# Change Notification for the UK Blood and Tissue Services

**Notification date** 22 July 2026
**Effective date** 19 August 2026
**Implementation** To be determined by each Service

CN 25-2026

## Chapter 9

## Microbiology tests for donors and donations: general specifications for laboratory test procedures

| | Content changed | Type of change | Guidelines affected |
|---|---|---|---|
| 1 | Chapter 9.2: Microbiology screening | Updated chapter | Red Book |
| 2 | Chapter 9.4: Reinstatement of blood donors | Updated chapter | Red Book |

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**Note:** this document indicates inserted and ~~deleted~~ text. This formatting will not apply in the published text.

# 1. Chapter 9.2: Microbiology screening

| Guidelines affected | Reason for change |
|---|---|
| Red Book | Updated guidance related to mandatory, discretional, optional and recommended screening for blood, tissue and stem cell donations.<br><br>Previous table of requirements for screening of tissue and stem cell donations has been separated into individual tables for each donation type. |

## 9.2: Microbiology screening

The guidance presented in this chapter describes the recommended minimum standards for screening of blood, tissues (living and deceased) and stem cells in the UK.

This guidance may be based on UK or Council of Europe guidelines, including:

- European Directorate for the Quality of Medicines and HealthCare (EDQM) 'Guide to the preparation, use and quality assurance of blood components' (known as the 'Blood Guide')
- EDQM 'Guide to quality and safety of tissues and cells for human application' (known as the 'Tissues and Cells Guide')
- European Union (EU) European Centre for Disease Prevention and Control (ECDC) outputs (e.g. HBsAg)
- a specific instruction from the Department of Health and Social Care (DHSC), including its advisory committees (e.g. HEV)
- an Act of Parliament (e.g. syphilis)
- best practice as approved by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and its advisory committees (e.g. selective HTLV screening)

Individual services can choose to test to a higher standard (e.g. individual testing or smaller pool sizes for molecular tests) but must obtain the minimum standards described in:

- Table 9.1 for blood donations
- Table 9.2 for living tissue donations
- Table 9.3 for deceased tissue donations
- Table 9.4 for stem cell and cord blood donations

In general, microbiology screening is carried out on individual donations. However, as nucleic acid testing (NAT) is highly sensitive, it is possible, in certain instances, to screen donations in pools. Where pooled NAT testing is employed, the pool size should be determined by risk assessment, taking into consideration sensitivity of the assay, the endemicity of the infectious agent in the population to be screened, the estimated residual risk and/or any fractionator requirement.

The current maximum validated pool sizes for use for NAT screening in the UK Blood Services are 16 donations for West Nile Virus (WNV), 24 donations for hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis E virus (HEV) and human immunodeficiency virus (HIV), and 96 donations for hepatitis A virus (HAV) and human parvovirus B19. When applied to microbiology screening, pool sizes must factor in the limit of detection of the specific assay being used. Certain donations that require molecular tests must be tested individually rather than in pools. In these instances, individual NAT (ID-NAT) is specified below. Tables 9.1 to 9.4 state which donations may be screened in pools, and which donations have been risk assessed to require ID-NAT.

Although neither are mandatory for blood donations in most of the UK, HIV RNA and HBV DNA are included in nucleic acid screening as the commercial systems available are multiplex assays. If HIV NAT testing is performed, dual-target HIV-1 assays and NAT assays that detect HIV-2 are recommended.

~~*Please note, the meanings of certain terms used in this section are defined in 9.2.6 below.*~~

### 9.2.1: Screening of donations/donors

Donation/donor screening can be broadly divided into two main categories:

1. **Mandatory** – an absolute requirement prior to the release of components. There are, however, different reasons for a specific infectious marker to be defined as 'mandatory' (see above). ~~*These include a UK or European Union regulatory requirement, a specific instruction from the Department of Health, including its Advisory Committees, and an Act of Parliament.*~~

2. ~~***Additional (also known as*** **Discretionary*****)***~~ – this test must be performed on certain donors/donations if indicated by medical, social or travel history (e.g. WNV). ~~*Performed because of specific additional and identifiable donor or recipient risk/regulatory requirement.*~~

Additional tests may be recommended by an advisory committee or a professional body but are not a regulatory requirement. Other testing can be optional, where testing is not mandatory but is done at the discretion of individual organisations or establishments. This also applies to situations where a mandatory test is repeated at the discretion of individual organisations or establishments.

