45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
SIMTI

Percorso di Accreditamento EFI nei laboratori di immunogenetica: panoramica europea

Marco Andreani

Laboratorio d'Immunogenetica dei Trapianti - Polo di Ricerca di San Paolo
Dipartimento di Oncoematologia e Terapia Cellulare e Genica
IRCCS Ospedale Pediatrico Bambino Gesù

Il sottoscritto, Marco Andreani, in qualità di Relatore, dichiara che *nell'esercizio della Sua funzione e per l'evento in oggetto,* ***NON È*** *in alcun modo portatore di interessi commerciali propri o di terzi; e che gli eventuali rapporti avuti negli ultimi due anni con soggetti portatori di interessi commerciali non sono tali da permettere a tali soggetti di influenzare le sue funzioni al fine di trarne vantaggio.*

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45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
SIMTI

EFI Mission

Mission and goals

It is the mission and goal of EFI:

1. To support the development of Immunogenetics in Europe as a discipline in medicine and promote research and training in this field.
2. To provide a forum for exchange of scientific information and to reinforce the skills and knowlegde of young scientists and others working in the field.
3. To create a formal organisation of workers in the field of immunogenetics, histocompatiblity testing and transplantation.
4. To develop recommendations for standardisation of techniques, quality control and criteria for accreditation and to support their implementation.
5. To promote the organisation and use of immunogenetic databases.
6. To develop relations with organisations with similar aims.

The association shall abstain from any type of political activity.

Sviluppare in Europa l'Immunogenetica, promuovendo la ricerca e la formazione in questo campo

Promuovere scambi di informazioni scientifiche e promuovere la conoscenza sia di giovani che di altri nel settore dell'immunogenetica

Sviluppare raccomandazioni per la standardizzazione delle tecniche di laboratorio, della gestione della qualità, dei criteri utili al supporto del processo di accreditamento

Consolidare le relazioni con organizzazioni mondiali simili ad EFI

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45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
SIMTI

La Struttura di EFI

Committees

Executive Committee

Accreditation Committee

Education Committee

EPT Committee

IT & Bioinformatics Committee

Scientific Committee

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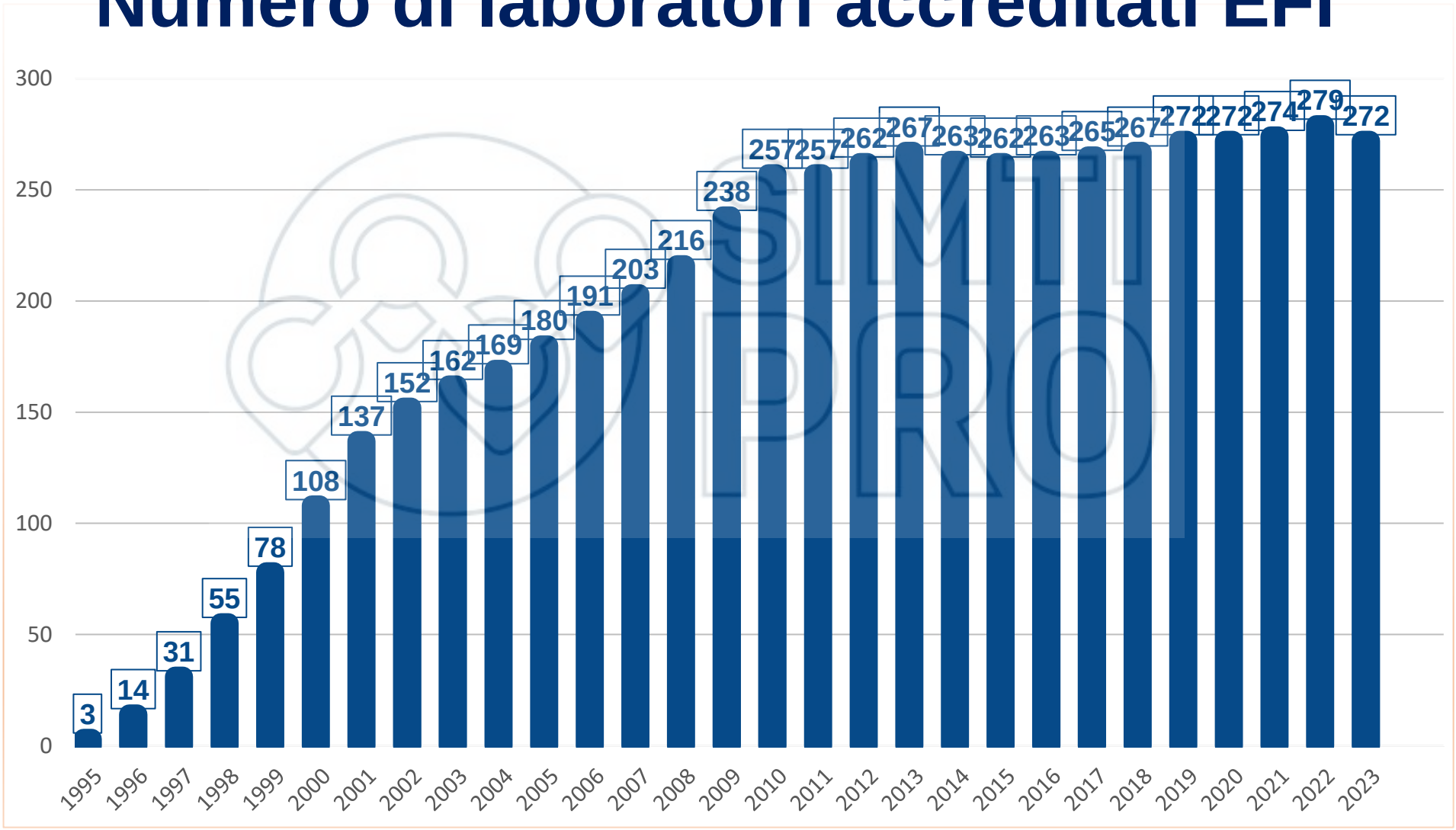
45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
SIMTI

Accreditation Committee

Promuovere il Sistema Qualità nell'attività di trapianti di organi solidi e cellule staminali ematopoietiche

Rilascio di una Certificazione di Accreditamento

Numero di laboratori accreditati EFI



Distribuzione dei laboratori accreditati EFI nel mondo nel 2023

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45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
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REGION	ACCREDITED LABORATORIES	
01	SCANDINAVIA	12
02	BENELUX	12
03	UK + IRELAND	20
04	GERMANY	40
05	CENTRAL EUROPE	20
06+11	FRANCE + SWITZERLAND	33
07	ITALY	50
08	SE EUROPE, ISRAËL, ARMENIA	28
09+10	SPAIN + PORTUGAL	26
99	SOUTH AFRICA, CHINA, KUWAIT, COLOMBIA, USA, INDIA, ARGENTINA, BRAZIL,	12
99	COMMISSIONERS LABS	19
	TOTAL	**272**

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45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
SIMTI

