

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

Transfusion Support

Category (What is done)	System (Assay System)	Methods (Specific assay)
Submitted Validation required	Submitted Validation required	Internal Validation – labs should send the commissioner an email to notify
Immunogenetics: HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing	High Resolution molecular Low Resolution molecular Serology Flow Cytometry	CDC (T and/or B) SSO SSP Sequencing Real time PCR Flow cytometric phenotyping
Crossmatching	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)
Antibody Testing: HLA, HPA, ABO-A1 Titer, MICA	Antibody Detection 1. Complement Dependent Cytotoxicity 2. Solid Phase 3. Other Antibody Identification 1. Complement Dependent Cytotoxicity 2. Solid Phase 3. Other	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)
Other Testing	Molecular Immunology Flow Cytometry Cellular Chimerism/Engraftment Monitoring	STR VNTR Flow-Immunophenotyping Immune Cell Function/MLC/PLT SNP Testing 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
1997	Deemed status with JCAHO, State of New York, Florida, Oregon and Washington.
1998	New name given, Accreditation Program. New structure, Accreditation Board, and process defined.
2004	ASHI Standards, Checklists, Guidelines, Inspection Packets, and Operations Manual updated.

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)