Guidelines for the Blood Transfusion Services

9.6: Recommended standards for microbiological screening

http://www.transfusionguidelines.org/red-book/chapter-9-microbiology-tests-for-donors-and-donations-general-specifications-for-laboratory-test-procedures/9-6-recommended-standards-for-microbiological-screening

9.6: Recommended standards for microbiological screening

9.6.1: Tissues

All microbiological culture testing is subject to quality control tests in accordance with national accreditation standards and guidelines. This ensures that the risk of disease transmission is minimised and that tissue allografts are suitable for their intended use.

A written policy documenting the bacteriological acceptance criteria for specified tissues must be drawn up in consultation with a designated microbiologist.

Tissues must be screened for bacterial and fungal contamination by validated methods in accredited laboratories. Samples for bacterial screening (e.g. swab culture, bone chips etc.) must be obtained aseptically and placed in appropriate culture media at the time of retrieval or processing. Samples must be culture tested before and after exposure to decontaminating agents by enrichment liquid cultures to maximise the recovery of aerobic and anaerobic bacteria and fungi. If pathogenic, highly virulent bacteria are recovered (e.g. *Clostridium* spp. *Streptococcus pyogenes*, *Staphylococcus aureus*, *Candida* spp.) the tissue must not be used for transplantation unless it is effectively sterilised by a process such as gamma irradiation. It is considered good practice to test cardiovascular tissues for the presence of *Mycobacterium* spp. Tissues contaminated with opportunist species of low virulence must be decontaminated by a validated process. Tissues which cannot be terminally sterilised (e.g. heart valves, amnion, menisci, osteochondrals) must be discarded if post-decontamination tests prove positive. An exception is cryopreserved skin allografts, which can be transplanted if non-pathogenic bacteria are present.

If no suitable sample is available for screening for bacterial and fungal contamination, then the products must be handled in the same way as those which have positive culture results for highly virulent bacteria: either discard or terminal sterilisation with a process such as gamma irradiation.

If a tissue fails culture testing, other tissues from the same donor must be discarded unless processed separately or an assessment of the risk shows otherwise.

9.6.2: Cord blood

Cord blood donations are subject to the NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration[6]. Cord blood collections must be screened for bacterial (aerobic and anaerobic) and fungal contamination using a system permissive for the growth of these microorganisms (European Pharmacopoeia 2.6.27). All unrelated donations collected for public banking found positive for microbial growth must be discarded. Identification of any organism isolated needs to be undertaken and results reviewed by a microbiologist to identify potential sources of contamination. A trend analysis of contamination rates must be performed periodically to maintain quality.

9.6.3: Stem cells

Stem cell products (peripheral blood stem cells, bone marrow and whole blood) are subject to the FACT-JACIE International Standards for Haematopoietic Cellular Therapy Product Collection, Processing, and Administration[7].

All products (fresh and cryopreserved) must be tested for microbial contamination (European Pharmacopoeia 2.6.27) unless the total sample volume is specifically requested by the transplant surgeon to optimise dose for the recipient. Microbial isolates recovered from products must be identified to species level and antimicrobial susceptibilities determined. A trend analysis of data must be reviewed by relevant experts to identify potential sources of contamination.

9.6.4: Serum eye drops

Eye drops made from serum are used to treat ocular surface disorders. The serum is diluted with saline or used neat and dispensed under closed aseptic conditions and bacteriologically tested (European Pharmacopoeia 2.6.27). Samples must be tested for sterility in accordance with regulations.

Identification of positive cultures needs to be performed and advice sought from a medical microbiologist regarding the suitability of a product for use via a quality concession.