

## United Kingdom - 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		NO	Adopted as per the Directives without alteration; NAT not mandatory in the UK; NAT can substitute for 180-day repeat testing under the circumstances specified in 2006/17/EC Annex II paragraph 2.6
	Anti-HIV 2	YES	NO	N/A	all	all			
	HIV 1p24								
	HIV NAT	NO	YES	HTA (paragraph 92d of <a href="https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf">https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf</a> )	all	all			
	Other technique								
Hepatitis B	HBs Ag	YES	NO	N/A	all	all		NO	Adopted as per the Directives without alteration; NAT not mandatory in the UK; NAT can substitute for 180-day repeat testing under the circumstances specified in 2006/17/EC Annex II paragraph 2.6
	Anti-HBc	YES	NO	N/A	all	all			
	Anti - HBs								
	HBV NAT	NO	YES	HTA (paragraph 92d of <a href="https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf">https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf</a> )	all	all			
	Other technique								
Hepatitis C	Anti-HCV	YES	NO	N/A	all	all		NO	Adopted as per the Directives without alteration; NAT not mandatory in the UK; NAT can substitute for 180-day repeat testing under the circumstances specified in 2006/17/EC Annex II paragraph 2.6
	HCV NAT	NO	YES	HTA (paragraph 92d of <a href="https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf">https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf</a> )	all	all			
	Other technique								
HTLV-1	Technique not specified							NO	(1) HTA advises that ECDC data should be used to determine areas

## United Kingdom - More stringent blood donor testing requirements 2015 Mapping exercise

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					Donor profile	Tissue/cell type	Comments		
	Anti-HTLV-1	YES	NO	N/A	Establishments are required to screen all donors for contact with high prevalence area as per the directive OR if not screening then all donor samples must be tested for Anti-HTLV-1	all		of high prevalence. (2) Adopted as per the Directives without alteration; NAT not mandatory in the UK; NAT can substitute for 180-day repeat testing under the circumstances specified in 2006/17/EC Annex II paragraph 2.6	
	HTLV-1 NAT	NO	YES	HTA (paragraph 92d of <a href="https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20or%20Patient%20Treatment.pdf">https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20or%20Patient%20Treatment.pdf</a> )	As with the other mandatory serology tests, if HTLV testing is determined mandatory based on donor screening results (or lack thereof as described above) then although HTLV NAT is not mandatory in the UK, NAT can substitute for 180-day repeat testing under the circumstances specified in 2006/17/EC Annex II paragraph 2.6	all			
	Other technique								
HTLV-2								HTLV-II testing is not specifically required in the UK; however on a practical level, most HTLV-I tests tend to detect HTLV-I/II. So,	
Chikungunya virus									
Cytomegalovirus	Technique not specified						YES; Implementation dates may vary		

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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		
	Anti-CMV	NO	YES	(1) SaBTO (Table 3 page 31 of <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> ) (2)JPAC (Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee) ( <a href="http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening">http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening</a> )	No specific donor profile	Haemopoietic progenitor cells (HPC) and therapeutic cells (TC) - IgG tests facilitate matching of donor/recipient serological status and risk management in recipient. (Source: doc identified in col F)		between England, Northern Ireland, Scotland and Wales but will usually be within three months from the date of changes made to the JPAC website.	
	CMV NAT	NO	YES	(1) SaBTO (Table 3 page 31 of <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> )	No specific donor profile	CMV NAT is performed to exclude CMV infection in cord blood donations.			
	Other technique	NO	YES	SABTO (Table 3 page 31 of <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> )	Combined antigen & antibody assays rather than antibody testing alone are required for HIV when NAT results are not available prior to transplantation and should be considered for HCV.	N/A			
Dengue Virus									
Ebola Virus									
Epstein-Barr virus	Technique not specified							NO	