The terminology used in this chapter aligns with that described in annex 7, and the meanings of these terms are defined below:

| | |
|---|---|
| **Mandatory** | The test is either a regulatory requirement or deemed necessary to ensure regulatory requirements relating to the assessment of donor suitability are met to ensure donor and recipient protection. |
| **Optional** | The test is not mandatory and is done at the discretion of individual organisations or establishments. This also applies to situations where a mandatory test is repeated at the discretion of individual organisations or establishments. |
| **Discretionary** | The test must be performed on certain donors/donations if indicated by medical, social or travel history, or donation history. |
| **Recommended** | This test is recommended by an advisory committee or a professional body but is not a regulatory requirement. |

| | |
|---|---|
| **Non-reactive (NR)** | A sample whose reactivity when first tested falls below the assay cut-off as defined by the manufacturer's instructions. This may also be referred to as a 'negative' test result. |
| **Initial reactive (IR)** | Any sample whose reactivity when first tested falls above the cut-off as defined by the manufacturer's instructions. |
| **Repeat reactive (RR)** | Any sample reactive on 2 or more occasions either in the same screening assay (duplicate), or in 2 or more screening assays that are used in combination sequentially, to determine the suitability of a donation for release for clinical use. |
| **Alternative screening assay** | When a second assay for the same screening target, and of similar sensitivity, is used sequentially to screen a sample which is either IR or RR in a first screening assay. |
| **Confirmatory testing** | Full investigation, in a designated reference laboratory, of a RR sample to determine whether the reactivity is specific to the infectious agent being screened for and indicative of current or past infection in the donor. |
| **Positive** | A sample whose reactivity in confirmatory testing meets pre-defined criteria. This may indicate current or past infection. |
| **Inconclusive** | A sample whose reactivity in confirmatory testing is not sufficient and/or specific enough to determine whether it reflects infection or possible non-specific reactivity. |
| **Negative** | A sample whose screen reactivity, on investigation, is either not demonstrable or is deemed not to reflect infection. |
| **Individual nucleic acid test (ID-NAT)** | Molecular screening of a donation as an individual sample (as opposed to pooled testing). |
| **Pooled nucleic acid test (NAT)** | NAT screening can be performed on pooled samples for certain donations. If testing in pools is permitted, the 95% limit of detection should be based on a risk assessment. |
| **95% limit of detection (LoD)** | Lowest concentration at which 95% of positive samples are detected. |

Importantly, the mandatory requirements for blood donation and for tissue and stem cell donations are different, with some tests that are defined as 'discretionary' ~~*'additional'*~~ for blood donations being 'mandatory' for non-blood donations (Tables 9.1 to 9.4 ~~*and 9.2*~~).

Although not required for all donations, where additional (discretionary, optional or recommended) screening is required, the results are an integral part of the criteria for the release of that donation/component/product. In addition, for certain donation types, there is the option of quarantine and follow-up serological screening before issue or the inclusion of genomic screening at donation.

For tissues (living and deceased), the EDQM 'Guide to the quality and safety of tissues and cells for human application' indicates that if anti-HBc is 'reactive', an additional determination using a highly sensitive HBV DNA test must be negative and recommends that the most sensitive test available is used. If anti-HBc is positive and HBsAg and HBV NAT are negative, the donated tissues can be released. As best practice in the UK, individual HBV DNA testing is recommended for all tissues (haemodilution may influence the limit of detection).

