

France - 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 | | |
| VIRAL | | | | | | | | | |
| HIV 1 and HIV 2 | Anti-HIV 1 | YES | NO | N/A | all | all | | | |
| | Anti-HIV 2 | YES | NO | N/A | all | all | | | |
| | HIV 1p24 | YES | NO | N/A | all | all | in France HIV testing is systematically a combined test with Anti-HIV1/2 and HIV1 p24 For cells donors HIV combined test and HIV test are mandatory. | | |
| | HIV NAT | YES | NO | N/A | all | all | | | |
| | Ag HIV Other technique | | | | | | | | |
| Hepatitis B | HBs Ag | YES | NO | N/A | all | all | | | |
| | Anti-HBc | YES | NO | N/A | all | all | | | |
| | Anti - HBs | YES | NO | N/A | all | all | only if anti-HBc is positive | | |
| | HBV NAT | YES | NO | N/A | all | all | no comment | | |
| | Other technique | | | | | | | | |
| Hepatitis C | Anti-HCV | YES | NO | N/A | all | all | | | |
| | HCV NAT | YES | NO | N/A | all | all | no comment | | |
| | Other technique | | | | | | | | |
| HTLV-1 | Technique not specified | YES | NO | N/A | all | all | no comment | | |
| | Anti-HTLV-1 | YES | NO | N/A | donors living in or originating from a high prevalence area, or parents or sexual partners originating from those areas | all | | | |
| | HTLV-1 NAT Other technique | | | | | | | | |
| HTLV-2 | Technique not specified | YES | NO | N/A | all | all | no comment | | |
| | Anti-HTLV-2 | YES | NO | N/A | all | all | no comment | | |
| | HTLV-2 NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| Chikungunya virus | Technique not specified | YES | NO | N/A | all | all | no comment | yes : regional | |

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|-----------------|-------------------------|-----------------|-------------------------------|--|---|-----------------------------|---|---|------------------|
| | | | | | Donor profile | Tissue/cell type | Comments | | |
| | Anti-CHIKV | NO | YES | A specific committee of ANSM in cooperation with other agencies (ABM, EFS, CTSA, InVS), national reference centers and the Health Ministry decides on the measures to be taken concerning donors' exclusion. There is no recommendation on a specific technique for donor testing. | all | all | | differences between procurement in areas with endemic risk and areas without endemic risk | |
| | CHIKV NAT | NO | YES | A specific committee of ANSM in cooperation with other agencies (ABM, EFS, CTSA, InVS), national reference centers and the Health Ministry decides on the measures to be taken concerning donors' exclusion. There is no recommendation on a specific technique for donor testing. | Tissues and cells donors without clinical signs who travel in countries with transmission risk during last 28 days. | all | Cornea and Kidney collected on area where epidemics happens in the past, donors are screened for anti-CHIKV. CHIKV NAT on sclera is triggered when serology is positive. If NAT is positive then cornea is not grafted. | | |
| | Other technique | | | | | | | | |
| Cytomegalovirus | Technique not specified | YES | NO | N/A | all | all | no comment | | |
| | Anti-CMV | YES | YES | ANSM | cell allogenic donors | all kind of allogenic cells | no comment | | |
| | CMV NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| Dengue Virus | Technique not specified | | | | | | | yes See attachment | |
| | Anti-DENV | | | | | | No CE marked technique available on the market | | |
| | NAT | | | | | | No CE marked technique available on the market | | |
| | Other technique | | | | | | | | |
| Ebola Virus | Technique not specified | | | | | | | See attachment | |
| | Ebola Virus NAT | | | | | | | | |

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| | | | | | Donor profile | Tissue/cell type | Comments | | |
| | Other technique | NO | YES | A specific committee of ANSM in cooperation with other agencies (ABM, EFS, CTSA, InVS), national reference centers and the Health Ministry decides on the measures to be taken concerning donors' exclusion. There is no recommendation on a specific technique for donor testing. | High risk donors (e.g. with travel history in a country with an ongoing Ebola outbreak during last 2 months or contact with another patient having Ebola) are excluded from donation by the specific committee of ANSM decides with other agencies (ABM, EFS, CTSA, InVS), national reference centers and the Health Ministry | all organs since June 2015 (only lungs before) | In case of positive test donor is excluded. For high risk deceased donors without known results, a patient specific benefit/risk analysis is performed. For alive donors, postponed donation is recommended when possible | | |
| Epstein-Barr virus | Technique not specified | | | | | | | | |
| | Anti-EBV | NO | YES | ANSM | cell allogenic donors | all kind of allogenic cells | no comment | | |
| | Other technique | | | | | | | | |
| Hepatitis E | Technique not specified | YES | NO | N/A | all | all | no comment | | |
| | Anti-HEV | | | | | | | | |
| | HEV NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| Human Parvovirus B19 | | | | | | | | | |
| West Nile Virus | Technique not specified | | | | | | | yes | |
| | WNV minipool NAT | | | | | | | See attachment | |