## United Kingdom - More stringent blood donor testing requirements 2015 Mapping exercise

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					Donor profile	Tissue/cell type	Comments		
	Anti-EBV	NO	YES	SaBTO (Table 3 page 31 of <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> )	No specific donor profile	Haemopoietic progenitor cells (HPC) and therapeutic cells (TC) - IgG tests facilitate matching of donor/recipient serological status and risk management in recipient. Human embryonic stem cells - good clinical practice. (Source: doc identified in col F)			
	Other technique								
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus									
West Nile Virus	Technique not specified								
	WNV minipool NAT	NO	YES	JPAC ( <a href="http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening">http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening</a> )	due to specifically identifiable risk (Source: doc identified in col E)	Same requirements apply to all types of tissues / cells		YES; Implementation dates may vary between England, Northern Ireland, Scotland and Wales but will usually be within three months from the date of changes made to the JPAC website.	Max pool size 16 donations
	WNV ID NAT								
	Other technique								
specify pathogen									
<b>PARASITIC</b>									
Babesiosis									
Leishmaniasis									
Malaria	Technique not specified							YES; Implementation dates may vary between England, Northern Ireland, Scotland and Wales but will usually be within three months from the date of changes made	anti-P. falciparum/vivax
	Microscopy								
	<i>Plasmodium sp.</i> Ab								
	<i>Plasmodium sp.</i> Ag								
	<i>Plasmodium sp.</i> Ag - rapid test								
	<i>Plasmodium sp.</i> NAT								

## United Kingdom - More stringent blood donor testing requirements 2015 Mapping exercise

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					Donor profile	Tissue/cell type	Comments			
	Other technique	NO	YES	JPAC ( <a href="http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening">http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening</a> )	due to specifically identifiable risk (Source: doc identified in col E)	Same requirements apply to all types of tissues / cells		to the JPAC website.		
Toxoplasmosis	Technique not specified								NO	
	Anti- <i>Toxoplasma gondii</i>	NO	YES	SaBTO (Table 3 page 31 of <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> )	See document in column E	See document in column E				
	Microscopy Other technique									
Trypanosomiasis	Technique not specified								YES; Implementation dates may vary between England, Northern Ireland, Scotland and Wales but will usually be within three months from the date of changes made to the JPAC website.	
	Anti- <i>Trypanosoma cruzi</i>	NO	YES	JPAC ( <a href="http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening">http://www.transfusionguidelines.org.uk/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-2-microbiology-screening</a> )	due to specifically identifiable risk (Source: doc identified in col E)	Same requirements apply to all types of tissues / cells				
	Microscopy Other technique									
specify pathogen										
<b>BACTERIAL</b>										
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	NO	N/A	all	all		NO	Adoped as per the Directives without alteration	
	Anti- <i>T. pallidum</i>									
	Microscopy									
	<i>T. pallidum</i> NAT									
	Other technique									
<i>Chlamydia trachomatis</i>										
<i>Neisseria gonorrhoeae</i>										
Brucellosis										
Tuberculosis										
Q-fever										
specify pathogen										
<b>FUNGI</b>										
specify pathogen										
Transmissible spongiform encephalopathies										
<b>Other Tests</b>										

### United Kingdom - More stringent blood donor testing requirements 2015 Mapping exercise

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					Donor profile	Tissue/cell type	Comments		
ABO blood group testing									
RhD blood group testing									
HLA testing									
Genetic testing, please specify condition									

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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	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 cells** (please note that for reproductive tissues - ovarian and testicular tissues - the requirements for non-reproductive tissues and cells apply - see UK-HTA fact sheet)

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	YES	HFEA: Licence condition T52(b) for donor gametes ( <a href="http://www.hfea.gov.uk/498.html">http://www.hfea.gov.uk/498.html</a> ), Licence condition T50(a) for partner donation ( <a href="http://www.hfea.gov.uk/503.html">http://www.hfea.gov.uk/503.html</a> ). Professional body (ACE and BFS) guidance on donor screening : <a href="http://informahealthcare.com/doi/pdf/10.10">http://informahealthcare.com/doi/pdf/10.10</a>	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments	NO	NAT testing is not currently mandatory in the UK, with the exception of the testing for Chlamydia. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing. The HTA considers that there is a very strong case for requiring mandatory NAT testing, particularly in instances where you might have a treatment involving donation from multiple donors and where the donations are not stored and therefore cannot be retested at 180 days.  Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes UK-licensed centres must comply with the selection criteria for donors and the requirements for laboratory tests and storage as noted in guidance.HFEA licence condition T53 requires: "The centre must ensure that the laboratory tests required by licence condition T52 meet the follow
	Anti-HIV 2	YES	YES	HFEA: Licence condition T52(b) for donor gametes ( <a href="http://www.hfea.gov.uk/498.html">http://www.hfea.gov.uk/498.html</a> ), Licence condition T50(a) for partner donation ( <a href="http://www.hfea.gov.uk/503.html">http://www.hfea.gov.uk/503.html</a> ). Professional body (ACE and BFS) guidance on donor screening : <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments		
HIV 1p24									

