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## **Change Notification UK National Blood Services No. 12 - 2016**

### **Chapter 9 – Sections 9.1 to 9.4**

**Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8<sup>th</sup> Edition 2013**

Sections 9.1 to 9.4 of “Chapter 9 Microbiology tests for donors and donations: general specifications for laboratory test procedures” have been updated to include Hepatitis E Virus (HEV), the recent changes to Human T-Lymphotropic Virus (HTLV) screening requirements and the change in reinstatement rules for West Nile Virus (WNV).

**Table 9.1 Screening required for blood donations**

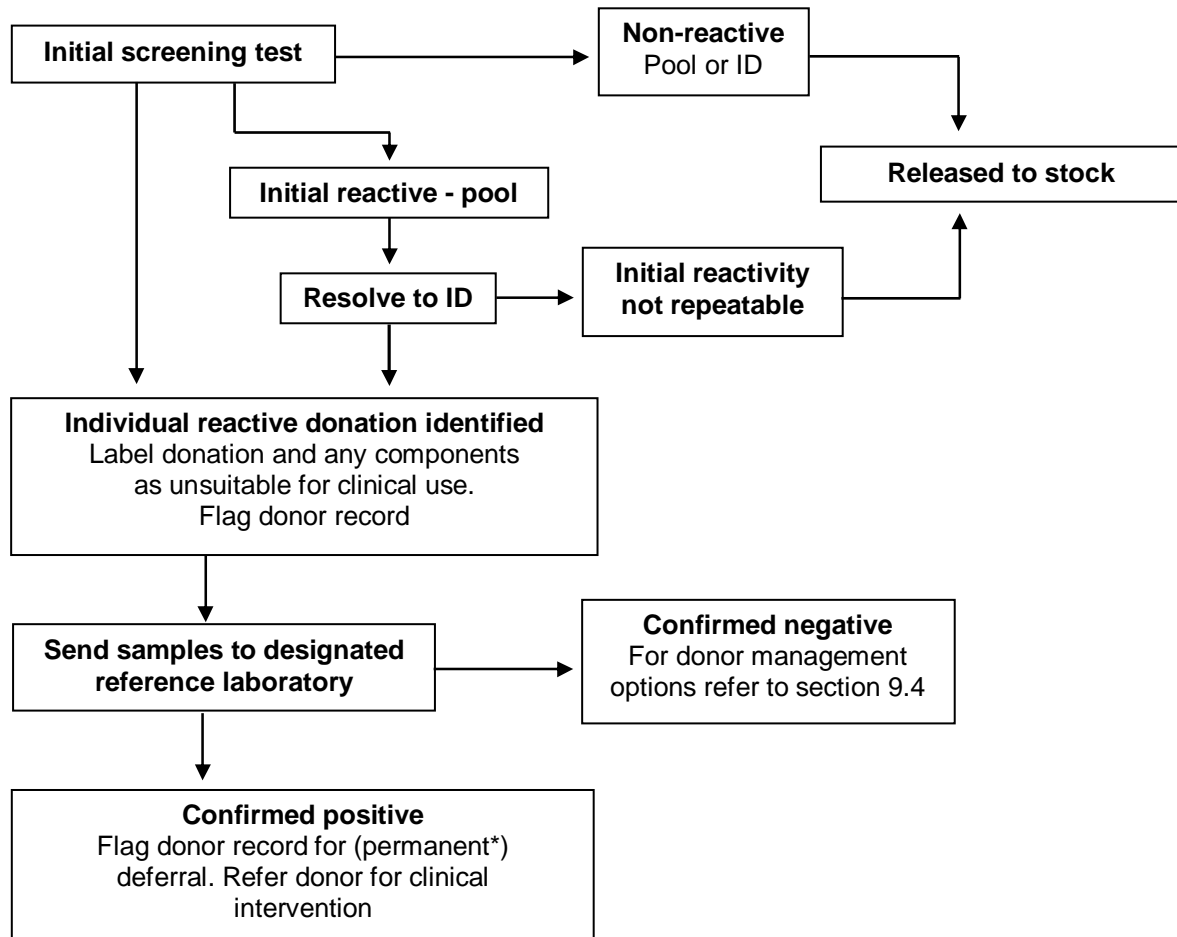
Infectious agent	Minimum requirement	Comments
HIV 1+2	anti-HIV 1+2 or HIV 1+2 Ag/Ab (M) HIV RNA*	RNA screening in pools of a maximum of 48 donations**
HCV	anti-HCV (M) HCV RNA (M)	RNA screening in pools of a maximum of 48 donations**
HBV	HBsAg (M) HBV DNA* anti-HBc [+ anti-HBs] (A)	DNA screening in pools of a maximum of 48 donations** Donations that are anti-HBc reactive and have anti-HBs >100 mIU/mL are considered suitable for release
Syphilis	anti-treponemal Ab (M)	
HTLV I/II	anti-HTLV I/II (A)***	ID or screening in pools of a maximum of 48 donations**
HEV	HEV RNA (A)	Screening in pools of a maximum of 24 donations**

