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CLIA #
UNOS #
Date:



AMERICAN SOCIETY FOR HISTOCOMPATIBILITY AND IMMUNOGENETICS

ACCREDITATION REVIEW PROGRAM

INTERIM APPLICATION

Revision 2/11/2008

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ASHI ACCREDITATION PROGRAM INTERIM REPORT A. COVER PAGE

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

+Director(s)*				
Technical Supervisors(s)*				
Clinical Consultant(s)*				
General Supervisor(s)*				
<small>* as defined in CFR 493.1441-1467</small>				
+Laboratory or Department Name				
+Institution				
Street Address				
City, State, Zip	City	State	Zip	
Country				
Contact Person				
Telephone				
FAX				
E-mail				
Individual Performing Self Inspection				
Date of Self Inspection				

AREAS OF ACCREDITATION

Put an "X" in all areas in which you wish to be evaluated for accreditation and record "**NEW**" for those areas you are adding and want ASHI to evaluate.

HSC/BM Transplantation: Related Donor	_____	Parentage Testing	_____
HSC/BM Transplantation: Unrelated Donor	_____	Histocompatibility Testing for Non-Transplant	_____
Solid Organ Transplantation: Deceased Donor	_____	Clinical Purposes	_____
Solid Organ Transplantation: Live Donor:	_____	Transfusion Support	_____

Other accreditation/certification held by laboratory (specify): _____

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METHODS/TECHNOLOGIES

Current accredited Methods/Technologies are noted in the first column. Put an “X” in the “NEW” column for all methods/technologies in which you wish to be evaluated for accreditation and record “X” in the Not Applicable (NA) column for those methods or techniques for which your lab is not currently accredited or have discontinued. List the Vendor and Kit used for each Method/Technology.

For all new technologies, please submit completed validation checklist (**Appendix 3**) along with all validation materials.

Methods/Technology: **Typing**

Current	New	NA		Vendor/Kit
			Class I Serology	
			Class I SSP – Low resolution	
			Class I SSP – High resolution	
			Class I SSO – Low resolution (includes Microarray)	
			Class I SSO – High resolution (includes Microarray)	
			Class I SBT – High resolution	
			Class I Single Antigen - Method(s)	
			Class II Serology	
			Class II SSP – Low resolution	
			Class II SSP – High resolution	
			Class II SSO – Low resolution (includes Microarray)	
			Class II SSO – High resolution (includes Microarray)	
			Class II SBT – High resolution	
			Class II Single Antigen - Method(s)	
			Other- Low resolution	
			Other- High resolution	

Methods/Technology: **Crossmatch Testing**

Current	New	NA		Vendor/Kit
			T Cell Crossmatch - CDC	N/A
			T Cell Crossmatch - AHG	N/A
			T Cell Crossmatch - Flow	N/A
			Class I Crossmatch - Solid Phase	

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			B Cell Crossmatch - CDC	N/A
			B Cell Crossmatch - AHG	N/A
			B Cell Crossmatch - Flow	N/A
			Class II Crossmatch - Solid Phase	
			Other:	

Methods/Technology: **Antibody Testing**

Current	New	N/A		Vendor/Kit
			Class I Antibody Screening - CDC	
			Class I Antibody Screening - AHG	
			Class I Antibody Screening - Solid Phase	
			Class I Antibody Screening - Flow	
			Class I Antibody Screening - Microarray	
			Class II Antibody Screening - CDC	
			Class II Antibody Screening - AHG	
			Class II Antibody Screening - Solid Phase	
			Class II Antibody Screening - Flow	
			Class II Antibody Screening - Microarray	
			Class I Antibody Identification - CDC	
			Class I Antibody Identification - AHG	
			Class I Antibody Identification - Solid Phase	
			Class I Antibody Identification - Flow	
			Class I Antibody Identification - Microarray	
			Class II Antibody Identification - CDC	
			Class II Antibody Identification- AHG	
			Class II Antibody Identification - Solid Phase	
			Class II Antibody Identification - Flow	
			Class II Antibody Identification - Microarray	
			Other:	

Methods/Technology: **Cellular/ABO/Engraftment/Other Testing**

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Current	New	NA		Vendor/Kit
			Engraftment – VNTR	
			Engraftment – STR	
			Cytokine	
			ABO/Rh	
			Anti-Ai Titer	
			MLC	
			Immunophenotyping	
			Killer Inhibitory Receptor (KIR)	
			Immune Function Testing	
			Minor Histocompatibility Antigen Typing	
			Other:	

