

## Sweden - 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		
<b>VIRAL</b>									
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	all	all		NO	The reason for this is the interpretation of DIR 2006/17/EC annex II p 2.5 (b) which has been interpreted as "if the tissue (i.e bone) is used within 180 days there is no requirement for a second test" (!) In practice, it meant that bones not yet used after 180 days were transferred from released to quarantain until results from the second test was ready. For any immunologist this praxis was unacceptable and therefore most of the TE's handling bone now use the NAT-testing offered at a reasonable price by the reimbursement from the Tissue Council.
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24	YES	NO	N/A	all	all	no comments		
	HIV NAT	NO	YES	Tissue Council	Living and diseased	Bone, tendons	1) Tissue Council promotes the use of NAT testing by reimbursement to one laboratory who provides the tests at a reduced cost. The kit : Multiplex PCR HCV/HBV/HIV		
	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	NO	YES	Tissue Council	Living and deceased	Bone, tendons	see above 1)		
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	
	HCV NAT	NO	YES	Tissue Council	Living and deceased	Bone, tendons	see above 1)		
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	NO	N/A	all	all	2) if the donor or his/hers sexual partner or parents originates from an area with high pre-valens it is mandatory		
	HTLV-1 NAT								
	Other technique								
HTLV-2	Technique not specified							NO	

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					Donor profile	Tissue/cell type	Comments		
	Anti-HTLV-2	YES	NO	N/A	all	all	2) if the donor or his/hers sexual partner or parents originates from an area with high pre-valens it is mandatory		
	HTLV-2 NAT								
	Other technique								
Chikungunya virus									
Cytomegalovirus	Technique not specified	YES	NO	N/A	all	HPC	3) depending on the background of the donor and the recipient	NO	
	Anti-CMV								
	CMV NAT Other technique								
Dengue Virus	Technique not specified	YES	NO	N/A	all	HPC	3) depending on the background of the donor and the recipient and 4) seasonal risks	NO	
	Anti-DENV								
	NAT Other technique								
Ebola Virus	Technique not specified								* special requirements may be inferred by the National Board of health and welfare if
Epstein-Barr virus	Technique not specified	YES	NO	N/A	all	HPC	3) depending on the background of the donor and the recipient	NO	
	Anti-EBV								
	Other technique								
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus	Technique not specified	YES	NO	N/A	all	HPC	3) depending on the background of the donor and 4) the seasonal risks	NO	
	WNV minipool NAT								
	WNV ID NAT Other technique								
specify pathogen									
<b>PARASITIC</b>									
Babesiosis									
Leishmaniasis	Technique not specified	YES	NO	N/A	all	all	3) depending on the background of the donor	NO	not eligible donor or testing

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					Donor profile	Tissue/cell type	Comments		
	Microscopy Anti - <i>Leishmania sp.</i> <i>Leishmania sp.</i> NAT Other technique								
Malaria	Technique not specified	YES	NO	N/A	all	all	3)depending on the background of the donor	NO	not eligible donor or testing
	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	Technique not specified	YES	NO	N/A	all	all	3)depending on the background of the donor	NO	
	Anti- <i>Toxoplasma gondii</i> Microscopy Other technique								
Trypanosomiasis	Technique not specified	YES	NO	N/A	all	all	3) depending on the background of the donor	NO	
	Anti- <i>Trypanosoma cruzi</i> Microscopy Other technique								
specify pathogen									
<b>BACTERIAL</b>									
<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									
<b>FUNGI</b>									
specify pathogen									
<b>Transmissible spongiform</b>									
<b>Other Tests</b>									
ABO blood group testing	ABO typing	YES	YES	see comment 5)	allogeneic donors	HSC	5) recommended by some orthopedic centers for bone donors	YES	

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					Donor profile	Tissue/cell type	Comments			
	Other technique									
RhD blood group testing										
HLA testing	Technique not specified	NO	YES	not legally binding, but a pre-requisit for the treatment. Techniques used are according to EFI-accreditation	allogeneic donors	HSC	no comments	NO		
	HLA Ab									
	HLA Ag									
	Other technique									
Genetic testing, please specify condition	Specify technique	NO	YES	if relevant / identified risk (National Board of Health and Welfare)	allogeneic donors	HSC	no comments	NO		

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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		
<b>VIRAL</b>									
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	all	gametes	5) third party sperm donors should be quarantined for 180 days and then retested	NO	
	Anti-HIV 2	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)		
	HIV 1p24	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)		
	HIV NAT								
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	gametes	third party sperm donors see above	NO	
	Anti-HBc	YES	NO	N/A	all	gametes	third party sperm donors see above		
	Anti - HBs								
	HBV NAT								
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)	NO	
	HCV NAT								
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)		
	HTLV-1 NAT								
	Other technique								
HTLV-2	Technique not specified							NO	
	Anti-HTLV-2	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)		
	HTLV-2 NAT								
	Other technique								
Chikungunya virus									
Cytomegalovirus									may be tested depending on the background of the donor ( see sheet 1 non-reproductive T&C )
Dengue Virus									
Ebola Virus									* special requirements may be inferred by

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					Donor profile	Tissue/cell type	Comments		
									the National Board of health and welfare if relevant
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									may be tested depending on the background/seasonal risks of the donor ( see sheet 1 all other tissues and cells )
specify pathogen									
<b>PARASITIC</b>									
Babesiosis									
Leishmaniasis									may be tested depending on the background/travel history of the donor ( see sheet 1 all other tissues and cells )
Malaria									
Toxoplasmosis									may be tested depending on the background/travel history of the donor ( see sheet 1 all other tissues and cells )
Trypanosomiasis									may be tested depending on the background/travel history of the donor ( see sheet 1 all other tissues and cells )
specify pathogen									
<b>BACTERIAL</b>									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	all	gametes	third party sperm donors see above comment 5)	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	NO	N/A	third party sperm donors	third party sperm donors			
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>	Technique not specified							NO	
	<i>N. gonorrhoeae</i> NAT	YES	NO	N/A	third party sperm donors	third party sperm donors	no comments		
	Culture								

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					Donor profile	Tissue/cell type	Comments		
	Other technique								
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
<b>FUNGI</b>									
specify pathogen									
Transmissible spongiform encephalopathies									
<b>Other Tests</b>									
ABO blood group testing									
RhD blood group testing									
HLA testing									
Genetic testing, please specify condition									only permitted if relevant / identified risk