Donations and any associated components/products must not be released to stock unless they have been screened and found negative for the mandatory, and any additional, microbiological screening required. In certain circumstances for certain donation/component types, a reactive screen result may not preclude release of the donations/component (see chapter 9.2.5 and chapter 9.4.1).

Where a number is indicated [#] in the table, refer to the explanatory notes below.

**Table 9.1: Screening required for blood donations**

(please note, the existing table has also been reordered alphabetically by infectious agent)

| **Infectious** agent | Marker ~~Minimum requirement~~ | Requirement | Format | ~~Comments [1]~~ |
|---|---|---|---|---|
| HAV | HAV RNA ~~(A)~~ | Optional [1] | Pooled | ~~RNA screening in pools of a maximum of 96 donations~~ |
| HBV | HBsAg ~~(M)~~ | Mandatory | Individual | ~~DNA screening in pools of a maximum of 24 donations [3]~~ |
| HBV | HBV DNA ~~[2]~~ | Recommended | Pooled | ~~Donations that are anti-HBc reactive and have anti-HBs >100 mIU/mL, tested in the past 24 months by a UK Blood Service, are considered suitable for release if HBsAg and ID HBV DNA negative~~ |
| HBV | anti-HBc ~~[+anti-HBs] (A) [4]~~ | Discretionary [2] | Individual | |
| HCMV | anti-HCMV [3] ~~(A)~~ | Optional | Individual | ~~Ideally both IgG and IgM, but IgG alone is considered sufficient~~ |
| HCV | anti-HCV ~~(M)~~ | Mandatory | Individual | ~~RNA screening in pools of a maximum of 24 donations [3]~~ |
| HCV | HCV RNA ~~(M)~~ | Mandatory | Pooled | |
| HEV | HEV RNA ~~(M)~~ | Mandatory | Pooled | ~~RNA screening in pools of a maximum of 24 donations [3]~~ |
| HIV ~~1+2~~ | ~~anti-HIV 1+2+O or~~ HIV 1+2~~+O~~ Ag/Ab [4] ~~(M)~~ | Mandatory | Individual | ~~RNA screening in pools of a maximum of 24 donations [3]~~ |
| HIV | HIV RNA [4] ~~[2]~~ | Mandatory/ Recommended [5] | Pooled | |
| HTLV ~~I/II~~ | anti-HTLV I/II ~~(M) [5]~~ | Discretionary [6] | Individual | ~~Serology screening individually or in pools of a maximum of 24 donations [3]~~ |
| Human B19 | B19 DNA ~~(A)~~ | Optional [1] | Pooled | ~~DNA screening in pools of a maximum of 96 donations~~ |
| *Plasmodium* sp. | anti-*P. falciparum*/*vivax* ~~(A)~~ | Discretionary | Individual | ~~None~~ |
| Syphilis | anti-treponemal ~~(M)~~ | Mandatory | Individual | ~~None~~ |
| *Trypanosoma cruzi* | anti-*T. cruzi* ~~(A)~~ | Discretionary | Individual | ~~None~~ |
| WNV | WNV RNA ~~(A)~~ | Discretionary | Pooled | ~~RNA screening in pools of a maximum of 16 donations [6]~~ |

**Notes on Table 9.1**

1. Required for plasma collected for the production of plasma derived medicinal products.
2. As a minimum, all blood donors are to be screened for anti-HBc at their first donation or their first donation after the introduction of anti-HBc screening. anti-HBc screening to be repeated if a donor lapses (over 2 years) or has a new HBV risk.
3. Ideally both IgG and IgM, but IgG alone is considered sufficient.
4. In addition to HIV-1 groups M and N, HIV-1 assays should also detect HIV group O.
5. HIV RNA is mandatory within Scotland.
6. As a minimum, all blood donors are to be screened for anti-HTLV at their first donation or their first donation after the introduction of anti-HTLV screening or if the blood donation is destined for use to prepare non-leucodepleted products. anti-HTLV screening to be repeated if a donor has a new HTLV risk.

