

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION K - QUALITY ASSURANCE

K1.000 QUALITY ASSURANCE PROGRAM

K2.200 Microbiological Tissue Cultures

Current (13th edition)

K2.210 Pre-Sterilization/Pre-Disinfection Cultures

(C, V) Standard E1.040 Sterilization/Disinfection of Tissue (C, V) applies.

- (S) Pre-processing skin cultures from representative anatomical areas shall be obtained prior to exposure of the tissue to antibiotic-containing *Processing* solutions or other disinfecting/sterilization methods. Culture results shall be documented in the donor's record. Individual anatomic areas yielding cultures positive for *Microorganisms* considered being pathogenic, highly virulent must be discarded unless the tissue can be disinfected/sterilized with a validated process (See E1.040 Sterilization/Disinfection of Tissue). The Medical Director or designee shall review all available pre-processing skin culture results prior to releasing the tissue for transplantation. Skin *Recovery* shall be performed as a separate zone from other tissue types so that culture results can be independently reviewed.

K2.220 Final/Pre-Packaging

(MS, OA, SB, C, V)

Microbiologic testing of processed tissue, which includes testing to detect bacteria and fungi, shall be performed on each donor *Lot*.

(with amendments)

K2.210 Pre-Sterilization/Pre-Disinfection Cultures

(C, V, [CT](#))

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