Netherlands - 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	N/A	both	universal screening	NO		
	RhD typing	YES	NO	N/A	both	universal screening	NO		
	Other, please specify	NO	YES	Health Council of the Netherlands	whole blood/ blood	selective screening	NO	The large majority of the	
	(Kell etc.)	NO	163	Interince of the Neutral August 1 (Intp://www.gezondheidsraad.nl/sites/default/files/200904.pdf; ISBN 978-90-5549-753-9], CBO [http://www.sanquin.nl/repository/documenten/en/prod-en-dienst/287294/blood-transfusion-guideline.pdf], and Medical Advisory Council of Sanquin Blood Supply Foundation [guidance document not available in the public domain]	components for transfusion	seietuve streetinig	NO	Dutch donor population is typed for the rhesus phenotype (C, c, D, E and e) and the K-type (K negative or K positive); for patients with clinically relevant alloantibodies and for certain patient categories, specific requirements are set with regard to the transfusion of typed red blood cells	
HLA testing	HLA/ Technique not	NO	YES	CBO	whole blood/ blood	selective screening	NO	In order to make HLA/HPA	
	specified			[http://www.sanquin.nl/repository/documenten/en/prod-en-dienst/287294/blood-transfusion-guideline.pdf], and Medical Advisory Council of Sanquin Blood Supply Foundation [guidance document not available in the public domain]	components for transfusion		NO	matched platelet transfusions possible, HLA/HPA testing of selected donors is performed using PCR based and solid-phase based techniques	
	HLA Ab HLA Ag	_							
	HLA gene								
Disease testing	Other technique								
_									
VIRAL	Ant: HD/4	VEC	NO	Int/a	h - 4h		luo	AItial	
HIV 1 and HIV 2	Anti-HIV 1	YES	NO	N/A	both	universal screening	NO	A multiplex real-time PCR test is used to simultaneously screen donated blood for HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA	
	Anti-HIV 2	YES	NO	N/A	both	universal screening			
	HIV 1p24 HIV NAT pool	NO	YES	Medical Advisory Council of Sanguin	both	universal screening			
	tut. pee.			Blood Supply Foundation [guidance document not available in the public domain]		anitersul servering			
	HIV NAT ID								
Hepatitis B virus	Other technique HBsAg	YES	NO	N/A	both	universal screening	NO	A multiplex real-time PCR	
	Anti-HBc	NO	YES	Adadisal Advisory Council of Council	both			test is used to simultaneously screen donated blood for HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA; all donations of blood and blood components are tested for presence of HBsAg, HBV DNA and anti-HBc; anti-HBs levels are determined for anti-HBc repeatedly reactive donations (donations showing anti-HBs levels <200 mIU/mL are then not released)	
	Allu-ribc	NO	165	Medical Advisory Council of Sanquin Blood Supply Foundation (guidance document not available in the public domain)	buii	universal screening			
	Anti-HBs	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation (guidance document not available in the public domain)	both	anti-HBc positive donors only are tested for the presence of anti- HBs			
	HBV NAT pool	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation [guidance document not available in the public domain]	both	universal screening			
	HBV NAT ID						1		
Hepatitis C virus	Other technique Anti-HCV	YES	NO	N/A	both	universal screening	NO	A multiplex real-time PCR	
		NO		Medical Advisory Council of Sanguin				test is used to	
	HCV NAT pool	NO	YES	Medical Advisory Council of Sanduin Blood Supply Foundation (guidance document not available in the public domain)	both	universal screening		simultaneously screen donated blood for HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA	
	HCV NAT ID Other technique								
Hepatitis E virus	outer technique						1	In order to meet the	
								requirements of the European Pharmacopeia,	

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								EMA guidelines, Plasma Master File and European Directives, plasma for the manufacture of PDMPs may be routinely tested by NAT for the presence of HEV RNA (HEV RNA positive plasma donations are then not released)
HTLV-1 HTLV-2	HTLV-1/ technique HTLV-2/ technique						NO NO	
	not specified Anti-HTLV-2	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation [guidance document not available in the public domain]	both	new donors only		