(~~*M) - mandatory (release criteria) for the purpose of these guidelines.*~~

~~*(A) - additional (release criteria) due to specifically identifiable risk.*~~

~~*1. All microbiology screening performed on individual donations unless specified otherwise.*~~

~~*2. Although neither are mandatory for blood donations in most of the UK, HIV RNA and HBV DNA are included in nucleic acid screening as the commercial systems available are now triplex assays. HIV RNA is, however, mandated within Scotland.*~~

~~*3. The minimum sensitivity of the molecular screening is dependent upon pool size. The maximum validated pool size for use for mandatory blood screening within the UK Blood Transfusion Services is 24 donations.*~~

~~*4. All blood donors are to be screened for anti-HBc at their first donation or their first donation after the introduction of anti-HBc screening. Anti-HBc screening to be repeated if a donor lapses (over 2 years) or has a new HBV risk.*~~

~~*5. anti-HTLV screening is only required for blood donations from previously untested donors and for blood donations destined for use to prepare non-leucodepleted products.*~~

~~*6. The maximum validated pool size for WNV RNA screening is 16 donations.*~~

Where a number is indicated [#] in the table, refer to the explanatory notes below.

**Table 9.2: Screening required for living tissue ~~and stem cell~~ donations**

(please note, the existing table has also been reordered alphabetically by infectious agent)

| Infectious agent | Marker<br>~~Minimum requirement~~ | Requirement | Format | ~~Comments [1]~~ |
|---|---|---|---|---|
| HBV | HBsAg ~~(M)~~ | Mandatory | Individual | ~~Stem cell donors: as for blood donors (for HBsAg and HBV DNA, anti-HBc mandatory for stem cell donors)~~ |
| HBV | anti-HBc [1] ~~(M)~~<br>~~[+anti-HBs] (O) [2]~~ | Mandatory | Individual | ~~**Either:** donations that are anti-HBc reactive and have anti-HBs ≥100 mIU/mL are considered suitable for release~~<br>~~**Or:** donations that are anti-HBc reactive and are HBsAg and ID HBV DNA negative do not require an anti-HBs level of ≥100 mIU/mL to be considered suitable for release [3]~~ |
| HBV | HBV DNA ~~(O) [3]~~ | Recommended [2] | Individual | |
| ~~HCMV~~ | ~~anti-HCMV (A)~~ | | | ~~Ideally both IgG and IgM, but IgG alone is considered sufficient~~ |
| HCV | anti-HCV ~~(M)~~ | Mandatory | Individual | ~~Stem cell donors: as for blood donors~~ |
| HCV | HCV Ag and/or<br>HCV Ag/Ab ~~(O)~~ | Optional | Individual | |
| HCV | HCV RNA ~~(O)~~ | Recommended [2] | Individual | |
| HEV | HEV RNA ~~(A)~~ | Optional [3] | Pooled [4] | ~~RNA screening in pools of a maximum of 24 donations [4]~~ |
| HIV ~~1+2~~ | ~~anti-HIV 1+2+O or~~<br>HIV 1+2~~+O~~ Ag/Ab [5] ~~(M)~~ | Mandatory | Individual | ~~Stem cell donors: as for blood donors~~ |
| HIV | HIV RNA [5] ~~(O)~~ | Recommended [2] | Individual | |
| HTLV ~~I/II~~ | anti-HTLV I/II ~~(M) [4,5]~~ | Discretionary [6] | Individual | ~~Serology screening individually or in pools of a maximum of 24 donations [4]~~ |
| *Plasmodium* sp. | anti-*P. falciparum/vivax* ~~(A)~~ | Discretionary | Individual | |
| *Plasmodium* sp. | *Plasmodium* spp. DNA ~~(A)~~ [7] | Optional | Individual | |
| Syphilis | anti-treponemal ~~(M)~~ | Mandatory | Individual | |
| *Trypanosoma cruzi* | anti-*T. cruzi* ~~(A)~~ | Discretionary | Individual | |
| WNV | WNV RNA ~~(A)~~ | Discretionary | Pooled [4] | ~~Maximum of 16 donations [6]~~ |