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B. DECLARATION OF INTENT

ASHI accreditation is recognized by several agencies and organizations as meeting their performance requirements for histocompatibility and immunogenetics testing. These organizations include: Centers for Medicare and Medicaid Services (CMS) for CLIA certification; Joint Commission on Accreditation of Healthcare Organizations (JCAHO); United Network for Organ Sharing (UNOS); SouthEastern Organ Procurement Foundation (SEOPF) and the National Marrow Donor Program (NMDP). Additionally, CMS recognizes the American Society for Histocompatibility and Immunogenetics (ASHI) for ABO/Rh testing in such cases where certification for immunohematology has not been obtained from another CMS approved accreditation agency/program. Each organization requires that ASHI provide certain information to validate a histocompatibility laboratory's accreditation and, in some cases, that ASHI notify the agency immediately of any action that would limit, suspend, revoke, or deny ASHI accreditation. Please indicate below your intent to utilize ASHI accreditation to fulfill the requirements of any listed organization. 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.

Please complete the section below, sign, and return this document. This document must be on file in the ASHI Executive Office for a laboratory evaluation to be performed. Thank you.

- To be Completed by the Laboratory Director or Other Individual with Appropriate Authority

I have indicated by checking "yes", below, my intent to use ASHI accreditation to fulfill the requirements of other organizations. Where "yes" is checked constitutes my permission for ASHI to provide information required to the organization, and only this information.

I understand it is my 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 HCFA or a HCFA agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program; 3). ASHI to release to HCFA 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). HCFA or a HCFA 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.

I understand that if I wish to change any of these arrangements, it is my obligation to inform ASHI of my intent to do so.

Place an "X" in the appropriate column.

YES	NO	ORGANIZATION
<input type="checkbox"/>	<input type="checkbox"/>	Centers for Medicare and Medicaid Services for CLIA certification: Histocompatibility
<input type="checkbox"/>	<input type="checkbox"/>	Centers for Medicare and Medicaid Services for CLIA certification: Histocompatibility and ABO/Rh Testing
<input type="checkbox"/>	<input type="checkbox"/>	Joint Commission (formerly JCAHO)
<input type="checkbox"/>	<input type="checkbox"/>	National Marrow Donor Program
<input type="checkbox"/>	<input type="checkbox"/>	SouthEastern Organ Procurement Foundation
<input type="checkbox"/>	<input type="checkbox"/>	United Network for Organ Sharing
<input type="checkbox"/>	<input type="checkbox"/>	Agency for Health Care Administration – State of Florida

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ATTESTATION STATEMENT

(Print name of director or other authorized individual) _____
does hereby apply to ASHI for laboratory accreditation in the area(s) of accreditation designated above.
I understand that granting of accreditation is dependent on complete compliance with all applicable standards.
I certify that all information provided is truthful and accurate.

Furthermore, the information submitted with this application attests that:

- A self-inspection of the laboratory occurred by the designated individual in Section A.
- Technical Competency (CT) records for the technologist noted in Section F were completed for the time period covered by this application and are available for review during the on-site application for accreditation of the laboratory.
- Continuing education for all staff members noted in Section F was completed for the time period covered by this application and is available for review during the on-site application for accreditation of the laboratory.
- The data used to complete this application (e.g. technical competency reports, continuing education records, laboratory activity data) will be available during the on-site inspection of the laboratory for review by the ASHI inspector and retained by the laboratory for a period of 2 years from the submission date.

Signature of authorized individual(s) _____

Type or Print Name _____ Date _____

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H. LABORATORY ACTIVITIES

Section 1

Period (12 month period preceding the application date) _____ to _____

Section 2

In the past twelve (12) month period preceding the application date, indicate the approximate percent of the lab's total clinical effort for each Area of Accreditation:

	Percent	%
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		
Totals 100%		

Average number of patients on the UNOS renal waiting list(s): _____

Section 3

In the past twelve (12) month period preceding the application date, complete the following indicating the number of individuals (do not include antibody screening samples) for which your laboratory provided services:

	Number
Candidates for HSC/BM	
Related Donors for HCS/BM	
Unrelated Donors for HSC/BM transplants	
Candidates/Recipients for Renal Transplant	
Renal – Living Donors	
Candidates/Recipients for Non-renal Solid Organ Transplant	
Non-renal Solid Organ Living Donors	
Deceased Donors: local (all)	
Deceased Donors: imports (all)	
Parentage Testing <u>cases</u>	
Non-transplant clinical typings	
Transfusion support <u>cases</u>	

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In the past twelve (12) month period preceding the application date, indicate the number of tests performed.