	HTLV-2 NAT pool HTLV-2 NAT ID	-						
Ebola Virus	Other technique							
Chikungunya virus								CHIKV detection by NAT is ready for implementation to practice in certain epidemiological situations
Cytomegalovirus	CMV/ technique not specified						NO	Anti-CMV IgG negative tested blood components
	Anti-CMV	NO	YES	CBO [http://www.sanquin.nl/repository/documenten/en/prod-en-dienst/287294/blood-transfusion-guideline.pdf]	whole blood/ blood components for transfusion	on demand testing		are provided at the request of treating experts for intra- uterine use or to administer to extremely premature babies
	CMV NAT pool CMV NAT ID							
West Nile Virus*	Other technique							WNV detection by NAT is ready for implementation to practice in certain epidemiological situations
Dengue Virus								DENV detection by NAT is ready for implementation to practice in certain epidemiological situations
Epstein-Barr virus Human Parvovirus B19	HPVB19/technique not specified	NO	YES	Health Council of the Netherlands [http://www.gezondheidsraad.nl/sites/d efault/files/0207n.pdf; ISBN 90-5549-432- 1], and CBO [http://www.sanquin.nl/repository/documenten/en/prod-en- dienst/287294/blood-transfusion- guideline.pdf]	whole blood/ blood components for transfusion	selective screening	NO	Parvo B19-virus safe cellular blood products are administered to selected groups of patients; donors with detectable IgG antibodies to B19 in two separate blood samples, one taken at least six months after the other, are
	HPVB19 NAT pool							considered to be B19 safe; in order to meet the
	HPVB19 NAT ID							requirements of the
Herpes simplex Nonspecific viral	Other technique							European Pharmacopeia, EMA guidelines, Plasma Master File and European Directives, plasma for the manufacture of PDMPs may be routinely tested by NAT for the presence of Parvo B19-virus DNA (B19 DNA positive plasma donations are then not released)

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Test	Test/ technique	Legally binding	Recommendation on	Recommending authority/ service/	Type of blood donation	Circumstances for	Regional	Further comments
			national level	association	(blood for transfection or plasma for fractionantion)		differences	
Hepatitis A virus								In order to meet the
Hepatitis A virus								In order to meet the requirements of the European Pharmacopeia, EMA guidelines, Plasma Master File and European Directives, plasma for the manufacture of PDMPs may be routinely tested by NAT for the presence of HAV RNA (HAV RNA positive plasma donations are then not released)
PARASITIC								
Malaria	Technique not specified						NO	Malaria antibody testing is performed to determine
	Microscopy							acceptance or rejection of
	Plasmodium sp . Ab	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation [guidance document not available in the public domain]	whole blood/ blood components for transfusion	selective screening		blood donor candidates who give a history of malaria and/or have lived in a malaria area for a
	Plasmodium sp . Ag							continuous period of 6
	Plasmodium sp. Ag - rapid test							months or more
	Plasmodium sp. NAT							
	pool Plasmodium sp. NAT ID							
	Other technique							
Trypanosomiasis								
Babesiosis Leishmaniasis								
Toxoplasmosis								
Other pathogen,								
BACTERIAL								
Treponema pallidum (Syphilis)	Technique not specified						NO	
	Microscopy							
	Anti-T. pallidum	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation (guidance document not available in the public	both	universal screening		
	T. pallidum NAT pool T. pallidum NAT ID							
	Culture Other technique							
Neisseria	Other technique						l	
Brucellosis Tuberculosis								
Q-fever								C. burnetii detection by
2.000								NAT is ready for implementation to practice in certain epidemiological situations
Bacterial contamination	Automated microbial growth and detection technology	NO	YES	Medical Advisory Council of Sanquin Blood Supply Foundation (guidance document not available in the public	all platelet products	platelet products only	NO	Products are released on a negative-to-date basis
<u></u>				domain]				
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