Istituti internazionali che richiedono l'accreditamento EFI o ASHI

WMDA (World Marrow Donor Association)
NMDP (National Marrow Donor Program)
JACIE (Joint Accreditation Committee of ISCT-Europe and EBMT)
FACT (Foundation for the Accreditation of Cellular Therapy)
NETCORD FAHCT (Cord Blood Sharing Organization)
BSBMT/UKCCSG (British Society for Bone Marrow Transplantation)
IBMDR (Italian Bone Marrow Donor Registry)
EUROTRANSPLANT (Organ Sharing Organization)

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45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
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Il percorso di accreditamento EFI

Categorie cliniche e tecniche

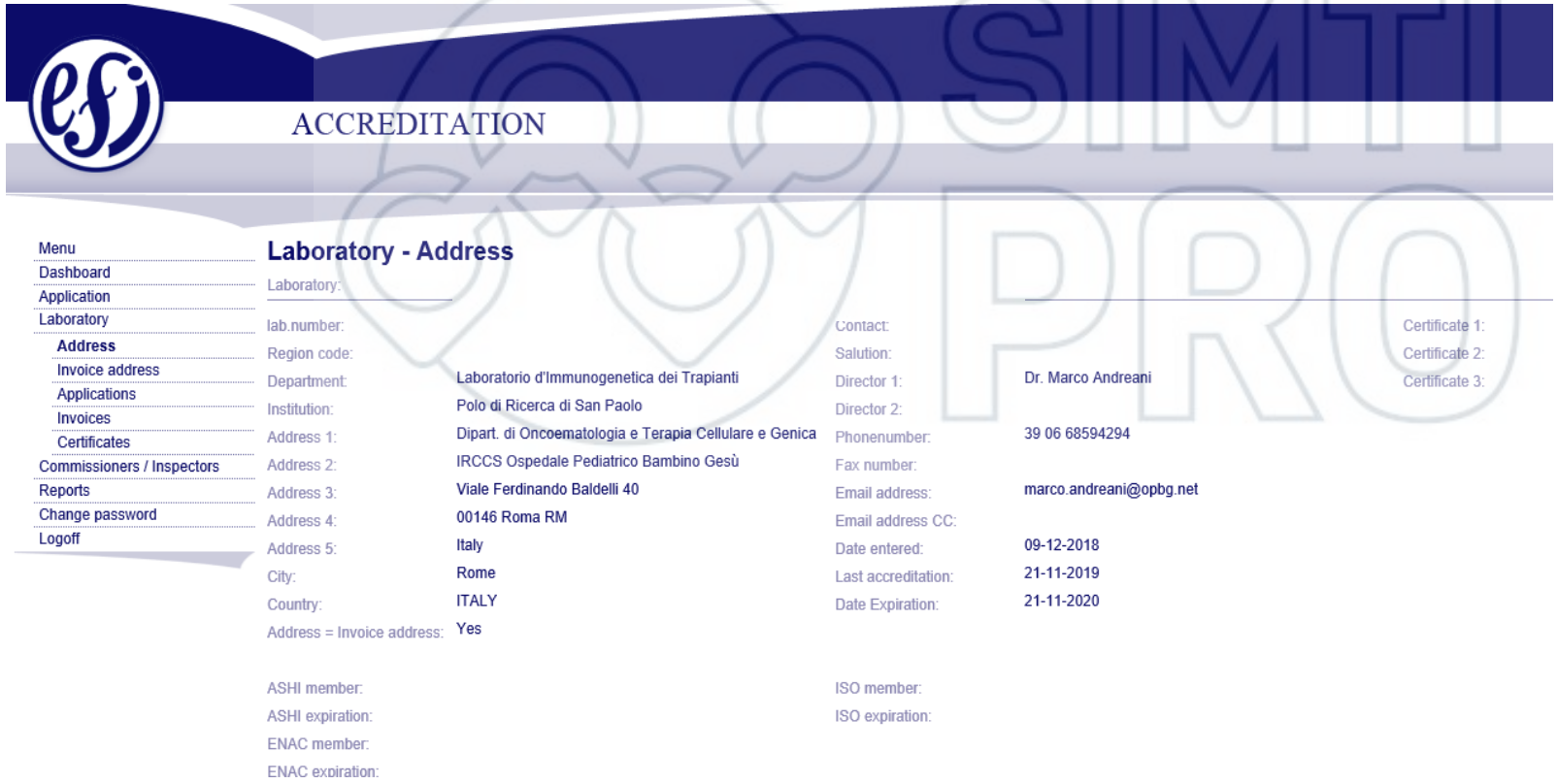
- **Clinical categories**
  - Renal Transplantation and Other Solid Organ Transplant
  - Haematopoietic Transplant
  - Disease Association
  - Blood Transfusion
- **Technical categories**
  - HLA Typing
  - Crossmatching
  - Antibody screening & identification

Categories	Minimum Requirements	Notes
Renal and/or Pancreatic Transplantation		
Recipient Typing	HLA Class I and II low resolution (1st field)	A,B,DR + other loci required by national regulations
Antibody Screening	Antibody detection HLA Class I and Class II	
Antibody Identification	Antibody specificity HLA Class I and Class II	
Donor Typing	HLA Class I and II low resolution (1st field)	
Crossmatching	Antibody specificity and Crossmatching.	If Virtual Crossmatching is used for any sensitised patients specificity with single antigen beads required
Other Solid Organ Transplantation		
Recipient Typing	For sensitized patients	
Antibody Screening	Antibody detection HLA Class I and Class II	
Antibody Identification	Mandatory if screening is positive	
Donor Typing	For sensitized recipients	
Crossmatching	For sensitized recipients	
Categories	**Minimum Requirements**	**Notes**
Haematopoietic Stem Cell Transplantation		
Donor Registry Typing	HLA Class I and Class II typing low resolution (1st field)	
Related Transplantation	HLA Class I and Class II typing high resolution (2nd field)	As required to determine identity
Unrelated Transplantation	HLA Class I and Class II typing high resolution (2nd field)	A,B,C,DRB1 + additional loci if required by transplant protocol
Cord Blood Typing	HLA Class I and Class II low resolution	
Crossmatching	Crossmatching or antibody specificity	For haplotype-identical Tx (currently recommended, to become mandatory in future version of standards)
Chimaerism and Engraftment Monitoring	As required by the transplant protocol	
Disease Association Studies	HLA Class I and Class II typing low resolution and high resolution as required	Where an association is with specific alleles typing to 2nd field is required
Transfusion	HLA/HPA/HNA antibody screening and typing as required	

In cosa consiste il processo di Accreditamento EFI

On-line submission

- Application form
- Multiple supporting documents



Application

EFI Accreditation Program EFI No.

Applicationfile accreditation EFI

Please fill in: Application A ☐ Application C ☐ Date:

Application is filled in according to the Standards version 8.0

Laboratory/institute name:

To complete the application A/C, we kindly ask you to fill in all the sections of the application file (indicate any section which are not applicable). Also please complete the separate sections for the address data and names as the should appear on the certificate and for the accreditation 'Categories', you will find both sections on the Accreditation website.

