France - More stringent blood donor testing requirements
2015 Mapping exercise

Colour key	
	Minimum requirements as set out in the 2004/33/EC Directive
	More stringent testing - legally binding on national level
	More stringent testing - recommended on national level
	Not legally binding and not recommended on national level

Test	Test/ technique	Legally binding	Recommendation on national level	Recommending authority/ service/ association	Type of blood donation (blood for transfection or plasma for fractionantion)	Circumstances for application/ donor profile	Regional differences	Further comments
Basic testing								
Blood group testing	AB0 typing	YES	NO	NO	both	Application to all donors at every donation	NO	
	RhD typing	YES	NO	NO	both	Application to all donors at every donation	NO	
	Other, please specify (Kell etc.)	YES	NO	NO	whole blood/ blood components for transfusion	Application to all donors at the first two donations	NO	Phenotyping Rh-Kell : C(RH2), E(RH3), c(RH4), e(RH5) and Kell(KEL1)
HLA testing	HLA/ Technique not specified	NO	YES	National recommendations of the Haute autorité de santé (HAS) http://www.has-sante.fr/portail/	whole blood/ blood components for transfusion	Application only for part of platelets components for transfusion, intended for patients with antibodies	YES	
	HLA Ab	NO	YES	Scientific advising recommendations	whole blood/ blood components for transfusion	Application only for part of platelets components for transfusion, intended for patients with antibodies		
	HLA Ag	NO	YES	Scientific advising recommendations	whole blood/ blood components for transfusion	Application only for part of platelets components for transfusion, intended for patients with antibodies		
	HLA gene	NO	YES	Scientific advising recommendations	whole blood/ blood components for transfusion	Application only for part of platelets components for transfusion, intended for patients with antibodies		
	Other technique							
Disease testing								
VIRAL								
HIV 1 and HIV 2	**Anti-HIV 1**	YES	NO	NO	both	Application to all donors at every donation	NO	In the French legislation, there are no differences for the mandatory list of screening tests between the donations of whole blood/ blood components for transfusion and plasma for fractionation. The Anti-HIV testing is a combination ELISA test anti-HIV 1 and 2 performed once at each donation. If the initial result is positive, this result shall be confirmed positive using apprpriate confirmatory testing. In case of confirmed positive results, blood components of the donation are stored separately and excluded from therapeutic use. And the donor is informed, using appropriate donor management procedure. The NAT HIV is performed in combination with NAT-HBV and NAT-HCV.
	Anti-HIV 2	YES	NO	NO	both	Application to all donors at every donation		
	HIV 1p24							
	HIV NAT pool or ID	YES	NO	NO	both	Application to all donors at every donation		
	HIV NAT ID	NO	YES	National blood service http://www.dondusang.net/rewrite/headingl1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	both	Application to all donors at every donation		
	Other technique							
Hepatitis B	**HBs Ag**	YES	NO	NO	both	Application to all donors at every donation	NO	In the French legislation, there are no differences for the mandatory list of screening tests between the donations of whole blood/ blood components
	Anti-HBc	YES	NO	NO	both	Application to all donors at every donation		

