Director Training Review 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 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” 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:

The screenshot shows a web application interface for accreditation. On the left, a sidebar lists various accreditation areas: HSC/BM Transplantation: Related Donor, HSC/BM Transplantation: Unrelated Donor, Solid Organ Transplantation: Deceased Donor, Solid Organ Transplantation: Live Donor, Relationship Testing, Histocompatibility Testing for Non-Transplant Clinical Purposes, and Transfusion Support. The main content area is partially obscured by a modal form titled "HSC/BM Transplantation: Related Donor: Complete Activity".

The modal form contains the following text and fields:

- 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. AND
- ATTACH: For each area in which you are seeking re-accreditation, submit an example of a transplant center agreement that relates to each particular area of accreditation. Click the green "Submit Area" button when complete.
- % of Clinical Effort (enter numbers only)\*:
- Redacted Case Report\*: [Choose from library](#) or [Upload](#)
- Transplant Center Agreement\*: [Choose from library](#) or [Upload](#)
- Buttons: [Save](#), [Cancel](#), [Submit Area](#)



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## 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. **\*\*NEW IN 2014: All uploaded PT must be reviewed/signed by the laboratory director or director designee. \*\***

**ATTACH:** PT Summary Report with documentation of lab review. (ASHI PT = “Participant’s Performance Report”)

**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. **\*\*NEW IN 2014: All uploaded PT must be reviewed/signed by the laboratory director or director designee. \*\***

**ATTACH:** PT Summary Report with documentation of lab review. (ASHI PT = “Participant’s Performance Report”)

**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. **\*\*NEW IN 2014: All uploaded PT must be reviewed/signed by the laboratory director or director designee. \*\***

**ATTACH:** PT Summary Report with documentation of lab review. (ASHI PT = “Participant’s Performance Report”)

**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. **\*\*NEW IN 2014: All uploaded PT must be reviewed/signed by the laboratory director or director designee. \*\***

**ATTACH:** PT Summary Report with documentation of lab review. (ASHI PT = “Participant’s Performance Report”)

**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. **\*\*NEW IN 2014: All uploaded PT must be reviewed/signed by the laboratory director or director designee. \*\***

**ATTACH:** PT Summary Report with documentation of lab review. (ASHI PT = “Participant’s Performance Report”)

**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](http://www.ashi-hla.org), click on Lab Center, then click on Accreditation, then click on Review Board.

## EXAMPLE TESTING CATEGORY SCREEN:

The screenshot shows a web application interface for entering PT data. On the left, a sidebar lists categories: 'Other', 'Antibody Detection (Screen)', 'Antibody Identification', and 'Other Testing Categories'. The 'Other Testing Categories' category is selected, and a modal form is open. The form is titled 'Enter PT Info and Volume' and contains the following fields and buttons:

- Test Volume: < 1k
- Method 1: SEP
- Proficiency Test Vendor\*: [text input]
- Method 1 Challenge 1 # Errors\*: [text input]
- Method 1 Challenge 1 Total Number Tested\*: [text input]
- Please upload your PT results for Challenge 1\*: [Upload a file button]
- Please upload any corrective actions for Challenge 1: [Upload a file button]
- Method 1 Challenge 2 # Errors\*: [text input]
- Method 1 Challenge 2 Total Number Tested\*: [text input]
- Please upload your PT results for Challenge 2\*: [Upload a file button]
- Please upload any corrective actions for Challenge 2: [Upload a file button]
- Method 1 Challenge 3 # Errors\*: [text input]
- Method 1 Challenge 3 Total Number Tested\*: [text input]
- Please upload your PT results for Challenge 3\*: [Upload a file button]
- Please upload any corrective actions for Challenge 3: [Upload a file button]
- Buttons at the bottom: Go Back, Save, Cancel, Move to Method 2 PT info, Finish

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## 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

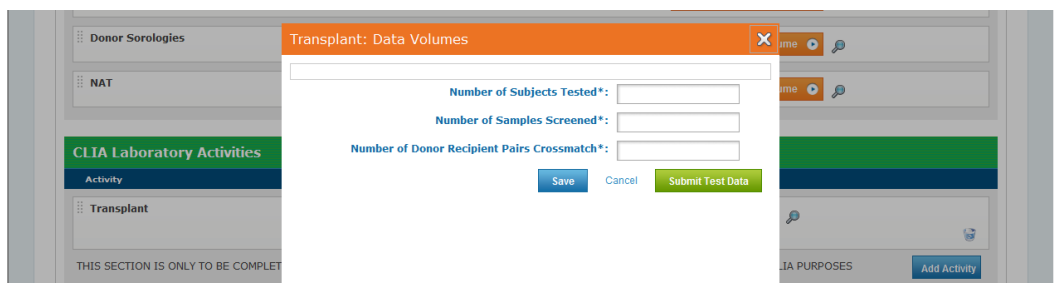
Add activities by clicking the blue “add activity” button. Use the orange “Select” buttons to pick the applicable areas of testing for your laboratory – including: Transplant, Non-Transplant and General Immunology.