Submit an organogram of the laboratory with positions and names of persons at the staff and supervisory levels including the quality manager (**addendum #1**). If the laboratory is part of a larger department, an overview of the department must also be provided (**addendum #2**). Indicate the position of the quality manager on addendum #1 and/or #2 as appropriate.

☐ I/We do hereby apply to EFI for laboratory accreditation in the area(s) indicated at the Accreditation website.

It is understood that granting of accreditation is dependent on compliance with all applicable EFI Standards. If a conflict of interest exists with any individual involved in the accreditation procedure I/we will bring that to the notice of the Chairperson of the EFI Accreditation Committee before the inspection takes place.

☐ The Directors confirm that all information is truthful and accurate to the best of our knowledge.

☐ I/we consent to the storage and use of the data submitted in this application for the purposes of EFI accreditation.

PERSONNEL

Director/Co-Director Qualifications

Last name	First name	What is the average hours spent in the laboratory per week.	Is emergency consultation available during your absence?	Weeks/year away from institution? *
			Yes	
			N/A	
			N/A	
			N/A	
			N/A	
			N/A	

*) for periods of > 3 consecutive workdays

Describe in an addendum (**addendum #3**) 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 policies. Include a policy defining who may act as a designated individual for signing reports. Confirm that you are aware of the relevant national legislation.

Submit a complete Curriculum Vitae (**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 and no later than 7 days following the change, a CV of the new director must be provided.

Tutti i documenti sono inizialmente valutati dal Commissario (3 in Italia)

Successivamente il Commissario sceglierà gli Ispettori, che valuteranno la documentazione, prima della site visit

In cosa consiste il processo di Accreditamento EFI

- **3 year cycle of accreditation**
  - Year 0: on-site inspection after lab Application(Packet A)
  - Year 1: & 2 document review + self inspection (Packet B1 & B2)
  - Year 3: on-site inspection (Packet C)

La visita Ispettiva

- 1 day on site inspection by 2 inspectors
  - Observe processes, request and review documents
  - Complete checklist
  - Report sent to Commissioner for review
- Commissioner sends report to lab
  - Lab completes any required corrective actions
  - Evidence of actions submitted to Commissioner
- Accreditation granted following satisfactory completion of actions

EFI Standards

Gli Standard EFI

European Federation for Immunogenetics

STANDARDS FOR HISTOCOMPATIBILITY & IMMUNOGENETICS TESTING

Version 8.0

Accepted by the Standards and Quality Assurance Committee on 8th May 2019
Accepted by the EFI Executive Committee on 28th August 2019
Effective from January 1st 2020

SECTION A – GENERAL POLICIES

SECTION B – PERSONNEL QUALIFICATIONS

SECTION C – QUALITY ASSURANCE

SECTION D – EXTERNAL PROFICIENCY TESTING

SECTION E – ANALYSIS PROCESSES

SECTION F – POST-ANALYSIS PROCESSES

TABLE OF CONTENTS

EFI Standard		Not Applic.	Required Yes	Required No	Recom.* Yes	Recom.* No
	SECTION B – PERSONNEL QUALIFICATIONS					
B1	For the purposes of this document, EFI defines the Director as the person who is responsible for the H&I laboratory activities for which accreditation is applied for					
B2	The laboratory **must employ** one or more individuals who meet the qualifications and fulfil the responsibilities of:					
B3	**The Director and/or Co-Director**					
B3.1	A Director, that **must**:					
B3.1.1	**Hold** a qualification approved by EFI, such as an ESHI or national diploma, earned doctoral degree in a biological science, or be a physician, and		☐	☐		
B3.1.2	*Have minimum qualification **experience equivalent to either of the following**:*					
B3.1.2.1	Four years' relevant experience two of which were devoted to full time training in human H&I testing, or		☐	☐		
B3.1.2.2	Four years of working experience at full time in human H&I testing		☐	☐		
B3.1.2.3	Additional qualifications required according to national legislation also apply	☐	☐	☐		
B3.1.2.4	If these tests are performed in a laboratory not performing H&I. For chimaerism, KIR, HPA, HNA two years of working experience at full time	☐	☐	☐		
B3.1.3	**Have documentation** of professional competence in the appropriate activities in which the laboratory is engaged. This s**hould be based** on sound knowledge of the fundamentals of immunology, genetics and histocompatibility testing as appropriate to the areas in which accreditation is sought		☐	☐		
B3.1.4	If a Co-Director is appointed, this person **must** also **fulfil Standards B3.1.1 - B3.1.3**	☐	☐	☐		
B3.1.5	*The Director or Co-Director **must**:*					
B3.1.5.1	**Be available** at on site to supervise the laboratory for at least 80% of the week		☐	☐		
B3.1.5.2	**Provide** adequate **supervision** of technical personnel		☐	☐		
B3.1.5.3	**Utilises his/her special scientific skills** in developing new procedures		☐	☐		
B3.1.5.4	**Be held responsible** for the proper performance, interpretation and reporting of all laboratory procedures		☐	☐		
B3.1.5.5	Ensure the laboratory's successful participation in proficiency testing.		☐	☐		
B3.1.5.6	**Be informed** of the relevant national legislation and professional standards		☐	☐		
B3.1.5.7	Comply with the relevant national legislation and professional standards		☐	☐		
B3.1.5.8	Demonstrate active participation in clinically relevant professional development, such as national or international conferences or workshops		☐	☐		
B3.1.6	*The Director or Co-Director should:*					
B3.1.6.1	Have publications in peer-reviewed journals				☐	☐
B4	**Technical Staff**					
B4.1	A Technical Supervisor, that **must**:					

Procedure Istruzioni e Moduli

EUROPEAN FEDERATION FOR IMMUNOGENETICS

45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
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Lista di Procedure Istruzioni

Titolo del Documento		Ed	REVISIONI 0 (data)	1 (data)	2 (data)	3 (data)	4 (data)	5 (data)
PO 22 LIT	GESTIONE DELLA QUALITA'	3	30/09/2019	01/10/2020				
PO 23 LIT	CONTROLLI DELLE TEMPERATURE	3	30/09/2019	11/03/2020	01/10/2020			
PO 24 LIT	MONITORAGGIO DELLA CONTAMINAZIONE	3	30/09/2019	01/10/2020				
PO 25 LIT	GESTIONE DEI REAGENTI E MATERIALE MONOUSO	3	30/09/2019	05/03/2020	01/10/2020	14/06/2022		
PO 26 LIT	PROGRAMMAZIONE DELL'ATTIVITA' E GESTIONE DEI DATI	3	30/09/2019	01/10/2020				
PO 27 LIT	TIPIZZAZIONE HLA	3	30/09/2019	01/10/2020				
PO 28 LIT	ESTRAZIONE DEL DNA	3	30/09/2019	30/04/2020	01/10/2020			
PO 29 LIT	TIPIZZAZIONE MEDIANTE PCR - SSP	3	30/09/2019	01/10/2020				
PO 30 LIT	TIPIZZAZIONE MEDIANTE PCR-SSO LUMINEX	3	30/09/2019	01/10/2020				
PO 31 LIT	MONITORAGGIO ATTECCHIMENTO	3	30/09/2019	01/10/2020				
PO 32 LIT	TIPIZZAZIONE MEDIANTE PCR - SBT	3	30/09/2019	01/10/2020	dismessa			
PO 33 LIT	TIPIZZAZIONE HLA MEDIANTE NGS	3	30/09/2019	01/10/2020	25/11/2020			
PO 34 LIT	DETERMINAZIONE E IDENTIFICAZIONE DI ANTICORPI ANTI - HLA	3	30/09/2019	01/10/2020	01/02/2021			
PO 35 LIT	ATTIVITà DI IMMUNOGENETICA NEL TRAPIANTO DI ORGANO SOLIDO	3	01/10/2020	01/02/2021				
PO 36 LIT	CROSSMATCH NEL TRAPIANTO DI ORGANO SOLIDO	3	01/10/2020	01/02/2021				
PO 37 LIT	STUDIO DEI GENI KIR NELL'ANALISI DEL DONATORE DI CSE	3	01/10/2020					
PO 38 LIT	DETERMINAZIONE CITOFLUORIMETRICA NELLE ANALISI DI CROSSMATCH FC-XM E FLOW PRA	3	01/10/2020	01/02/2021				

