CELLRIGHT TECHNOLOGIES

INDEPENDENT LABORATORY TESTING

CONCELLTRATE® 100

IN-VIVO OSTEOINDUCTION ASSAY IN ATHYMIC RAT

Every donor lot (Tables A1-A4 indicate up to 2 lots) is tested in 2 different rats (# indicates rats: 3 and 4) which are euthanized on Day 28. Histological criteria for evidence of osteoinduction include the presence of: Chondrocytes, Osteoblasts, Cartilage, Bone Marrow, and New Bone (see last column). X verifies presence. Implants displaying a Grade score of #1 or greater are considered osteoinductive.

TABLE A1: PRELIMINARY ANIMAL DATA

Animal Number	Test Article Lot #		Initial Weight	Terminal Weight	Gained Weight
	Left Side	Right Side			
3	CRT 130005-DBMD -OI1	CRT 140051-DBMD -OI1	181.4	263.7	+82.3
4	CRT 130005-DBMD -OI1	CRT 140051-DBMD -OI1	161.1	272.1	+111.0

TABLE A2: MACROSCOPIC OBSERVATIONS

Animal Number	Left Side		Right Side	
	Location	Scope	Location	Scope
3	IM	I	IM	M
4	IM	M	M	M

KEY:
I: Intact in a single piece
M: Multiple pieces scattered
IM: Found in or between muscle groups

TABLE A3: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT130005-DBMD-OI1

Animal Number	Size	Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
3	LL	X	X	X	X	X	X	4

TABLE A4: SUMMARY OF PATHOLOGY REPORT - LOT # : CRT140051-DBMD-OI1

Animal Number	Size	Chondroblasts /cytes	Osteoblasts /cytes	Cartilage /osteoid	New Bone	Bone Marrow	Original DBM	Grade (0-4)
4	RL	X	X	X	X	X	X	3

KEY:
X: Presence of elements
-: Element not present
LL: Left leg
RL: Right leg

OSTEOINDUCTIVE IN-VIVO LOT VERIFIED every lot . . . every time

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CONCELLTRATE® 100

IN-VITRO ALKALINE PHOSPHATE INDUCTION ASSAY

Table 1

ACCESSION NUMBER 15-002572 THRU 15-002573					
CONCELLTRATE® 100					
	Sample Number	Concentration Tested (mg/well)	Protein Dilution Factor	AP Dilution Factor	Specific Activity AP Units/mg Protein
N/A	BMP Control	N/A	N/A	N/A	6.909
	Cell Lysate Control	N/A	N/A	N/A	<LOQ
15-002572 CRT130024-DBM-D OI-2	0001	50	10x	Neat	278.914
15-002573 CRT130041-DBM-D OI-2	0001	50	Neat	Neat	264.194

ConCelltrate® 100 (Table 1) test articles 15-002572 and 15-002573 indicate the Specific Activity AP Units/mg Protein values exceed the BMP control by a factor of up to 40 times greater.

TEST SYSTEM DESCRIPTION

CellRight's ConCelltrate® 100 has demonstrated the ability to induce ectopic new bone formation in the soft tissue of experimental animals. Some of this activity can be attributed to the presence of stimulatory proteins, including bone morphogenic proteins (BMPs). BMPs irreversibly induce differentiation of perivascular mesenchymal-type cells into osteoprogenitor cells. BMPs can also act in-vitro to activate a differentiation pathway in the pluripotent myoblast C2C12 cell line. C2C12 cells stimulated by these compounds produce increased levels of alkaline phosphatase. This assay was designed to quantitatively detect the presence of these stimulatory compounds in bone products by their ability to induce alkaline phosphatase activity in C2C12 cell culture.

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