HCMV	anti-HCMV (A)	Ideally both IgG and IgM, but IgG alone is considered sufficient
Plasmodium sp.	anti-P. falciparum/vivax (A)	
Trypanosoma cruzi	anti-T. cruzi (A)	
West Nile Virus (WNV)	WNV RNA (A)	RNA screening in pools of a maximum of 16 donations****
(M) – mandatory (release criteria) for the purpose of these guidelines		
(A) – additional due to specifically identifiable risk		
* Although neither are mandatory for blood donations in most of the UK, HIV RNA and HBV DNA are included in the nucleic acid amplification techniques (NAT) screen as the commercial systems available are now triplex assays. HIV RNA is mandated within Scotland.		
** The minimum sensitivity of the molecular screening is dependent upon pool size. The maximum validated pool size for use for blood screening within the UK Blood Transfusion Services is 48 donations.		
*** 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		
**** The maximum validated pool size for WNV NAT screening is 16 donations.		

**Table 9.2 Screening required for tissue and stem cell donations\***

Infectious agent	Minimum requirement	Comments
HIV 1+2	anti-HIV 1+2 or HIV 1+2 Ag/Ab (M) HIV RNA (O)	Maximum pool size of 24 donations**
HCV	anti-HCV (M) HCV Ag and/or HCV Ag/Ab (O) HCV RNA (O)	Maximum pool size of 24 donations**
HBV	HBsAg (M) anti-HBc [+ anti-HBs] (M)	Donations that are anti-HBc reactive and have anti-HBs >100 mIU/mL are

	HBV DNA** (O)	considered suitable for release
Syphilis	anti-treponemal Ab (M)	
HTLV I/II	anti-HTLV I/II (M)***	ID or maximum pool size of 24 donations**
HCMV	anti-HCMV (A)	
Plasmodiumsp.	anti-P.falciparum/vivax (A)	
Trypanosoma cruzi	anti-T. cruzi (A)	
West Nile Virus (WNV)	WNV RNA (A)	Maximum pool size of 16 donations****
(M) – mandatory		
(O) – optional, genomic screening for HIV, HCV and HBV is not mandated but can be performed on the original donation sample as an alternative to 180 days’ quarantine and follow-up serological testing		
(A) – additional due to specifically identifiable risk		
* UK screening requirements. Other testing, e.g. Epstein-Barr virus, 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 testing requirements.		
** All screening of deceased tissue donations is performed on individual samples. HCV and HIV RNA and anti-HTLV I/II screening of surgical tissues/stem cells can be performed using pools of a maximum of 24 samples. HBV DNA screening should be on individual samples.		
*** Not mandatory for avascular tissue donations but may be considered good practice.		
**** The maximum validated pool size for WNV RNA screening is 16 donations.		



\* Donors confirmed to be HEV or WNV RNA positive need only be deferred for 6 months from pick-up.