Titolo del Documento		ED	REVISIONI 0 (data)	1 (data)	2 (data)	3 (data)	4 (data)	5 (data)
ISTR 01 PO 24 LIT	ESECUZIONE DEI CONTROLLI DI CONTAMINAZIONE	3	30/09/2019					
ISTR 01 PO 25 LIT	utilizzo del sistema microneo	3	30/09/2019					
ISTR 01 PO 26 LIT	ISTRUZIONE OPERATIVA SOFTWARE GESTIONALE DNLab	3	30/09/2019	01/10/2020				
ISTR 01 PO 27 LIT	TIPIZZAZIONE HLA PER LA RICERCA DI UN DONATORE CORRELATO	3	30/09/2019	01/10/2020				
ISTR 01 PO 28 LIT	ESTRAZIONE DEL DNA	3	30/09/2019	30/04/2020				
ISTR 01 PO 29 LIT	TIPIZZAZIONE PCR - SSP	3	30/09/2019	01/10/2020				
ISTR 01 PO 30 LIT	TIPIZZAZIONE PCR -SSO LUMINEX	3	30/09/2019	01/10/2020				
ISTR 01 PO 31 LIT	MONITORAGGIO ATTECCHIMENTO KIT STR	3	30/09/2019	01/10/2020				
ISTR 01 PO 32 LIT	TIPIZZAZIONE MEDIANTE PCR - SBT	3	30/09/2019	01/10/2020	dismessa			
ISTR 01 PO 33 LIT	TIPIZZAZIONE HLA MEDIANTE NGS	3	30/09/2019	21/04/2020	01/10/2020	25/11/2020		
ISTR 02 PO 24 LIT	ESECUZIONE DEL MPW TEST/OPEN TUBE TEST	3	30/09/2019	01/10/2020				
ISTR 02 PO 25 LIT	PREPARAZIONE DEI REAGENTI	3	30/09/2019					
ISTR 02 PO 26 LIT	ESECUZIONE BACK - UP DATI	3	30/09/2019	01/10/2020				
ISTR 02 PO 27 LIT	TIPIZZAZIONE HLA PER LA RICERCA DI UN DONATORE NON CORRELATO	3	30/09/2019	01/10/2020				
ISTR 02 PO 28 LIT	QUANTIFICAZIONE DEL DNA	3	01/10/2020					
ISTR 02 PO 29 LIT	GEL ELETTROFORESI	3	30/09/2019	01/10/2020				
ISTR 02 PO 31 LIT	SEPARAZIONI SOTTOPOPOLAZIONI CELLULARI	3	30/09/2019	01/10/2020				
ISTR 01 PO 33 LIT	TIPIZZAZIONE HLA MEDIANTE NGS	3	30/09/2019	01/10/2020				
ISTR 01 PO 34 LIT	DETERMINAZIONE E IDENTIFICAZIONE DI ANTICORPI ANTI-HLA	3	30/09/2019	non in uso				
ISTR 02 PO 34 LIT	DETERMINAZIONE DI ANTICORPI anti-HLA MEDIANTE TEST DI SCREENING FlowPRA	3	01/10/2020	01/02/2021				
ISTR 03 PO 34 LIT	DETERMINAZIONE DI ANTICORPI anti-HLA CON METODICA SCREENING LABScreen MIXED TEII	3	01/10/2020					
ISTR 04 PO 34 LIT	IDENTIFICAZIONE DI ANTICORPI anti-HLA MEDIANTE TEST LUMINEX SINGLE ANTIGEN (LSA)	3	01/10/2020	01/02/2021				

Singole Procedure Istruzioni

Bambino Gesù OSPEDALE PEDIATRICO	PROCEDURA OPERATIVA **Estrazione del DNA**		Cod. PO 28 LIT
			Rev. 1
			Pagina 1 di 6
Data di emissione:	**05/04/2023**	**Data di entrata in vigore:**	**19/04/2023**

SOMMARIO

Preparato: Sig.ra Annalisa Guagnano Verificato: Dott.ssa Nadia Tuccini Responsabile Funzione Certificazione	Approvato ed emesso: Responsabile LIT ..... *(Dott. Marco Andreani)* Data: 05/04/2023

Bambino Gesù OSPEDALE PEDIATRICO	ISTRUZIONE **ESTRAZIONE DEL DNA**		Cod. ISTR.01 PO28 LIT
			Rev.0
			Pagina 1 di 5
Data di emissione:	**22/09/2022**	**Data di entrata in vigore:**	**06/10/2022**

Approvato ed emesso: Dott. Marco Andreani
Responsabile LIT

Firma_____ Data: **22/09/2022**

1. METODICHE DI ESTRAZIONE

1.1. METODICA DI ESTRAZIONE DI DNA DA SANGUE PERIFERICO, SANGUE MIDOLLARE E SOTTOPOPOLAZIONI LINFOCITARIE.

I prelievi di sangue periferico e sangue midollare e pellet delle sottopopolazioni linfocitarie (precedentemente separate e diluite in 400 ml di PBS) vengono trattati direttamente con la metodica EZ1 ® ADVANCED XL QIAGEN, in base al Manuale utente EZ1 Advanced XL 05/2009 A-5.

