



# ExoElite 70

Certificate of Analysis



# Introduction



Cellgenic Flow represents the pinnacle of innovation in regenerative medicine. As an advanced exosome-based therapeutic product, Cellgenic Flow harnesses the power of mesenchymal stem cell-derived exosomes to promote cellular repair, enhance immune modulation, and support overall tissue rejuvenation.

With its proprietary formulation, Cellgenic Flow offers a highly potent solution designed for both intravenous and targeted local applications.

## Products Highlights


- **Concentrated Potency:** Available in multiple declared strengths depending on presentation, ensuring effective dosing for a variety of therapeutic applications.
- **Cutting-Edge Formulation:** Derived from mesenchymal stem cells sourced from Wharton's Jelly, Cellgenic Flow boasts unparalleled bioactivity and therapeutic benefits.
- **Versatile Applications:** Suitable for intravenous, intrathecal, intra-articular, and topical use, making it adaptable to diverse medical needs.
- **Rigorous Standards:** Produced in state-of-the-art facilities, Cellgenic Flow adheres to stringent quality control measures, maintaining safety, purity, and efficacy.

## Advanced Delivery and Storage

Cellgenic Flow is shipped frozen to maintain the integrity of its exosomes. Once received, the product can be stored in standard refrigeration conditions to ensure ease of use and convenience for medical practitioners.

## Innovating Patient Outcomes

Backed by cutting-edge research and rigorous quality testing, Cellgenic Flow is poised to revolutionize patient care in regenerative medicine. By leveraging the natural healing properties of exosomes, it provides a groundbreaking approach to addressing age-related degeneration, chronic inflammation, and immune dysfunction.

	<b>Certificate of Analysis</b>	Record #: PEX-00000041
		Version: 3.0
Title: Certificate of Analysis for ExoElite 70		Issuance Date: 07 Sep 2025

**Declared Product Strength – Label Claim**

Parameter	Declared Value	Basis
Product Name	ExoElite 70	----
Declared Exosome Content	70 billion exosome particles per vial	Formulation target
Fill Volume	5 mL	Finished product
Batch-Specific Quantification	Not performed	----

Declared exosome content is based on formulation parameters and is not derived from batch-specific particle quantification assays.

General Information			
<b>MANUFACTURER:</b>	Cellgenic, LLC	<b>Lot Number</b>	CFE - 07022025-001
<b>PRODUCT NAME:</b>	ExoElite 70	<b>Date of Manufacture</b>	7 July, 2025
<b>DONOR ID:</b>	CFE-DTR-002	<b>Date of Release</b>	12 September, 2025
<b>DONOR CONSENT:</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
<b>PRODUCT LABEL:</b>			
<b>KEY NOTES:</b>	Cellgenic Flow Exosomes has been dermatologically tested and clinically proven to be hypoallergenic, safe, non-irritating, and suitable for dry, oily, or normal skin.		

TEST	RESULT	SPECIFICATION	TEST LOCATION; TEST METHOD
<b>SAFETY - RELEASE TESTING</b>			
<b>ENDOTOXIN:</b>	<0.001 EU/mL	<4.5 EU/mL	Eurofins; LAL Method
<b>Sterility:</b>	No Growth	No Growth	Eurofins; 14-day Sterility
<b>HRIPT (Human Repeat Insult Patch Test)</b>	Hypoallergenic, non-irritating	Hypoallergenic, non-irritating	PCR Corp; PCRRIP1
<b>COVID-19</b>	Negative	Negative	Tissue Acquisition Company; Donor Eligibility Questionnaire
<b>IDENTITY</b>			
<b>PAMG-1</b>	Positive	Positive	Cellgenic LLC; ELISA

TEST	RESULT	SPECIFICATION	TEST LOCATION; TEST METHOD
<b>PURITY - CHARACTERIZATION</b>			
Color	Clear, tinted yellow	Clear to light amber or 0.000-0.200 AU @420nm	Cellgenic LLC; Visual Observation
Total Cell Count	0 cells/mL	0 cells/mL	Cellgenic LLC; NC3000
Turbidity	5 NTU	<15NTU	Cellgenic LLC; Turbidity meter
<b>QUALITY - CHARACTERIZATION</b>			
pH	7.2	6.5-7.5	Cellgenic LLC; pH Meter
Osmolality	273 mOsm/kg	260-310 mOsm/kg	Cellgenic LLC; Osmometer
Zeta Potential	Mean	-19.2 mV	Cellgenic LLC; TRPS
	Mode	-16.7 mV	
Sub-Visible Particulate	≥ 10 μm	0 particles/mL	Cellgenic LLC; Microscopic Analysis
	≥ 25 μm	0 particles/mL	