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:



The screenshot displays a software interface for entering laboratory activity data. A central dialog box titled "Transplant: Data Volumes" is open, featuring three input fields: "Number of Subjects Tested\*", "Number of Samples Screened\*", and "Number of Donor Recipient Pairs Crossmatch\*". Below these fields are three buttons: "Save" (blue), "Cancel" (grey), and "Submit Test Data" (green). The background shows a sidebar with navigation options like "Donor Sorologies", "NAT", "CLIA Laboratory Activities", "Activity", and "Transplant". A blue "Add Activity" button is visible at the bottom right of the main interface.

## 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.

**ATTACH:** State licensure for personnel, if applicable

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.

<b>Start date M/D/Y:</b>	Enter the month/day/year the staff member began work in this laboratory
<b>Name:</b>	Enter the Name of the Individual
<b>Position:</b>	Enter the position the staff member holds in the laboratory
<b>Degrees:</b>	Enter the highest degree this staff member has attained (i.e. PhD, MS, BS,)
<b>Certifications:</b>	Enter any certification this staff member has attained (i.e. D(ABHI), CHS, CHT, MT, MLA)
<b>Years HHT:</b>	Enter the number of years of working experience in human histocompatibility testing (HHT)
<b>OC:</b>	Mark YES or NO if the individual participates in <b>on-call</b> activities for deceased donor testing
<b>Competency Assessment Performed:</b>	<p>Mark YES or NO certifying that <b>Technologist Competency Assessment</b> for this individual was completed for the time period covered by this interim application.</p> <p><i><b>Note:</b> This information must be available for review during any on-site inspection of the laboratory.</i></p>
<b>Total CE:</b>	<p>Include total number of <b>continuing education</b> hours for each staff member of the clinical staff.</p> <p><i><b>Note:</b> If staff members are currently ABHI certified enter ‘0’ and then record the ABHI 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:</i></p> <ul style="list-style-type: none"> <li>▪ <b>Director/Technical Supervisor: 50 hours</b></li> <li>▪ <b>Clinical Consultant: 12 hours</b></li> <li>▪ <b>Director-in-Training: 27 hours</b></li> <li>▪ <b>Technologist: 12 hours</b></li> <li>▪ <b>Supervisor: 27 hours</b></li> </ul>

**EXAMPLE PERSONNEL SCREEN:**

The screenshot displays a web application interface with a modal window titled "Personnel Record: Add Personnel". The modal contains the following fields and values:

- Start Date: 12/22/2011
- Name: Jane Doe
- Position: General Supervisor
- Degrees: BS
- Certifications: CHS
- HHT Years: 8
- On Call: No
- Technically Competent: Yes
- Total CE Hours: 27
- ABHI Certification #: 123456

At the bottom of the modal are three buttons: "Save", "Cancel", and "Record Person".

The background interface includes a sidebar with sections: "Transplant", "Personnel", "Pay Application Fee", "Inspection", and "Application Questions". The "Personnel" section is currently active, showing a table with columns for Name and other details. Other sections like "Pay Application Fee" and "Inspection" contain text and buttons such as "Add Activity", "Add Personnel", "Pay Fees", "Submit Application", and "Overview".

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## 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:

Other Testing Categories

Enter other testing categories data in this section.

CLIA Laboratory Activities

THIS SECTION IS ONLY TO BE COMPLETED BY INTERIM LABORATORIES.

Personnel

Enter details on all personnel in the laboratory.

General Questions

Complete this task (required)

Application Questions

Complete this task (required)

Declarations/Attestations

Complete the final miscellaneous questions and answers.

Pay Application Fee

Pay your laboratory's annual accreditation fees here.

Application Questions: Answer Questions

Self-Inspection Form (INTERIM LABS ONLY!):

Please list any other accreditations:

Please list any discontinued tests:

Please list any new methods or technologies:

CLIA Certification Expiration Date:

CLIA Certificate Upload: [Choose from library](#) or

Validation: [Choose from library](#) or

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## 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.

