



Interim Guidance Document

Standard K2.210 Pre-Sterilization/ Pre-Disinfection Cultures

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*American Association of Tissue Banks
Suite 450
1320 Old Chain Bridge Road
McLean, Virginia 22101
(703) 827-9582 (703) 356-2198 Facsimile*

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American Association of Tissue Banks
Suite 450
1320 Old Chain Bridge Road
McLean, Virginia 22101
www.aatb.org

For questions on the content of the document, please contact the AATB at:

(703) 827-9582 or (703) 356-2198 (Fax)

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TABLE OF CONTENTS

I.	Introduction	4
II.	Sampling Methods	4
III.	Test Methods	5
IV.	Summary	5
V.	References	6

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I. INTRODUCTION

AATB Standard K2.210 requires that appropriate pre-sterilization/pre-disinfection cultures from each donor shall be obtained and evaluated. This Interim Guidance Document is designed to provide basic information to assist tissue banks with the development of generally accepted pre-sterilization/pre-disinfection culture methods and sampling plans. However, please note that the methods summarized in this document are only a few limited examples of sampling strategies and culture methods tissue banks may adopt. In the future, the AATB will issue more detailed guidance related to this subject.

AATB Standard E1.700 requires that in-process control and testing be established. The outcome of a disinfection or sterilization process is related to the capability of that process to reduce or eliminate an expected level and mix of microorganisms on the particular tissue type being exposed to the process. If pre-sterilization/pre-disinfection microbiological load exceeds what the process has been validated to remove or inactivate, there is a lack of assurance that the process will result in the reduction or removal of microorganisms to acceptable numbers. Pre-sterilization/pre-disinfection microbiological cultures play a critical role in ensuring that the validated process capability will not be exceeded.

II. SAMPLING METHODS

Pre-sterilization/pre-disinfection samples may be recovered at the time of tissue recovery prior to exposing the tissue to antibiotics, disinfecting chemicals, or sterilizing agents. Samples may also be obtained at the processing facility provided tissues were not exposed to disinfection/sterilization agents prior to sampling. Samples may be collected from each individual tissue or may be collected in accordance with a sampling strategy to represent all the tissues received from a particular donor.

Indirect or direct sampling methods may be used to obtain pre-sterilization/pre-disinfection culture test samples. Indirect sampling is usually accomplished by either a swab or a fluid extraction method. In the swab method, samples of individual tissues are tested by swabbing the surface of each tissue and placing the swab into growth medium followed by incubation and reading the samples as positive or negative for microbial growth. Swab testing of individual tissues are often used to obtain pre-sterilization/pre-disinfection culture results for musculoskeletal tissue.

In the fluid extraction method, individual samples or grouped samples are tested by immersing them in fluid and then testing the fluid. Often the fluids are filtered and the filter is placed onto growth medium followed by incubation and counting the number of colonies that have grown on the filter. Samples from fluid used to transport tissue can be used to obtain pre-sterilization/pre-disinfection culture results for cardiovascular and skin tissues.

Direct sampling is usually accomplished by placing samples of the tissue directly into growth media followed by incubation and reading of the samples qualitatively or quantitatively for microbial growth. Examples of direct sampling methods include testing of representative samples of tissue from various anatomical areas or samples from individual tissues recovered. Tissue banks may use a combination of indirect and direct sampling techniques depending upon the tissue type and disinfection/sterilization method.

Both indirect and direct pre-sterilization/pre-disinfection sampling methods have inherent strengths and weaknesses. For example, swab and fluid indirect test methods are able to cover large exterior surface areas of the tissue and are able to test the actual tissues to be released for transplant. However, the organism recovery efficiency for swab and fluid tests is generally lower than the direct sample method. Note that the organism recovery efficiency is a determination of the ability of the test method to remove microorganisms from the tissue. Recovery efficiencies are generally performed by the microbiology testing laboratory using standard test methods as part of a test method validation protocol.

III. TEST METHODS

Qualitative microbiological test methods are used to detect the presence of viable microorganisms. They can only provide a growth or no growth result. Samples that are positive for growth shall have the organism identified to the genus, and, where appropriate, the species level (see K3.300 Microbiologic Subcultures). Pre-sterilization/pre-disinfection cultures using swabs are qualitative microbiological test methods. Tissue banks use these results to determine the acceptability of tissue for future processing.

Quantitative microbiological test methods are used to determine the quantity and types of organisms present. This bioburden approach offers the advantage of quantifying the microbiological challenge to the disinfection or sterilization process. In certain circumstances establishing quantifiable bioburden, actual colony forming units per tissue, may be accomplished via fluid-extraction and filter-culturing techniques. Quantitative bioburden testing is a fundamental part of the validation of a disinfection or sterilization process; such testing is particularly important for irradiation sterilization validation.

IV. SUMMARY

Pre-sterilization/pre-disinfection microbiological cultures play a critical role in monitoring the microbial challenge to the disinfection or sterilization process to ensure that the process capability will not be exceeded. Tissues can present unique testing challenges. Furthermore, some microorganisms are difficult to culture, so, if present at low levels, may not be detected through routine testing. Tissue banks should consider all relevant issues such as tissue type, potential microorganisms and sterilization/disinfection processes as they develop pre-sterilization/pre-disinfection culture and sampling strategies used to represent all tissues received from a particular donor.

V. REFERENCES

1. Current AATB *Standards for Tissue Banking*
2. FDA/Centers for Disease Control and Prevention workshop entitled, “Processing Methods for Orthopedic, Cardiovascular, and Skin Allografts”, October 11-12, 2007 (<http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetings/Conferences/TranscriptsMinutes/UCM054425.pdf>) - accessed December 28, 2010
3. *Sterilization of health care products—Radiation—Guidance on sterilization of human tissue-based products*, (TIR37:2007), Section 5.4.1. Association for the Advancement of Medical Instrumentation (AAMI)