



EFI ACCREDITATION PROGRAM		EFI No.:
Application Packet A	Cover Page	Date:

PROVIDE NAMES AS THEY SHOULD APPEAR ON THE CERTIFICATE

Director(s):	
Laboratory/Department:	
Institution:	
Street/Address:	
Postal Zip Code, City, Country:	
Telephone(include country code):	FAX(include country code):
Contact Person:	E-mail:

ACCREDITATION CATEGORIES

Renal transplantation:

- Recipient typing Yes No
- Antibody screening Yes No
- Antibody identification Yes No
- Donor typing Yes No
- Cross-matching Yes No

Non renal transplantation:

- Recipient typing Yes No
- Antibody screening Yes No
- Antibody identification Yes No
- Donor typing Yes No
- Cross-matching Yes No

Haematopoietic stem cell transplantation (HSCT):

- Donor registry typing Yes No
- Cord blood registry Yes No
- Related donor transplantation Yes No
- Unrelated donor transplantation Yes No
- Cross-matching Yes No

Disease association studies

- Yes No

Transfusion

- Yes No

ACCREDITATION TECHNIQUES:

Class I typing by:

- CDC Yes No
- Flow cytometry (HLA-B27,etc.) Yes No
- DNA: 2 digits Yes No
- DNA: 4 digits Yes No

Class II typing by:

- CDC Yes No
- DNA: 2-digits Yes No
- DNA: 4 digits Yes No

Antibody testing

Screening:

- CDC Yes No
- Flow cytometry Yes No
- ELISA Yes No
- Bead array Yes No

Identification:

- CDC Yes No
- Flow cytometry Yes No
- ELISA Yes No
- Bead array Yes No

Cross-matching:

- CDC Yes No
- Flow cytometry Yes No
- ELISA Yes No
- Bead array Yes No

(Print name of applicant) does hereby apply to EFI for laboratory accreditation in the area(s) designated above. I understand that granting of accreditation is dependent on complete compliance with all applicable EFI Standards. I certify that all information provided is truthful and accurate.

Date:	Applicant's Signature:
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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Director Qualifications	Date:

Submit an organogram of the laboratory with positions and names of persons at the staff and supervisory levels (addendum #1). If the laboratory is part of a larger department, an overview of the department must be provided also (addendum #2).

I. Director/Co-Director Qualifications

A. Name (Last)	First
Hours/week in lab.	
Weeks/year away from institution (for periods of > 3 consecutive work days)	

B. Do you spend at least 50% of your time in the laboratory?	Yes	no
Is emergency consultation available during your absence?	Yes	no

C. Describe in an addendum your duties in your present position, especially your role in the laboratory, including the extent to which you participate in the review, interpretation and reporting of test results, development and performance or supervision of test procedures, training and evaluation of staff and fellows and establishment of laboratory policy (addendum #3).

D. Submit a complete C.V. (addendum #4). This C.V. must also include the degrees earned, training received, length of time in present position. Submit a list of publications (addendum #5). Note: in case of change in directorship of a laboratory the commissioner must be informed immediately.

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Supervisor Qualifications	Date:

II. Technical Supervisor Qualifications
To be completed by technical supervisor(s).

A. Name (Last)	First

Degree	Year	Institution	Location	Major subject

B. Describe in an addendum your duties in your present position, especially your role in the laboratory (addendum #3).

C. Experience:
List laboratory working experience; begin with the most recent prior to your present position.

Name of Institution:	Name of Director:	Your title:	Dates:	Hrs/week:	Description of duties:

D. Length of time in present position:

E. Submit a C.V. (#addendum 4) and a list of publications (addendum #5) unless you have recently been appointed in the present position; in the latter case a complete list must be submitted.

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Technical Staff	Date:

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Laboratory Activities	Date:

Laboratory Activities

I. Quantitative Information on Activities:

Covering the year: 200.. (1 January till 31 December).

Fill in above the year previous to this application.

