History

Accreditation Program Background

Mission, Purpose and Goal

The mission is to promote quality practice in Histocompatibility and Immunogenetics through the objective and consistent evaluation of compliance with ASHI standards. The purpose of the accreditation program is to evaluate laboratory personnel, procedures and facilities to determine if they are in compliance with those published standards of ASHI and with those standards of organizations by which ASHI is deemed and which apply to the activities of that laboratory. Laboratories will be evaluated for the technology utilized and, if applicable, the clinical services provided.

The goals of the accreditation program are:

1. To perform the evaluation process in an ethical, objective and timely fashion
2. To promote the educational aspects of the accreditation process.
3. To provide to various committees of the Society, data obtained in the accreditation process, which are useful for maintaining the Society's awareness of standard and novel procedures and methodologies.

A Brief History of the Accreditation Program . . .

With the objective of maintaining the highest standards of reliability and quality in histocompatibility testing laboratories, ASHI established its accreditation program in 1974. ASHI Accreditation was originally and still remains voluntary. Its purpose is to evaluate laboratory personnel, procedures, and facilities to determine if they are in compliance with ASHI standards; to promote the educational aspects of the accreditation process, particularly in assisting laboratories in the correction of deficiencies; to provide expert advice and assistance to committees of the society; and to maintain the society's awareness of standard and novel procedures and methodologies. Categories and techniques of accreditation include:

Areas Of Accreditation

HCS/BM Transplantation: Related Donor
HCS/BM Transplantation: Unrelated Donor
Solid Organ Transplantation: Deceased Donor
Solid Organ Transplantation: Live Donor
Histocompatibility Testing for Other Clinical Purposes
<table>
<thead>
<tr>
<th>Category (What is done)</th>
<th>System (Assay System)</th>
<th>Methods (Specific assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted Validation required</td>
<td>Submitted Validation required</td>
<td>Internal Validation – labs should send the commissioner an email to notify</td>
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**Immunogenetics: HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing**

- **High Resolution molecular**
  - CDC (T and/or B)
- **Low Resolution molecular**
  - Sequencing
- **Serology**
  - Real time PCR
- **Flow Cytometry**
  - Flow cytometric phenotyping

**Crossmatching**

- **Complement Dependent**
  - CDC (T and/or B)
- **Cytotoxicity**
  - AHG (T and/or B)
- **Flow Cytometry**
  - Flow (T and/or B)
- **Other**
  - Solid Phase (Class I and/or II)

**Antibody Testing:**

- **Antibody Detection**
  - CDC (T and/or B)
- **HLA, HPA, ABO-A1 Titer, MICA**
  - AHG (T and/or B)
- **Dependent**
  - ELISA (Class I and/or II)
- **Cytotoxicity**
  - Flow (Class I and/or II)
- **2. Solid Phase**
  - Microarray (Class I and/or II)
- **3. Other**

**Antibody Identification**

- **1. Complement Dependent**
- **Cytotoxicity**
- **2. Solid Phase**
- **3. Other**

**Other Testing**

- **Molecular STR**
- **Immunology VNTR**
- **Flow Cytometry Flow-Immunophenotyping**
- **Cellular Immune Cell Function/MLC/PLT**
- **Chimerism/Engraftment SNP Testing**
- **Monitoring Soluble Biomarker Testing**

This voluntary program has accredited over 200 histocompatibility laboratories and is administered through the ASHI Accreditation Review Board. The Centers for Medicare and Medicaid (CMS), National
Marrow Donor Program (NMDP), United Network for Organ Sharing (UNOS), The American Foundation for Donation and Transplantation (AFDT, formerly SEOPF) and the states of California, Florida, Oregon and Washington grant deemed status to ASHI accredited labs. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recognizes ASHI Accreditation with Cooperative status. Any of these organizations may do their own inspections, however, for validation purposes or complaint response.

Accreditation Program Historical Timeline

ASHI Accreditation was originally and still remains voluntary.

1974 Establishment of the Accreditation Committee
1976 Start of Laboratory Evaluations
1986 Upon recognition of the increasing diversity of histocompatibility testing and the growing number of laboratories seeking ASHI Accreditation, the ASHI Council charged the Accreditation Committee to revise the program to make it more specific to the activities of the laboratory
1987 The reorganization program began in August 1986 and became effective in January 1987 Accreditation was granted or denied for specific laboratory activities

Recognizing the need for a responsive program, which could perform a thorough and unbiased evaluation of histocompatibility laboratories performing testing for organ transplantation, UNOS contracted with ASHI to perform evaluation of laboratories applying for membership

1988 ADTF (formerly SEOPF) adopted a policy of accepting ASHI Accreditation as a recognized approval of its member laboratories
1990 The NMDP contracted with ASHI for laboratory evaluation services
1992 NMDP began requiring ASHI Accreditation for its contract and transplant center laboratories
1995 The ASHI Accreditation program achieved its deemed status with CMS (formerly HCFA) and CLIA
1998 New name given, Accreditation Program. New structure, Accreditation Board, and process defined.
2005  CMS grants deemed status to ASHI as an accrediting organization for a period of 6 years, March 25, 2011

2005  New ASHI Accreditation Program debuts, May 1, 2005 including a new online Interim Application and online Inspection’s Checklist

2006  The ARB debuts the online On Site Application Packet

2008  The ARB gains approval from CMS to accredit laboratories for General Immunology Testing subspecialty.

2011  CMS grants deemed status to ASHI as an accrediting organization for a period of 5 years, through March, 2016

ASHI enters in to a cooperative agreement with The Joint Commission.

2013  ASHI discontinues accreditation for the area of accreditation: Parentage Testing (formerly Genetic Identification/Relationship Testing)