

Romania - 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	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	NO
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs	YES	NO	N/A	all	all	no comments		
	HBV NAT								
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	NO
	HCV NAT								
	Other technique								
HTLV-1	Technique not specified	NO	NO	N/A	N/A	N/A	no comments	NO	NO
	Anti-HTLV-1	YES	NO	Ministry of Health - Order no. 1763/2007 - www.transplant.ro	For donors coming from high risk areas or whose sexual partners or parents come from high risk areas.	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2									
Chikungunya virus									
Cytomegalovirus									Anti-CMV testing is not mandatory by law, but, because the prevalence of infection with CMV is very high in Romania, the anti-CMV testing is usually performed, even if it is not mandatory.
Dengue Virus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									

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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		
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria									
Toxoplasmosis									
Trypanosomiasis									
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	all	all		NO	NO
	Anti-T. <i>pallidum</i>								
	Microscopy								
	T. <i>pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform									
Other Tests									
ABO blood group testing	ABO typing	YES	NO	N/A	all	all	no comments	NO	NO
	Other technique								
RhD blood group testing	RhD typing	YES	NO	N/A	all	all	no comments	NO	NO
	Other technique								
HLA testing									
Genetic testing, please specify condition									

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	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

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	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	NO
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs	YES	NO	N/A	all	all	no comments		
	HBV NAT								
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	NO
	HCV NAT								
	Other technique								
HTLV-1	Technique not specified							NO	NO
	Anti-HTLV-1	YES	YES	Ministry of Health - Order no. 1763/2007 - www.transplant.ro	For donors coming from high risk areas or whose sexual partners or parents come from high risk areas.	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2									
Chikungunya virus									
Cytomegalovirus									Anti-CMV testing is not mandatory by law, but, because the prevalence of infection with CMV is very high in Romania, the anti-CMV testing is usually performed, even if it is not mandatory.
Dengue Virus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									

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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		
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria									
Toxoplasmosis									
Trypanosomiasis									
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	ALL DONORS	ALL DONORS		NO	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	all sperm donors except partners	sperm	mandatory for all sperm donors except partners		
	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	NO	N/A	all	all	no comments	NO	NO
	Other technique								
RhD blood group testing	RhD typing	YES	NO	N/A	all	all	no comments	NO	NO
	Other technique								
HLA testing									

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					Donor profile	Tissue/cell type	Comments		
Genetic testing, please specify condition	Specify technique	YES	YES	Romanian Association of Embryologists	Non-partner donation: donors with history of autosomal recessive genetic diseases in family	all	no comments	NO	NO