A. Category: organ transplantation

1.	Total number of organ donors typed (A-, B-, DR-) :				
2.	Approximate number of organ transplants performed in your region: Renal transplants (cadaveric) Renal transplants (living (un)related) Heart transplants Liver transplants				
	Other transplants:	pancreas:	lung:	cornea:	
3.	Approximate number of patients on the active waiting list of your region: Approximate number renal transplant candidates:				
	Other patient groups:	heart:	liver:	lung:	other:
4.	Approximate number of "new" patients typed in the period covered: Renal transplant candidates:			
	Other patient groups:	heart:	liver:	lung:	other:

B. Category: Haematopoietic Stem Cell Transplantation (HSCT)

1.	Approximate number of transplant candidates (index patients) typed: Serological typings: 2-digit DNA typings: class I <input type="text"/> class II <input type="text"/> 4-digit DNA typings: class I <input type="text"/> class II <input type="text"/>				
2.	Approximate number of relatives of index patients typed: Serological typings: 2-digit DNA typings: class I <input type="text"/> class II <input type="text"/> 4-digit DNA typings: class I <input type="text"/> class II <input type="text"/>				
3.	Approximate number of unrelated bone marrow registry donors typed: Serological typings: 2-digit DNA typings: class I <input type="text"/> class II <input type="text"/> 4-digit DNA typings: class I <input type="text"/> class II <input type="text"/>				

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Application Packet A Laboratory Activities	Date:

4.	Approximate number of cord blood samples typed: Serological typings: 2-digit DNA typings: class I <input style="width: 50px;" type="text"/> class II <input style="width: 50px;" type="text"/> 4-digit DNA typings: class I <input style="width: 50px;" type="text"/> class II <input style="width: 50px;" type="text"/>	
5.	Approximate number of allogeneic HSCT: with related donors: with unrelated registry donors:	

C. HLA-Antibody Assays:

Approximate number of patient sera (bleedings) tested for presence/absence of HLA antibodies by:

	CDC	ELISA	Flow cytometry	Bead Array Technique	Other method
Class I	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
Class II	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

Approximate number of patient sera (bleedings) tested for specificity of HLA antibodies by:

	CDC	ELISA	Flow cytometry	Bead Array Technique	Other method
Class I	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
Class I	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

D. Approximate number of blood samples typed for:

B27	
DQ2	
Other Antigens:	
(Platelet) transfusion:	

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A HLA Typing	Date:

II. HLA Typing by Serology.

A Serologic Specificities

For each specificity indicate whether it is tested as part of the typing procedure routinely (**R**), occasionally (**O**), or never (**N**).

“Routinely” defines the specificities identified with routine typing trays.

“Occasionally” defines specificities that are identified only by including additional typing trays.

“Never” defines specificities that cannot be identified with any of the typing trays used in the laboratory.

A	R O N	B	R O N	B	R O N	B	R O N
1	5	21	Bw4
2	51	49	Bw6
3	52	50		
9	7	22		
23	8	54		
24	12	55		
10	44	56		
25	45	27		
26	13	35	Cw	R O N
34	14	37	1
66	64	40	2
11	65	60	3
19	15	61	9
29	62	41	10
30	63	42	4
31	75	46	5
32	76	47	6
33	77	48	7
74	16	53	8
28	38	59
68	39	67
69	17	70
36	57	71
43	58	72
80	18	73
		81	78

DR	R O N	DR	R O N	DR	R O N	DQ	R O N
1	11	51	1
103	12	52	5
2	6	53	6
15	13			2
16	14			3
3	1404			7
17	7			8
18	8			9
4	9			4

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EFI ACCREDITATION PROGRAM		EFI No.:
Application Packet A	HLA Typing	Date:

B. Submit a copy of the reading sheets for all typing trays currently in use.
Print the tray name or other tray identifier at the top of each page (addendum #8).

C. Describe the cytotoxicity techniques used routinely in the laboratory for HLA typing

	standard Class I	standard Class II
cell type		
serum incubation: time temp		
number of wash steps		
special reagent (specify)		
complement incubation: time temp		
detection of viable cells		
detection of cell kill		

D. Provide the scoring system used for cytotoxicity testing.

Score:
% Cell death:

E. Briefly describe other typing techniques employed and their application; reference the SOP number(s) documenting these procedures.