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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					Donor profile	Tissue/cell type	Comments		
	HIV NAT	NO	NO	NAT testing just mandatory (HFEA Licence condition T52) for chlamydia: "e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)". The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion /transplantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> . However, "The role of nucleic amplification tests for the detection of blood borne viruses such as HIV is discussed, but it remains the recommendation that this be achieved by serological testing to detect antibody or antigen as appropriate with a quarantine period of 180 days."	Non-partner donation: all	Eggs, sperm and embryos	no comments		a. the test must be carried out by a qualified labor  b. blood samples must be obtained within a timef  Quarantine and re-testing is also not required if th
	Other technique - 180 day quarantine	NO	YES	The quarantine of sperm where a NAT test had been performed is not required.Guidance provided at sections 11.22 and 11.24 of the 8th Code of Practice recommends that in addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with current professional guidance ( <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a> ). It is also recommends that in addition to meeting the mandatory requirements, the centre should quarantine donated gametes in line with guidance from the relevant professional bodies. The mandatory requirements outlined in standard licence condition T52(c) reflect the minimum standard for donor screening and quarantine but professional body guidelines are considered to represent best practice. The UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008)	Non-partner donation: all; Partner donation: when stored	Eggs, sperm and embryos	no comments		
Hepatitis B	HBs Ag	YES	YES	HFEA: Licence condition T52(b) for donor gametes, Licence condition T50(a) for partner donation. Professional body guidance: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments	NO	Guidance issued to clinics from the HFEA: The risks of transmission of HBV through treatment with gametes from partners who have screened negative for HBsAg but who have not been subject to anti-HBc screening is likely to be lower than the risk of infection as a result of physical intimacy. It is still a requirement to screen partners for anti-HBc. However, if centres are non-compliant with the requirement, this will normally be categorised in reports as an 'other' breach

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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					Donor profile	Tissue/cell type	Comments		
	Anti-HBc	YES	YES	HFEA: Licence condition T52(b) for donor gametes, Licence condition T50(a) for partner donation. Professional body guidance: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments	an 'other breach'	
	Anti - HBs	YES	YES	HFEA: Licence condition T52(b) for donor gametes, Licence condition T50(a) for partner donation. Professional body guidance: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments		
	HBV NAT	NO	NO	HFEA: Licence condition T52(b) for donor gametes, Licence condition T50(a) for partner donation. Professional body guidance: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	non-partner donors	all	no comments		
	Other technique								
Hepatitis C	Anti-HCV	YES	YES	HFEA: Licence condition T52(b) for donor gametes, Licence condition T50(a) for partner donation	Non-partner donation: all; Partner donation: all	Eggs, sperm and embryos	no comments	NO	Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes UK-licensed centres must comply with the selection criteria for donors and the requirements for laboratory tests and storage as noted in guidance."
	HCV NAT	NO	NO	NAT testing just mandatory (HFEA Licence condition T52) for chlamydia: "e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)". The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/trans-plantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> . However, other professional body guidelines (ACE and BFS) state: "The role of nucleic amplification tests for the detection of blood borne viruses such as HIV is discussed, but it remains the recommendation that this be achieved by serological testing to detect antibody or antigen as appropriate with a quarantine period of 180 days."	non partner donation: all	Eggs, sperm and embryos	no comments		
	Other technique								

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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					Donor profile	Tissue/cell type	Comments		
HTLV-1	Technique not specified	YES	YES	HFEA: Licence condition T52(g) for non-partner donation: "HTLV-1 antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas, "; Licence condition T50(c) for partner donation: "Perform HTLV- 1 antibody testing for patients living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas"	Non-partner donation and partner donation: Donors living in, or originating from, high-prevalence areas, or with sexual partners originating from those areas, or where the donor's parents originate from those areas.	Eggs, sperm and embryos	no comments	NO	In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T. cruzi)  Gametes and embryos come under the authority of the Human Fertilisation and Embryology Authority (HFEA) in the UK. Extra tests must be undertaken, for example HTLV-1, when the conditions in Annex 111, 2.4 apply.
	Anti-HTLV-1	YES	YES	see row above	Non-partner donation and partner donation: Donors living in, or originating from, high-prevalence areas, or with sexual partners originating from those areas, or where the donor's parents originate from those areas.	Eggs, sperm and embryos	no comments		
	HTLV-1 NAT	NO	NO	NAT testing just mandatory (HFEA licence condition T52) for chlamydia: "e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)". The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/trans-plantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a> . However, other professional body guidelines (ACE and BFS) state: "The role of nucleic amplification tests for the detection of blood borne viruses such as HIV is discussed, but it remains the recommendation that this be achieved by serological testing to detect antibody or antigen as appropriate with a quarantine period of 180 days."	Non-partner donation: all	Eggs, sperm and embryos			
	Other technique								
HTLV-2	Technique not specified	NO	YES	Professional body (ACE and BFS) guidance on donor screening: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all	Eggs, sperm and embryos	no comments		

