Certificate of Analysis

Human Umbilical Cord Stem Cell-Derived Exosomes

Lot #003-7-230215-230304 (5 mL)

Expiration Date: March 3, 2024

Manufactured under xeno-free conditions: No animal derived products were used in the manufacturing process.

Final product is provided as 5 mL sterile solution in 0.9% saline.

Endotoxin <USP 85>: < 0.1 EU: PASS (see attached report, EU = Endotoxin Units)

14-day sterility <USP71> : PASS (see attached reports)

Particle Diameter: PASS 141.9 nm (mean) (see attached report)

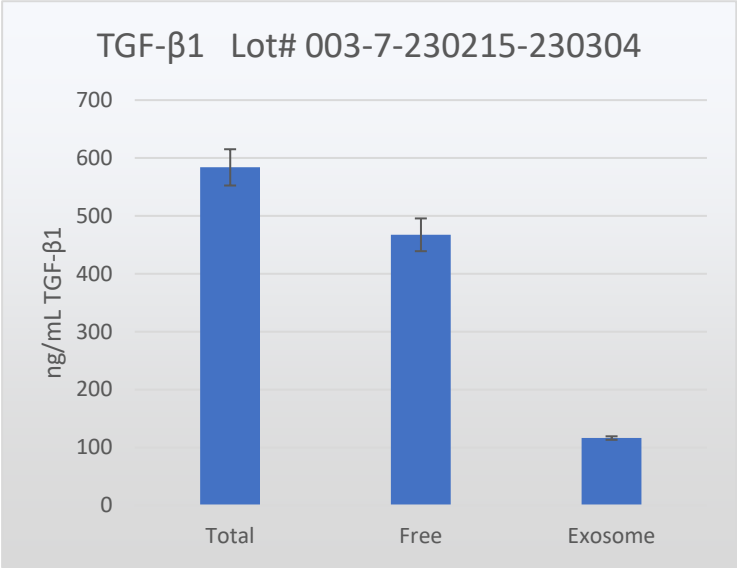
CD81 – Exosome Marker Protein

Exosomes in final product are quantified using CD81 ELISA

Results: 2.1×10^{10} Exosomes per mL final product (= 21 billion per mL)