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Antibody Screening	Date:

III. Antibody Screening/Identification

A1. Is complement-dependent lymphocytotoxicity used for antibody screening?

Yes	No
-----	----

A2. Is complement-dependent lymphocytotoxicity used for the determination of antibody specificity?

Yes	No
-----	----

A3. Do you use commercially or locally produced complement?

B1. Is an ELISA assay used for class I or/and class II antibody screening?

Yes	No
-----	----

If yes, name of commercial product(s) used:

B2. Is an ELISA assay used for class I or/and class II antibody specificity determination?

Yes	No
-----	----

If yes, name of commercial product(s) used:

C. Name other assays used including the provider of the test:

D1. Are CDC tests used to detect class I antibodies with T-cell preparations?

Yes	No
-----	----

If no, explain:

D2. Are CDC tests used to detect class II antibodies with purified B cells?

Yes	No
-----	----

If no, explain:

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Application Packet A Antibody Screening	Date:

Provide the following information for the serum screening panels:

- E1. Do you use a separate panel (mostly of smaller size) for (preliminary) CDC screening if a serum contains class I antibodies (against high-frequency HLA specificities)?

Yes	No
-----	----

If yes, provide the following information on the panel cells used:

number of subjects: fresh frozen

ethnic heterogeneity (y/n)

Is the panel consistent from test to test?

Yes	No
-----	----

- E2. Do you use in a CDC test a separate panel (mostly of larger size) for determination of anti-class I specificities in a serum?

Yes	No
-----	----

If yes, provide the following information for the panel used for screening of antibody specificities:

number of subjects: fresh frozen

ethnic heterogeneity (y/n)

Is the panel consistent from test to test?

Yes	No
-----	----

- E3. Do you use a separate panel to determine by CDC anti-class II specificities in a serum?

Yes	No
-----	----

If yes, provide the following information for the panel used for testing

anti-class II antibody specificity:

number of subjects: fresh frozen

ethnic heterogeneity(y/n)

Is the panel consistent from test to test?

Yes	No
-----	----

- E4. Describe in detail (addendum #9), how positively for antibodies and/or specificity of these antibodies in a serum have been defined. Include how you separate auto-reactivity from allo-reactivity and detect class II antibodies in the presence of class I antibodies.

If you treat patient sera with DTT, describe how positively for antibodies and/or specificity of these antibodies in a serum has been defined.

- E5. Indicate if computer-assisted analysis of antibody-specificity is in use and submit an example of a computer report (addendum #10).

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Application Packet A	Antibody Screening	Date:

F. Using the panel composition list below, indicate for each antigen the frequency in which it is present in the panels used routinely below for serum screening (S) and antibody identification (I). You may provide information on other screening panels used on separate sheets. Use the broad antigen designation only when the splits are not defined (i.e. do not list the same subject in both categories).

F1. Panel composition list: Class I antibody screening

HLA-A		HLA-B		HLA-B		HLA-Cw	
S	I	S	I	S	I	S	I
1	5	22	1
2	51	54	2
3	52	55	3
9	7	56	9
23	8	27	10
24	12	35	4
10	44	37	5
25	45	40	6
26	13	60	7
34	14	61	8
66	64	41		
11	65	42		
19	15	46		
29	62	47		
30	63	48		
31	75	53		
32	76	59		
33	77	67		
74	16	70		
28	38	71		
68	39	72		
69	17	73		
36	57	78		
43	58	81		
80	18				
		21				
		49				
		50				

F2. Panel composition list: Class II antibody screening

HLA-DR		HLA-DR		HLA-DR		HLA-DQ	
S	I	S	I	S	I	S	I
1	5	51	1
103	11	52	5
2	12	53	6
15	6			2
16	13			3
3	14			7
17	1404			8
18	7			9
4	8			4
		9				
		10				

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Crossmatches	Date:

IV. Crossmatches.

Using the chart below, describe the cytotoxicity tests used for crossmatching.

