

## Exosome Certificate of Analysis Interpretation Report

*(For Physician and Clinical Use)*

**Date:** October 2025

**Lot Tested:** Refer to attached COA

### Overview

This report provides a professional interpretation of the accompanying Certificate of Analysis (COA) for the exosome formulation tested in October 2025.

Each parameter on the COA confirms the **purity, potency, consistency, and biological integrity** of the product. The results demonstrate a **highly concentrated, uniform, and therapeutically relevant exosome preparation** suitable for regenerative, orthopedic, aesthetic, and longevity applications.

### Sample Sizes:

**Sample 1:** 0.25ml

**Sample 2:** 0.25ml

**Sample 3:** 1.0 ml

### 1. Particle Concentration (Particles per mL)

#### Sample Results:

- **Sample 1:**  $5.0 \times 10^{12}$  particles/mL
- **Sample 2:**  $6.8 \times 10^{12}$  particles/mL
- **Sample 3:**  $2.1 \times 10^{13}$  particles/mL

#### Interpretation:

This metric measures the total number of exosome particles suspended in each ml of solution. It directly represents **product potency** — the higher the number, the more bioactive vesicles are available to deliver cellular signals.

To visualize:

- $5.0 \times 10^{12}$  = 5 **trillion** exosomes per mL
- $6.8 \times 10^{12}$  = 6.8 **trillion** exosomes per mL
- $2.1 \times 10^{13}$  = 21 **trillion** exosomes per mL

These results confirm an **exceptionally high concentration** of extracellular vesicles, well above standard research levels ( $10^{11}$ – $10^{12}$ /mL) and consistent with **premium clinical-grade formulations**.

### Clinical Significance:

High exosome concentrations like these allow for:

- Enhanced paracrine signaling
- Improved uptake at target tissues
- Greater biological efficacy, even at smaller injection volumes

## 2. Protein Concentration (mg/mL, abs@280)

### Sample Results:

- Sample 1: 58.63 mg/mL
- Sample 2: 58.72 mg/mL
- Sample 3: 60.10 mg/mL

### Interpretation:

Protein concentration, measured by UV absorbance at 280 nm (abs@280), reflects the total protein content per ml — including exosomal surface proteins, membrane proteins, and signaling molecules.

The near-identical values across all three samples demonstrate **excellent consistency** and **high-quality process control**.

When viewed alongside the particle counts, these data indicate a **dense vesicle population with minimal free protein contamination**, which is ideal for therapeutic-grade preparations.

## 3. Nucleic Acid Content

Metric	Sample 1	Sample 2	Sample 3
Nucleic Acid (ng/μL)	1655.2	1665.7	1710.7
A260/280 Ratio	0.71	0.71	0.71

Metric	Sample 1	Sample 2	Sample 3
A260/230 Ratio	0.50	0.50	0.49

**Interpretation:**

Exosomes naturally carry **RNA and microRNA cargo** that regulate gene expression and tissue repair.

The nucleic acid readings confirm this expected biological payload.

- **Nucleic acid concentration (1655–1710 ng/μL):** High and uniform, indicating consistent RNA content.
- **A260/280 ≈ 0.7:** Reflects a protein-rich environment typical of true exosomes rather than free nucleic acids.
- **A260/230 ≈ 0.5:** Indicates minimal buffer or salt carryover, normal for vesicle suspensions.

These results confirm that the preparation contains **authentic exosomes carrying functional RNA**, not simply protein aggregates or residual media components.

**4. Particle Size (Diameter Mean & Mode)**

Metric	Sample 1	Sample 2	Sample 3
Diameter Mean (nm)	127.2	111.1	113.1
Diameter Mode (nm)	115.4	99.6	92.5

**Interpretation:**

Particle size determines biological behavior, biodistribution, and cellular uptake efficiency. All samples fall within the **30–150 nm range** — the classic size window for exosomes.

- **Mean Diameter:** Represents the average particle size.
- **Mode Diameter:** Represents the most common particle size (peak frequency).

The small variation between mean and mode ( $\leq 20$  nm) indicates a **monodisperse and uniform vesicle population**, free of aggregation or larger microvesicles.

This uniformity enhances **cellular uptake, circulation stability, and clinical predictability.**

## 5. Summary of Findings

Quality Metric	Target Range	Results	Interpretation
Particles/mL	$10^{11}$ – $10^{13}$	$5.0 \times 10^{12}$ , $6.8 \times 10^{12}$ , $2.1 \times 10^{13}$	Ultra-concentrated, potent formulation
Protein (mg/mL)	20–80	58.6–60.1	Excellent consistency
Nucleic Acid (ng/ $\mu$ L)	Variable	1655–1710	Strong RNA content
A260/280	0.6–0.8 (expected for exosomes)	0.71	Ideal composition
Diameter Mean (nm)	30–150	111–127	Correct exosome size
Diameter Mode (nm)	30–150	92–115	Uniform vesicle population

## 6. Clinical Relevance

- **High particle counts (up to 21 trillion per mL)** confirm exceptional potency and biological richness.
- **Consistent protein and nucleic acid profiles** demonstrate stable manufacturing and reproducible exosome composition.
- **Uniform nanoscale size** ensures optimal delivery, bioavailability, and predictable patient response.

Together, these findings validate the formulation as a **high-quality, therapeutic-grade exosome preparation** optimized for clinical outcomes.

## 7. Key Takeaway

This Certificate of Analysis confirms that the tested exosome product demonstrates:

- **High potency:** 5–21 trillion vesicles per mL
- **Excellent purity and uniformity**

- **Ideal size distribution (90–130 nm)**
- **Proper biochemical composition (protein-rich, RNA-loaded vesicles)**

These data collectively affirm that the preparation meets the highest standards for **biological quality, potency, and clinical reliability** in regenerative and aesthetic applications.

**Prepared by:**

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