



AmnioCyte™ Amniotic Fluid Allograft

AmnioCyte™ is a minimally manipulated human tissue allograft derived from amniotic fluid. AmnioCyte™ is processed to preserve the cytokines, growth factors and proteins in amniotic fluid for homologous use.

Innovative Development

Predictive Biotech's innovative human cell and tissue products are processed in our FDA registered lab. Our minimally manipulated tissue products are prepared utilizing proprietary production methods that reduce the loss of important proteins, cytokines and growth factors.

Quality Assurance

AmnioCyte™ is processed from donated human tissue from full-term deliveries. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with standards established by FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493.

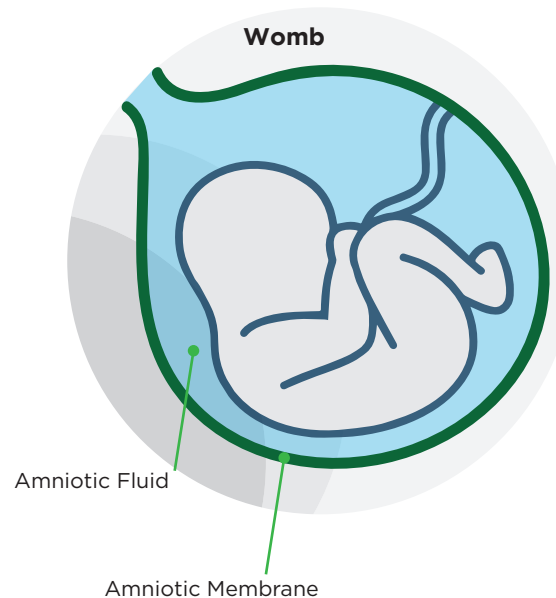
FDA Regulatory Compliance

AmnioCyte™ is processed from human amniotic fluid. The FDA has recently stated that amniotic fluid is no longer regulated by 21 CFR 1271 and Section 361 of the PHS Act, and has been classified as a secreted product. This product, derived from amniotic fluid, is exempt from regulation under 21 CFR 1271 and Section 361 of the PHS Act. AmnioCyte™ is manufactured under cGMP regulations per CFR 210 and 211.

Key Characteristics of Amniotic Fluid

Amniotic fluid undergoes dynamic changes during the multiple developmental periods in order to sustain fetal growth and well being. Amniotic fluid contains growth factors carbohydrates, proteins, amino acids and a multitude of essential molecules.

Amniotic fluid also plays a very important role in providing a protective cushioning and acts as a lubricant to allow for easier fetal movement and promoting muscular/skeletal development.



Key Cytokines Present in Amniotic Fluid

General Cytokines	pg/ml
Fetuin-A	✓✓
Interleukin 37	✓
Macrophage Colony Stimulating Factor	✓✓
Serpin A4	✓✓
Syndecan - 4	✓✓
Growth Factor Cytokines	
Bone Morphogenic Protein - 7	
Complement Component 5a	✓✓
Fibroblast Growth Factor	
Platelet Derived Growth Factor - AA	✓✓✓
Thrombospondin - 2	✓✓
Scaffolding Cytokines	
Adhesion G Protein	
Collagen 1, 2, 3	
Elastin	
Fibronectin	
Hyaluronic Acid	✓
Homeostatic Cytokines	
Cystatin - B	✓✓
Galectin - 9	✓
Granulysin	✓
Lipocalin - 2	✓✓
Intracellular Adhesion Molecule 1	✓✓✓