cell type	unseparated	T-lymphocytes	B-lymphocytes
isolation method			
serum incubation: time			
	temp		
number of wash steps			
special reagent (specify)			
complement incubation: time			
	temp		
detection of viable and/or dead cells			

Name of other procedures used for crossmatching:

Interpretation of crossmatch results

Describe in detail in an addendum (addendum #11), how a positive crossmatch is defined including the type of cell preparation used and the DTT treatments. Describe in an addendum (addendum #12) what positive crossmatch results are considered a contraindication for transplantation. Examples of variables are: first or retransplant, antibody positivity of patient, acceptance of class I and/or class II mismatches in relation to antibody specificity, crossmatch outcome with peak historic sera and with recent serum sample, DTT sensitivity of antibodies, crossmatch result with separated donor T- and B-lymphocytes. If these criteria have been described in organ transplant protocols, submit these protocols as addendum.

EFI ACCREDITATION PROGRAM		EFI No.:
Application Packet A	DNA typing	Date:

V. DNA typing.

For each technique of class I and class II DNA typing, a list of primers and probes used and their nucleotide sequences must be documented and be locally available for inspection.

Make an overview (addendum #13) of the molecular biology techniques used for each of the HLA Class I (HLA-A, B, Cw) and Class II loci (HLA-DRB1, DRB3/4/5,, DQB1, DQA1, DPB1) tested at the different levels of resolution (2-digit and 4-digit).

The overview for each locus should list whether the technique (e.g. PCR-SSP, reverse dot blot, sequencing, etc) is used routinely or occasionally, with references to the procedures used.

Give for each of the loci and the level of resolution the name of the commercial kits in use.

Indicate whether you use locally prepared primers and/or probes.

Give for each technique and locus the approximate number of samples tested per year.

Indicate the patient groups (e.g. organ transplant recipient, solid organ donor, bone marrow recipient, etc) that you test with each technique.

Indicate in addendum #14 the source of the computer-assisted analysis used to assign alleles for each of the techniques (kits) in use.

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Renal Transplantation	Date:

VI. Histocompatibility Testing - Renal Transplantation.

Are personnel for the required histocompatibility testing available: - for 24 hours a day yes no - for 7 days a week yes no
Name of Organ Exchange Program in which your laboratory participates:
Your centre code in the Organ Exchange Program:
Are local protocols on typing, screening and crossmatch for renal transplantation in accordance with the regulations of this Organ Exchange Program: yes no

Describe in an addendum (addendum #15) the local protocols for typing, screening and crossmatching. Define the term ‘current serum’ in your local protocol. Indicate whether you use historic sera in addition to the current sera when performing a crossmatch. Indicate whether you follow different protocols in transplantations with post-mortem or living donors.

Answer the following questions using, where appropriate:
R = routinely, **O**= occasionally, **N**= never

A. Typing	R	O	N
1. Are recipients typed for HLA-A, B, and DR?			
2. Are donors typed for HLA-A, B, and DR?			
3. Submit an anonymous copy of a transplant candidate typing record (addendum #16).			
B. Serum Screening	R	O	N
1. Are recipient sera screened prior to transplantation for:			
HLA class I antibodies; how often?			
HLA class II antibodies; how often?			
2a. Are recipient anti-class I specificities determined?			
2b. Are recipient anti-class II specificities determined?			
3. Are recipient sera screened following nephrectomy? how often			
4. Submit anonymous copies of a serum screening report and an antibody status overview (addendum #17).			
5. Are recipient antibodies characterised for DTT-sensitivity			

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Application Packet A	Renal Transplantation	Date:

C. Crossmatching	R O N
1. Are crossmatches prior to transplantation performed in the recipient center?	
2. Are crossmatches prior to transplantation performed in all transplant recipients, irrespective of status of immunisation?	
3. Are crossmatches prior to transplantation performed: a. in patients with a recent sensitising event with sera collected within 48 hours pre-transplantation? b. in currently sensitised patients with sera collected within: 48 hours pre-transplantation? 3 months if recently non-transfused?	
4. Are potentially peak reactive sera (at least 14 days post-sensitisation) used for crossmatching prior to transplantation?	
5. Are historic peak reactive sera used for crossmatch prior to transplantation?	
6. Is a system in use to notify the laboratory on sensitising events in patients (e.g. transfusion)?	
7. Are prospective cross-matches performed in duplicate?	
8. Are prospective cross-matches performed by more than one technique?	
9. Are crossmatch samples tested undiluted?	
10. Are crossmatch samples tested at one or more dilutions?	
11. Are auto-crossmatches performed?	
D. Other tests: Specify:	