**Notes on Table 9.2**

1. anti-HBc reactive tissue donations can be considered suitable for release if both HBsAg and individual HBV DNA are negative (this can be a multiplex ID-NAT).
2. NAT testing is not mandatory for living tissue donors, however if not done on the donation sample, the tissue must be quarantined for at least 180 days and a further sample taken for serological testing before it can be released. If the quarantine option is not utilised, due to the recommendation for individual HBV DNA testing and due to the triplex nature of commercial NAT assays, all tissues will undergo ID-NAT (for HCV, HIV and HBV).
3. HEV RNA testing is not mandatory for living tissue donations, no specific identifiable risk.
4. Samples from living tissue donors may be pooled for HEV RNA testing (current maximum pool size is 24 samples) and WNV RNA testing (current maximum pool size is 16 donations).
5. In addition to HIV-1 groups M and N, HIV-1 assays should also detect HIV group O.
6. HTLV testing is not mandatory for all living tissue donors, but is 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. In practice, all tissue donations are tested for anti-HTLV I/II.
7. For acceptance of anti-malaria positive tissue donations, see 'Malaria' in the Tissue (Live Donors) Donor Selection Guidelines (TL-DSG).

~~*(M) - mandatory (release criteria) for the purpose of these guidelines.*~~

~~*(A) - additional (release criteria) due to specifically identifiable risk.*~~

~~*(O) - optional, genomic screening for HIV, HCV and HBV nucleic acids is not mandated but can be performed on the original donation sample as an alternative to 180 days' quarantine and follow-up serological testing.*~~

~~*1. All microbiology screening performed on individual donations unless specified otherwise.*~~

~~*2. UK screening requirements. Other testing (e.g. EBV, toxoplasmosis) may be required as additional tests depending upon specific additional risk and/or special requests for individual recipients. For certain product types that are exported, there may be additional end user screening requirements.*~~

~~*3. anti-HBc reactive tissue and stem cell donations do not need to have an anti-HBs level ≥100 mIU/ml to be considered suitable for release if both HBsAg and ID HBV NAT are negative on screening.*~~

~~*4. All screening of deceased tissue donations should be performed on individual samples. Anti-HTLV I/II screening of surgical tissues/stem cells may be performed using pools of a maximum of 24 samples. HEV RNA screening of surgical tissues may be performed using pools of a maximum of 24 samples.*~~

~~*5. Not mandatory for avascular tissue donations but may be considered good practice.*~~

~~*6. The maximum validated pool size for WNV RNA screening is 16 donations.*~~

~~*7. Certain tissues and cord bloods from donors with malaria risk and which are found to be malaria antibody positive may be released for use if additional testing for malaria DNA is performed and malaria DNA is not detected (see Tissue Donor Selection Guidelines)*~~

Where a number is indicated [#] in the table, refer to the explanatory notes below.

**Table 9.3: Screening required for deceased tissue donations**

| Infectious agent | Marker | Requirement | Format |
|---|---|---|---|
| HBV | HBsAg | Mandatory | Individual |
| HBV | anti-HBc [1] | Mandatory | Individual |
| HBV | HBV DNA | Mandatory | Individual |
| HCV | anti-HCV | Mandatory | Individual |
| HCV | HCV Ag and/or HCV Ag/Ab | Optional | Individual |
| HCV | HCV RNA | Mandatory | Individual |
| HEV | HEV RNA | Optional [2] | Individual [3] |
| HIV | HIV 1+2 Ag/Ab [4] | Mandatory | Individual |
| HIV | HIV RNA [4] | Mandatory | Individual |
| HTLV | anti-HTLV I/II | Discretionary [5] | Individual |
| *Plasmodium* sp. | anti-*P. falciparum/vivax* | Discretionary | Individual |
| *Plasmodium* sp. | *Plasmodium* spp. DNA [6] | Optional | Individual |
| Syphilis | anti-treponemal | Mandatory | Individual |
| *Trypanosoma cruzi* | anti-*T. cruzi* | Discretionary | Individual |
| WNV | WNV RNA | Discretionary | Individual [3] |

