

Certificate of DBM Osteoinductivity Potential (150822-0)

DBM Osteoinductive Potential Screening

Each lot of DBM incorporated into ALLOMATRIX® Putty is assayed *in vitro* using human bone forming cells², which was correlated to the athymic rat model^{1,2} and clinical results² of the assayed DBM; thereby, verifying that only osteoinductive DBM is used in ALLOMATRIX® Putty.

Or

Each lot of DBM incorporated into ALLOMATRIX® Putty is assayed *in vitro* for a native protein (BMP-2) as a surrogate test marker for osteoinductive potential.³ Results from this immunoassay were correlated to the athymic rat model for the DBM alone and the ALLOMATRIX® Putty³. Testing each lot of DBM with this immunoassay assures that only DBM with osteoinductivity potential is used in the ALLOMATRIX® Putty.

Determination of Final Product Osteoinductive Potential

Additionally, the DBM native protein *in vitro* assay correlation with the ALLOMATRIX® Putty predicts the osteoinductive potential of the ALLOMATRIX® Putty in the athymic rat model³. Although only one native protein is used as the test marker, it is the combination of various proteins in the DBM that is responsible for its osteoinductivity potential. Additionally, it is unknown how osteoinductivity potential, measured by this surrogate immunoassay, will correlate with human clinical performance of the Allomatrix Putty.

As an alternative to the native protein *in vitro* assay of DBM, ALLOMATRIX® Putty may be assayed *in vivo* in the rat muscle pouch model¹ to confirm osteoinductive potential of the final product. It is unknown how the results of the athymic rat muscle pouch relate to clinical performance.

ALLOMATRIX® is a registered trademark of Wright Medical Technology, Inc.

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

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- 1 Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in composite grafts of bone marrow and bone matrix, *Clin Orthop* 1980 Jul-Aug;(150):288-300.
Note: The product is considered osteoinductive if one specimen (explant) contains new bone (i.e. bone occupied with lamellae), cartilage, and/or chondrocytes.
- 2 Wilkins, R.M. (1999) Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture, *Advances in Tissue Banking*. 3:113-124
- 3 Data on file at Wright Medical Technology, Inc.