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Related HSCT	Date:

2. Describe on this page the protocol(s) for **related HSCT** of the Transplant Centre(s) served by your laboratory.

Minimum requirements for compatibility

All available members of the immediate family are typed with the following methods:

- o HLA-A, B by serology (split specificities)
- o HLA-A, B, DR by serology
- o HLA-A, B by serology and DRB1 by molecular DNA methods (2-digits)
- o HLA-A, B, DRB1 by molecular DNA methods (Class I 2-digits, Class II 4-digits)
- o other:

Submit local clinical protocol for related HSCT (addendum #18).

To establish HLA identity for HLA phenotypically identical siblings, and/or compatibility for non-HLA identical siblings, describe how and at which level the donor/recipient pair is typed:

Locus	2-digits	4-digits*	Method
A			
B			
C			
DRB1			
DRB3/4/5			
DQA1			
DQB1			
DPB1			

*If your laboratory subcontracts another laboratory for 4-digit HLA typing, provide name of the Director, address and a copy of the EFI certificate in addendum #19.

When an HLA identical sibling is not available, is a haplotype-mismatched family member considered as a donor? Yes No

If yes, how many mismatches are accepted:

No. of mismatches	Class I	Class II	Indifferent
1			
2			
more			

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Unrelated HSCT	Date:

3. Describe on this page the protocol(s) for **unrelated HSCT** of Transplant Centre(s) served by your laboratory:

Source of haematopoietic stem cells	Adult	Paediatric
Bone marrow (bm)		
Peripheral Blood Stem Cells (pbsc)		
Cord Blood (cb)		

When a donor is selected as compatible with a recipient, describe at which level and how the donor/recipient pair is typed

Locus	2-digits	4-digits*	Method
	bm pbsc cb	bm pbsc cb	
A			
B			
C			
DRB1			
DRB3/4/5			
DQA1			
DQB1			
DPB1			

*If your laboratory subcontracts another laboratory for Class I 4-digit typing, provide the name of the Director, address, and a copy of the EFI certificate in addendum #19.

When the laboratory applies for the accreditation of HSCT and does not apply for the accreditation of four digit typing of HLA class I alleles submit a transplant protocol signed by the responsible transplant clinician (addendum #20).

Is the class I and class II typing of the unrelated donor repeated if your centre is the recipient centre?	R O N
Is Sequencing Based Typing in use for compatibility testing?	

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Donor registry	Date:

4. Donor-registry typing

In case of typing as a donor-registry-centre for HSCT with unrelated donors, are donors typed for: all WHO-recognized HLA-A, B specificities? HLA-A, B, and DR by serology? HLA class I alleles by DNA techniques? HLA class II alleles by DNA techniques?	R O N

5. Cord blood registry typing

In case of typing as a cord blood registry for HSCT, are cord blood cells typed for: All WHO-recognized HLA-A, B specificities? HLA-A, B, and DR by serology? HLA class I alleles by DNA techniques? HLA class II alleles by DNA techniques?	R O N

6. What other assays are used to evaluate compatibility e.g.?

7. Submit (addendum #21) an anonymous copy of all reports on HLA typings performed for a selected case of HSCT with a related donor.

8. In case your centre has a registry of unrelated HSCT donors, and/or a cord blood registry submit the consent form used for subjects to be included in the registry, or for the mother to obtain cord blood collection (addendum #22).

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Application Packet A Disease Association Studies	Date:

IX. Disease Association Studies

List the antigens specifically typed for disease association	
Specify typing technique:	

In case of serologic typing, submit reading sheet of typing tray (addendum #8).

