



TECHNICAL TIP

LABORATORY TESTING OF HUMAN TISSUE

Laboratory testing of human tissue requires special consideration to ensure safe product handling and accurate results. This TechTip addresses those considerations that should be addressed by both the donor organization and the test laboratory.

It is important to recognize that there is additional regulatory scrutiny for human tissue transplantation used to improve quality of life (bone, skin or soft tissue) compared to life-saving transplanted tissues (organs, vascular or optical tissues). This document focuses on those tissues transplanted for improving quality of life.

Safety Concerns for the Test Laboratory

When performing tissue testing, the primary concern for the test laboratory is to minimize the risk of transmitting infection and communicable disease. Infection can occur from a variety of sources in the transplantation process, whether it is collection, storage, tissue processing, testing, transportation, transplantation or a combination of these factors. Other factors to be considered include the type of tissue and the source of the tissue, including cause of death and other health conditions of the donor (e.g. TSE, malignancy, drug use). Risk should be mitigated through a robust quality program and routine audits of pre- and post-processed tissue. Testing of the donor for communicable diseases, such as HIV or Hepatitis, should also be performed prior to submission of samples to a test laboratory for microbiological analysis to ensure technician safety during testing.

Accurate Results

The audit program includes the microbiological evaluation of pre-processed tissue by bioburden assay. The method used to recover bacteria and fungi from the pre-processed tissue must be validated in order to account for the efficiency of the bioburden method for removal of organisms. Additionally, the tissue tested after disinfection processing, particularly if there

is antibiotic or chemical disinfection, should be assessed for inhibitory properties. An example of potential inhibition could be the antibiotic treatment that a donor was placed on prior to death. ISO 11737-1 Annex B states that samples should be screened for the release of substances affecting bioburden determinations and for the adverse effects of physical stress. This testing is performed by inoculation of low levels of different organism types and recovering acceptable populations against a set of control samples.

Considerations for bioburden assay should include the significance of the sample size, consistency of sample quality and size, and physical cleanliness of tissue samples. Lipids, oils and other debris can confound the bioburden assay and lead to inconsistency in reported results.

Contamination and Recipient Considerations

Incubation conditions of the test assay should be evaluated to address recovery of problematic organisms. Organisms recovered should be identified to determine pathogenicity of the contaminated donor tissue. Donors found to have pathogenic organisms should undergo terminal sterilization, such as gamma irradiation. Donors found to have organisms of less virulence may either undergo a validated disinfection process or be terminally sterilized.

Bacterial endotoxin testing is also performed to ensure the tissue does not generate a pyrogenic response to the recipient due to Gram-negative bacteria endotoxin. Testing should consider the impact of beta-glucan-like chemicals that can interfere with the testing. The method used for LAL testing should reconcile issues of inhibition or enhancement.

Sterility testing must also be tested for inhibition of organism growth. The sterility method suitability test (also known as Bacteriostasis/Fungistasis test) must be performed to eliminate the potential for false negative results.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies

Web: www.steris-ast.com // Email: ast_info@steris.com

(EMEA) +44 (0) 8456 88 99 70

(Americas) 877.783.7479





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REFERENCES

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2. ISO 11737-1:2006 (R2011) Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
3. ANSI/AAMI ST72:2011 Bacterial Endotoxin – Test Methodologies, routine monitoring, and alternatives to batch testing

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