1.4. METODICA DI ESTRAZIONE CON ESTRATTORE AUTOMATICO EZ1 ® ADVANCED XL QIAGEN

Reagenti e Materiale

- Estrattore EZ1 ® ADVANCED XL QIAGEN.
- Cartucce reagenti (da n. 1 a n. 14 a seconda del numero di campioni da estrarre) realizzate in polipropilene alloggiate su un apposito supporto

Alcuni esempi

Caratteristiche delle aree e delle strutture di lavoro

Processo di accettazione dei campioni biologici

Appropriata manutenzione delle attrezzature

Controlli di qualità esterni

Qualifica del Personale

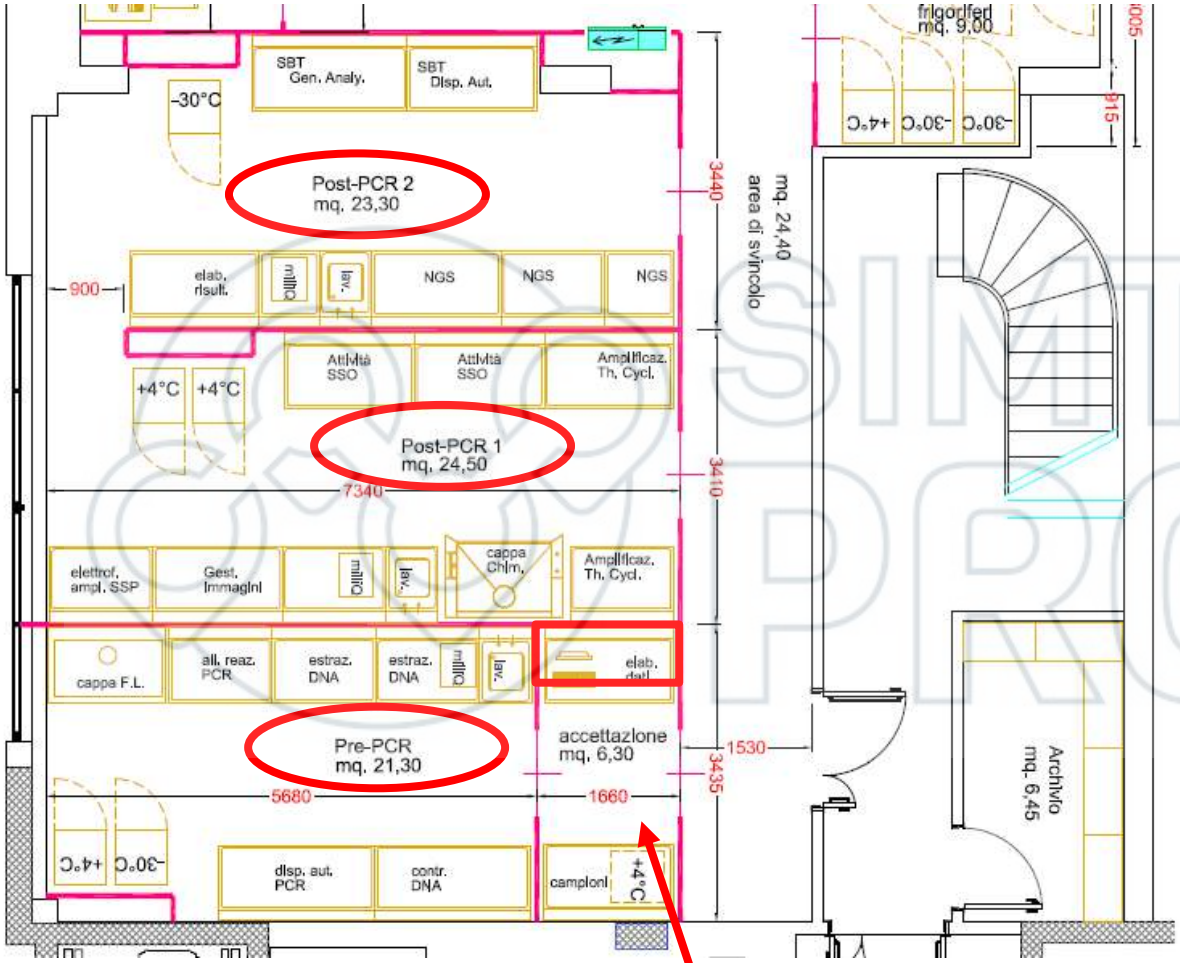
Validazione

Caratteristiche delle aree e delle strutture di lavoro

C2.1.3	Laboratories performing amplification of nucleic acids must use:
C2.1.3.1	A dedicated work area with restricted traffic flow
C2.1.3.2	Physical and/or biochemical barriers to prevent DNA contamination, including the use of dedicated
C2.1.3.2.1	Equipment
C2.1.3.2.2	Laboratory coats
C2.1.3.2.3	Disposable supplies
C2.1.4	Pre-amplification procedures must be performed in an area which excludes amplified DNA that has the potential to serve as a template for amplification in any of the genetic systems tested in the laboratory
C2.1.5	All activities occurring from and including thermal cycling must take place in the post-amplification area

I laboratori che eseguono amplificazione degli acidi nucleici, per prevenire la possibile contaminazione devono disporre di aree specifiche, strumenti, camici etc. dedicati all'area definita di Pre-PCR

Caratteristiche delle aree e delle strutture di lavoro



Filter area

Caratteristiche delle aree e delle strutture di lavoro

- I frigoriferi e I congelatori che contengono reagenti dedicati ad attività Pre- o Post-PCR devono essere necessariamente posizionati nelle aree specifiche
- I camici del personale che transitano da aree Pre- a Post-PCR devono essere abitualmente cambiati nell'area considerate filtro

Filter Area

Pre-PCR

Post-PCR 1

Post-PCR 2

Caratteristiche delle aree e delle strutture di lavoro

C2	**TECHNICAL**			
C2.1	**Facilities**			
C2.1.1	*The following facilities **must be adequate** and immediately available to the laboratory:*			
C2.1.1.1	Sufficient space so that all procedures **can be carried out** without crowding to the extent that errors may result, in accordance with national regulations		✓	
C2.1.1.2	Lighting		✓	
C2.1.1.3	Ventilation		✓	

Processo di accettazione dei campioni biologici

C3.2	**Sample acceptance**			
C3.2.1	*The laboratory **must:***			
C3.2.1.1	**Maintain** a system to ensure reliable specimen identification		✓	
C3.2.1.2	**Document** each step in the processing and testing of patient specimens **to assure** that accurate test results are recorded		✓	
C3.2.1.3	Have criteria for specimen rejection		✓	
C3.2.1.4	Have mechanism to assure that specimens are not tested when they do not meet the laboratory's criteria for acceptability		✓	

No SOP describing the appropriate criteria for specimen rejection is present in the lab

I laboratori devono disporre di un sistema che permetta la corretta identificazione dei campioni biologici, di documentazione che assicuri l'accuratezza dei risultati raccolti, di criteri scritti per eventualmente rigettare un campione biologico etc.