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	Anti - HBs	YES	NO	NO	plasma for fractionation	Application to donations for plasma for fractionation intended to the production of IgIV anti-HBS		for transfusion and plasma for fractionation. If the initial result of HBs Ag testing and/or of anti-HBc is/are positive, this result/results shall be confirmed positive using apprpriate confirmatory testing. In case of confirmed positive results, blood components of the donation are stored separately and excluded from therapeutic use. And the donor is informed,
	HBV NAT pool or ID	NO	YES	National blood service http://www.dondusang.net/rewrite/headingl1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	both	Application to all donors at every donation		
	HBV NAT ID							
	Other technique							
Hepatitis C	**Anti-HCV**	YES	NO	NO	both	Application to all donors at every donation	NO	In the French legislation, there are no differences for the mandatory list of screening tests between the donations of whole blood/ blood components for transfusion and plasma for fractionation. If the initial result of the Anti-HCV testing is positive, this result shall be confirmed positive using apprpriate confirmatory testing. In case of confirmed positive results, blood components of the donation are stored separately and excluded from therapeutic use. And the donor is informed, using appropriate donor management procedure. The NAT HCV is performed in combination with NAT-HIV and NAT HBV.
	HCV NAT pool or ID	YES	NO	NO	both	Application to all donors at every donation		
	HCV NAT ID	NO	YES	National blood service http://www.dondusang.net/rewrite/headingl1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	both	Application to all donors at every donation		
	Other technique							
Hepatitis E	HEV/ technique not specified						YES	Screening tests HEV (hepatitis E virus) NAT (pool of 96 samples) was implemented by the national blood service in December 2012 for FFP-SD, and by the Military blood center in the beginning of 2013 for lyophilized plasma manufacturing pools. Testing of a certain percentage of plasma for transfusion was recently implemented in the beginning of 2015
	Anti-HEV							
	HEV NAT pool or ID	NO	YES	National blood service http://www.dondusang.net/rewrite/headingl1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	both	Application to certain percentage of plasma for transfusion, in order to ensure the availibility of "HEV free" plasma for immunocompromised patients.		
	HEV NAT ID	NO	YES	National blood service http://www.dondusang.net/rewrite/headingl1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	both	Application if the result of the pool is positive		
	Other technique							
HTLV-1	HTLV-1/ technique not specified						NO	In the French legislation, there are no differences for the mandatory list of screening tests between the donations of whole blood/ blood components for transfusion and plasma for fractionation. The Anti-HTLV testing is a combination ELISA test anti-HTLV I and anti-HTLV II performed once at each donation. If the initial result is positive, this result shall be confirmed positive using apprpriate confirmatory testing. In case of confirmed positive results, blood components of the donation are stored separately and excluded from therapeutic use. And the donor is informed, using appropriate donor management procedure.
	Anti-HTLV-1	YES	NO	NO	both	Application to all donors at every donation		
	HTLV-1 NAT pool or ID							
	HTLV-1 NAT ID							
	Other technique							

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HTLV-2	HTLV-2/ technique not specified						NO	In the French legislation, there are no differences for the mandatory list of screening tests between the donations of whole blood/ blood components for transfusion and plasma for fractionation. The Anti-HTLV testing is a combination ELISA test anti-HTLV I and anti-HTLV II performed once at each donation. If the initial result is positive, this result shall be confirmed positive using apprpriate confirmatory testing. In case of confirmed positive results, blood components of the donation are stored separately and excluded from therapeutic use. And the donor is informed, using appropriate donor management procedure.
	Anti-HTLV-2	YES	NO	NO	both	Application to all donors at every donation		
	HTLV-2 NAT pool or ID							
	HTLV-2 NAT ID							
	Other technique							
Ebola Virus								
Chikungunya virus	CHIKV/ technique not specified	NO	YES	Specific committee of ANSM = Crisis management team (CMT) which decides with other agencies (National Agency for organs and tissues, National blood service, Military blood center, French Institute for pubblic health surveillance), national reference laboratories and the Ministry of Health	both	Application for specific epidemiologic situations and to donations collected inside alert area	YES	
	Anti-CHIKV							
	CHIKV NAT pool or ID							
	CHIKV NAT ID							
	Other technique							
Cytomegalovirus	CMV/ technique not specified	NO	YES	National blood service http://www.dondusang.net/rewrite/heading1/758/efs.htm?idRubrique=758 and the Military blood center http://www.defense.gouv.fr/sante/notre-expertise/transfusion-sanguine	plasma for fractionation	Application to donations for plasma for fractionation intended to the production of IgIV anti-CMV	NO	
	Anti-CMV	YES	NO	NO	whole blood/ blood components for transfusion	Application to part of donors who have a history of anti-CMV negative donation and to first time donors		
	CMV NAT pool or ID							
	CMV NAT ID							
	Other technique							
West Nile Virus	WNV/ technique not specified						NO	
	WNV NAT pool or ID	NO	YES	Specific committee of ANSM = Crisis management team (CMT) which decides with other agencies (National Agency for organs and tissues, National blood service, Military blood center, French Institute for pubblic health surveillance), national reference laboratories and the Ministry of Health	both	Application for specific epidemiologic situations and to donations collected inside alert area (alternative is cancelling blood collection session)		
	WNV NAT ID	NO	YES	Specific committee of ANSM = Crisis management team (CMT) which decides with other agencies (National Agency for organs and tissues, National blood service, Military blood center, French Institute for pubblic health surveillance), national reference laboratories and the Ministry of Health	both	Application if the result of the pool is positive		
	Other technique							
Dengue Virus								No availibility on the market of IVD/Methods/technics CE marked
Epstein-Barr virus								