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| | | | | | Donor profile | Tissue/cell type | Comments | | |
| | WNV ID NAT | NO | YES | specific committee of ANSM which decides with other agencies (ABM, EFS, CTSA, InVS), national reference centers and the Health Ministry | Collection and testing depend on travel history in countries with transmission risk during last 28 days after patient specific benefit/risk analysis | Test performed for tissue and cells collected inside risk areas. Tissues and cells collected outside risk areas are not tested. | In case of positive test donor is excluded. For high risk deceased donors without clinical sign, a patient specific benefit/risk analysis is performed. For alive donors, postponed donation is recommended when possible. <i>The relevance of these measures was not evaluated at the moment of submission of the reply to this survey.</i> | | |
| | Other technique | | | | | | | | |
| specify pathogen | | | | | | | | | |
| PARASITIC | | | | | | | | | |
| Babesiosis | | | | | | | | | |
| Leishmaniasis | | | | | | | | | |
| Malaria | Technique not specified | NO | YES | ABM | tissue donors (from deceased donor) and cells from allogenic donor | | Plasmodium tests are recommended but the type of test is decided by the transplantation center | NO | |
| | Microscopy | NO | YES | ABM | | | | | |
| | <i>Plasmodium sp.</i> . Ab | NO | YES | ABM | | | | | |
| | <i>Plasmodium sp.</i> . Ag | NO | YES | ABM | | | | | |
| | <i>Plasmodium sp.</i> . Ag - rapid test | NO | YES | ABM | | | | | |
| | <i>Plasmodium sp.</i> . NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| Toxoplasmosis | Technique not specified | YES | NO | N/A | all | all | no comment | NO | |
| | Anti- <i>Toxoplasma gondii</i> | NO | YES | ANSM | cell allogenic donors | all kind of allogenic cells | no comment | | |
| | Microscopy | | | | | | | | |
| | Other technique | | | | | | | | |
| Trypanosomiasis | Technique not specified | | | | | | | Yes | only for Chagas disease |
| | Anti- <i>Trypanosoma cruzi</i> | NO | YES | ABM | tissue and cells donors depending stays in countries at risk | all | no comment | | |
| | Microscopy | | | | | | | | |
| | Other technique | | | | | | | | |
| specify pathogen | | | | | | | | | |
| BACTERIAL | | | | | | | | | |

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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>Treponema pallidum</i> (Syphilis) | Technique not specified | YES | NO | N/A | all | all | | NO | | |
| | Anti- <i>T. pallidum</i> | NO | YES | ANSM | all | all | no comment | | | |
| | Microscopy | | | | | | | | | |
| | <i>T. pallidum</i> NAT | | | | | | | | | |
| Other technique | | | | | | | | | | |
| <i>Chlamydia trachomatis</i> | | | | | | | | | | |
| <i>Neisseria gonorrhoeae</i> | | | | | | | | | | |
| Brucellosis | | | | | | | | | | |
| Tuberculosis | | | | | | | | | | |
| Q-fever | | | | | | | | | | |
| specify pathogen | | | | | | | | | | |
| FUNGI | | | | | | | | | | |
| specify pathogen | | | | | | | | | | |
| Transmissible spongiform | | | | | | | | | | |
| Other Tests | | | | | | | | | | |
| ABO blood group testing | ABO typing | YES | NO | N/A | cell donors | allogeneic and autologous cells | no comment | | | |
| | Other technique | | | | | | | | | |
| RhD blood group testing | RhD typing | YES | NO | N/A | cell donors | allogeneic and autologous cells | no comment | | | |
| | Other technique | | | | | | | | | |
| HLA testing | Technique not specified | | | | | | | | | |
| | HLA Ab | | | | | | | | | |
| | HLA Ag | YES | NO | N/A | HSC donors | hematopoietic allogeneic stem cells | no comment | | | |
| | HLA gene | | | | | | | | | |
| Other technique | | | | | | | | | | |
| Genetic testing, please specify condition | | | | | | | | | | |

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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 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 | | |
| VIRAL | | | | | | | | | |
| HIV 1 and HIV 2 | Anti-HIV 1 | YES | NO | N/A | All ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | In France HIV testing is systematically a combined test with Anti-HIV1/2 and HIV1 p24 | No regional differences (national requirements) | <p><u>According to regulations in place,</u></p> <ul style="list-style-type: none"> - In non partner sperm donation, 2 testing (Anti-HIV, HCV, HBC) are mandatory (the 2nd testing must be performed 6 months after the last sperm collection). - In non partner egg donation, 2 testing (Anti-HIV, HCV, HBC) are mandatory (the 2nd at the beginning of the ovarian stimulation). <p><u>According to new regulations proposed (foreseen for 2015),</u></p> <ul style="list-style-type: none"> - In non partner sperm donation, NAT testing for HIV, HCV and HBC at the last collection will be possible in order to avoid the 180 days quarantine, - In non partner egg donation, NAT testing will be mandatory |
| | Anti-HIV 2 | YES | NO | N/A | All ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | | | |
| | HIV 1p24 | YES | NO | N/A | ALL ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | | | |
| | HIV NAT Ag HIV Other technique | | | | | | | | |
| Hepatitis B | HBs Ag | YES | NO | N/A | For all : <ul style="list-style-type: none"> - ART patients (both members of the couple) - Patient (fertility preservation) - Non partner donors | all | Additional tests can be required depending of the context and the results | idem HIV regarding non partner donors: the same changes are expected. | |
| | Anti-HBc | YES | NO | N/A | ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | | | |

