

Guidelines for the Blood Transfusion Services

20.5: Donor testing

<http://www.transfusionguidelines.org/red-book/chapter-20-tissue-banking-selection-of-donors/20-5-donor-testing>

20.5: Donor testing

The general principles of microbiological testing and the specific testing requirements for tissue donors are covered in Annex B of the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment, and Chapter 9 of this Guide. Testing must be completed in a licensed Tissue Establishment or under a third-party agreement between the testing laboratory and the licensed Tissue Establishment. If a third-party laboratory is used to perform any aspect of donor testing, the specific requirements and responsibilities of both parties in achieving them must be defined in a written agreement. Such testing should, as a minimum, be performed in accordance with regulatory requirements and the guidance in this document. There should be protocols for assuring the veracity and security of the sample, labelling, and supporting documentation. The time from sample acquisition to initial processing, testing or freezing of the sample should be minimised and must be compliant with test kit manufacturers' recommendations. Any deviations from these must be validated for the purpose. Due consideration should be given to dilution of the sample (see section 20.7).

The Tissue Establishment should have a documented policy to follow in the case of donors with reactive screening tests. There should be protocols for alternative or confirmatory testing and acceptance or rejection of donations.

A positive result should be notified urgently to the source Tissue Establishment, Specialist Nurse Organ Donation or supplier of the tissue or cells so that clinicians in all centres that have received material from the same donor can be informed and take appropriate action. Where tissue or cells from a donor have been sent to other Tissue Establishments or centres, these Tissue Establishments or centres must be told about the positive result. Reports of positive tests should be included in the routine donor surveillance programmes and notified to the relevant public health authority. (See section 21.8).

In addition to mandatory tests done on all donor samples, additional discretionary testing may be required (e.g. for malaria, Chagas disease or West Nile Virus), dependent on the donor's travel history. RhD testing may be required on donors if the retrieved tissues will contain residual red cells or red cell membranes at the time of implantation. Discretionary tests, where undertaken, must be undertaken in accordance with the requirements set out above, to ensure that results can be relied upon.