Appropriata manutenzione delle attrezzature

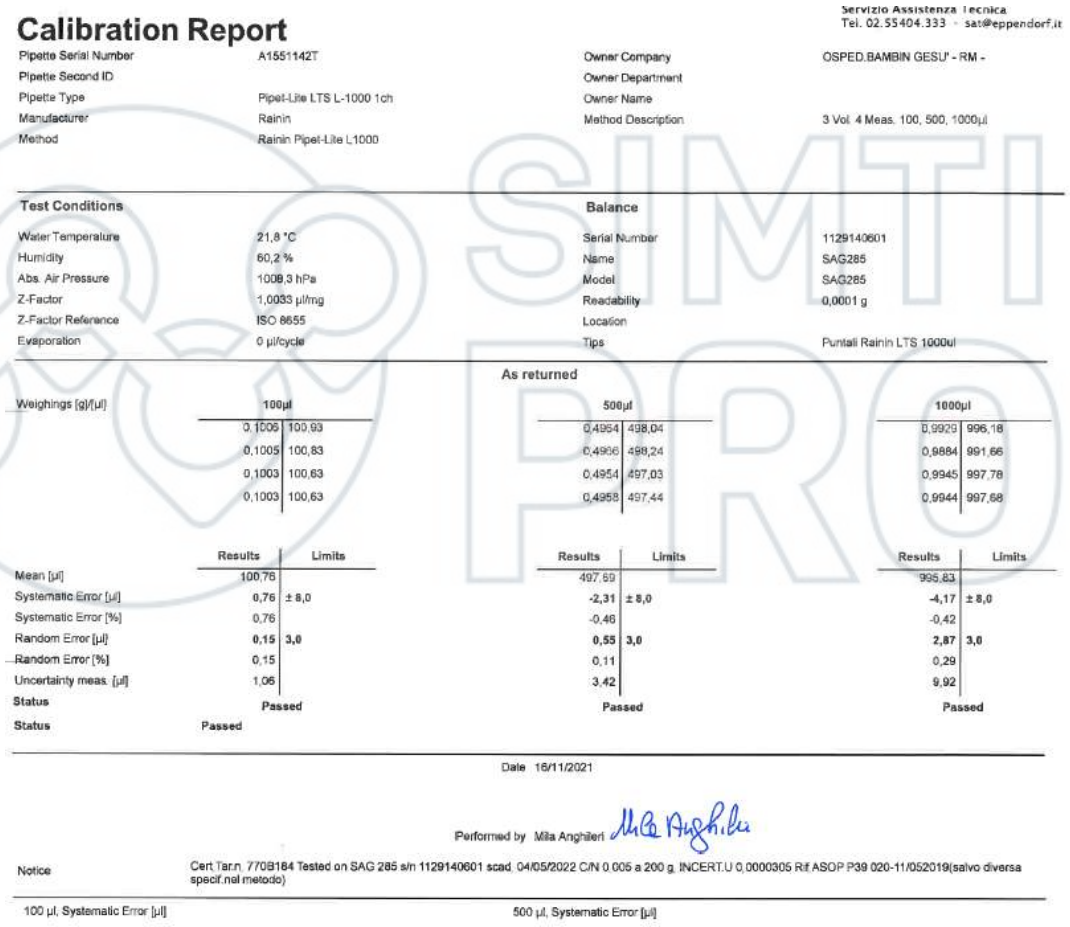
Calendario annuale che identifichi le date della manutenzione per ciascuna grande o piccola attrezzatura

Stabilire politiche e procedure per una corretta manutenzione delle apparecchiature

C2.2.1	The laboratory must establish and employ policies and procedures for the proper maintenance of equipment, instruments and test systems by:
C2.2.1.1	Defining its preventive maintenance programme for each instrument and piece of equipment at least once a year
C2.2.1.2	Performing and documenting function checks on equipment with at least the frequency specified by the manufacturer
C2.2.1.3	The laboratory must use calibrated dispensing instruments (e.g. pipettes, etc.) to perform assays
C2.2.1.3.1	Calibration of dispensing instruments must be performed at least once a year
C2.2.1.3.2	Calibration must be documented
C2.2.2	Refrigerators and freezers:
C2.2.2.1	Acceptable ranges for each refrigerator and freezer must be documented
C2.2.2.2	Must be monitored to detect unacceptable temperatures
C2.2.2.3	Should be coupled to recording thermometers
C2.2.2.4	Should be coupled to alarm systems with an audible alarm where it can be heard 24 hours a day
C2.2.2.5	Corrective actions for when the temperature is outside the documented acceptable range must be defined and documented

Appropriata manutenzione delle attrezzature

Report di manutenzione per ciascuna singola pipetta automatica



Calibration Report

Servizio Assistenza Tecnica
Tel. 02.55404.333 - sat@eppendorf.it

Pipette Serial Number	A1551142T	Owner Company	OSPED.BAMBIN GESU' - RM -
Pipette Second ID		Owner Department	
Pipette Type	Pipet-Lite LTS L-1000 1ch	Owner Name	
Manufacturer	Rainin	Method Description	3 Vol. 4 Meas. 100, 500, 1000µl
Method	Rainin Pipet-Lite L1000		

Test Conditions		Balance	
Water Temperature	21,8 °C	Serial Number	1129140601
Humidity	60,2 %	Name	SAG285
Abs. Air Pressure	1008,3 hPa	Model	SAG285
Z-Factor	1,0033 µl/mg	Readability	0,0001 g
Z-Factor Reference	ISO 8655	Location	
Evaporation	0 µl/cycle	Tips	Puntali Rainin LTS 1000ul

As returned

Weighings [g]/[µl]	100µl		500µl		1000µl	
	0,1005	100,93	0,4954	498,04	0,9929	996,18
	0,1005	100,83	0,4966	498,24	0,9884	991,66
	0,1003	100,63	0,4954	497,03	0,9945	997,78
	0,1003	100,63	0,4958	497,44	0,9944	997,68

	Results	Limits	Results	Limits	Results	Limits
Mean [µl]	100,76		497,69		995,83	
Systematic Error [µl]	0,76	± 8,0	-2,31	± 8,0	-4,17	± 8,0
Systematic Error [%]	0,76		-0,46		-0,42	
Random Error [µl]	0,15	3,0	0,55	3,0	2,87	3,0
Random Error [%]	0,15		0,11		0,29	
Uncertainty meas. [µl]	1,06		3,42		9,92	
Status	Passed		Passed		Passed	
Status	Passed					

Date 16/11/2021

Performed by Mila Anghileri

Notice: Cert.Tar.n. 770B184 Tested on SAG 285 s/n 1129140601 scad. 04/05/2022 C/N 0,005 a 200 g. INCERT.U 0,0000305 Rif.ASOP P39 020-11/052019(salvo diversa specif.nel metodo)

100 µl, Systematic Error [µl]

500 µl, Systematic Error [µl]

Controlli di qualità esterni

Specifiche SOP che determinino le modalità di esecuzione dei Controlli di Qualità Esterni