In case of DNA typing, complete page PA-15.

In case of flow-cytometry, submit list of sera/monoclonal antibodies used (addendum #23).

X. Transfusion: Platelet/ Granulocyte	R	O	N
A. Typing: are donors and recipients typed for HLA-A and B antigens/alleles?			
B. Serum screening: are recipients screened for lymphocytotoxic antibodies?			
Are recipients screened for (other) antibodies? If yes, specify technique:			

C. Crossmatching: are lymphocyte crossmatches performed?	
Are other crossmatches performed? If yes, specify:	

XI. Records.

Are permanent subject records maintained?	Yes	No
Are records maintained of results obtained with:		
- each lot of typing trays	Yes	No
- each lot of primers/probes	Yes	No
Is computer data storage used?	Yes	No
If yes, are back-up files maintained?	Yes	No

XII. Worksheets

Submit as addendum # 24 blank copies of all worksheets in use (lay-outs of trays for serological typing have already been requested in addendum # 8)

XIII. Computer screens for data storage

In case your computer screens for data-storage are different from hardcopy-worksheets, make prints of these screens and submit them as addendum #25. This applies specifically for specimen registration, routing of requested tests/techniques, links between worksheets and computer-storage of results (manual transfer of interpreted data).

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Quality Assurance (QA)	Date:

XIV. Quality Assurance (QA):

1. Standard Operation Procedures (SOPs)

Provide a list of titles of available SOPs (addendum #26).

2. External Proficiency testing.

Submit the results of all consecutive samples in all external proficiency testing programmes performed during the period covering 1 January till 31 December of the year previous to this application (serological typing, screening, crossmatching, DNA typing, flowcytometry, etc); send also the consensus report for each sample, an overview of the results obtained by other laboratories participating in the program(s), and eventually a copy of the certificate(s) obtained. Please indicate your laboratory identification (addendum #27).

Summarize your proficiency testing results on page PA-26.

3. Internal quality control.

Submit a copy of the SOP describing how internal quality control tests are performed in your laboratory (persons performing the test, c.f. typing/screening/crossmatch (addendum #28).

4. Evaluation of tests

Are protocols available for the evaluation of:		
a. typing sera to improve the quality of typing trays?	Yes	No
b. primers and probes used to improve the quality of DNA typing?	Yes	No

5. Is a QA-officer or official with similar position employed in your laboratory?	Yes	No
If yes, name of the employee:		

Indicate in the organogram of the department (addendum #1) the position of this employee.

6. Are the QA-activities of the laboratory described in a Quality Manual?	Yes	No
If yes, send a list of contents of the Quality Manual (addendum #29)		

When internal audits are performed by your QA Officer, submit a report on the latest internal audit (addendum #30).

7. Are temperatures monitored daily for the following?		
all work areas	Yes	No
all incubators	Yes	No
all refrigerators	Yes	No
all freezers (excluding liquid nitrogen)	Yes	No
are temperature records maintained?	Yes	No

8. Is routine maintenance and function checks for all equipment documented?	Yes	No
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FOR AN OFFICIAL APPLICATION PLEASE CONTACT THE EFI ACCREDITATION OFFICE.**

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Proficiency Testing	Date:

RESULTS OF PROFICIENCY TESTING: PLEASE COMPLETE THIS FORM

Submit below data of all consecutive samples of the EPT program(s) for the period covering 1 January till 31 December of the year previous to this application. Also indicate if any samples were not tested, indicate your laboratory identification number.

