Inspectors Webinar

Online via GoToMeeting
Friday 12th February 2021| 2 – 4 pm CET

The EFI Accreditation Committee presents an Inspectors webinar

Speakers: Dr. Andrea Harmer

Dr. Blanka Vidan-Jeras, Dr. Christien Voorter

Dr. Marco Andreani

Accreditation – responding to the pandemic

- Last inspections performed in March 2020
- Travel stopped
- New process put in place
- AC activities continue
  - Commissioners review packets
  - AC meeting held by videoconfernce

New Accreditation Cycle

- Accreditation Programme Changes due to Covid-19 Pandemic
  - On-site inspections stopped in March 2020
  - Labs due to be re-inspected in 2020 submit an extra B application
  - A four year accreditation cycle introduced

	Current application schedule	Revised application schedule
March 2020-Feb 2021	C	B (extra)
March 2021-Feb 2022	B1	C
March 2022-Feb2023	B2	B1
March 2023-Feb2024	C	B2
	Current application schedule	Revised application schedule
March 2020-Feb 2021	B1	B1
March 2021-Feb 2022	B2	B2
March 2022-Feb2023	C	B (extra)
March 2023-Feb2024	C	C
	Current application schedule	Revised application schedule
March 2020-Feb 2021	B2	B2
March 2021-Feb 2022	C	B (extra)
March 2022-Feb2023	B1	C
March 2023-Feb2024	B2	B1

- Accreditation Cycle returns to 3 year in 2024
- Accreditation fee for 2021
  - Fee includes contribution to inspection costs
  - No costs incurred from March 2020 until 2021
  - Discount of €150 applied in 2021
- New applications
  - Applications have been accepted
  - Delay in process until 2021

- Resuming Inspections
  - Ongoing restrictions on travel continuing in 2021
  - Inspection process cannot be delayed further
  - Agreed inspections must resume in March/April 2021
  - Inspectors questionnaire
    - Most inspectors able to inspect in own country
    - Travel by private car is ok, travel by train or air currently not possible for many
    - Vaccination may increase ability to travel
    - Restrictions by employers or governments limit options
  - Commissioners and inspectors must adapt to circumstances

- Resuming Inspections
  - Options to perform remote inspections must be available
  - Agreed hierarchy for inspections
    - 1. On-site inspection with 1 local and 1 outside inspector
    - 2= On-site inspection with 2 local inspectors
    - 2= On-site with 1 local inspector + remote connection with 1 outside inspector
    - 3. Fully remote with 1 local and 1 outside inspector
  - Additional documentation can be requested to support remote review
  - Inspectors expenses associated with remote inspection (e.g. video conferencing/telephone costs) will be paid

Laboratory	City	Commissioner	Status	Applica
07-IT-014.986 Sezione HLA - Servizio di Immunologia Clinica e Tipizzazione Tessutale	Torrette di Ancona	Dr. Franco Papola	Active	C
07-IT-015.985 Sezione di Tipizzazione Tissutale UOC di Immunoematologia e Medicina Trasfusionale	Roma	Dr. Franco Papola	Active	C
07-IT-017.983 Settore di Immunogenetica UOSD Diagnostica ad alta complessità	Pesaro	Dr. Franco Papola	Active	B1
07-IT-026.974 Medical Genetics / DMS A.O. S.Camillo-Forlanini/University La Sapienza	Rome	Dr. Franco Papola	Active	B1
07-IT-042.958 Laboratorio HLA UOC Immunotrasfusionale	Padova	Dr. Franco Papola	Active	B1
07-IT-045.955 Lab. di Tipizzazione HLA, Serv. Di Immunoematologia e Medicina Trasfusionale	Milano	Dr. Franco Papola	Active	B2
07-IT-048.952 SD-Immunogenetica, Medicina di Laboratorio Azienda Ospedaliero Universitaria Pisana	Pisa	Dr. Franco Papola	Active	C
07-IT-050.950 U.O.S. Laboratorio di Tipizzazione Tissutale Centro Donatori di Midollo Osseo (CD-CT02)	Catania	Dr. Franco Papola	Active	B2
07-IT-069.931 Laboratorio di Tipizzazione Tissutale Servizio di Immunoematologia e Medicina Trasfusionale	Cuneo	Dr. Franco Papola	Active	B2
07-IT-100.900 Scienze Biomediche, Metaboliche e Neuroscienze Serv. di Medicina legale Laboratorio di Gen	Modena	Dr. Franco Papola	Active	A

