

### Italy - 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		In some regions (e.g. Toscana and Veneto) the NAT test in living donors of tissues is always performed even if serology has been repeated after 180 days.	
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT	YES	NO	N/A	living donor HPCs; for living donor of tissues if serology is not repeated after 180 days	all HPCs (BM, PBSC and CB); all tissues from living donors	no comments		
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all		In some regions (e.g. Toscana and Veneto) the NAT test in living donors of tissues is always performed even if serology has been repeated after 180 days.	Anti - HBs maybe performed if anti - HbC results are positive
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs								
	HBV NAT	YES	NO	N/A	living donor HPCs; for living tissue donor if serology is not repeated after 180 days	all HPCs (BM, PBSC and CB); all tissues from living donors	no comments		
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		In some regions (e.g. Toscana and Veneto) the NAT test in living donors of tissues is always performed even if serology has been repeated after 180	
	HCV NAT	YES	NO	N/A	living donor HPCs; for living tissue donor if serology is not repeated after 180 days	all HPCs (BM, PBSC and CB); all tissues from living donors	no comments		
	Other technique								
HTLV-1	Technique not specified							NO	
	Anti-HTLV-1	YES	NO	N/A	HTLV - 1 testing is carried out only on donors with identified risk	all			
	HTLV-1 NAT								
	Other technique								
HTLV-2	Technique not specified							NO	
	Anti-HTLV-2	YES	NO	N/A	HTLV - 2 testing is carried out only on donors with identified risk	all	no comments		

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					Donor profile	Tissue/cell type	Comments			
	HTLV-2 NAT									
	Other technique									
Chikungunya virus	Technique not specified	YES	NO	N/A	all	all	no comments	NO	All donors that have been in risky areas 28 days before or are symptomatic are excluded without further testing. The testing is	
	Anti-CHIKV									
	CHIKV NAT									
	Other technique									
Cytomegalovirus	Technique not specified							NO	According to the National guidelines on tissues ( <a href="https://www.trapianti.salute.gov.it/imgs/C_17_normativa_27_allegato.pdf">https://www.trapianti.salute.gov.it/imgs/C_17_normativa_27_allegato.pdf</a> ) the NAT test has to be performed if anti -CMV IgM results are positive.	
	Anti-CMV	YES	YES	IBMDR Standard - <a href="http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation">http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation</a> for HPCs. For tissues: Italian guideline on quality and safety of tissues - july 2013.	living and cadaveric donors	HPCs, skin, cardiac valves, vessels, amniotic membrane	no comments			
	CMV NAT									
	Other technique									
Dengue Virus	Technique not specified							NO	All donors that have been in risky areas or are symptomatic are excluded. All the other donors must be tested.	
	Anti-DENV	YES	NO	N/A	all	all	no comments			
	NAT									
	Other technique									
Ebola Virus	Technique not specified							no	All donors that have been in risky areas or are symptomatic are excluded. All the other donors	
	NAT	YES	NO	N/A	all	all	no comments			
	Other technique									
Epstein-Barr virus	Technique not specified							NO	According to the Ministerial Decree n.16 of January 25, 2010 ( <a href="https://www.google.it/#q=decret">https://www.google.it/#q=decret</a>	
	Anti-EBV	YES	NO	N/A	all	all	no comments			
	Other technique									
Hepatitis E										
Human Parvovirus B19										
Herpes simplex virus										
West Nile Virus	Technique not specified							NO		
	WNV minipool NAT									
	WNV ID NAT	YES	NO	N/A	testing is carried out only on donors with identified risk	HPCs and bone only if frozen	no comments			
	Other technique									
specify pathogen										
<b>PARASITIC</b>										
Babesiosis										
Leishmaniasis										
Malaria	Technique not specified							NO	According to the Ministerial Decree n.16 of January 25, 2010 ( <a href="https://www.google.it/#q=decreto+legislativo+16+2010">https://www.google.it/#q=decreto+legislativo+16+2010</a> ) malaria testing has to be performed	
	Microscopy									
	<i>Plasmodium sp.</i> . Ab	YES	NO	N/A	testing is carried out only on donors with identified risk	all	no comments			

