

**Germany - 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 transfusion or plasma for fractionation)	Circumstances for application/ donor profile	Regional differences	Further comments
Basic testing								
Blood group testing	ABO typing	YES	NO	N/A	whole blood/ blood components for transfusion	first and second donation	NO	
	RhD typing	YES	NO	N/A	whole blood/ blood components for transfusion	first and second donation	NO	specific requirement for weak RhD testing
	Other, please specify (C, c, E, e, Kell)	YES	NO	N/A	whole blood/ blood components for transfusion	first and second donation	NO	
HLA testing								
Disease testing								
VIRAL								
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	both	all donations	NO	HIV-NAT: dual-target NAT for whole blood / blood components for transfusion Mandatory for routine screening: HIV-1 NAT (10.000mIU/ml) and HCV-NAT (5.000 IU/ml)
	Anti-HIV 2	YES	NO	N/A	both	all donations		
	HIV 1p24							
	HIV NAT pool or ID	YES	NO	N/A	whole blood/ blood components for transfusion	all donations		
	HIV NAT ID							
	Other technique							
Hepatitis B	HBs Ag	YES	NO	N/A	both	all donations	NO	Not mandatory, but used for routine screening by many blood establishments, mainly those who also deliver plasma for fractionation: HBV-NAT, HAV-NAT, Parvovirus B19 NAT
	Anti-HBc	YES	NO	N/A	whole blood/ blood components for transfusion	all donations; in case of the constellation <i>blood donor with repeatedly reactive anti-HBc, anti-HBs-antibody ≥ 100 IU/L, HBV-genome analysis by NAT (sensitivity at least 12 IU/ml) negative</i> blood donation is considered to be possible under the precondition of testing of anti-HBs in intervals of 2 years. If anti-HBs-antibody < 100		
	Anti - HBs							
	HBV NAT pool or ID	NO	YES	BAnz. 13.06.2006, Nr. 109, pp 4370), Votum 31 AK Blut, http://www.rki.de/DE/Content/Kommissionen/AK_Blut/Voten/Uebersicht/V_31/V_31_HBc.pdf?__blob=publicationFile	both	see comment Anti-HBc // Circumstances for application/ donor profile: travel history, residence, medical history, age, seasonal requirements etc.		
	HBV NAT ID							
	Other technique							
Hepatitis C	Anti-HCV	YES	NO	N/A	both	all donations	NO	Mandatory for routine screening: HIV-1 NAT (10.000mIU/ml) and HCV-NAT (5.000 IU/ml)
	HCV NAT pool or ID	YES	NO	N/A	whole blood/ blood components for transfusion	all donations		
	HCV NAT ID							
	Other technique							
Hepatitis E								
Hepatitis A								
								Not mandatory, but used for routine screening by many blood establishments, mainly those who also deliver plasma for fractionation: HBV-NAT, HAV-NAT, Parvovirus B19 NAT
HTLV-1								
HTLV-2								
Ebola Virus								
Chikungunya virus								
Cytomegalovirus								
West Nile Virus*								
Dengue Virus								
Epstein-Barr virus								
Human Parvovirus B19								Not mandatory, but used for routine screening by many blood establishments, mainly those who also deliver plasma for fractionation: HBV-NAT, HAV-NAT, Parvovirus B19 NAT
Herpes simplex virus								

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Nonspecific viral infection								
Other pathogen, specify								
PARASITIC								
Malaria								
Trypanosomiasis								
Babesiosis								
Leishmaniasis								
Toxoplasmosis								
Other pathogen, specify								
BACTERIAL								
Treponema pallidum (Syphilis)	Technique not specified						NO	
	Microscopy							
	Anti- <i>T. pallidum</i>	YES	NO	N/A	whole blood/ blood components for transfusion	all donations		
	<i>T. pallidum</i> NAT pool or ID							
	<i>T. pallidum</i> NAT ID							
	Culture							
	Other technique							
Neisseria								
Brucellosis								
Tuberculosis								
Q-fever								
Other pathogen, specify								
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