Test	Specification	Result
Sterility test: bacteria, yeast and fungi (qPCR + culture)	Negative	Negative
Endotoxins	< 3.0 EU/mL	< 3.0 EU/mL
Mycoplasma (PCR)	Negative	Negative
<b>Characterization</b>		
CD9	Present	20.27%
CD63	Present	0.94%
CD81	Present	23.49%
CD90	Present	76.39%

Gate Number	%Total	%Gated	Cells/μL
All	504,925	66.62	100,985
A	102,350	13.50	20,470

Gate Number	%Total	%Gated	Cells/μL
All	102,350	13.50	20,470
B	96,584	12.74	19,317

Gate Number	%Total	%Gated	Cells/μL
All	96,584	12.74	19,317
C	22,689	2.99	4,538
D	51,094	6.74	10,219

Gate Number	%Total	%Gated	Cells/μL
All	96,584	12.74	19,317
E (1)	905	0.12	181

Gate Number	%Total	%Gated	Cells/μL
All	96,584	12.74	19,317
G	20,607	2.72	4,121

## TEST SUMMARY DESCRIPTION

TEST	IMPORTANCE
<b>Endotoxin</b>	Endotoxins can cause inflammatory responses and potentially serious adverse reactions, even in small amounts.
<b>Sterility</b>	Critical quality control measure that ensures the product is free from viable microorganisms. Critical batch release test, ensuring each lot meets the highest safety standards before distribution.
<b>COVID-19</b>	Ensures the product is free from SARS-CoV-2 contamination, and important safety measure, especially given the global impact of SARS-CoV-2 pandemic.
<b>HRIPT (Human Repeat Insult Patch Test)</b>	To assess the potential of the product to cause irritation, sensitization, and allergic contact on the skin.
<b>Tetrapanin (CD81, CD63, CD9)</b>	These tetrapanins are considered canonical markers for exosomes. Tetraspanins are important in mutual cell contact, exosome uptake, gamete maturation, fertilization, and embryo development.
<b>PAMG-1</b>	Placental Alpha Microglobulin-1 (PAMG-1) is highly specific to human amniotic fluid. It is produced by the decidual cells of the placenta and is present in high concentrations. Used for identity and strength analysis, ensuring product is unadulterated human amniotic fluid.
<b>Exosome Size Distribution</b>	Exosome size distribution provides crucial insights into the exosomes biological properties, functional capabilities, and overall quality of the amniotic fluid preparation. Exosome size can influence their cellular uptake, biodistribution, cargo content, and ultimately their therapeutic potential.
<b>Color</b>	Important visual indicator of product quality and purity. Amniotic fluid is typically clear with a slight yellow or amber tint.
<b>Turbidity</b>	Turbidity is an important quality parameter as it can indicate the presence of particles, cellular debris, or other components that might affect the product's purity, stability, and efficacy.
<b>Total Cell Count</b>	To ensure complete removal of cells and confirm a cellular nature of product, as cells have been associated with adverse effects.
<b>pH</b>	Important for ensuring product stability, efficacy, and biocompatibility.
<b>Osmolality</b>	Useful for evaluating the concentration of dissolved particles, required to meet standards.
<b>Zeta Potential</b>	Zeta potential provides important information about the stability and overall surface charge of particles in a suspension, like exosomes in amniotic fluid. It can help predict the tendency of the exosomes to aggregate in amniotic fluid, which can impact safety and efficacy of the product.
<b>Sub-Visible Particulate</b>	Subvisible particle specifications are crucial for ensuring quality and safety. These specifications help the presence of particles that are too small to be seen with the naked eye but have the potential to cause adverse effects.

For more information visit

[cellgenic.com](https://cellgenic.com)