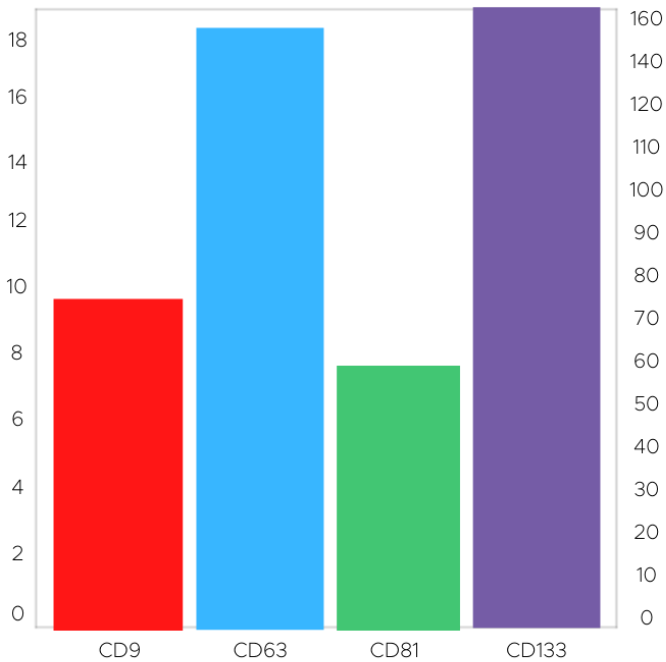


CYTOSOMES™



Molecular Surface Markers

Growth Factors

BMP-7 (2 ng/mL)
EGF (150 pg/mL)
FGF-7 (3 ng/mL)
hCG (11 ng/mL)
HGF (2 ng/mL)

Anti-inflammatory

Adiponectin (11 ng/mL)
Timp-1 (12 ng/mL)
Timp-2 (100 ng/mL)
TNF-RI (400 pg/mL)
TNF-RII (2.5 ng/mL)

Hyaluronic acid (150 ng/mL)

Major Proteins and Growth Factors

SELECTED PUBLICATIONS FROM OUR LEADERSHIP

Arora, H... White IA (2020) Neuregulin-1, in a Conducive Milieu with Wnt/BMP/Retinoic Acid, Prolongs the Epicardial-Mediated Cardiac Regeneration Capacity of Neonatal Heart Explants. *Stem Cells & Regenerative Medicine*. 17(1).

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Goldschmidt-Clermont PJ... White IA. (2019) eLetter: "Amniotic Exosomes and Pregnancy". *Science Translational Medicine*. <https://stm.sciencemag.org/content>

Alimi M, ... Njoku I, et al. (2017) Radiographic and Clinical Outcome of Silicate-substituted Calcium Phosphate (Si-CaP) Ceramic Bone Graft in Spinal Fusion Procedures. *Clin Spine Surg*. Jul; 30(6):E845-E852.

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White IA, Sanina C, Balkan W, Hare JM. (2016) Mesenchymal Stem Cells in Cardiology. *Methods Mol Biol*. 1416:55-87

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White IA, Gordon J, Balkan W, Hare JM. (2015) Sympathetic Reinnervation Is Required for Mammalian Cardiac Regeneration. *Circulation. Research*. Dec 4; 117(12):990-4

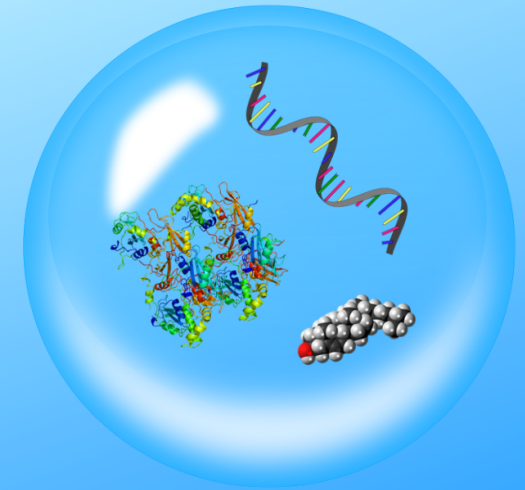
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NEOBIOSIS

