

Bulgaria - 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		
VRAL									
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	all	all	For living donors if HIV has been tested by NAT no further testing is mandatory	NO	For tissues and cells that can be stored for long periods, the test must be repeated after 180 days; for child donors aged up to 3 months, the mother is also tested after delivery; all tests must be performed in accredited laboratories
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba%206%202014.pdf	living donors only	all			
	Other technique								
Hepatitis B	HBs Ag	YES	YES		all	all	Additional testing if Anti-HBc is positive and HBsAg is negative. Tests for active replication and/or viral load. Anti-HBs should be > 50 IU/l.	NO	For tissues and cells that can be stored for long periods, the test must be repeated after 180 days; for child donors aged up to 3 months, the mother is also tested after delivery; all tests must be performed in accredited laboratories
	Anti-HBc	YES	YES		all	all			
	Anti - HBs								
	HBV NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba%206%202014.pdf	living donors only	all			
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all	no comments	NO	For tissues and cells that can be stored for long periods, the test must be repeated after 180 days; for child donors aged up to 3 months, the mother is also tested after delivery; all tests must be performed in accredited laboratories
	HCV NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba%206%202014.pdf	living donors only	all	no comments		
	Other technique								
HTLV-1	Technique not specified							NO	no comments
	Anti-HTLV-1	YES	NO	N/A	donors/partners/parents originating/have been living/coming from high risk area	all	no comments		
	HTLV-1 NAT								

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					Donor profile	Tissue/cell type	Comments		
	Other technique								
HTLV-2									
Chikungunya virus									Tests should be performed only if donor history reveals a high risk for this infectious disease
Cytomegalovirus	Technique not specified							NO	no comments
	Anti-CMV	YES	NO	N/A	In immuno-suppressed donors	all	no comments		
	CMV NAT								
	Other technique								
Dengue Virus									Tests should be performed only if donor history reveals a high risk for this infectious disease
Ebola Virus									Tests should be performed only if donor history reveals a high risk for this infectious disease
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									Tests should be performed only if donor history reveals a high risk for this infectious disease
West Nile Virus									Tests should be performed only if donor history reveals a high risk for this infectious disease
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria	Technique not specified	YES	NO	N/A	Testing is mandatory for all donors with travel history in a high-risk country or high-risk of acquiring the disease.	all	no comments	NO	No local malaria. Some local short outbursts from imported malaria.
	Microscopy								
	<i>Plasmodium sp.</i> . Ab								
	<i>Plasmodium sp.</i> . Ag								
	<i>Plasmodium sp.</i> . Ag - rapid test								
<i>Plasmodium sp.</i> . NAT									

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					Donor profile	Tissue/cell type	Comments		
	Other technique								
Toxoplasmosis									
Trypanosomiasis									Tests should be performed only if donor history reveals a high risk for this infectious disease
specify pathogen									
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	partner and non-partner	all	no comments	NO	If the non-specific antibody test is positive - specific tests are mandatory (e.g. NAT or TPPA assay)
	Anti- <i>T. pallidum</i>	YES	NO	N/A	all	all	mandatory VDRL		
	Microscopy								
	<i>T. pallidum</i> NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba%206%202014.pdf	all	all	recommended		
	Other technique	NO	YES			all	TPPA assay mandatory if VDRL proves positive		
<i>Chlamydia trachomatis</i>	Technique not specified	YES	NO	N/A	Mandatory only if donor history reveals elevated risk of the infectious agent		no comments		
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT								
	Culture								
Other technique									
<i>Neisseria gonorrhoeae</i>									Tests should be performed only if donor history reveals a high risk for this infectious disease
Brucellosis									
Tuberculosis									Tests should be performed only if donor history reveals a high risk for this infectious disease

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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		
Q-fever									Tests should be performed only if donor history reveals a high risk for this infectious disease
specify pathogen									
FUNGI									
specify pathogen									
Transmissible spongiform encephalopathies									Tests should be performed only if donor history reveals a high risk for this infectious disease
Other Tests									
ABO blood group testing	ABO typing	YES	NO	N/A	all	all	no comments	NO	no comments
	Other technique								
RhD blood group testing	RhD typing	YES	NO	N/A	all	all	no comments	NO	no comments
	Other technique								
HLA testing	Technique not specified							NO	Immunological preparation for allogeneic bone marrow transplantation and peripheral hematopoietic stem cells and stem cells from umbilical cord is performed according to Ordinance № 43 of 26 August 2010 establishing medical standards "immunological preparation for organ, tissue and cell transplantation"
	HLA Ab	YES	YES	Bulgarian Association of Clinical Immunology	all	see further comments	no comments		
	HLA Ag	YES	YES	Bulgarian Association of Clinical Immunology	all	see further comments	no comments		
	HLA gene	YES	YES	Bulgarian Association of Clinical Immunology	all	see further comments	no comments		
	Other technique								
Genetic testing, please specify condition									Tests should be performed only if donor history reveals a high risk for inherited diseases

