

Germany - 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	Validation of the serological and NAT assays for use with cadaveric samples are required (recommendations for validation studies: http://www.pei.de/DE/infos/pu/ge)
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT	NO	YES	Paul-Ehrlich-Institut (PEI)	all	all except cornea and skin			
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all		NO	Validation of the serological and NAT assays for use with cadaveric samples are required (recommendations for validation studies: http://www.pei.de/DE/infos/pu/ge)
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs								
	HBV NAT	NO	YES	PEI	all	all except cornea and skin			
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	Validation of the serological and NAT assays for use with cadaveric samples are required
	HCV NAT	NO	YES	PEI	all	all except skin			
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	NO	N/A	donors from countries with high prevalence of HTLV-1	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2									
Chikungunya virus									
Cytomegalovirus									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
Dengue Virus									
Ebola Virus									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated

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Epstein-Barr virus									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
Toxoplasmosis									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
Trypanosomiasis									Additional testing may be required depending on the donor's history and 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	Validation of the serological and NAT assays for use with cadaveric samples are required (recommendations for validation studies: http://www.pei.de/DE/infos/pu/ge)
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>	Technique not specified	NO	YES	PEI	living	only for amnion membrane		NO	
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT								
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									

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					Donor profile	Tissue/cell type	Comments		
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform									
Other Tests									
ABO blood group testing									
RhD blood group testing									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
HLA testing									Additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated
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	all	all		NO	
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT								
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all		NO	
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs								
	HBV NAT								
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	
	HCV NAT								
	Other technique								
HTLV-1	Technique not specified	YES	NO	N/A	Donors from countries with high prevalence of HTLV-1	all	no comments	NO	
	Anti-HTLV-1	YES	NO	N/A	donors from countries with high prevalence of HTLV-1	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2									
Chikungunya virus									
Cytomegalovirus									Additional testing may be required depending on the donor's history
Dengue Virus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									

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Malaria									Additional testing may be required depending on the donor's history
Toxoplasmosis									
Trypanosomiasis									Additional testing may be required depending on the donor's history
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	Donations other than by partners	all		NO	
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
<i>Chlamydia trachomatis</i>	Technique not specified	YES	NO	N/A	donations other than by partners	sperm	no comments	NO	Sperm donors must additionally be negative for chlamydia on a urine sample tested by nucleic acid amplification technique (NAT)
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT	YES	NO	N/A	donations other than by partners	Sperm			
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform									
Other Tests									
ABO blood group testing									
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HLA testing									
Genetic testing, please specify condition									