**Notes on Table 9.3**

1. anti-HBc reactive tissue donations can be considered suitable for release if both HBsAg and individual HBV DNA are negative (this can be a multiplex ID-NAT).
2. HEV RNA testing is not mandatory for deceased tissue donations (no specific identifiable risk).
3. Samples from deceased tissue donors, if taken ante-mortem before circulatory arrest, may be pooled for HEV RNA testing (current maximum pool size is 24 samples) and WNV RNA testing (current maximum pool size is 16 donations).
4. In addition to HIV-1 groups M and N, HIV-1 assays should also detect HIV group O. Dual-target HIV-1 assays and NAT assays that detect HIV-2 are recommended.
5. HTLV testing is not mandatory for deceased tissue donors but is 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. In practice, all tissue donations are tested for anti-HTLV I/II.
6. For acceptance of anti-malaria positive tissue donations, see 'Malaria' in the Tissue (Deceased Donors) Donor Selection Guidelines (TD-DSG).

Where a number is indicated [#] in the table, refer to the explanatory notes below.

**Table 9.4: Screening required for haematopoietic progenitor cells (HPC), therapeutic cells (TC), cord blood and human embryonic stem cell donations**

| Infectious agent [1] | Marker | Requirement | Format |
|---|---|---|---|
| EBV | anti-EBV [2] | Recommended/Optional | Individual |
| HBV | HBsAg | Mandatory | Individual |
| HBV | anti-HBc [3] | Mandatory | Individual |
| HBV | HBV DNA | Recommended [4] | Pooled |
| HCMV | anti-HCMV [5] | Recommended/Optional | Individual |
| HCV | anti-HCV | Mandatory | Individual |
| HCV | HCV RNA | Recommended [4] | Pooled |
| HEV | HEV RNA | Discretionary | Pooled |
| HIV | HIV 1+2 Ag/Ab [6] | Mandatory | Individual |
| HIV | HIV RNA [6] | Recommended [4] | Pooled |
| HTLV | anti-HTLV I/II | Discretionary [7] | Individual |
| *Plasmodium* sp. | anti-*P. falciparum/vivax* | Discretionary | Individual |
| *Plasmodium* sp. | *Plasmodium* spp. DNA [8] | Optional | Individual |
| Syphilis | anti-treponemal | Mandatory | Individual |
| *Toxoplasma gondii* | anti-*T. gondii* IgG/IgM [9] | Recommended/Optional | Pooled |
| *Trypanosoma cruzi* | anti-*T. cruzi* | Discretionary | Individual |
| WNV | WNV RNA | Discretionary | Pooled |

**Notes on Table 9.4**

1. Other testing (e.g. EBV, toxoplasmosis) may be required depending upon specific additional risk and/or special requests for individual recipients. For certain product types that are exported, there may be additional end user screening requirements.
2. See annex 7.
3. anti-HBc reactive cell donations can be considered suitable for release if both HBsAg and HBV DNA by individual HBV NAT are negative.
4. NAT testing for HBV, HCV and HIV is not mandatory for stem cell donations but replaces the need for quarantine and follow-up serological screening.
5. Ideally both IgG and IgM, but IgG alone is considered sufficient – see annex 7.
6. In addition to HIV-1 groups M and N, HIV-1 assays should also detect HIV group O.
7. HTLV testing is not mandatory for all cell donations but is 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. However, in practice, all cell donations are tested for anti-HTLV I/II.
8. For acceptance of anti-malaria positive donations, see 'Malaria' in the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines (BM-DSG) and 'Malaria' in the Cord Blood Donor Selection Guidelines (CB-DSG).
9. anti-*T. gondii* IgG and IgM should be testing for in the setting of allogeneic HPC and TC donation – see annex 7.