**Figure 9.3 Molecular screening: blood donations**

### 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 and anti-HBc, where anti-HBs is present at a level  $\geq 100$  mIU/mL), samples from the donor/donation must undergo confirmatory testing at a designated reference laboratory.

- If HEV 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 or WNV RNA positive donation: see section 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.

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 section 9.4.

#### **9.3.11: Hepatitis C virus RNA (HCV NAT)**

- The UK requirement for the minimum level of sensitivity for the performance of HCV NAT is 5000 IU/mL in an individual donation. An HCV international standard is available from the NIBSC.
- The assay must include a specific internal control for each sample tested.
- No series of tests should be considered acceptable unless the result of the assay manufacturer's and any additional quality control samples have satisfied the criteria laid down.
- Each manufacturer's batch/lot of HCV RNA test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening

#### **9.3.12: Hepatitis B virus DNA (HBV NAT)**

- There is currently no specific UK requirement for the minimum level of sensitivity for the performance of HBV NAT. An HBV international standard is available from the NIBSC.
- The assay must include a specific internal control for each sample tested.
- No series of tests should be considered acceptable unless the result of the assay manufacturer's and any additional quality control samples have satisfied the criteria laid down.
- Each manufacturer's batch/lot of HBV DNA test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening

#### **9.3.13: Human immunodeficiency virus RNA (HIV NAT)**

- There is currently no specific UK requirement for the minimum level of sensitivity for the performance of HIV NAT. An HIV international standard is available from the NIBSC.

- The assay must include a specific internal control for each sample tested.
- No series of tests should be considered acceptable unless the result of the assay manufacturer's and any additional quality control samples have satisfied the criteria laid down.
- Each manufacturer's batch/lot of HIV RNA test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening

#### 9.3.14: Hepatitis E virus RNA (HEV NAT)

- There is currently no specific UK requirement for the minimum level of sensitivity for the performance of HEV NAT
- The assay must include a specific internal control for each sample tested
- No series of tests should be considered acceptable unless the result of the assay manufacturer's and any additional quality control samples have satisfied the criteria laid down
- Each manufacturer's batch/lot of HEV RNA test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening

#### 9.3.15: West Nile virus RNA (WNV NAT)

The exclusion criteria for donors from a WNV risk area is given in the JPAC *Donor Selection Guidelines*.<sup>3</sup> These guidelines specify some situations where donations may only be released if a test for WNV RNA is negative. WNV RNA screening can be performed on donations provided by donors within the exclusion period and the donations released if WNV RNA negative.

- There is currently no specific UK requirement for the minimum level of sensitivity for the performance of WNV NAT.
- The assay must include a specific internal control for each sample tested.
- No series of tests should be considered acceptable unless the result of the assay manufacturer's and any additional quality control samples have satisfied the criteria laid down.
- Each manufacturer's batch/lot of WNV RNA test kits must be shown to conform with nationally established minimum criteria for specificity and sensitivity prior to being accepted for use for screening

## 9.4: Reinstatement of blood donors

### 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.
- Donors with acute HBV infection may be reinstated provided that they meet the criteria for an individual with previous (recovered) hepatitis B virus infection laid out in the current edition of the UK Donor Selection Guidelines
- Donors with confirmed HEV or WNV infection should be deferred for 6 months from the date of first detection of HEV/ 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 and HEV IgG positive, the donor may be reinstated immediately

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

Where a blood donation sample is found to be repeatedly reactive on screening, the donation and any components must not be released for clinical use.

- The donor's record must be flagged in accordance with standard operating procedures to prevent the issue of subsequent donations while awaiting the results of confirmatory testing in the reference laboratory
- The screen repeat reactive sample must be sent to a designated reference laboratory for confirmatory testing
- If the donation sample is determined by the reference laboratory to be demonstrating non-specific reactivity, subsequent donations from the donor may be considered suitable for issue provided that the associated donation samples are negative in the primary or an alternative screening assay (Figure 9.5).

### ~~9.4.1~~ 9.4.3: Process to reinstate a confirmed non-specific reacting blood donor



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