	SECTION D – EXTERNAL PROFICIENCY TESTING			
D1	**PROCEDURE OF EXTERNAL PROFICIENCY TESTING**			
D1.1	**Registration for EPT schemes**			
D1.1.1	*The laboratory **must participate in EPT programme(s)** to cover*		✓	
D1.1.1.1	All the accredited laboratory applications (HLA typing, antibody screening and identification, crossmatching, etc.)		✓	
D1.1.1.2	All techniques used individually or in combination as routinely employed to produce a final result		✓	
D1.1.2	If no established scheme exists for a specific category (e.g. HNA antibody detection and identification) laboratory **must participate** in an EPT workshop or trial offered by an EPT Provider or **must take part in** an inter-laboratory exchange of samples		✓	
D1.1.3	If (an) EPT scheme(s) or EPT workshop(s)/trial(s) for a specific category exist(s) but the laboratory has no access, the laboratory **must** at least **participate** in an inter-laboratory exchange of samples.	✓		
D1.2	*The laboratory **must prospectively define** core and supplemental techniques according to the Accreditation Application.*		✓	
D1.2.1	Core techniques are used individually or in combination to produce a final result		✓	
D1.2.2	Supplemental techniques are used occasionally for rare cases in combination with core techniques to refine final results		✓	
D1.3	*The laboratory **must***			
D1.3.1	**Prospectively document** the relevant EPT schemes or workshops on an annual basis		✓	
D1.3.2	**Have** a predetermined policy for testing EPT samples and **must document** this prior to the annual commencement of the EPT cycle		✓	
D1.3.3	**Have** a predetermined policy if they select individual shipments or samples for EPT		✓	
D1.3.4	**Have** a predetermined policy for the selection of samples or shipments for supplemental techniques		✓	

Controlli di qualità esterni

D1.3	The laboratory must
D1.3.1	Prospectively document the relevant EPT schemes or workshops on an annual basis
D1.3.2	Have a predetermined policy for testing EPT samples and must document this prior to the annual commencement of the EPT cycle
D1.3.3	Have a predetermined policy if they select individual shipments or samples for EPT
D1.3.4	Have a predetermined policy for the selection of samples or shipments for supplemental techniques

Calendario che indichi le modalità di esecuzione dei Controlli di Qualità Esterni, in base alle categorie scelte per l'accreditamento e alle metodiche utilizzate in laboratorio

EUROPEAN FEDERATION FOR IMMUNOGENETICS

45° Convegno Nazionale di Studi di Medicina Trasfusionale
Rimini | 29-31 maggio 2024
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Controlli di qualità esterni

PROGRAMMAZIONE CONTROLLI DI QUALITA' ESTERNI ANNO 2022

Si prevede l'invio di 10 campioni per la tipizzazione HLA da parte dell'Istituto Superiore di Sanità.
I campioni utilizzati come CQ esterni saranno tipizzati secondo il seguente schema.

ISS-2022	LOW RESOLUTION					HIGH RESOLUTION								
	HLA-A	HLA-B	HLA-C	DRB1	DQB1	HLA-A	HLA-B	HLA-C	DRB1	DRB3-B4-B5	DQA1	DQB1	DPB1	DPA1
1° INVIO														
Campione 1	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS
Campione 2	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO LR-SSP	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ SBT/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS
Campione 3	SSO-LR	SSO-LR	SSO-LR	SSO-LR	SSO-LR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS
Campione 4	SSO-LR	SSO-LR	SSO-LR	SSO-LR	SSO-LR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS
2° INVIO														
Campione 5	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS
Campione 6	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS
Campione 7	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS
3° INVIO														
Campione 8	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS
Campione 9	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS
Campione 10	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	SSO-XR/ NGS	NGS

Dott. Marco Andreani
Direttore
Laboratorio d'Immunogenetica dei Trapianti
Dip. di Oncoematologia e Terapia Cellulare e Genetica

Calendario specifico per l'esecuzione dei Controlli di Qualità Esterni per la tipizzazione HLA molecolare, suddiviso per numero di campioni biologici da testare e le metodiche da utilizzare

Controlli di qualità esterni

D1.5	**Minimum number of samples for EPT per year**			
D1.5.1	*The minimum number of samples applies to all core techniques used to produce a final result:*			
D1.5.1.1	Serological typing: 10 samples	✓		
D1.5.1.2	Each low resolution DNA-based typing technique: 10 samples		✓	
D1.5.1.3	Each high resolution DNA-based typing technique: 10 samples		✓	
D1.5.1.4	Each allelic resolution DNA-based typing technique: 10 samples	✓		
D1.5.1.5	HPA/HNA/KIR/MICA typing: 10 samples		✓	
D1.5.1.6	HLA antibody detection: 10 samples for HLA class I and 10 samples for HLA class II The same samples can be used for the detection of both classes		✓	
D1.5.1.7	HLA antibody identification by CDC: 10 samples		✓	
D1.5.1.8	HLA antibody identification by solid phase assays: All HLA class I and II antibody positive samples as defined in D1.5.1.6. If the HLA antibody identification is a separate scheme the minimum number is 10 samples. A laboratory may test only for class I or class II antibodies according to their clinical requirements and D1.1		✓	
D1.5.1.9	HPA/MICA antibody detection and identification: 5 samples	✓		
D1.5.1.10	Crossmatching: 20 tests of different donor/recipient combinations of each accredited cell subtype (B-/T-/unseparated cells) which **must include** a minimum of two cell samples and 10 different sera		✓	
D1.5.1.11	Haematopoietic chimaerism and engraftment monitoring: 10 tests of different donor/ recipient mixtures in the range 0% - 100% excluding the reference donor and recipient samples		✓	

Specifici standard di riferimento relativi al numero minimo di campioni biologici da testare per ciascuna singola metodica nei Controlli di Qualità Esterni

EUROPEAN FEDERATION FOR IMMUNOGENETICS

Controlli di qualità esterni

C1.3.2.2	Regular evaluation of results obtained in external and internal QC testing

Centro Nazionale Trapianti
ISTITUTO SUPERIORE DI SANITÀ

Controllo di Qualità nazionale

Schema: Tipizzazione genomica HLA - Alta risoluzione

REPORT FINALE - Anno 2020

Responsabile:
Francesca Quintieri
Centro Nazionale Trapianti
Istituto Superiore di Sanità

Risultati discussi durante la riunione CLT del 3/11/21

Dott. Nunzio Andreani
Direttore

Qualifica del Personale

SECTION B – PERSONNEL QUALIFICATIONS

B1	For the purposes of this document, EFI defines the Director as the person who is responsible for the H&I laboratory
B2	The laboratory must employ one or more individuals who meet the qualifications and fulfil the responsibilities of:
B3	**The Director and/or Co-Director**
B3.1	A Director, that must:
B3.1.1	Hold a qualification approved by EFI, such as an ESHI or national diploma, earned doctoral degree in a biological science, or be a physician, and
B3.1.2	Have minimum qualifying experience equivalent to either of the following:
B3.1.2.1	Four years' relevant experience two of which were devoted to full time training in human H&I testing, or
B3.1.2.2	Four years of working experience at full time in human H&I testing
B3.1.2.3	Additional qualifications required according to national legislation also apply
B3.1.3	Have documentation of professional competence in the appropriate activities in which the laboratory is engaged. This should be based on sound knowledge of the fundamentals of immunology, genetics and histocompatibility testing
B3.1.4	If a Co-Director is appointed, this person must also fulfil Standards B1.1.1 - B1.1.3
B3.1.5	The Director and/or Co-Director must:
B3.1.5.1	Be available on site to supervise the laboratory for at least 80% of the week
B3.1.5.2	Provide adequate supervision of technical personnel
B3.1.5.3	Utilises his/her special scientific skills in developing new procedures
B3.1.5.4	Be held responsible for the proper performance, interpretation and reporting of all laboratory procedures

Qualifica del Personale

EUROPEAN FEDERATION FOR IMMUNOGENETICS

45° Convegno Nazionale di Studi di Medicina Trasfusionale
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European Federation for Immunogenetics Accreditation Programme

APPLICATION FOR EFI DIRECTORSHIP

Every applicant for directorship according to EFI standards B must provide the informatic requested on this form and the additional documents as listed at the end of this form. Please send the completed form and the documents to your Regional Commissioner.