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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 comments	NO	Oocyte donors are tested at recruitment and at the day of donation (NAT recommended) and results should be available before transfer of embryos. Sperm is usually quarantined for 180 days and donors retested after this period; all tests must be performed only in accredited laboratories.
	Anti-HIV 2	YES	NO	N/A	all	all	no comments		
	HIV 1p24								
	HIV NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba_28_Work.pdf	only for non partner donors	all	Sperm donors can skip after-180-days testing if tested by NAT		
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all	no comments	NO	Oocyte donors are tested at recruitment and at the day of donation (NAT recommended) and results should be available before transfer of embryos. Sperm donors are usually quarantined for 180 days and retested; all tests only in accredited laboratories.
	Anti-HBc	YES	NO	N/A	all	all	no comments		
	Anti - HBs								
	HBV NAT	NO	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba_28_Work.pdf	only for non partner donors	all	Sperm donors can skip after-180-days testing if tested by NAT		
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all	no comments	NO	Oocyte donors are tested at recruitment and at the day of donation (NAT recommended) and results should be available before transfer of embryos. Sperm donors are usually quarantined for 180 days and retested.
	HCV NAT	YES	YES	Ministry of Health; http://bgtransplant.bg/iat/docs/Naredba_28_Work.pdf	only for non partner donors	all	Sperm donors can skip after-180-days testing if tested by NAT		
	Other technique								
HTLV-1	Anti-HTLV-1	YES	NO	N/A	Testing for antibodies to HTLV-I is performed for all donors who were born or lived in areas with high risk or have sexual partners originating from those regions, as well as the donor's parents are from such regions.	all	no comments	NO	
	HTLV-1 NAT								
	Other technique								
HTLV-2									
Chikungunya virus									No cases yet in Bulgaria, but since 2011 <i>Aedes</i>

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					Donor profile	Tissue/cell type	Comments		
									<i>albopictus</i> is found in Bulgaria (mostly eastern parts near the Black sea)
Cytomegalovirus	Technique not specified							NO	
	Anti-CMV	YES	NO	N/A	Testing required in high risk donors (if health history discloses such risk).	all	no comments		
	CMV NAT								
	Other technique								
Dengue Virus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria	Technique not specified	YES	NO	N/A	For all donors with a history of travel in a high risk country or the presence of a high risk for the disease.	all	no comments	NO	No local malaria. Some local short outbursts from imported malaria.
	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									IgG testing before pregnancy is recommended by TEs as for rubella testing. IgG positive are considered immune. Moderate (24.11% - for 2011) prevalence of seropositive people in the
Trypanosomiasis	Technique not specified	YES	NO	N/A	For all donors with a history of travel in a high risk country or the presence of a high risk for the disease.	all	no comments	NO	
	Anti- <i>Trypanosoma cruzi</i>								
	Microscopy								
	Other technique								

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					Donor profile	Tissue/cell type	Comments		
specify pathogen	specify technique								
BACTERIAL									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	partner and non-partner	all	no comments	NO	If the non-specific antibody test is positive - specific tests are mandatory (e.g. NAT or TPPA assay)
	Anti- <i>T. pallidum</i>	YES	NO	N/A	all	all	mandatory VDRL		
	Microscopy								
	<i>T. pallidum</i> NAT	NO	YES	Ministry of Health;	all	all	recommended		
	Other technique	NO	YES	http://bgtransplant.bg/iat/docs/Naredba_28_Work.pdf	all	all	TPPA assay mandatory if VDRL proves positive		
<i>Chlamydia trachomatis</i>	Technique not specified							NO	EIA still available, but high prevalence of seropositive people. NAT performed from urine in males and from cervical smear in females.
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT	YES	NO	N/A	partner and non-partner	all	no comments		
	Culture								
	Other technique								
<i>Neisseria gonorrhoeae</i>	Technique not specified	YES	NO	N/A	all	all	no comments	NO	Both culture and NAT are allowed.
	<i>N. gonorrhoeae</i> NAT								
	Culture	YES	NO	N/A	all	all	no comments		
	Other technique								
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
<i>Candida</i> spp.	Culture	YES	NO	N/A	all	all	no comments	NO	no comments
Transmissible spongiform	Prion (PrP) detection								
	Other technique								
Other Tests									
ABO blood group testing	ABO typing	YES	NO	N/A	all	all	no comments	NO	no comments
	Other technique								
RhD blood group testing	RhD typing	YES	NO	N/A	all	all	no comments	NO	no comments
	Other technique								
HLA testing									
Genetic testing, please specify condition	Technique not specified	YES	NO	N/A	all	all	Karyotyping, testing for monogenic diseases etc.	NO	Tissue establishments working with non partner donors are karyotyping them as a rule; mandatory by law to test non partner donors if coming from a region or group with high prevalence or with family history of certain genetic diseases (e.g. muscle dystrophia, cystic fibrosis, beta-thalassaemia etc.)