

**Spain - 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	Recom mende	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	YES	Spanish Tissue Banks Association	all	all		NO		
	Anti-HIV 2	YES	YES	Spanish Tissue Banks Association	all	all				
	HIV 1p24	NO	YES	Spanish Tissue Banks Association	all	all	no comments			
	HIV NAT	NO	YES	Spanish Tissue Banks Association	living donors	all	optional testing to avoid re-testing after 180 days in case of long term storage			
	Ag HIV Other technique									
Hepatitis B	HBs Ag	YES	YES	Spanish Tissue Banks Association	all	all		NO		
	Anti-HBc	YES	YES	Spanish Tissue Banks Association	all	all				
	Anti - HBs									optional testing, in particular performed when HBs Ag negative and Anti HBc positive
	HBV NAT	NO	YES	Spanish Tissue Banks Association	all	all	optional testing, in particular performed when HBs Ag negative and Anti HBc positive			
	Other technique									
Hepatitis C	Anti-HCV	YES	YES	Spanish Tissue Banks Association	all	all	no comments	NO		
	HCV NAT	YES	YES	Spanish Tissue Banks Association	all	only for HPC	no comments			
	Other technique									
HTLV-1	Technique not specified								NO	
	Anti-HTLV-1	YES	NO	N/A	donors living in or originating from a high prevalence area, or parents or sexual partners originating from those areas	all	no comments			

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					Donor profile	Tissue/cell type	Comments		
	HTLV-1 NAT	NO	YES	Spanish Tissue Banks Association	living donors	all	testing is performed to avoid repeat sampling and additional testing after 180 days when tissues and cells can be stored for long time periods		
	Other technique								
HTLV-2	Technique not specified							NO	
	Anti-HTLV-2	YES	NO	N/A	donors living in or originating from a high prevalence area, or parents or sexual partners originating from those areas	all	no comments		
	HTLV-2 NAT	NO	YES	Spanish Tissue Banks Association recommended for all donors	living donors	all	testing is performed to avoid repeat sampling and additional testing after 180 days when tissues and cells can be stored for long time periods		
	Other technique								
Chikungunya virus									optional testing depending on clinical history or epidemiologic risk of the disease
Cytomegalovirus									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Dengue virus									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Epstein-Barr virus									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Hepatitis E									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Human Parvovirus B19									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Herpes simplex virus									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated

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					Donor profile	Tissue/cell type	Comments		
West Nile Virus									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
specify pathogen									
PARASITIC									
Babesiosis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Leishmaniasis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Malaria									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Toxoplasmosis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Trypanosomiasis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	all	all		NO	
	Anti- <i>T. pallidum</i>	YES	YES	Spanish Tissue Banks Association	all	all	no comments		
	Microscopy								
	<i>T. pallidum</i> NAT	YES	YES	Spanish Tissue Banks Association	all	all	testing is performed when the non-specific test is positive		
	Other technique								
<i>Chlamydia trachomatis</i>									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
<i>Neisseria gonorrhoeae</i>									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Brucellosis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated

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					Donor profile	Tissue/cell type	Comments			
Tuberculosis									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated	
Q-fever									testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated	
specify pathogen										
FUNGI										
specify pathogen										testing may be performed depending on donor's history and on the characteristics of the tissue or cells donated
Transmissible spongiform encephalopathies										
Other Tests										
ABO blood group testing										
RhD blood group testing										
HLA testing										
Genetic testing, please specify										

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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	YES	Real Decreto-ley 9/2014, and professional associations (SEF-Spanish Fertility Society and ASEBIR-Spanish embryologist association recommendations. Links: 1. https://www.boe.es/boe/dias/2014/07/05/pdfs/BOE-A-2014-7065.pdf 2. http://www.sefertilidad.net/docs/biblioteca/libros/recomendaciones.pdf	all	all	Semen: all donors must have a negative Ag HBs and Anti Hbc previous donation and after 180 days. Egg donor : all donor must have a negative AhgHBs and anti Hbc previous every donation . SEF-ASEBIR recommendations: egg donor should have HIV NAT before every donation.	NO		
	Anti-HIV 2	YES	YES	Same as above	all	all	Semen: all donors must have a negative Ag HBs and Anti Hbc previous donation and after 180 days. Egg donor : all donor must have a negative AhgHBs and anti Hbc previous every donation . SEF-ASEBIR recommendations: egg donor should have HIV NAT before every donation.			
	HIV 1p24									
	HIV NAT	YES	YES	Same as above	Non-partner donation of sperm	Sperm	HIV NAT testing allows for release of sperm without repeat testing after 180 days after donation			
	Ag HIV Other technique									
Hepatitis B	HBs Ag	YES	YES	Same as above	all	all	Semen: all donors must have a negative Ag HBs and Anti Hbc previous donation and after 180 days. Egg donor : all donor must have a negative AhgHBs and anti Hbc previous every donation . SEF-ASEBIR recommendations: egg donor should have HBV NAT before every donation.	NO		

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					Donor profile	Tissue/cell type	Comments		
	Anti-HBc	YES	YES	Same as above	all	all	Semen: all donors must have a negative Ag HBs and Anti Hbc previous donation and after 180 days. Egg donor : all donor must have a negative AhgHBs and anti Hbc previous every donation . SEF-ASEBIR recommendations: egg donor should have HBV NAT before every donation.		
	Anti - HBs								
	HBV NAT	YES	YES	Same as above	all	Sperm	Testing is performed when the donation is not in quarantine		
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all	Semen: all donors must have a negative Ag HBs and Anti Hbc previous donation and after 180 days. Egg donor : all donor must have a negative AhgHBs and anti Hbc previous every donation . SEF-ASEBIR recommendations: egg donor should have HCV NAT before every donation.	NO	
	HCV NAT	YES	NO	N/A	all	Sperm	Testing is performed when the donation is not in quarantine		
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	YES	Same as above	Donors living in or originating from areas of high prevalence of HTLV-1	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2	Technique not specified							NO	
	Anti-HTLV-2	YES	YES	Same as above	Donors living in or originating from areas of high prevalence of HTLV-2	all	no comments		
	HTLV-2 NAT	YES	NO	N/A	Donors living in or originating from areas of high prevalence	all	no comments		
	Other technique								
Chikungunya virus									
Cytomegalovirus									Additional tests (malaria, toxoplasma, Tripanosoma cruzi, dengue, CMV, VEB, RhD) could be required in specific circumstances:
Dengue Virus									Same as above
Ebola Virus									
Epstein-Barr virus									Same as above

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					Donor profile	Tissue/cell type	Comments		
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									
Rubella									
specify pathogen									
PARASITIC									
Babesiosis									
Malaria								Same as above	
Toxoplasmosis								Same as above	
Trypanosomiasis								Same as above	
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	YES	Same as above	According to EU Directive tissues and cells	all	no comments	NO	
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
Other technique									
<i>Chlamydia trachomatis</i>	Technique not specified							NO	
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT	YES	YES	Same as above	Sperm donors	Sperm	Testing is performed with an urine sample		
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform encephalopathies									
Other Tests									
ABO blood group testing	ABO typing	YES	YES	Same as above	all	all	no comments	NO	
RhD blood group testing	RhD typing	YES	YES	Same as above	all	all	no comments	NO	
HLA testing									
Genetic testing, please specify	Specify technique	YES	YES	Same as above	all	all	physician criteria: karyotype (always), cystic fibrosis, etc.	NO	