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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					Donor profile	Tissue/cell type	Comments		
	Anti-HTLV-2	NO	YES	Professional body (ACE and BFS) guidance on donor screening: <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation: all	Eggs, sperm and embryos	no comments		
	HTLV-2 NAT								
	Other technique								
Chikungunya virus									
Cytomegalovirus	Technique not specified								
	Anti -CMV	NO	YES	Professional body (ACE and BFA) guidance states: "It is therefore recommended that prospective sperm, egg and embryo donors should continue to be screened for the presence of cytomegalovirus IgG and IgM antibodies using the appropriate serological test". More detail at <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a> . HFEA licence condition T50 states: "In certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi) Positive results will not necessarily prevent the use of the partners' gametes."	Non-partner donation: all. Partner donation: in certain circumstances	Eggs, sperm and embryos	no comments	NO	
	CMV NAT								
	Other technique								
Dengue Virus									
Ebola Virus	Technique not specified	NO	YES	the Department of Health's Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recommends that potential gamete donors should defer from donating for two months after leaving an area affected by Ebola <a href="http://www.hfea.gov.uk/docs/SaBTO_Guidance_on_Ebola_Virus_and_SoHO_15_October_2014.pdf?utm_source=nov14&amp;utm_medium=web&amp;utm_campaign=clinicfocus">http://www.hfea.gov.uk/docs/SaBTO_Guidance_on_Ebola_Virus_and_SoHO_15_October_2014.pdf?utm_source=nov14&amp;utm_medium=web&amp;utm_campaign=clinicfocus</a>	Non partner donation: all	Eggs, sperm and embryos	no comments	NO	
	NAT								
	Other technique								
Epstein-Barr virus									
Hepatitis E									
Human Parvovirus B19									
Herpes simplex virus	Technique not specified							NO	
	HSV Ag								
	HSV Ab								
	HSV NAT								

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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					Donor profile	Tissue/cell type	Comments		
	Other technique	NO	YES	Professional body (ACE and BFS) guidance states: "Genital warts or herpes should again be excluded at the end of donation by physical examination and medical history"	Non partner donor: all	Eggs, sperm and embryos	no comments		
West Nile Virus									
specify pathogen									
<b>PARASITIC</b>									
Babesiosis									
Leishmaniasis									
Malaria	Technique not specified	YES	YES	HFEA: Licence condition T52(h) for true donation; Licence condition T50(c) for partner donation	Non-partner donation and partner donation: In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi). SABTO professional guidelines also recommend testing in certain situations: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a>	Eggs, sperm and embryos	no comments	NO	
	Microscopy								
	<i>Plasmodium sp.</i> - Ab								
	<i>Plasmodium sp.</i> - Ag								
	<i>Plasmodium sp.</i> - Ag - rapid test								
	<i>Plasmodium sp.</i> - NAT								
	Other technique								
Toxoplasmosis									
Trypanosomiasis	Technique not specified	YES	NO	HFEA: Licence condition T52(h) for true donation; Licence condition T50(c) for partner donation	Non-partner donation and partner donation: In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi).	Eggs, sperm and embryos	no comments	NO	

