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	Recommending	Circumstances for appli	cation		Regional differences	Further comments
rested pathogen	Donor testy teeningue	Legary britaing	on national level	_	Donor profile	Tissue/cell type	Comments	Regional anterences	Tarther comments
VIDAL			on national level	ductioney, association	Donor profile	1133de/ceil 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		_	1		l			
	HIV NAT	YES	NO	N/A	deceased, living (only allogeneic donors)	all	All deceased donors need to be tested by serological test AND viral NAT-tests (HIV, HBV, HCV). All living donors (allogenic grafts) need to be tested by serological tests AND viral NAT-tests (no quarantine) or 180-day-test (quarantine). Living donors (autologous grafts) need to be tested by serological tests.		
	Ag 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	YES	NO	N/A	deceased, living (only allogeneic donors)	all	All deceased donors need to be tested by serological test AND viral NAT-tests (HIV, HBV, HCV). All living donors (allogenic grafts) need to be tested by serological tests AND viral NAT-tests (no quarantine) or 180-day-test (quarantine). Living donors (autologic grafts) need to be tested by serological tests.		
	Other technique		1	T .		Γ			
Hepatitis C	Anti-HCV HCV NAT	YES	NO NO	N/A N/A	all deceased, living (only allogeneic donors)	all	All deceased donors need to be tested by serological test AND viral NAT-tests (HIV, HBV, HCV). All living donors (allogenic grafts) need to be tested by serological tests AND viral NAT-tests (no quarantine) or 180-day-test (quarantine). Living donors (autologic grafts) need to be tested by serological tests.	NO	
	Other technique								

Tested pathogen	Donor test/ technique	Legally binding	Recommended	Recommending authority/ association	Circumstances for appli	ication	Regional differences	Further comments	
			on national level		Donor profile	Tissue/cell type	Comments		
HTLV-1	Technique not specified	YES	NO	N/A	risk groups	all		NO	
	4			,	3 3 4 4				
	Anti-HTLV-1	YES	NO	N/A	donors living in or	all			
					originating from a high				
					prevalence area, or				
					parents or sexual				
					partners originating				
					from those areas				
	HTLV-1 NAT Other technique	-							
HTLV-2	Technique not specified	YES	NO	N/A	risk groups	all		NO	
HILV-Z	recinique not specifieu	TES	INO	N/A	risk groups	all		INO	
	Anti-HTLV-1								
	HTLV-2 NAT								
	Other technique								
Chikungunya virus	·	•						•	
Cytomegalovirus	Technique not specified	YES	NO	N/A	risk groups	all		NO	
	Anti-CMV								
	CMV NAT								
	Other technique								
Dengue Virus									
Ebola Virus	T 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	VEC	luo.	In. 14	1.,	Τ.,,		Tuo	T
Epstein-Barr virus	Technique not specified	YES	NO	N/A	risk groups	all		NO	
	Anti-EBV								
	Other technique	_							
Hepatitis E	Other technique								
Human Parvovirus B19	e e e e e e e e e e e e e e e e e e e								
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC									
Babesiosis									
Leishmaniasis									
Malaria	Technique not specified	YES	NO	N/A	risk groups	all		NO	
								_	
	Microscopy								
	Plasmodium sp . Ab								
	Plasmodium sp . Ag								
	Plasmodium sp. Ag - rapid								
	test Plasmodium sp. NAT	-							
	riusiiiouiuiii sp. NAT								
	Other technique								
Toyonlasmosis	Other technique	VES	NO	IN/A	risk groups	all		NO	
Toxoplasmosis	Other technique Technique not specified	YES	NO	N/A	risk groups	all		NO	
Toxoplasmosis		YES	NO	N/A	risk groups	all		NO	