### 9.2.2: Deceased neonatal and infant tissue donors

(no changes to this section)

### 9.2.3: Serology screening algorithms

(no changes to this section)

### 9.2.4: Molecular screening algorithm

(no changes to this section)

### 9.2.5: Confirmatory testing

When a donation is screen reactive for any of the serological or molecular mandatory or additional microbiology tests described above (except for anti-HCMV) samples from the donor/donation must undergo confirmatory testing at a designated reference laboratory.

Blood donations that are anti-HBc positive with an anti-HBs titre greater than 100 IU/L can be accepted, and the donor may continue to donate although this is at the discretion of individual blood services. If these donors are allowed to donate, they must remain HBV DNA negative by ID-NAT at each subsequent donation and their anti-HBs titre must be retested at least every 2 years and remain greater than 100 IU/L.

~~*For blood, donations that are confirmed positive for anti-HBc from donors with anti-HBs >100 mIU/mL, tested in the past 24 months by a UK Blood Service, are considered suitable for release if HBsAg and ID HBV DNA negative.*~~

For tissues and cells, donations that are HBsAg negative and anti-HBc positive may be considered suitable for release if a sensitive HBV DNA test (a 95% LoD of 20 IU/L or below) is negative.

~~*For tissues and cells, **either** donations that are anti-HBc reactive and anti-HBs ≥100 mIU/mL are considered suitable for release **or** donations which are anti-HBc reactive and are HBsAg and ID HBV DNA negative are considered suitable for release without the need for anti-HBs level of ≥100 mIU/mL.*~~

anti-*T. gondii* IgG and IgM screening is recommended for HSC, donor lymphocyte infusions and other therapeutic cells (e.g. selected and cultured products including T-cells, natural killer cells, mesenchymal stem cells, cytotoxic T-lymphocytes, T-regulatory cells, tumour derived cells) and embryonic stem cell lines intended for clinical use derived from human embryos initially created for fertility treatment with the use of IgM positive donors avoided. Confirmation of anti-*T. gondii* IgM only reactivity is recommended due to known specificity issues with IgM assays.

If HEV, HAV or WNV RNA is confirmed in a donor, the donor record must be flagged as ‘temporary exclusion’ for 6 months. The donor can be reinstated automatically at least 6 months after the date of the index HEV, HAV or WNV RNA positive donation (see chapter 9.4).

If human B19 DNA is confirmed in a donor, the donor record must be flagged as 'temporary exclusion' for 4 weeks. The donor can be reinstated automatically at least 4 weeks after the date of the index DNA positive donation (see chapter 9.4).

In all other cases, the donor record must be flagged as ‘permanent exclusion risk - not to be used for clinical use’ or equivalent.

In all cases where a positive result is confirmed, arrangements should be made to inform the donor and to ensure that the donor is given appropriate advice.

Please note, autologous stem cell donations may be collected from individuals who are known to be infected with one or more of the infectious agents for which donations are routinely screened. Such individuals are not generally classified as donors for the purposes of these guidelines.

If a negative, inconclusive or indeterminate result is reported following confirmatory testing, and the initial reactivity is determined by the reference laboratory to be non-specific, use of further donations or the same donation (tissue and stem cell donors only) may be possible, as covered in chapter 9.4.

#### 9.2.5.1: Specific requirements for HBsAg confirmation

The designated reference laboratory should, when appropriate, perform specific neutralisation tests for HBsAg to ensure that donors with low-level HBsAg reactivity, in the absence of other HBV markers, are not incorrectly reported as non-specifically reactive.

