



Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices¹

This standard is issued under the fixed designation F748; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice recommends generic biological test methods for materials and devices according to end-use applications. While chemical testing for extractable additives and residual monomers or residues from processing aids is necessary for most implant materials, such testing is not included as part of this practice. The reader is cautioned that the area of materials biocompatibility testing is a rapidly evolving field, and improved methods are evolving rapidly, so this practice is by necessity only a guideline. A thorough knowledge of current techniques and research is critical to a complete evaluation of new materials.

1.2 These test protocols are intended to apply to materials and medical devices for human application. Biological evaluation of materials and devices, and related subjects such as pyrogen testing, batch testing of production lots, and so on, are also discussed. Tests include those performed on materials, end products, and extracts. Rationale and comments on current state of the art are included for all test procedures described.

1.3 The biocompatibility of materials used in single or multicomponent medical devices for human use depends to a large degree on the particular nature of the end-use application. Biological reactions that are detrimental to the success of a material in one device application may have little or no bearing on the successful use of the material for a different application. It is, therefore, not possible to specify a set of biocompatibility test methods which will be necessary and sufficient to establish biocompatibility for all materials and applications.

1.4 The evaluation of tissue engineered medical products (TEMPs) may, in some cases, involve different or additional testing beyond those suggested for non-tissue-based materials and devices. Where appropriate, these differences are discussed in this practice and additional tests described.

1.5 The ethical use of research animals places the obligation on the individual investigator to determine the most efficient

methods for performing the necessary testing without undue use of animals. Where adequate prior data exists to substantiate certain types of safety information, these guidelines should not be interpreted to mean that testing should be unnecessarily repeated.

1.6 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

- [E1262 Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay](#)
- [F619 Practice for Extraction of Medical Plastics](#)
- [F719 Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation](#)
- [F720 Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test](#)
- [F749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit](#)
- [F750 Practice for Evaluating Material Extracts by Systemic Injection in the Mouse](#)
- [F756 Practice for Assessment of Hemolytic Properties of Materials](#)
- [F763 Practice for Short-Term Screening of Implant Materials](#)
- [F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices](#)
- [F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity](#)
- [F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone](#)
- [F1027 Practice for Assessment of Tissue and Cell Compatibility of Orofacial Prosthetic Materials and Devices](#)

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

Current edition approved April 1, 2016. Published May 2016. Originally approved in 1982. Last previous edition approved in 2010 as F748 – 06 (2010). DOI: 10.1520/F0748-16.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.