



Biocompatibility Overview

FDA is now screening submissions for biocompatibility data according to the ISO guideline for biocompatibility "AAMI/ANSI/ISO 10993, Volume 4, Biological Evaluation of Medical Devices", with certain modifications. These modifications are indicated by circles on the included FDA Modified Biocompatibility Table taken from FDA blue book memorandum G95-1 5/1/95 "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices". The guideline requires various tests depending on the device contact type, contact duration and clinical use of your device. Please note that the FDA reserves the right to modify the testing requirements specified in the table as needed. We recommend consulting with the FDA prior to testing to ensure your test plans will satisfy all regulatory requirements.

The new guidelines emphasize the guideline nature of the test matrix. Therefore, consideration of each device should be made with particular usage in mind as certain tests may not apply in all situations. Additionally, data beyond that outlined in the table may be required in certain situations (i.e. for C.E. marking or unique device applications).

Please see the Biocompatibility Testing Matrix for a complete listing of test categories with options, prices, turn around time, and sample requirements. Moreover, there are two other tests which are worth considering for inclusion in your biocompatibility testing package: fourier transfer infrared spectroscopy (FTIR) and differential scanning calorimetry (DSC). These are characterization tests that provide basic material identification information about the components in your device.

One factor should be kept in mind regarding preparation of devices for testing: Prior to testing, a device should undergo all procedures (solvent rinsing, sterilization, etc.) which the final, marketable device will undergo. This point is essential in assuring that test results will reflect the true nature of the finished device.

You will need to determine an extraction temperature for your testing. The extraction parameters should be appropriated to the nature and use of the final product. The following table lists the parameters recommended in the AAMI standard:

- | | |
|---|--|
| <input type="checkbox"/> 50°C ± 2°C for 72 hours ± 2 hours | <input type="checkbox"/> 70°C ± 2°C for 24 hours ± 2 hours |
| <input type="checkbox"/> 121EC ± 2°C for 1 hour ± 0.2 hours | <input type="checkbox"/> 37°C ± 1°C for 72 hours ± 2 hours |
| Other: _____ | |

Please select you parameter from this list and include it with your samples and submission form. If you have any questions, or would like a specific price quote with recommendations, please contact our customer service department. We will look forward to working with you.