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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		
	Anti- <i>Trypanosoma cruzi</i>	NO	YES	SABTO professional guidelines also recommend testing in certain situations: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf</a>					
	Microscopy								
	Other technique								
specify pathogen									
<b>BACTERIAL</b>									
<i>Treponema pallidum</i> (Syphilis)	Technique not specified	YES	YES	HFEA: Licence condition T52(b) and T52(d). Professional guidance (ACE and BFS) states: "To minimise the risk of transmission of bacterial infections, all prospective donors should, prior to donation, screen negative for: Syphilis ( <i>Treponema pallidum</i> ); . Gonorrhoea ( <i>Neisseria gonorrhoea</i> ); . Chlamydia ( <i>Chlamydia trachomatis</i> )."	Non-partner donation: all	Eggs, sperm and embryos	no comments	NO	HFEA licence condition states: A validated testing algorithm must be applied to exclude the presence of active infection with <i>Treponema pallidum</i> . The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific <i>Treponema</i> confirmatory test is non-reactive. The donor whose specimen test reacted on a <i>Treponema</i> -specific test will require a thorough risk assessment to determine eligibility for clinical use. Professional guidance states: "prior to donation and every 6 months until donation is complete. Immediately after last donation, Gonorrhoea and Chlamydia should be repeated. A repeat Syphilis should follow 1 month later;"
	Anti- <i>T. pallidum</i>								
	Microscopy								
	<i>T. pallidum</i> NAT								
	Other technique								
<i>Chlamydia trachomatis</i>	Technique not specified	NO	YES		Non-partner donation: all	Sperm, eggs and embryos	no comments	NO	NAT testing is not currently mandatory in the UK, with the exception of the testing for Chlamydia.
	<i>C. trachomatis</i> DFA								
	<i>C. trachomatis</i> EIA								
	<i>C. trachomatis</i> NAT	YES	YES	HFEA: Licence condition T52(b) and T52(d). Professional guidance (ACE and BFS) states: "To minimise the risk of transmission of bacterial infections, all prospective donors should, prior to donation, screen negative for: Syphilis ( <i>Treponema pallidum</i> ); . Gonorrhoea ( <i>Neisseria gonorrhoea</i> ); . Chlamydia ( <i>Chlamydia trachomatis</i> )."	Non-partner donation: all	Sperm, eggs and embryos	no comments		Professional guidance states: "prior to donation and every 6 months until donation is complete. Immediately after last donation, Gonorrhoea and Chlamydia should be repeated. A repeat Syphilis should follow 1 month later;"
	Culture								
	Other technique								

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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			
<i>Neisseria gonorrhoeae</i>	Technique not specified	NO	YES	Professional guidance (ACE and BFS) states: "To minimise the risk of transmission of bacterial infections, all prospective donors should, prior to donation, screen negative for: Syphilis ( <i>Treponema pallidum</i> ); Gonorrhoea ( <i>Neisseria gonorrhoea</i> ); Chlamydia ( <i>Chlamydia trachomatis</i> )."	Non-partner donation: all	Sperm, eggs and embryos	no comments	NO	Professional guidance states: "prior to donation and every 6 months until donation is complete. Immediately after last donation, Gonorrhoea and Chlamydia should be repeated. A repeat Syphilis should follow 1. SABTO guidelines recommend NAT testing month later;"	
	<i>N. gonorrhoeae</i> NAT	NO	YES	SABTO guidelines recommend NAT testing	Non-partner donation: all	Sperm, eggs and embryos	no comments			
	Culture									
	Other technique									
Brucellosis										
Tuberculosis										
Q-fever										
specify pathogen										
<b>FUNGI</b>										
specify pathogen										
<b>Transmissible spongiform encephalopathies</b>	Prion (PrP) detection	NO	YES	Professional guidance (ACE and BFS) states: "Given the indeterminate risk of transmitting TSEs through sperm, egg and embryo donation, it is suggested that donors should not be accepted who have: . been diagnosed with a prion-related disease or have first degree family members similarly diagnosed; . undergone invasive neurosurgical procedures; . received human pituitary-derived growth hormone, cornea, sclera or dura mater"	Non-partner donation: all	Sperm, eggs and embryos	please specify analyte (brain, tonsil, appendix, other)	NO		
	Other technique									
<b>Other Tests</b>										
ABO blood group testing	ABO typing	NO	YES	Professional guidance (ACE and BFS) states: "The use of donor gametes and embryos creates the potential for rhesus incompatibility. All donors should have their blood group and rhesus status recorded for matching purposes when required."	Non-partner donation: all	Sperm, eggs and embryos	no comments	NO		
	Other technique									

**United Kingdom - More stringent blood donor testing requirements  
2015 Mapping exercise**

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		
RhD blood group testing	RhD typing	YES	YES	HFEA: Licence condition T52(h) for true donation; Licence condition T50(c) for partner donation. Professional body guidance (ACE and BFS) states: "The use of donor gametes and embryos creates the potential for rhesus incompatibility. All donors should have their blood group and rhesus status recorded for matching purposes when required." <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Non-partner donation and partner donation: In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T. cruzi).	Eggs, sperm and embryos	no comments	NO	
	Other technique								
<b>HLA testing</b>									
Genetic testing, please specify condition	Specify technique	YES	YES	HFEA: Licence condition T52(i), guidance note 11. Professional guidance (ACE and BFS) <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a> .	For all non-partner donation HFEA requires: "Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained". Further guidance on genetic testing of donors is provided by professional bodies (ACE and BFS): <a href="http://informahealthcare.com/doi/pdf/10.1080/14647270802563816">http://informahealthcare.com/doi/pdf/10.1080/14647270802563816</a>	Eggs, sperm and embryos	no comments	NO	