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 To be determined by each Service

Change Notification UK National Blood Services No. 23 - 2015

Removal of Section 9.4.2. and Figure 9.6 in Chapter 9

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

- Section 9.4.2. Process to reinstate a tissue/stem cell donor following confirmation that screen reactivity is not indicative of current/past infection
- Figure 9.6. Action chart tissue and cell donor reinstatement following confirmation that screen reactivity is not indicative of current or past infection

These sections of the guidelines have been reviewed by JPACs Standing Advisory Committee on Transfusion Transmitted Infection and it has been determined that Section 9.4.2, and the associated Figure 9.6, are redundant, and should be removed.

If a tissue or stem cell donor, who was previously screen reactive and the reactivity confirmed as nonspecific, provides a subsequent donation, the handling of that donation in respect of any screen reactivity is covered under Section 9.2.3.2. Effectively tissue/stem cell donors are not re-instated as the Red Book already allows for their donations to be used on the basis of reference results. The donor, therefore, is never actually deferred unless confirmed positive, in which case a subsequent donation would not be collected, except from an autologous stem cell donor.

JPAC approved the removal of Section 9.4.2 and Figure 9.6 from the 8th Edition of the Guidelines for Blood Transfusion Services in the United Kingdom and confirmed that the handling of screen reactive Tissue and Stem Cell donations should follow the guidelines set out in Section 9.2.3.2.

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Please remove:

9.4.2: Process to reinstate a tissue/stem cell donor following confirmation that screen reactivity is not indicative of current/past infection

A tissue/stem cell donor with screen reactivity that is concluded by the reference laboratory as not indicative of current/past infection may be considered for return to active status on a subsequent donation, and products from the subsequent donation issued for clinical use, provided that:

- the subsequent sample tests negative with the primary screening assay OR
- the subsequent sample tests negative with an alternative validated screening assay OR
- the subsequent sample, reactive in both the primary screening assay and the alternative screening assay, is once again tested in the reference laboratory and is confirmed to be negative for evidence of the infection in question.

See Figure 9.6 for an action chart depicting tissue and cell donor reinstatement.

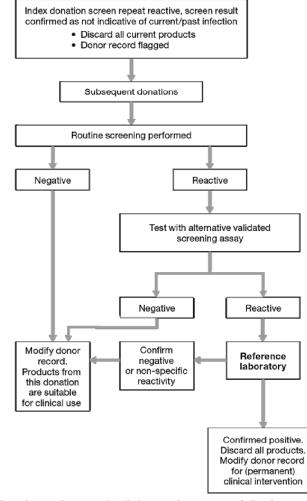


Figure 9.6 Action chart – tissue and cell donor reinstatement following confirmation that screen reactivity is not indicative of current or past infection