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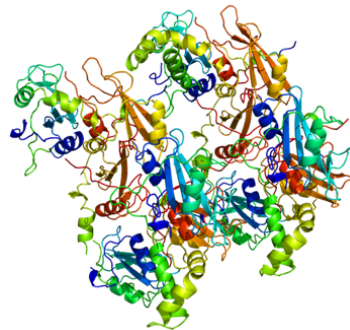
FDA Registration
FEI # 3017371366

Who is Neobiosis?

- Neobiosis, LLC is an FDA-registered CDMO (Contract Development & Manufacturing Organization) operating under cGMP (current Good Manufacturing Practice) standards.
- Neobiosis produces perinatal tissues, cells and EVs for research and clinical trials.
- Dr. Ian A. White, President & Chief Scientific Officer received his PhD from Cornell University, Ansary Stem Cell Institute, Division of Regenerative Medicine, and oversees all product development and production.
- Dr. Innocent Njoku, Chief Medical Officer, is a Cornell trained physician with experience in neurosurgery and orthopedics. Dr. Njoku is currently completing a spine research fellowship at University Hospitals, Cleveland Medical Center/Case Western Reserve Medical School.
- Beth Roxland, J.D., M.Bioethcis, is our senior advisor on law, policy and bioethics, and the ethical voice of Neobiosis guiding our research and development through the regulatory process with the FDA and beyond.

What are Cytosomes™?

- Cytosomes™ are small, membrane bound extracellular vesicles (EVs) released by the developing fetus, placenta, and mother into amniotic fluid (AF).
- Cytosomes™ are clinical-grade EVs derived from amniotic fluid for the purpose of research and clinical trials.
- Cytosomes™ are harvested from amniotic fluid collected by AATB accredited tissue banks following FDA and CDC guidelines, during full-term, healthy Cesarean births with maternal consent.
- Donors are screened, qualified and tested for infectious diseases as required by FDA, CDC and WHO.



[Total protein]
(growth factors,
cytokines, etc)

Avg. 7.48 mg/mL

Aren't all flowable amniotic tissue products the same?

- No, Amniotic fluid flowable tissue products differ in source material, quality of manufacturing, sterilization technique, particle size, concentration, protein and RNA concentration and potential risk of fungal and bacterial contamination.
- Cytosomes™ are crystal clear, never pink and never cloudy, which may compromise outcome data.
- When cells communicate in a paracrine fashion, they use EVs to package and transmit the messages. Cytosomes™ are produced to the highest possible standards to retain the integrity of their cargo.



[Total RNA]
(RNA, miRNA)

Avg. 176.4 ng/uL

Cytosomes™ - the Clear Difference

- Each 1 cc vial of Cytosomes™ contains an average of 250 billion (+/- 100 billion) EVs.
- Cytosomes™ particle size is consistently between 50-150 nm and sterility is validated by a qualified, independent, CLIA-certified laboratory.
- Cytosomes™ are twice sterile filtered and never UV irradiated. UV irradiation destroys RNA.
- Cytosomes™ are produced, on site, by highly trained scientists within our Neobiosis cGMP-compliant, FDA-registered, ISO 7 cleanrooms.

The US Food and Drug Administration prohibits manufacturers from making claims about their product's ability to treat specific health conditions.

As a manufacturer we encourage our customers to research and determine whether Cytosomes™ are right for their research and clinical trial needs.

Cytosomes™ are manufactured following cGMP guidelines in an FDA-registered laboratory in Gainesville, FL. (FDA Establishment Identifier: 3017371366, Neobiosis, LLC).

Donor suitability and manufacturing is performed in compliance with Public Health Acts, regulated under 21 CFR 1271 HCT/PS, subpart D cGTP, and 21 CFR 31 (INDs), 210 & 211 (cGMP), 606 and 610.

