RE: Amniosomes

Amniosomes™ are small, membrane-bound extracellular vesicles released during pregnancy by the developing fetus, placenta and mother into the amniotic fluid. They contain RNA, microRNA, and growth factor proteins, peptides, which together facilitate tissue growth, angiogenesis and immune modulation. EV’s are a product of placental and embryonic stem cells that have created a healthy fetus/ delivered baby and kept the mother healthy.

Amniosomes™ are produced during gestation of a healthy fetus, the birth tissues are collected from consented healthy donor mothers who have been screened extensively, in their social, family, medical and surgical histories. We have a specific inclusion criteria and exhaustive exclusion criteria. Once a donor mother is accepted, on the day of elective C-Section, blood is drawn for serology testing of all potential communicable disease including Zika, Lyme, Corona among many more.

The placental tissues are collected in an aseptic manner and brought to our tissue bank within 12-16 hours. Processing is immediate in a cGMP/cGTP clean room processing laboratory.

Amniosomes™ (extracellular vesicles floating in purified amniotic fluid) are suspended in amniotic fluid. Amniotic Fluid is the “Carrier”. By using Amniosomes™ you can avoid any potential issues associated with the transfer of cellular material. Amniosomes™ are small and can easily circulate through capillaries, are intracellular messengers, upregulating signaling to upregulate the recipient’s potential for regeneration.

Particle size of the EV’s are within the range of 50nm-150nm. Which is about 1000 times smaller than a cell, thus can pass though the capillaries and blood-brain barrier.

Amniosomes™ are stored at cryogenic temperatures to prevent the proteins from deactivating. Storage warmer than -20°C destabilizes the surface characteristics, morphological features, and protein content of exosomes.

There are 692 Peptides in AF and P53 is a known anti-tumorigenic protein. These proteins provide direct cell to cell communications.

250+ various microRNA such as mRNA 146, 146b are known to provide significant Anti-inflammatory function, specifically in human airway function. mRNA 302 and 367 are known to regulate Angiogenesis and Vasculogenesis. One more significant micro RNA is mRNA 294 which has been shown to play a role in heart function.
Extracellular vesicles can also be utilized to tackle toxicity and immunogenicity issues. The paracrine activity has been already shown to be the key mediator of their elicited regenerative effects, it is these ECV that move the proteins to the areas that are signaling injury.

1mL of Amniosomes™ contains, on average, 250 Billion EVs, which is the concentration chosen, by nature, to be optimal. We don't concentrate or dilute the product, Amniosomes™ are suspended in pure amniotic fluid, which contains Hyaluronic Acid high density molecules, pH balanced, and water. Amniosomes™ are cryo-frozen and ready for off-the-shelf use.

Best regards,

Dr. Bruce Werber
Director of Operations and Manufacturing
Amniosomes™