Section 4

Methods/Technology: **Typing**

Number of Tests	
	Class I Serology
	Class I SSP – Low resolution
	Class I SSP – High resolution
	Class I SSO – Low resolution (includes Microarray)
	Class I SSO – High resolution (includes Microarray)
	Class I SBT – High resolution
	Class I Single Antigen - Method(s)
	Class II Serology
	Class II SSP – Low resolution
	Class II SSP – High resolution
	Class II SSO – Low resolution (includes Microarray)
	Class II SSO – High resolution (includes Microarray)
	Class II SBT – High resolution
	Class II Single Antigen - Method(s)
	Other- Low resolution
	Other- High resolution

Section 5

Methods/Technology: **Crossmatch Testing**

Number of Tests	
	T Cell Crossmatch - CDC
	T Cell Crossmatch - AHG
	T Cell Crossmatch - Flow
	Class I Crossmatch - Solid Phase
	B Cell Crossmatch - CDC
	B Cell Crossmatch - AHG
	B Cell Crossmatch - Flow
	Class II Crossmatch - Solid Phase
	Other:

Do not include crossmatches performed on preliminary crossmatch trays (ROP).

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Section 6

Methods/Technology: **Antibody Testing**

Number of Tests	
	Class I Antibody Screening - CDC
	Class I Antibody Screening - AHG
	Class I Antibody Screening - Solid Phase
	Class I Antibody Screening - Flow
	Class I Antibody Screening - Microarray
	Class II Antibody Screening - CDC
	Class II Antibody Screening - AHG
	Class II Antibody Screening - Solid Phase
	Class II Antibody Screening - Flow
	Class II Antibody Screening - Microarray
	Class I Antibody Identification - CDC
	Class I Antibody Identification - AHG
	Class I Antibody Identification - Solid Phase
	Class I Antibody Identification - Flow
	Class I Antibody Identification - Microarray
	Class II Antibody Identification - CDC
	Class II Antibody Identification - AHG
	Class II Antibody Identification - Solid Phase
	Class II Antibody Identification - Flow
	Class II Antibody Identification - Microarray
	Other:

Section 7

Methods/Technology: **Cellular/ABO/Engraftment/Other Testing**

Number of Tests	
	Engraftment - VNTR
	Engraftment - STR
	Cytokine
	ABO/Rh
	Anti-Ai Titer
	MLC
	Immunophenotyping
	Killer Inhibitory Receptor (KIR)
	Immune Function Testing
	Minor Histocompatibility Antigen Typing
	Other:

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I. LABORATORY ACTIVITIES

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 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.

LABORATORY TEST DATA

For calendar year _____

Laboratory: _____
 ASHI # _____
 Individual providing data: _____

	Transplant	Non-Transplant
Number of subjects typed		
Number of serum samples screened		
Number of donor-recipient pairs crossmatch tested		

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J. PROFICIENCY RESULTS SUMMARY FORM

Period (twelve [12] month period preceding the application date)

Typing Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance (%)	Method(s)
	Class I Serologic				
	Class I DNA-Low Resolution				
	Class I DNA-High Resolution				
	Class II Serologic				
	Class II DNA-Low Resolution				
	Class II DNA-High Resolution				
	ABO/Rh Typing				
	Anti-Ai Titer				
Crossmatch Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance (%)	Method(s)
	T Cell CDC				
	T Cell AHG				
	T Cell Flow				
	B Cell Solid Phase				
	B Cell CDC				
	B Cell AHG				
	B Cell Flow				
	T Cell Solid Phase				

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Ab Screen Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance (%)	Method(s)
	Class I CDC				
	Class I AHG				
	Class I ELISA				
	Class I Flow				
	Class I Microarray				
	Class II CDC				
	Class II AHG				
	Class II ELISA				
	Class II Flow				
	Class II Microarray				

Ab ID Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance (%)	Method(s)
	Class I CDC				
	Class I AHG				
	Class I ELISA				
	Class I Flow				
	Class I Microarray				
	Class II CDC				
	Class II AHG				
	Class II ELISA				
	Class II Flow				
	Class II Microarray				

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Other Surveys	Technology	No. of specimens with errors	No. specimens tested	Concordance (%)	Method(s)
	Paternity				
	Chimerism				
	Cell Surface Phenotyping				
	KIR Typing				
	Immune Function				
	MLC				
	Minor Histocompatibility Testing				

Include corrective action documentation for each error.

Include Semi-annual evaluations for clinical tests for which proficiency testing surveys are not currently available (e.g. MLC, Immune Function, KIR Typing, Minor Histocompatibility Typing)