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|-------------|-------------------------|-----|----|-----|---|-----|---|--|--|
| | Anti - HBs | YES | NO | N/A | ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | no comment | | |
| | HBV NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| Hepatitis C | Anti-HCV | YES | NO | N/A | For all : ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | Additional tests can be required depending of the context and the results | | |
| | HCV NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| HTLV-1 | Technique not specified | | | | | | | | |
| | Anti-HTLV-1 | YES | NO | N/A | Mandatory for non partner donors. Not mandatory for patients requesting fertility preservation (depending on whether they live in regions with high incidence of HTLV-1 or who are originating from these regions, or whose sex partners or parents are from these regions) | all | | | |
| | HTLV-1 NAT | | | | | | | | |
| | Other technique | | | | | | | | |
| HTLV-2 | Technique not specified | | | | | | | | |

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| | | | | | | | | | | |
|-----------------------------|-------------------------|-------------------------|-----|-----|---|--|-----------------|------------|--|--|
| | Anti-HTLV-2 | YES | NO | N/A | Mandatory for non partner donors. Not mandatory for patients requesting fertility preservation (depending on whether they live in regions with high incidence of HTLV-1 or who are originating from these regions, or whose sex partners or parents are from these regions) | all | no comment | | | |
| | HTLV-2 NAT | | | | | | | | | |
| | Other technique | | | | | | | | | |
| Chikungunya virus | | | | | | | | | | |
| Cytomegalovirus | | | | | | | | | | |
| | Technique not specified | | | | | | | | | |
| | Anti-CMV | YES | NO | N/A | Mandatory for non-partner donors | all | no comment | | | |
| | CMV NAT | | | | | | | | | |
| | Other technique | | | | | | | | | |
| Dengue Virus | | | | | | | | | | |
| Ebola Virus | | | | | | | | | | |
| Epstein-Barr virus | | | | | | | | | | |
| Hepatitis E | | | | | | | | | | |
| Human Parvovirus B19 | | | | | | | | | | |
| Herpes simplex virus | | | | | | | | | | |
| West Nile Virus | | | | | | | | | | |
| | Rubella | Technique not specified | YES | NO | N/A | female partner in the ART couple (depending on previous results and vaccine, if available) | oocytes, embryo | no comment | | |
| | specify technique | | | | | | | | | |
| specify pathogen | | | | | | | | | | |
| PARASITIC | | | | | | | | | | |
| Babesiosis | | | | | | | | | | |
| Leishmaniasis | | | | | | | | | | |
| Malaria | | | | | | | | | | |
| Toxoplasmosis | | | | | | | | | | |
| Trypanosomiasis | | | | | | | | | | |
| specify pathogen | | | | | | | | | | |
| BACTERIAL | | | | | | | | | | |

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|---|---------------------------|-----|----|-----|---|-----|--|
| <i>Treponema pallidum</i> (Syphilis) | Technique not specified | YES | NO | N/A | For all : ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | 2 tests systematically (mandatory) associated such as Anticardiolipids + Anti T pallidum |
| | Anti- <i>T. pallidum</i> | YES | NO | N/A | ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | |
| | Microscopy | YES | NO | N/A | ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | |
| | <i>T. pallidum</i> NAT | | | | | | |
| | Other technique | YES | NO | N/A | ART patients (both members of the couple), patient (fertility preservation), non-partner donors | all | Anti cardiolipids (VDRL) |
| <i>Chlamydia trachomatis</i> | Technique not specified | | | | | | |
| | <i>C. trachomatis</i> DFA | | | | | | |
| | <i>C. trachomatis</i> EIA | | | | | | |
| | <i>C. trachomatis</i> NAT | YES | NO | N/A | Mandatory in non partner donors | all | |
| | Culture | | | | | | |
| Other technique | | | | | | | |
| <i>Neisseria gonorrhoeae</i> | | | | | | | |
| Brucellosis | | | | | | | |
| Tuberculosis | | | | | | | |
| Q-fever | | | | | | | |
| specify pathogen | | | | | | | |
| FUNGI | | | | | | | |
| specify pathogen | | | | | | | |
| Transmissible spongiform encephalopathies | | | | | | | |
| Other Tests | | | | | | | |
| ABO blood group | | | | | | | |
| RhD blood group | | | | | | | |

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| | |
|---|--|
| HLA testing | |
| Genetic testing, please specify condition | |