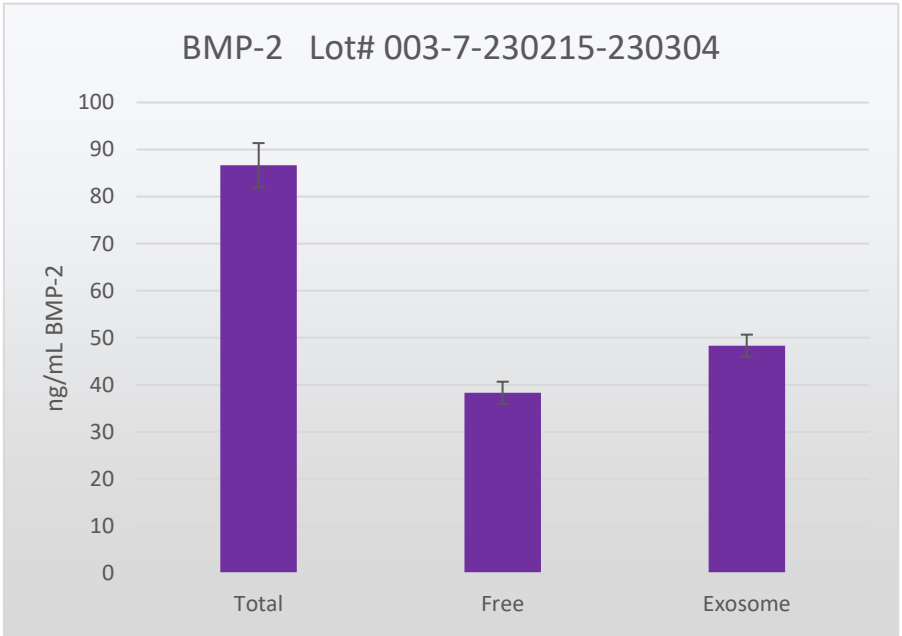
Transforming Growth Factor β 1

Transforming Growth Factor β1 (TGF-β1) regulates cell proliferation, differentiation, wound healing, and angiogenesis. TFG-β1 is measured in final product using a quantitative ELISA method. Two samples are prepared with intact and lysed exosomes, respectively. Lysed exosome sample represents the total amount of TFGβ1, whereas intact exosomes show amount of non-exosomal TGF-β1. The difference represents the concentration of TGF-β1 in intact exosomes.



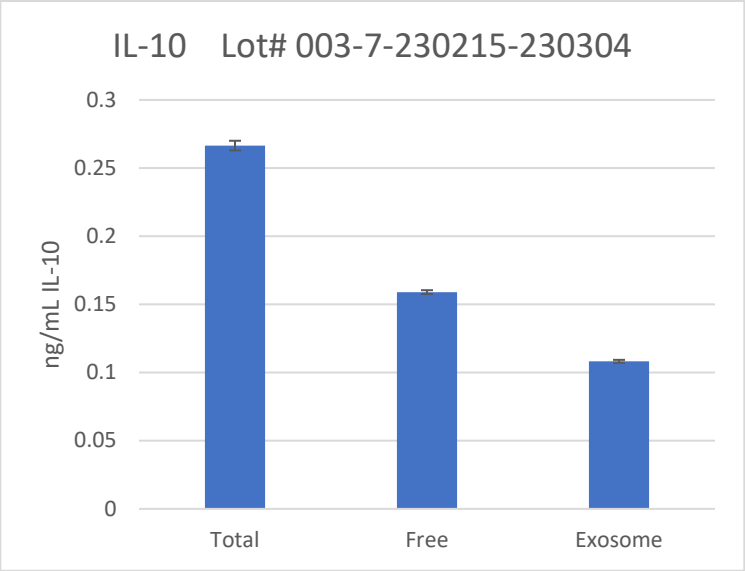
Bone Morphogenetic Protein 2

Bone morphogenetic proteins are osteoinductive proteins with the primary role of promoting bone formation. BMP-2 is measured in final product using a quantitative ELISA method. Two samples are prepared with intact and lysed exosomes, respectively. Lysed exosome sample represents the total amount of BMP-2, whereas intact exosomes show amount of non-exosomal BMP-2. The difference represents the concentration of BMP-2 in intact exosomes.



Interleukin 10

Interleukin 10 (IL-10) is a potent anti-inflammatory cytokine. IL-10 is measured in final product using a quantitative ELISA method. Two samples are prepared with intact and lysed exosomes, respectively. Lysed exosome sample represents the total amount of IL-10, whereas intact exosomes show amount of non-exosomal IL-10. The difference represents the concentration of IL-10 in intact exosomes.



Exosome size and concentration prior to dilution

zenbio

CERTIFICATE OF ANALYSIS

PRODUCT: Exosomes
CATALOG NUMBER: CA-09
STORAGE: -80°C
LOT NUMBER: 230215-FH1
LOT COMPOSITION:
Number of donor(s) : NA
Passage number : NA

HANDLING INSTRUCTIONS:
Exosomes provided by client

DESCRIPTION
Samples were received and exosomes characterized as described below.

QUALITY CONTROL
Exosomes were characterized using a Thermo NanoDrop spectrophotometer for protein determination and approximate RNA concentration by direct absorbance; ***exosomes were not lysed, stained, or RNA extracted prior to measurements.*** Particle diameter and concentration were assessed by Nanoparticle Tracking Analysis (NTA) using a Particle Metrix ZetaView®.