Laboratory	City	Commissioner	Status	Applica
04-DE-010.990 HLA/Transplantlabor Institut für Transfusionsmedizin (Campus Merheim)	Köln	Prof. Dr. med Christian H. Seidl	Active	C
07-IT-021.979 Laboratorio di Tipizzazione Tissutale Servizio Trasfusionale e di Immunoematologia e Medici	Varese	Dr. Marco Andreani	Active	B2
07-IT-022.978 Laboratorio di Tipizzazione Tissutale HLA S.I.T. Trento Serv. Di Immunoematologia e Trasfusi	Trento	Dr. Marco Andreani	Active	B2
07-IT-028.972 Unità Operativa Semplice di Immunogenetica HLA Servizio Immunoematologia e Trasfusior	Vicenza	Dr. Marco Andreani	Active	B2
07-IT-056.944 Lab. HLA - Serv. Di Immunoematiologia & E Medicina Trasfusionale, Dipt. Medicina di Labora	Milano	Dr. Marco Andreani	Active	C
07-IT-064.936 Laboratorio di Tipizzazione Tissutale HLA U.O. Immunoematologia e Medicina Trasfusionale	Livorno	Dr. Marco Andreani	Active	B2
07-IT-077.923 Laboratorio di Immunogenetica dei Trapianti DAI di Medicina di Laboratorio e Trasfusionale	Napoli	Dr. Marco Andreani	Active	B2
07-IT-080.920 P.O. San Francesco / ASL Nuoro Servizio Immunoematologia e Medicina Trasfusionale	Nuoro	Dr. Marco Andreani	Active	C
07-IT-099.901 Clinical lab ROSE Genomics ITALIA Srl.	Milano	Dr. Marco Andreani	Active	A
07-IT-102.898 Dipartimento di Oncoematologia e Pneumologia AORN A. Cardarelli	80131 Napoli	Dr. Marco Andreani	Active	A

Laboratory	City	Commissioner	Status	Applicati
07-IT-010.990 Immunogenetic	Milano	Dr. Luca Mascaretti	Active	B2
07-IT-012.988 Immunogenetic	Firenze	Dr. Luca Mascaretti	Active	C
07-IT-025.975 Centro Regional	Rome	Dr. Luca Mascaretti	Active	C
07-IT-027.973 Unita Operativa	Verona	Dr. Luca Mascaretti	Active	C
07-IT-030.970 Dip.Diagnosticc	Parma	Dr. Luca Mascaretti	Active	B2
07-IT-043.957 Laboratorio Tipi	Matera	Dr. Luca Mascaretti	Active	B2

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07-IT-025.975 Centro Regional	Rome	Dr. Luca Mascaretti	Active	C
07-IT-027.973 Unita Operativa	Verona	Dr. Luca Mascaretti	Active	C
07-IT-030.970 Dip.Diagnosticc	Parma	Dr. Luca Mascaretti	Active	B2
07-IT-043.957 Laboratorio Tipi	Matera	Dr. Luca Mascaretti	Active	B2
07-IT-049.951 Laboratorio di Is	Treviso	Dr. Luca Mascaretti	Active	B2
07-IT-087.913 Lab. di Tipizzazic	Roma	Dr. Luca Mascaretti	Active	A

Additional requirements asked to the laboratory						
Commissionner	**45 days before the inspection**	**ask to the director to prepare a connection to share screen with the virtual inspector**				
		asks to the lab director this list of documents (Documents reviewed by the two inspectors and not by commissioner)				
		1- Check list with self inspection	1- Check list_Self			
		2- Plan of the lab with all rooms, equipment... and the traffic or a tour in the lab with video/photos	2- Plan of the lab or a tour in the lab with video or photos			
		3- List of equipments and schedule of maintenance for the current year	3- Equipments and maintenance			
		4- Sample request and MOP of sample rejection	4- Sample request and MOP of sample rejection			
		5- One example of non conformity (detection/documentation/resolution)	5- Non conformity			
		6- Programmation of the wipe-test + One example (September/October 2020)	6- Wipe test			
		7- One example of validation of a new lot and shipment of a commercial kit in use for each method used in the lab (including result + conclusion)	7- validation of reagent			
		8- One example of validation of one software version used in the lab (and data base if needed)	8- validation of software + database			
		9- Anonymous copy of a selected case of a kidney patient waiting for at least one year a postmortem kidney (reports of the tests for registration on the waiting list + periodic monitoring of antibody detection and	9- Report _ Kidney postmortem			
		10- Anonymous copy of a selected case of a kidney patient waiting for a living donor (reports of the tests performed before the kidney transplantation, including report to the clinic)	10- Report _ Kidney living			
		11- The last virtual XM (+ protocole + report to clinicians + re-evaluation of the retrospective crossmatches after virtual crossmatching)	11-Virtual XM			
		12- Anonymous copy of a selected case of all other clinical categories (excluding HSCT)	12- Reports _ other categories			
		If a new method/reagent:				
		1) Validation of the new method/reagents	A- New method/reagents			
		2) Validation/Qualification of a new intrument (if relevant)	B- New instrument			
		3) All MOP	C- NewMOP			
		4) EPT results	D- NewEPT			
		5) Technicien competencies	E- New competencies			
Lab director	**21 days before the inspection**	**downloads documents in the EFI website**				
		1- Check list with self inspection	1- Check list_Self	addenda	local inspector	other inspector
		2- Plan of the lab with all rooms, equipment... and the traffic or a tour in the lab with video/photos	2- Plan of the lab or a tour in the lab with video or photos	addenda	yes	yes
		3- List of equipments and schedule of maintenance for the current year	3- Equipments and maintenance	addenda	yes	yes
		4- Sample request and MOP of sample rejection	4- Sample request and MOP of sample rejection	addenda	yes	yes
		5- One example of non conformity (detection/documentation/resolution)	5- Non conformity	addenda	yes	yes
		6- Programmation of the wipe-test + One example (September/October 2020)	6- Wipe test	addenda	yes	yes
		7- One example of validation of a new lot and shipment of a commercial kit in use for one method used in the lab (including result + conclusion)	7- validation of reagent	addenda	yes	yes
		8- One example of validation of one software version used in the lab (and data base)	8- validation of software + database	addenda	yes	yes
		9- Anonymous copy of a selected case of a kidney patient waiting for at least one year a postmortem kidney (reports of the tests for registration on the waiting list + periodic monitoring of antibody detection and	9- Report _ Kidney postmortem	addenda	yes	yes
		10- Anonymous copy of a selected case of a kidney patient waiting for a living donor (reports of the tests performed before the kidney transplantation, including report to the clinic)	10- Report _ Kidney living	addenda	yes	yes
		11- The last virtual XM (+ protocole + report to clinicians + re-evaluation of the retrospective crossmatches	11-Virtual XM	addenda	yes	yes