Tested pathogen	Donor test/ technique	Legally binding	Recommended on national level	Recommending authority/ association	Circumstances for app	ication	Regional differences	Further comments	
	,	J ,			Donor profile	Tissue/cell type	Comments		
	Microscopy								
	Other technique								
Trypanosomiasis	Technique not specified	YES	NO	N/A	risk groups	all		NO	
	Anti-Trypanosoma cruzi				1				
	Microscopy	-							
:6+1	Other technique								
specify pathogen									
BACTERIAL					_				
Treponema pallidum (Syphilis)	Anti-T. pallidum	YES	NO	N/A	all	all	According to the directive: A validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. A donor whose specimen tests reactive on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use.	NO	
	Microscopy T. pallidum NAT								
	Other technique								
Chlamydia trachomatis									
Neisseria gonorrhoeae									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible									
spongiform									
encephalopathies									
Other Tests									
ABO blood group testing									
RhD blood group	RhD typing	YES	NO	N/A	risk groups	all		NO	
testing	Other technique							1	
HLA testing	Technique not specified	YES	NO	N/A	risk groups	all		NO	
	1			1	1	1	1	4	1

Tested pathogen	Donor test/ technique	Legally binding	Recommended	Recommending	Circumstances for appl	Circumstances for application			Further comments
			on national level	authority/ association	Donor profile	Tissue/cell type	Comments		
	HLA Ab								
	HLA Ag								
	HLA gene								
	Other technique								
Genetic testing, please									
specify condition									

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

Reproductive tissues and cells

Tested pathogen	Donor test/ technique	Legally binding	Recommended		Circumstances for appl	ication		Regional differences	Further comments
	· ·		on national level		Donor profile	Tissue/cell type	Comments		
VIRAL	<u> </u>					•			
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	all except IUI (partner donation, direct use)	all		NO	No testing is required in the case of partner donation of reproductive cells for direct use - IUI.
	Anti-HIV 2	YES	NO	N/A	all except IUI (partner donation, direct use)	all			
	HIV 1p24			•	•				
HIV 1524 HIV NAT	HIV NAT	YES	NO	N/A	sperm donor (non- partner donation) **	sperm	All deceased donors need to be tested by serological test AND viral NAT-tests (HIV, HBV, HCV). All living donors (allogenic grafts) need to be tested by serological tests AND viral NAT-tests (no quarantine) or 180-day-test (quarantine). Living donors (autologous grafts) need to be tested by serological tests.		
	Ag HIV								
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all except IUI (partner donation, direct use)	all		NO	
	Anti-HBc	YES	NO	N/A	all except IUI (partner donation, direct use)	all			
	Anti - HBs								
	HBV NAT	YES	NO	N/A	sperm donors (non- partner donation) **	sperm	**) NAT OR 180-day-re-testing required		
	Other technique						·		
Hepatitis C	Anti-HCV	YES	NO	N/A	all except IUI (partner donation, direct use)	all		NO	
	HCV NAT	YES	NO	N/A	sperm donor (non- partner donation) **	sperm	**) NAT OR 180-day-re-testing required		
	Other technique								
HTLV-1	Technique not specified	NO	NO	N/A	risk groups	all		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			

Tested pathogen	Donor test/ technique	Legally binding	Recommended	Recommending	Circumstances for appl	ication		Regional differences	Further comments
, 3				authority/ association	Donor profile	Tissue/cell type	Comments		
	HTLV-1 NAT					· · · · · ·			
	Other technique								
HTLV-2									
Chikungunya virus									
Cytomegalovirus									
Dengue Virus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus									
specify pathogen									
PARASITIC	_								
Babesiosis									
Leishmaniasis									
Malaria									
Toxoplasmosis									
Trypanosomiasis									
specify pathogen									
BACTERIAL									
Treponema pallidum (Syphilis)	Technique not specified	YES	NO	N/A	non-partner donors	all		NO	
	Anti-T. pallidum								
	Microscopy								
	T. pallidum NAT								
	Other technique								
Chlamydia trachomatis	Technique not specified							NO	
	C. trachomatis DFA								
	C. trachomatis EIA		1	1		1			
	C. trachomatis NAT	NO	NO	N/A	sperm donors (non- partner donation)	sperm			
	Culture								
	Other technique								
Neisseria gonorrhoeae									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
FUNGI									
specify pathogen									
Transmissible									
spongiform									
encephalopathies									
Other Tests ABO blood group									
testing									
RhD blood group testing									

Tested pathogen	Donor test/ technique	Legally binding	Recommended	Recommending	Circumstances for appli	Circumstances for application			Further comments
			on national level	authority/ association	Donor profile	Tissue/cell type	Comments		
HLA testing									
Genetic testing, please									
specify condition									

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