

Portugal - More stringent blood donor testing requirements 2015 Mapping exercise

Colour key	
	Minimum requirements as set out in Directive 2004/23/EC
	More stringent testing - legally binding on national level
	More stringent testing - recommended on national level
	Not legally binding and not recommended on national level

Non-reproductive tissues and cells

Tested pathogen	Donor test/ technique	Legally binding	Recommended on national level	Recommending authority/ association	Circumstances for application			Regional differences	Further comments
					Donor profile	Tissue/cell type	Comments		
VIRAL									
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	all	all		NO	
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT	YES	NO	N/A	all	all	no comments		
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all		NO	
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	Hematopoietic Progenitor Cells.	Only when Anti-HBc is reactive.		
	HBV NAT	YES	NO	N/A	all	all	no comments		
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	
	HCV NAT	YES	NO	N/A	all	all	no comments		
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	NO	N/A	Donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas	all			

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					Donor profile	Tissue/cell type	Comments		
	HTLV-1 NAT	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	Hematopoietic Progenitor Cells	no comments		
	Other technique								
HTLV-2	Technique not specified							NO	
	Anti-HTLV-2	YES	NO	N/A	Donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.	all	no comments		
	HTLV-2 NAT	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	Hematopoietic Progenitor Cells.	no comments		
	Other technique								
Chikungunya virus									
Cytomegalovirus	Technique not specified	YES	NO	N/A	all	all	no comments	NO	

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					Donor profile	Tissue/cell type	Comments			
	Anti-CMV	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	all	CMV positive tissues are not recommended for application into immunodeficient patients, however, in urgent cases, and when in shortage for some type of tissues (for instances when skin is needed in cases of severe burns), this criterion is not applied.			
	CMV NAT									
	Other technique									
Dengue Virus										
Ebola Virus	Technique not specified								NO	
Epstein-Barr virus	Technique not specified								NO	
Hepatitis E										
H1N1	Technique not specified	NO	YES	IPST: http://www.ipst.pt/SiteIPST/files/circular_normativa_n_17GDG.pdf	In certain circumstances of outbreaks, when there is suspicion of a possible infection, and only if donation is urgent.	Hematopoietic Progenitor Cells.	no comments	NO		
Leishmaniasis										
Toxoplasmosis	Technique not specified	YES	NO	N/A	In certain circumstances that might require additional testing depending on the donor's history.	Depending on the characteristics of the tissue or cells donated.	Usually, donors with risk for Toxoplasmosis are not considered	NO		
	Anti-Toxoplasma gondii									
	Microscopy									
	Other technique									
Trypanosomiasis	Technique not specified	YES	NO	N/A	In certain circumstances that might require additional testing depending on the donor's history.	Depending on the characteristics of the tissue or cells donated.	Usually, donors with risk for Trypanosomiasis are not considered	NO		

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					Donor profile	Tissue/cell type	Comments		
	Anti- <i>Trypanosoma cruzi</i>								
	Microscopy								
	Other technique								
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	all	all		NO	
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform encephalopathies									
Other Tests									
ABO blood group testing	ABO typing	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	all	no comments	NO	
	Other technique								
RhD blood group testing	RhD typing	YES	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	all	no comments	NO	
	Other technique								

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					Donor profile	Tissue/cell type	Comments		
HLA testing	Technique not specified							NO	
	HLA Ab								
	HLA Ag								
	HLA gene	NO	YES	There is NO national recommendation, however, it is an IPST (Instituto Português do Sangue e da Transplantação) institutional requisite within IPST organic units.	all	all	HLA typing is carried out whenever appropriate determine compatibility; for PH, SCU, corneal tissues...		
	Other technique								
Genetic testing, please specify condition									

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Reproductive tissues and cells