## ~~9.2.6: Definitions~~

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| ~~**Non-reactive (NR)**~~ | ~~A sample whose reactivity when first tested falls below the assay cut-off as defined by the manufacturer’s instructions. May also be referred to as a ‘Negative’ test result.~~ |
| ~~**Initial reactive (IR)**~~ | ~~Any sample whose reactivity when first tested falls above the cut-off as defined by the manufacturer's instructions.~~ |
| ~~**Repeat reactive (RR)**~~ | ~~Any sample reactive on 2 or more occasions either in the same screening assay (duplicate) or in 2 or more screening assays that are used in combination sequentially, to determine the suitability of a donation for release for clinical use.~~ |
| ~~**Alternative screening assay**~~ | ~~When a second assay for the same screening target and of similar sensitivity is used sequentially to screen a sample which is either IR or RR in a first screening assay.~~ |
| ~~**Confirmatory testing**~~ | ~~Full investigation, in a designated reference laboratory, of a repeat reactive sample to determine whether the reactivity is specific to the infectious agent being screened for and indicative of current or past infection in the donor.~~ |
| ~~**Positive**~~ | ~~A sample whose reactivity in confirmatory testing meets pre-defined criteria. This may indicate current or past infection.~~ |
| ~~**Inconclusive**~~ | ~~A sample whose reactivity in confirmatory testing is not sufficient and/or specific enough to determine whether it reflects infection or possible non-specific reactivity.~~ |
| ~~**Negative**~~ | ~~A sample whose screen reactivity, on investigation, is either not demonstrable or is deemed not to reflect infection.~~ |
| ~~**Individual nucleic acid test (ID-NAT)**~~ | ~~Molecular screening of a donation as an individual sample (as opposed to pooled testing).~~ |

# 2. Chapter 9.4: Reinstatement of blood donors

| Guidelines affected | Reason for change |
|---|---|
| Red Book | Updated to align with changes to guidance on mandatory, discretional, optional and recommended screening for blood, tissue and stem cell donations in chapter 9.2. |

## 9.4: Reinstatement of blood donors

(no changes to this section)

### 9.4.1: Donors whose samples are confirmed positive

Donors whose blood samples are confirmed positive cannot normally be reinstated, even after successful treatment, as screening test reactivity will persist in serological assays, for example anti-HCV and TPHA.

Blood donations that are anti-HBc positive with an anti-HBs titre greater than 100 IU/L can be accepted, and the donor may continue to donate although this is at the discretion of individual blood services. If these donors are allowed to donate, they must remain HBV DNA negative by ID-NAT at each subsequent donation and their anti-HBs titre must be retested at least every 2 years and remain greater than 100 IU/L.

~~*For blood, donations that are confirmed positive for anti-HBc from a donor with anti-HBs >100 mIU/mL, tested in the past 24 months in a UK Blood and Tissue Service (UKBTS), are considered suitable for release if HBsAg and ID HBV DNA negative.*~~

For tissues and cells, donations that are confirmed as HBsAg negative and anti-HBc positive may be considered suitable for release if a sensitive HBV DNA test (a 95% LoD of 20 IU/L or below) is negative.

~~*For tissues and cells, either donations that are anti-HBc confirmed positive and anti-HBs ≥100 mIU/mL are considered suitable for release, or donations which are anti-HBc reactive and are HBsAg and ID HBV DNA negative do not require an anti-HBs level of ≥100 mIU/mL to be considered suitable for release.*~~

Donors with confirmed HEV, HAV or WNV infection should be deferred for 6 months from the date of first detection of HEV/HAV/WNV RNA. These donors may be reinstated without further testing 6 months from the date of the index RNA positive donation.

If a previously confirmed HEV infected donor is tested prior to the end of the 6-month deferral period and found to be HEV RNA negative on individual testing and HEV IgG positive at ≥1 IU/ml using the PEI International standard for HEV IgG (HEV IgM may or may not still be present), the donor may be reinstated immediately.

Donors with confirmed human B19 DNA should be deferred for 4 weeks from the date of first detection of B19 DNA. These donors may be reinstated without further testing 4 weeks from the date of the index DNA positive donation.

### 9.4.2: Donors whose samples are repeatedly reactive, but concluded after reference testing to represent non-specific reactivity

(no changes to this section)

### 9.4.3: Process to reinstate a confirmed non-specific reacting blood donor

(no changes to this section)