Proficiency testing	Names of Proficiency Testing Program(s)	Technique(s)	Number of specimens		? Number of errors
			tested	not tested	
HLA -A, B by serology					
HLA -C by serology					
HLA -DR by serology					
HLA -DQ by serology					
HLA -A*, B* by DNA 2-digit					
HLA -C* by DNA 2-digit					
HLA -DRB1* by DNA 2-digit					
HLA -DQB1* by DNA 2-digit					
HLA -A*, B* by DNA 4-digit					
HLA -C* by DNA 4-digit					
HLA -DRB1* by DNA 4-digit					
HLA -DRB3/4/5* by DNA 4-digit					
HLA -DQB1* by DNA 4-digit					
HLA -DQA1* by DNA 4-digit					
HLA -DPB1* by DNA 4-digit					
Cross matches class I					
Cross matches class II					
Screening class I					
Screening class II					

? Examples of errors have been formulated by the EPT committee (see member section of EFI website)
 # For serology, report the results for each of the techniques used: e.g. CDC, ELISA, FC, Bead Array Techniques, etc
 # For DNA typing, report the results for each the techniques used: e.g. SSP, SSO, SBT, etc.

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A Facilities	Date:

XV. Facilities

1. What is the total laboratory floor space, excluding storage areas and offices? sq.m.
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2. Have available for inspection a short description of the laboratory's equipment:
centrifuges (e.g. types and numbers)
freezers (e.g. freezing temperatures and numbers)
refrigerators (e.g. numbers)
liquid nitrogen units (e.g. numbers and volumes)
microscopes (e.g. numbers, types, fluorescence device)
thermocyclers (e.g. numbers, types)
incubators, water baths, hoods, additional equipment essential for satisfactory performance.

3. Is the laboratory in accordance with relevant national legislation?

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EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A List of Documents	Date:

List of requested documents (addenda).

#addendum	Document	Submitted
#1	Organogram of laboratory with names /positions of staff/supervisor	
#2	Overview/ organogram of institute if laboratory is subpart of institute	
#3	Overview of duties of the director(s), co-director(s) and technical supervisor(s)	
#4	Complete C.V. 's of director(s), co-director(s) and technical supervisors	
#5	List of publications	
#6 *	Changes in the lab over last three years	
#7	Continuing education	
#8	Tray reading sheets	
#9	Criteria for positivity in screening	
#10	Report of computer-assisted antibody analysis	
#11	Criteria for positivity in crossmatch	
#12	Protocol crossmatch result and transplant advise	
#13	Overview molecular biology techniques for each locus	
#14	Report of computer-assisted analysis of DNA based HLA-type	
#15	Regulations for cadaveric and/or living-transplant testings	
#16	Anonymous typing report	
#17	Serum screening report and renal patient antibody status overview	
#18	Local clinical protocol related HSCT	
#19	Copy of certificate subcontracted laboratory	
#20	Protocol unrelated donor compatibility	
#21	Bone marrow file	
#22	Registry consent form (HSCT)	
#23	List of sera for B27 by flow cytometry	
#24	Worksheets	
#25	Prints of screens for data storage	
#26	List of content procedure manual/SOP's	
#27	Proficiency test results, including consensus report and certificate if available	
#28	SOP internal quality control testing	
#29	List of content of QA Manual from QA Officer (if applicable)	
#30	Result of internal audit by QA Officer (if applicable)	
After inspection:		
EFI-IQ	Completed inspection questionnaire (EFI-IQ)	
PA-27	Proposal for changes in Standards	

* addendum #6 not applicable for Packet A

EFI ACCREDITATION PROGRAM	EFI No.:
Application Packet A	Date:

EFI ACCREDITATION PROGRAM: UPDATING OF STANDARDS

Post inspection questionnaire: evaluation of EFI Standards to be completed by Inspectors and/or Directors of inspected laboratory.

Name:
Laboratory inspected:
City/Country

Proposal(s) for DELETIONS, ADDITIONS or CHANGES in EFI STANDARDS (formulate new version).

Section A to N	No.	Current version (relevant sentence)	Proposed version	Comments

Thank you for your help and comments to amend and update the EFI Standards. Please send this questionnaire to: EFI Accreditation Office, Dr. A. van Leeuwen – Ms. Sonja Mesander, Leiden University Medical Centre, Dept. of Immunohematology and Blood Transfusion, Bldg. 1 E3-Q, Albinusdreef 2, P.O. Box 9600, 2300 RC Leiden, The Netherlands. Your comments will be carefully examined and discussed during the next meeting of the Standards and Quality Assurance Committee. If this committee accepts them they will be presented to the EFI membership for approval