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					Donor profile	Tissue/cell type	Comments		
	<i>Plasmodium sp. Ag</i> <i>Plasmodium sp. Ag - rapid test</i> <i>Plasmodium sp. NAT</i> Other technique								depending on the donor's history and the characteristics of the tissues
Toxoplasmosis	IgM on amniotic membrane donors Anti- <i>Toxoplasma gondii</i>  Microscopy Other technique	YES	YES	IBMDR Standard - <a href="http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation-for-HPCs">http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation-for-HPCs</a> .	all donors	all	no comments	NO	According to the Ministerial Decree n.16 of January 25, 2010 ( <a href="https://www.google.it/#q=decreto+legislativo+16+2010">https://www.google.it/#q=decreto+legislativo+16+2010</a> ) and the national guidelines on tissues ( <a href="https://www.trapianti.salute.gov.it/imgs/C_17_normativa_27_allegato.pdf">https://www.trapianti.salute.gov.it/imgs/C_17_normativa_27_allegato.pdf</a> ) toxoplasmosis testing has to be performed on all amniotic membrane donors and for the
Trypanosomiasis	Technique not specified Anti- <i>Trypanosoma cruzi</i>  Microscopy Other technique	YES	NO	N/A	testing is carried out only in donors with identified risk	all	no comments	NO	According to the Ministerial Decree n.16 of January 25, 2010 ( <a href="https://www.google.it/#q=decreto+legislativo+16+2010">https://www.google.it/#q=decreto+legislativo+16+2010</a> ) Trypanosoma testing has to be performed depending on the
specify pathogen									
<b>BACTERIAL</b>	Blood cultures	NO	YES	Jacie Standard - <a href="https://docs.google.com/viewer?a=v&amp;pid=sites&amp;srcid=amFjaWUub3JnfGphY2lfGd4OjM2Mzc5YzZmYTk0YmYzNzY">https://docs.google.com/viewer?a=v&amp;pid=sites&amp;srcid=amFjaWUub3JnfGphY2lfGd4OjM2Mzc5YzZmYTk0YmYzNzY</a>	HPC donors	all HPCs (BM, PBSC and CB)		NO	
<i>Treponema pallidum</i> (Syphilis)	Technique not specified Anti- <i>T. pallidum</i> Microscopy <i>T. pallidum</i> NAT Other technique	YES YES	NO NO	N/A N/A	all all donors	all all	no comments	NO	
<i>Chlamydia trachomatis</i>									
<i>Neisseria gonorrhoeae</i>									
Brucellosis									
Tuberculosis									
Q-fever									
specify pathogen									
<b>FUNGI</b>									
specify pathogen	specify technique	NO	YES	Jacie Standard - <a href="https://docs.google.com/viewer?a=v&amp;pid=sites&amp;srcid=amFjaWUub3JnfGphY2lfGd4OjM2Mzc5YzZmYTk0YmYzNzY">https://docs.google.com/viewer?a=v&amp;pid=sites&amp;srcid=amFjaWUub3JnfGphY2lfGd4OjM2Mzc5YzZmYTk0YmYzNzY</a>	HPC donors	all HPCs (BM, PBSC and CB)	no comments	NO	

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					Donor profile	Tissue/cell type	Comments			
<b>Transmissible spongiform encephalopathies</b>									For HPCs: donors that have performed surgery or transfusion between 1980 to 1996 in UK are excluded	
<b>Other Tests</b>										
ABO blood group testing	ABO typing	YES	NO	National laws: legge 219/2005 and DM 3.3.2005 ( <a href="http://www.centronazionaleangue.it/pagine/normativa-000">http://www.centronazionaleangue.it/pagine/normativa-000</a> )	HPC donors	all HPCs (BM, PBSC and CB)	no comments	NO	For the other tissues it's not required	
	Other technique									
Rhd blood group testing	Rhd typing	YES	NO	National laws: legge 219/2005 and DM 3.3.2005 ( <a href="http://www.centronazionaleangue.it/pagine/normativa-000">http://www.centronazionaleangue.it/pagine/normativa-000</a> )	HPC donors	all HPCs (BM, PBSC and CB)	no comments	NO	For the other tissues it's not required	
	Other technique									
HLA testing	Technique not specified								NO	For the other tissues it's not required
	HLA Ab									
	HLA Ag									
	HLA gene	YES	YES	National laws: legge 219/2005 and DM 3.3.2005 ( <a href="http://www.centronazionaleangue.it/pagine/normativa-000">http://www.centronazionaleangue.it/pagine/normativa-000</a> )	HPC donors	all HPCs (BM, PBSC and CB)	no comments			
Other technique										
Genetic testing, please specify condition	The type of techniques depends from what kind of infection/disease you suspect or you are looking for. The techniques are detailed in the IBMDR Standards	YES	YES	IBMDR Standard - <a href="http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation-for-HPCs">http://ibmdr.galliera.it/english-version/ibmdr-manual-of-operation-for-HPCs</a> .	HPCs	Cord Blood and PBSC	no comments	NO	In case of relevant medical testing or anamnestic history of hemoglobinopathies or of coagulation defects	

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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	partner donor	gametes		NO	General note: all the information that is given for reproductive T&C refers exclusively to partner donation. Italy has introduced only recently the heterologous donation
	Anti-HIV 2	YES	NO	N/A	partner donor	gametes			
	HIV 1p24								
	HIV NAT								
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	partner donor	gametes		NO	
	Anti-HBc	YES	NO	N/A	partner donor	gametes			
	Anti - HBs								
	HBV NAT								
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	partner donor	gametes		NO	
	HCV NAT								
	Other technique								
HTLV-1	Technique not specified	YES	NO	N/A	partner donor	gametes	no comments	NO	
	Anti-HTLV-1	YES	NO	N/A	Anti-HTLV 1 is mandatory for donors living in or coming from areas with high prevalence of HTLV or whose sexual partners or parents live or originate from areas with high prevalence of HTLV-1	all	no comments		
	HTLV-1 NAT								
	Other technique								
HTLV-2	Technique not specified	YES	NO	N/A	partner donor	gametes	no comments	NO	
	Anti-HTLV-2								
	HTLV-2 NAT								
	Other technique								
Chikungunya virus									
Cytomegalovirus									
Ebola Virus									
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									

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					Donor profile	Tissue/cell type	Comments		
West Nile Virus									
specify pathogen									
<b>PARASITIC</b>									
Babesiosis									
Leishmaniasis									
Malaria									
Toxoplasmosis									
Trypanosomiasis									
specify pathogen									
<b>BACTERIAL</b>									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	non-partner donors	all		NO	bacteriology testing of tissues/cells is a requirement for all types of donations
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>	Technique not specified	YES	NO	N/A	partner donors	all	no comments	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									
<b>FUNGI</b>									
specify pathogen									
Transmissible spongiform encephalopathies									
<b>Other Tests</b>									
ABO blood group									
RhD blood group									
HLA testing									
Genetic testing, please specify condition									