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Human Parvovirus B19	HPVB19/ technique not specified						NO	
	HPVB19 NAT pool or ID	NO	YES	National blood service http://www.dondusang.net/rewrite/heading1/758/efs.htm?idRubrique=758 and the LFB (the French Laboratory of Fractionation and Biotechnology)	plasma for fractionation	NO		
	HPVB19 NAT ID							
	Other technique							
Hepatitis A Virus	HAV/ technique not specified						NO	
	HAV NAT pool or ID	NO	YES	National blood service http://www.dondusang.net/rewrite/heading1/758/efs.htm?idRubrique=758 and the LFB (the French Laboratory of Fractionation and Biotechnology)	plasma for fractionation	NO		
	HAV NAT ID	NO	YES	National blood service http://www.dondusang.net/rewrite/heading1/758/efs.htm?idRubrique=758 and the LFB (the French Laboratory of Fractionation and Biotechnology)	plasma for fractionation	Application if the result of the pool is positive		
	Other technique							
Herpes simplex virus								
Malaria	Technique not specified	YES	NO	NO	both	If necessary (individuals who have lived in a malaria area or with history of undiagnosed febrile illness, visitors to endemic areas...)	NO	Screening tests and confirmatory tests if screening tests are positive
	Microscopy	NO	YES	National Biological standards	both	If necessary (individuals who have lived in a malaria area or with history of undiagnosed febrile illness, visitors to endemic areas...)		
	Plasmodium sp . Ab	NO	YES	National Biological standards	both	If necessary (individuals who have lived in a malaria area or with history of undiagnosed febrile illness, visitors to endemic areas...)		
	Plasmodium sp . Ag	NO	YES	National Biological standards	both	If necessary (individuals who have lived in a malaria area or with history of undiagnosed febrile illness, visitors to endemic areas...)		
	Plasmodium sp. Ag - rapid test							
	Plasmodium sp. NAT pool or ID							
	Plasmodium sp. NAT ID							
	Other technique							
Trypanosomiasis	Technique not specified	YES	NO	NO	both	If necessary (individuals who have lived in a Chagas disease area, or whose mother was born in an endemic area, or with history of Chagas disease, visitors to endemic area ...)	NO	
	Microscopy							
	Anti-*Trypanosoma cruzi*							
	T. cruzi NAT pool or ID							
	T. cruzi NAT ID							
	Other technique							
Babesiosis								
Leishmaniasis								
Toxoplasmosis								

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Other pathogen, specify								
BACTERIAL								
Treponema pallidum (Syphilis)	Technique not specified	YES	NO	NO	both	Application to all donors at every donation	NO	
	Microscopy							
	Anti-*T. pallidum*							
	T. pallidum NAT pool or ID							
	T. pallidum NAT ID							
	Culture							
	Other technique							
Neisseria gonorrhoeae								
Brucellosis								
Tuberculosis								
Q-fever								
Other pathogen,								
FUNGI								
specify pathogen								

* For West Nile Virus NAT ID, see 2004/33/EC as amended by 2014/110/EU with a deadline for transposition into national law of December 31, 2015