	Protein (mg/mL)	Nucleic Acid			Diameter	Diameter	Particles
Sample	Abs @ 280	ng/µl	A260/280	A260/230	Mean (nm)	Mode (nm)	per mL
230215-FH1	3.194	76.42	0.6	0.15	141.9	93.4	5.00E+11

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Final Report

Order Details		Ordering Professional
Primary ID	003-7-230215-230304	V2173 - DynaCord 3535 South Sherwood Forest Blvd Suite 251 Baton Rouge, LA 70816

Request / Accession	R-030823-00066
Received	03/08/2023 09:57
Final Report	03/08/2023 16:22
Report Generated	03/08/2023 16:22
Time Zone	Mountain Standard Time

Samples | Final Product (sample type) | 03/04/2023 11:00 Central Standard Time (collection date/time)

Sample ID	CELL COUNT (Mycoplasma/Endotoxin)	Source	Status
S-030823-05612 Post-Processing			

73451: Chromogenic Routine Endotoxin Completed: 03/08/2023 16:22

	Endotoxin Pyros
Result	<0.100
Result Units	EU/mL
PPC Recovery	99

Test Reference(s)

Code	Name	
73451	Chromogenic Routine Endotoxin	Associates of Cape Cod Pyros Kinetic Flex Photometric Testing. PPC Recovery range is 50-200%.

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Final Report

Order Details		Ordering Professional
Primary ID	003-7-230215-230304	V2173 - DynaCord 3535 South Sherwood Forest Blvd Suite 251 Baton Rouge, LA 70816

Request / Accession	R-030823-00128
Received	03/08/2023 09:57
Final Report	03/26/2023 17:22
Report Generated	03/26/2023 17:22
Time Zone	Mountain Standard Time

Report Comment(s)

Sample testing encompasses aerobic and anaerobic organisms as well as spore formers, yeast and fungus.

62003 (test code) | 14 Day Sterility (source) | Final Product (sample type) |
03/04/2023 11:00 Central Standard Time (collection date/time)

Sample ID	Site/Product Description	Result	Status
S-030823-08488 Post-Processing		No Growth, Day 14	Final
S-030823-08489 Post-Processing		No Growth, Day 14	Final
S-030823-08490 Post-Processing		No Growth, Day 14	Final
S-030823-08491 Post-Processing		No Growth, Day 14	Final
S-030823-08492 Post-Processing		No Growth, Day 14	Final
S-030823-08493 Post-Processing		No Growth, Day 14	Final
S-030823-08494 Post-Processing		No Growth, Day 14	Final
S-030823-08495 Post-Processing		No Growth, Day 14	Final
S-030823-08496 Post-Processing		No Growth, Day 14	Final
S-030823-08497 Post-Processing		No Growth, Day 14	Final
S-030823-08498 Post-Processing		No Growth, Day 14	Final
S-030823-08499 Post-Processing		No Growth, Day 14	Final
S-030823-08500 Post-Processing		No Growth, Day 14	Final
S-030823-08501 Post-Processing		No Growth, Day 14	Final
S-030823-08502 Post-Processing		No Growth, Day 14	Final

Order Details		Ordering Professional
Primary ID	003-7-230215-230304	V2173 - DynaCord 3535 South Sherwood Forest Blvd Suite 251 Baton Rouge, LA 70816

Request / Accession	R-030823-00128
Received	03/08/2023 09:57
Final Report	03/26/2023 17:22
Report Generated	03/26/2023 17:22
Time Zone	Mountain Standard Time

62003 (test code) | 14 Day Sterility (source) | Final Product (sample type) |
03/04/2023 11:00 Central Standard Time (collection date/time)

Sample ID	Site/Product Description	Result	Status
S-030823-08503 Post-Processing		No Growth, Day 14	Final
S-030823-08504 Post-Processing		No Growth, Day 14	Final
S-030823-08505 Post-Processing		No Growth, Day 14	Final
S-030823-08506 Post-Processing		No Growth, Day 14	Final
S-030823-08507 Post-Processing		No Growth, Day 14	Final

Method Reference(s)

Code	Name
62003	14 Day Sterility