



Standard Guide for *in vivo* Evaluation of Osteoinductive Potential for Materials Containing Demineralized Bone (DBM)¹

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1. Scope

1.1 This guide covers general guidelines to evaluate the effectiveness of DBM-containing products intended to cause and/or promote bone formation when implanted or injected *in vivo*. This guide is applicable to products that may be composed of one or more of the following components: natural biomaterials (such as demineralized bone), and synthetic biomaterials (such as calcium sulfate, glycerol, and reverse phase polymeric compounds) that act as additives, fillers, and/or excipients (radioprotective agents, preservatives, and/or handling agents) to make the demineralized bone easier to manipulate. It should not be assumed that products evaluated favorably using this guidance will form bone when used in a clinical setting. The primary purpose of this guide is to facilitate the equitable comparison of unique bone-forming products in *in vivo* heterotopic models of osteoinductivity. The purpose of this guide is not to exclude other established methods.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with the use of DBM-containing bone-forming/promoting products. It is the responsibility of the user of this standard to establish appropriate safety and health practices involved in the development of said products in accordance with applicable regulatory guidance documents and in implementing this guide to evaluate the bone-forming/promoting capabilities of the product.*

2. Referenced Documents

2.1 ASTM Standards:²

D1193 Specification for Reagent Water

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.44 on Assessment for TEMPs.

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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.

D5056 Test Method for Trace Metals in Petroleum Coke by Atomic Absorption

E508 Test Method for Determination of Calcium and Magnesium in Iron Ores by Flame Atomic Absorption Spectrometry

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

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

F1854 Test Method for Stereological Evaluation of Porous Coatings on Medical Implants

F2131 Test Method for *In Vitro* Biological Activity of Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) Using the W-20 Mouse Stromal Cell Line

F2721 Guide for Pre-clinical *in vivo* Evaluation in Critical Size Segmental Bone Defects

2.2 Federal Documents:³

21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies

21 CFR 820 Quality System Regulation

21 CFR 1270 Human Tissue Intended for Transplantation

21 CFR 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products

21 CFR 610.12 General Biological Products Standards—General Provisions—Sterility

Q1E Evaluation of Stability Data, FDA Guidance for Industry

Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products, FDA Guidance Document

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Guidance for Industry

Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance

³ Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, <http://www.fda.gov>.