Tested pathogen	Donor test/ technique	Legally binding	Recommended on national level	Recommending authority/ association	Circumstances for application			Regional differences	Further comments
					Donor profile	Tissue/cell type	Comments		
VIRAL									
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	Testing for HIV 1 and 2 is mandatory for partner and non partner donation. In case of partner donation with a positive result for HIV it is required a system	All	NAT is not mandatory for HIV but it requires a second test on samples collected after quarantine period. If the sample is additionally tested for HIV	NO	For non-partner donation blood samples must be obtained in the 3 months prior to donation. Non-partner sperm donations must be quarantined for a minimum of 180
	Anti-HIV 2	YES	NO	N/A					
	HIV 1p24								
	HIV NAT								
Hepatitis B	Other technique				Testing for HBV is mandatory for partner and non partner donation. In case of partner donation with a positive result for HBV it is required a system	All reproductive T&C	NAT is not mandatory for HCV but it requires a second test on samples collected after quarantine period. If the sample is additionally tested for HCV	NO	For non-partner donation blood samples must be obtained in the 3 months prior to donation. Non-partner sperm donations must be quarantined for a minimum of 180
	HBs Ag	YES	NO	N/A					
	Anti-HBc	YES	NO	N/A					
	Anti-HBs								
Hepatitis C	HBV NAT				In the case of partner donation not for direct use, the clinician responsible for the donor		NAT is not mandatory for HCV but it requires a second test on samples collected after quarantine	NO	For non-partner donation blood samples must be obtained at the time of donation. Non-partner
	Other technique								
	HCV NAT								
HTLV-1	Technique not specified				HTLV-I antibody testing must be performed for donors living in or coming from high-incidence areas or with sexual partners	All	No comments	NO	Recommendation of the National Competent Authority to consider the ECDC HTLV prevalence map.
	Anti-HTLV-1	YES	NO	N/A					
	HTLV-1 NAT								
HTLV-2	Other technique				HTLV-II antibody testing must be performed for donors living in or coming from high-incidence areas or with sexual partners	All	No comments	NO	Recommendation of the National Competent Authority to consider the ECDC HTLV prevalence map.
	Technique not specified								
	Anti-HTLV-2	YES	NO	N/A					
Chikungunya virus	HTLV-2 NAT				In certain circumstances that might require additional testing depending on the donor's history, and the		No comments	NO	Whenever there is an outbreak with
	Other technique								
	CMV NAT								
Cytomegalovirus	Technique not specified	YES	NO	N/A			No comments	NO	
	Anti-CMV								
	Other technique								
Dengue Virus									Whenever there is an outbreak with relevance to reproductive T&C donation, there is a national notice defining additional measures or deferral.
Ebola Virus									Whenever there is an outbreak with relevance to reproductive T&C donation, there is a national notice defining additional measures or deferral.
Epstein-Barr virus									There are no binding obligations, but centres can define more stringent testing requirements .

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					Donor profile	Tissue/cell type	Comments		
Hepatitis E									There are no binding obligations, but centres can define more stringent testing requirements for non-partner donation.
Human Parvovirus B19									There are no binding obligations, but centres can define more stringent testing requirements .
Herpes simplex virus									There are no binding obligations, but centres can define more stringent testing requirements .
Leishmaniasis									
Malaria	Technique not specified	YES	NO	N/A	In certain circumstances additional testing is required depending on the donor's history, and the characteristics of the tissue or cells donated. This reference applies to partner and non-partner donation.	All	No comments	NO	
	Microscopy								
	<i>Plasmodium sp.</i> . Ab								
	<i>Plasmodium sp.</i> . Ag								
	<i>Plasmodium sp.</i> . Ag - rapid test								
	<i>Plasmodium sp.</i> . NAT								
Other technique									
Toxoplasmosis									
Trypanosomiasis	Technique not specified	YES	NO	N/A	Testing applies for all donations and donor profiles (partner and non-partner donation).	All	No comments	NO	
	Anti- <i>Trypanosoma cruzi</i>								
	Microscopy								
	Other technique								
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	This reference applies to partner and non-partner donation.	All	The National Law requires testing for non-partner donation. The National ART CA add the obligation to screen also for partner donation.	NO	
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>	Technique not specified				For non-partner donation	Sperm	No comments	NO	
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT	YES	NO	N/A					
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									

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					Donor profile	Tissue/cell type	Comments		
Q-fever									Whenever there is an outbreak with relevance to reproductive T&C donation, there is a national notice defining additional
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform									
Other Tests									
ABO blood group testing	ABO typing	NO	YES	National ART CA	For non-partner donation	All	No comments	NO	
	Other technique								
RhD blood group testing	RhD typing	YES	NO	N/A	In certain circumstances that might require additional testing depending on the donor's history, and the characteristics of the tissue or cells donated. This reference applies to partner and non-partner donation.	All	No comments	NO	
	Other technique								
HLA testing	Technique not specified	YES	NO	N/A	For partner donation	Embryos	No comments	NO	When there is a forceful need to obtain compatible HLA group for the purposes of treating a serious illness. Must be authorised by the National CA.
	HLA Ab								
	HLA Ag								
	HLA gene								
Other technique									
Genetic testing, please specify condition	Specify technique	YES	NO	N/A	For non-partner donation	All	No comments	NO	Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out.