

Guidelines for the Blood Transfusion Services

20.11: Release criteria

<http://www.transfusionguidelines.org/red-book/chapter-20-tissue-banking-selection-of-donors/20-11-release-criteria>

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For allogeneic donors the concluded result of all microbiological assays, with the exception of syphilis and anti-HBc, must be negative for a tissue to be released from quarantine for issue. For donors who are found to be 'repeat reactive' in any screening assay but for whom subsequent testing confirms lack of infection, the initial reactivity in the screening assay is due to non-specific reactivity and any tissue products from this donation may be safely released for clinical use (see Chapter 9). In the case of allogeneic donors, the completed donor records must be reviewed and assessed for suitability and signed by a registered healthcare professional.

In the case of a deceased infant donor where a maternal sample is found to be positive for any mandatory marker of infection, the donation must not be used irrespective of the test result for the infant.

Donors with reactive confirmatory tests for the presence of treponemal infection should be fully assessed, taking into account the results of confirmatory (reference) testing and medical history. The presence of current (active) infection will exclude the use of tissues from such donors. Where the assessment leads to the conclusion that the risk of active infection is remote, then non-cardiovascular tissues may be used. The presence of serological marker patterns of treponemal infections (e.g. IgM positivity) should not be used as a sole criterion to determine the presence of active infection (and therefore their eligibility). Any reactive results obtained on confirmatory testing should be discussed with staff experienced in interpreting treponemal test results, before a decision is made to use tissues.

For autologous donors positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of mix-ups at issue.