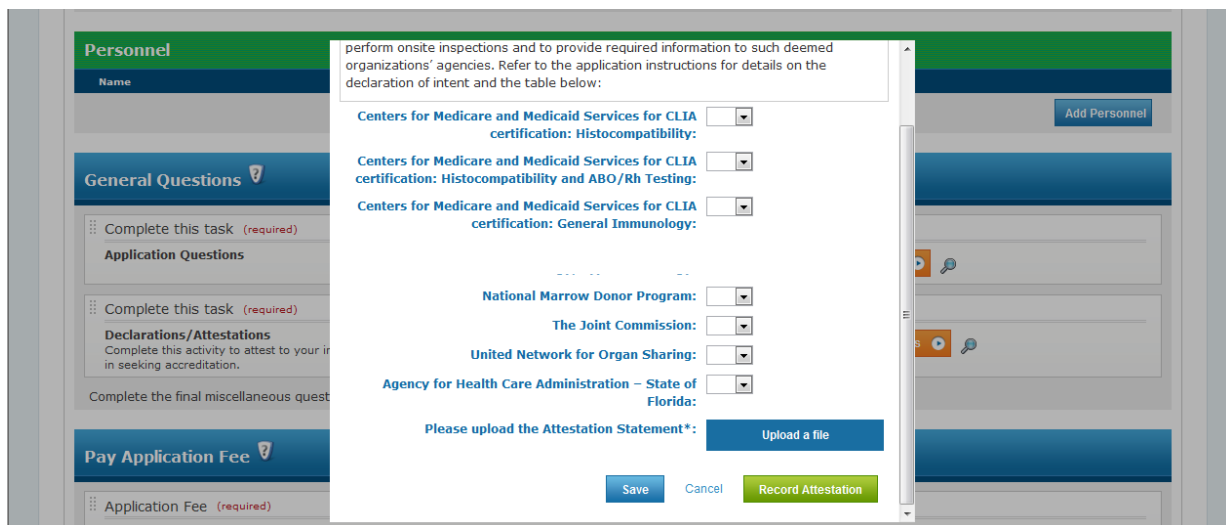
In addition, I have indicated by checking “yes”, my laboratory’s intent to use ASHI accreditation to fulfill the requirements of other organizations. By checking “yes,” I grant to ASHI, on behalf of my laboratory, permission to perform on-site inspections and provide information required to the indicated 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:**



## J. Payment

*\*\*Note – you do not have to complete this section if you have mailed a check (see option #2 below). The application can be submitted even if this payment activity is incomplete.*

### Option 1: Credit Card

The preferred method of payment is by credit card online. ASHI accepts MasterCard, Visa, and American Express. All credit card payments are taken by way of a secure server. No credit card information is stored. Click on the orange "Pay Fees" button to continue.

A receipt will be generated and sent to the laboratory contact person via email.

### Option 2: Check

If you would like to pay the accreditation fees by check, please mail the check and a copy of the invoice to the following address:

ASHI Headquarters  
c/o Rebecca Riedesel  
1120 Rt. 73, Suite 200  
Mt. Laurel, NJ 08054

### EXAMPLE PAYMENT SCREEN:

The screenshot shows a 'Check Out' page with a 'Return to: [Learning Plan](#)' link in the top right. The main content is a form with several sections:

Title	Price	Quantity	Total
ASHI Accreditation Fee	\$1,625.00	1	\$1,625.00
<b>Total:</b>			<b>\$1,625.00</b>

**Credit Card Information**

Total Charge: \$1,625.00

Card Type:

Card Number\*:

CVV/CVC Code\*:

Expiration Date\*:

**Contact Information**

Bill To\*:

Address\*:

City, State, Postal Code\*:

Country\*:

Phone Number:

You will be able to review your purchase before finalizing.

---

## K. 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 DTRC

\_\_\_ 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 DTRC; 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

<b>Category</b> (What is done) Submitted Validation required	<b>System</b> (Assay System) Submitted Validation required	<b>Methods</b> (Specific assay) Internal Validation – labs should send the commissioner an email to notify
<b>Immunogenetics:</b> HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing	Molecular Serology Flow Cytometry Next Generation Sequencing*	CDC (T and/or B) SSO SSP Sanger Sequencing Real time PCR Flow cytometric phenotyping
<b>Crossmatching</b>	Complement Dependent Cytotoxicity Flow Cytometry Other	CDC (T and/or B) AHG (T and/or B) Flow (T and/or B) Solid Phase (Class I and/or II)
<b>Antibody Testing:</b> HLA, HPA, ABO-A1 Titer, MICA	Antibody Detection <ol style="list-style-type: none"> <li>1. Complement Dependent Cytotoxicity</li> <li>2. Solid Phase</li> <li>3. Other</li> </ol> Antibody Identification <ol style="list-style-type: none"> <li>1. Complement Dependent Cytotoxicity</li> <li>2. Solid Phase</li> <li>3. Other</li> </ol>	CDC (T and/or B) AHG (T and/or B) ELISA (Class I and/or II) Flow (Class I and/or II) Microarray (Class I and/or II)
<b>Other Testing</b>	Molecular Immunology Flow Cytometry Cellular Chimerism/Engraftment Monitoring	STR VNTR Flow-Immunophenotyping Immune Cell Function/MLC/PLT SNP Testing Soluble Biomarker Testing

*\*novel, emerging technologies such as NGS 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).