Clinical categories of the applicant's laboratory (please check boxes):

- ☐ Renal and/or pancreatic transplantation
- ☐ Other solid organ transplantation (organs: _____)
- ☐ Haematopoietic stem cell transplantation
  - ☐ Donor registry typing
  - ☐ Related stem cell transplantation
  - ☐ Unrelated stem cell transplantation
  - ☐ Cord blood transplantation
- ☐ Transfusion
- ☐ Disease association
- ☐ Chimaerism

European Federation for Immunogenetics Accreditation Programme

Table 1: Experience and expertise in molecular immunogenetics

Only samples/examinations for which a technical and medical plausibility check and validation have been carried out are counted. Please specify approximate number of tests for each method. If number exceeds 1000, specifying ">1000" is sufficient.

Technical Category	Approx. number of tests	Methods
Low-resolution HLA typing (minimum HLA-A, -B, -C, -DRB1 and -DQB1 per sample)		
High-resolution HLA typing (minimum HLA-A, -B, -C, -DRB1 and -DQB1 per sample)		
Selective HLA typing (e.g. HLA-B27)		HLA antigen or allele/resolution of typing/clinical application:

Qualifica del Personale

EUROPEAN FEDERATION FOR IMMUNOGENETICS

45° Convegno Nazionale di Studi di Medicina Trasfusionale
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European Federation for Immunogenetics Accreditation Programme

Table 3: Experience and expertise in risk assessment and consulting. If number exceeds 1000, specifying ">1000" is sufficient.

Risk assessment and consulting for renal and/or pancreatic transplantation	Approx. number of living donor transplantations:	Approx. number of deceased donor transplantations:
Risk assessment and consulting for other organ transplantation	Approx. number of transplantations:	Organs:
Risk assessment and consulting for stem cell transplantations	Approx. number of related donor transplantations:	Approx. number of unrelated donor transplantations:
Risk assessment and consulting for transfusion	Approx. number:	Transfusion product:
Risk assessment and consulting for disease association	Approx. number:	Diseases:
Risk assessment and consulting for chimaerism	Approx. number	

The following documents must be provided (please check boxes):

- ☐ **Curriculum vitae** (clearly define education e.g. biologist and PhD in biological science)
- ☐ **Description of duties in the lab**
- ☐ **List of publications**
- ☐ **List of continuing education** (for format please see EFI Accreditation Application Packet: organiser, meeting/title of lecture, duration, level of participation)
- ☐ **ESHI diploma and/or national/international H&I specialisation diploma** (if applicable)

☐ I confirm that all information is truthful and accurate.
☐ I consent to the storage and use of the data submitted in this application for the purposes of EFI accreditation.
☐ Upon request by the accreditation committee, I agree to an oral discussion about my stated experience and expertise.

_____

Date, signature of the applicant

EUROPEAN FEDERATION FOR IMMUNOGENETICS

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Validazione

C1.3	**Systems for Continuous Test Evaluation and Monitoring**
C1.3.1	The laboratory must establish and employ policies and procedures, and document actions taken when:
C1.3.1.1	Test systems do not meet the laboratory's established criteria
C1.3.1.2	Quality control results are outside of acceptable limits
C1.3.1.3	Errors are detected in the reported patient results. In this instance, the laboratory must:
C1.3.1.3.1	Promptly notify the authorised person ordering or individual utilising the test results of reporting errors
C1.3.1.3.2	Issue corrected reports
C1.3.1.3.3	Maintain copies of the original report as well as the corrected report for at least two years
C1.3.2	The laboratory must have mechanisms in place for continuous monitoring of all test systems and equipment used, including:
C1.3.2.1	Validation/verification, before introduction into routine use, of all new tests, by systematic comparative evaluation of results obtained in parallel with the new and the standard system
C1.3.2.2	Regular evaluation of results obtained in external and internal QC testing
C1.3.2.3	Regular monitoring of test validity in routine testing, by recording observations diverging from the expected results (e.g. cross-reactivity of probes or primer mixes, day-to-day variations)

Validazione

Evidenza scritta di validazione per nuovi reagenti o introduzione di nuove metodiche in laboratorio

Bambino Gesù OSPEDALE PEDIATRICO	VERBALE DI VALIDAZIONE KIT HLA	Cod.: MD 02 PO 25 LIT
		Data: 30/09/2019
		Ed. 3 – Rev. 0
		Pagina 1 di 1

IDENTIFICAZIONE DEL KIT

Descrizione	Ditta	Temp.	Lotto	Scadenza	Spedizione	Data arrivo

IDENTIFICATIVO VALIDAZIONE

Data	DNA Rif.N°	Esito Validazione	Firma

INIZIO UTILIZZO: .....

OSSERVAZIONI	ANALISI DEL DATO

FIRMA RESP.: ..... data.....

NGS Validation

Work flow		
Platform	XY, YX etc.	
Kit used	Commercial or Local	
Number of samples to test	**20 – 60 up to 100**	
Number of alleles to test		
Analyze HLA-A, -B, -C, -DRB1, -DQB1		**100 – 300 up to 500 test**
If used in routine, also analyze HLA-DRB3/DRB4/DRB5, -DQA1, -DPB1		**100 – 600 up to 1000 test**

Written evidence of comparison with previous results

Validazione

C1.3.2.3	Regular monitoring of test validity in routine testing, by recording observations diverging from the expected results (e.g. cross-reactivity of probes or primer mixes, day-to-day variations)

	A	B	C	D	E	F	G	H	I	J
1	Bambino Gesù OSPEDALE PEDIATRICO		Monitoraggio Qualità SSO HLA-DQB1/DQA1						MD 03 PO 16 LIT	Pag.1/1
2	**Data**	**DNA**	**Lotto**	**Scadenza**	**Ditta**	**Biglia**	**Tipizzazione Iniziale**	**Tipizzazione Corretta**	**Note/Natura dell'anomalia**	**Legenda**

Evidenza scritta di risultati non attesi

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Received: 26 April 2018 | Accepted: 28 April 2018

DOI: 10.1111/tan.13289

WILEY HLA
Immune Response Genetics

REVIEW ARTICLE

Accreditation of histocompatibility and immunogenetics laboratories: Achievements and future prospects from the European Federation for Immunogenetics Accreditation Programme

A. Harmer[1,2] | L. Mascaretti[2,3] | E. Petershofen[2,4]

Gruppo degli Ispettori EFI

Per informazioni: la segreteria EFI

- http://www.efiweb.eu/
  - http://www.efiweb.eu/efi-committees.html
- EFI Office

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Grazie per l’attenzione