



## CoreCyte™ Wharton's Jelly Allograft

CoreCyte™ is a minimally manipulated human tissue allograft derived from the Wharton's jelly of the umbilical cord. CoreCyte™ is processed to preserve the integrity of Wharton's jelly for homologous use and cryogenically preserved.

### 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

CoreCyte™ 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

CoreCyte™ is a minimally manipulated, cryogenically preserved human tissue allograft derived from the Wharton's jelly of the umbilical cord. The membrane is broken up into component parts using a mechanical process to isolate the tissue elements (collagen fibers, elastin, hyaluronan, growth factors and cytokines). Although CoreCyte™ does contain live cells, Predictive Biotech does not claim that CoreCyte™ is dependent on the metabolic activity of living cells for its primary function. The cushioning and protective elements from Wharton's jelly consist of a network of structural proteins, pericytes, mesenchymal stem cells, cytokines, chemokines and growth factors. The structural support function of CoreCyte™ is not reliant on the presence nor on the metabolism of the cells in the allograft. CoreCyte™ does meet the criteria under 1271.3(d) as an HCT/P, and therefore is regulated under 21 CFR 1271 and Section 361 of the PHS Act. CoreCyte™ is manufactured under cGMP regulations per CFR 210 and 211.

## Key Characteristics of Wharton's Jelly

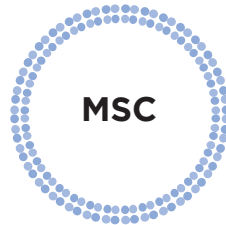
Wharton's jelly is a gelatinous substance in the umbilical cord that provides cushioning and support to the umbilical vein and arteries. The cushioning and protective elements from Wharton's jelly consist of a network of proteins, pericytes, mesenchymal stem cells, cytokines, chemokines and growth factors.

## Analysis of Wharton's Jelly



### 440+ Cytokines

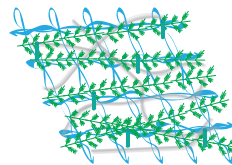
Interleukins  
Growth Factors  
Chemokines



MSC

### Cells per cm of Umbilical Cord:

MSC: 240,000



### Extracellular Matrix Composition:

Collagen 3.6%  
Glycoprotein 0.3%  
Hyaluronin 0.31%

\*All % wet weight

## Key Cytokines Present in Wharton's Jelly

### 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	✓✓