		11- The last virtual XM (+ protocole + report to clinicians + re-evaluation of the retrospective crossmatches after virtual crossmatching)	11-Virtual XM	addenda	yes	yes
		12- Anonymous copy of a selected case of other clinical categories (excluding HSCT)	12- Reports _ other categories	addenda	yes	yes
		If a new method/reagent:				
		1) Validation of the new method/reagent	A- New method/reagents	addenda	yes	yes
		2) Validation/Qualification of a new intrument (if relevant)	B- New instrument	addenda	yes	yes
		3) All MOP	C- NewMOP	addenda	yes	yes
		4) EPT results	D- NewEPT	addenda	yes	yes
		5) Technicien competencies	E- New competencies	addenda	yes	yes
Connection between the the two inspectors						
Inspectors	**at least 2 weeks before the inspection date**	**Inspectors meeting to check all documents and prepare the inspection --> who does what + fulfill the checklist**				
		1) Who does what on site / virtual				
		2) Preparation of a list of document to prepare for the "virtual inspector" : tracability				
		ex: Records of competency of 2 techniciens / Monitoring of one method/ Documentation of calibration of one pipette/Result of one EPT tested/Corrective actions of EPT/ Work sheet				
		3) Preparation of a list of additional documents				
		4) Fullfill partially the checklist based on documents				
		5) Arrange a way to communicate the day of the inspection (not including the lab)				
Connection between the laboratory and the inspectors						
Lab director	**at least 1-2 weeks before the inspection date**	**establish a connection with the Inspectors to:**				
		1) Test the connection and share of screens/documents				
		2) Define with the labo who will answer the questions on site and virtually				
		3) Define the process of the inspection (possibility to finish the day after, virtually: deficiencies/Corrective actions/Check list)				
		4) Preparation of the documents for the "virtual inspector" (tracability) + additional documents, for the day of inspection				
Inspection day						
		Not more than 5 hours				
		Breaks are welcome				
		The morning --> Meeting with the two inspectors and the director				
		The morning --> Meeting with the inspector on site, the director and personnal				
		The morning --> Tour of the lab by the inspector on site				

Changes due in 2021

	Retiring	New
Chair	Andrea Harmer	Blanka Vidan Jeras
Co-Chair	Ed Petershofen	Christien Voorter
General Secretary	Luca Mascaretti	Sabine Scherer
Commissioner Region 2	Christien Voorter	Junior Lardy
Commissioner Region 3	Martin Howell	Colin Brown
Commissioner Region 3	Ann-Margaret Little	Kay Poulton
Commissioner Region 4	Matthias Marget	
Commissioner Region 5	Blanka Vidan Jeras	Zorana Grubic
Commissioner Region 6	Dominique Masson	Sylvie Ferrari-Lacraz
Commissioner Region 7	Luca Mascaretti	
Commissioner Region 8	Amal Bishara	Nina Svetlicky

Nomination process for Commissioners

Regional Commissioner
Appointment and Term

- is proposed by the chairperson of the AC following consultation with relevant National Scientific Societies
- is approved and appointed by the EFI Executive Committee
- the term of office is 3 years with the option of reappointment by the responsible Chairperson for two renewable 3-year terms. Reappointment is subject to approval by the EFI Executive Committee. Within the first six months, the activities of the newly appointed commissioner will be supervised by his/her predecessor

Qualifications

- is an active inspector
- is a member of EFI
- is employed in an EFI accredited laboratory of the same region