Videodrop: A Suitable Tool to Monitor Extracellular Vesicles in Bioproduction

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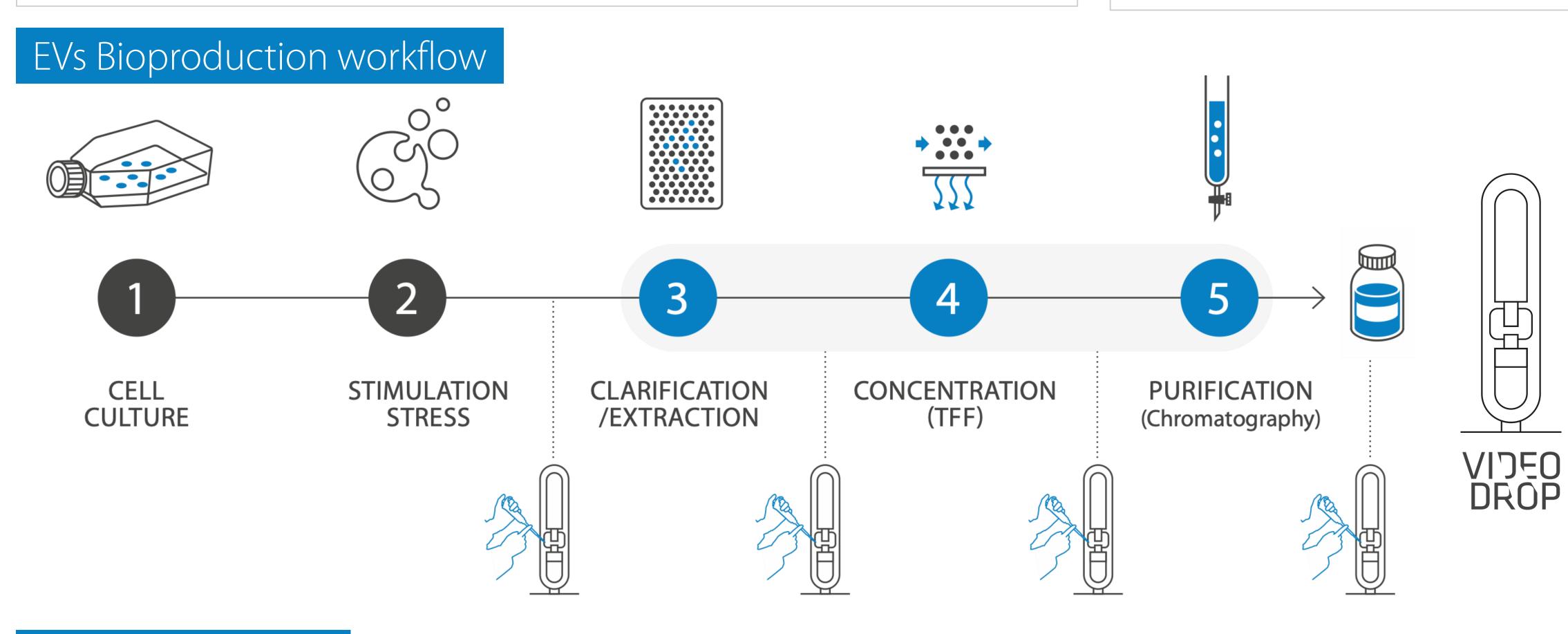
Extracellular vesicles (EVs) are an emerging therapeutic agents for regenerative medicine. In order to ensure EV-based therapies quality, EVs concentration needs to be tighly monitored throughout the bioproduction process during development and manufacturing stages.

myriade

Videodrop is a user-friendly, **21 CFR Part 11 compliant** nanoparticle detection system which allows to get EVs titers ¹ in real time (less than 1 minute) from a single droplet (5-10ul). Here, we showed that the Videodrop is a precise and reproducible tool that correlates with standard method for EVs titers assessment (NTA technology).



EVerZom is a French biotechnology company specializing in the development of **exosome-based therapeutics** for regenerative medicine. The company has successfully developed an innovation platform protected by several patents, covering the entire technological value chain: cell sourcing, exosome generation, exosome loading, and formulation.



Real-time process monitoring

- Purification steps optimization
- Yield calculation
- Recovery efficiency
- In process controls: "gatekeeper"

Final product characterization

- Release test
- Batch-to-batch comparison
- Stability study

Materials & Methods

6 EVs samples were issued from **different production batches and purification steps** (provided by EVerZom). These samples were diluted in PBS to reach instruments specific concentration ranges. Technical replicates where made with distinct droplets from a same biological sample.

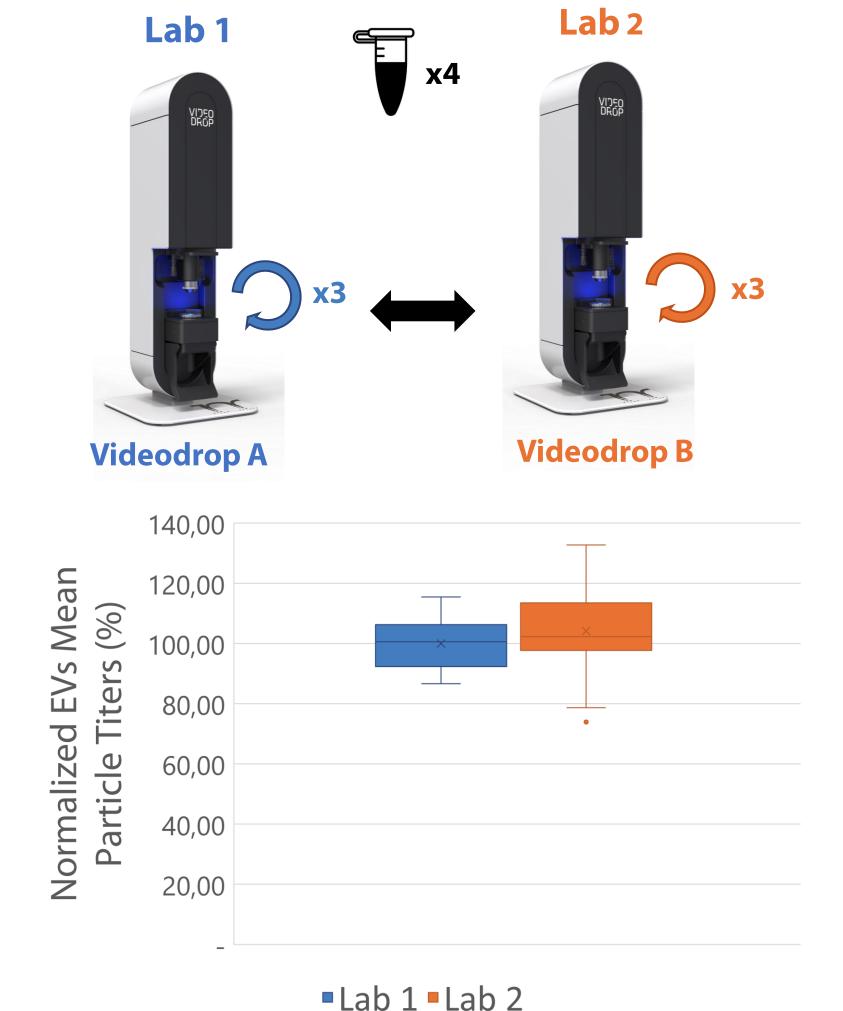
Precision and Reproducibility assays were performed with **2 different Videodrops located in distinct labs**, and an ANOVA Gauge R&R test was performed to assess overall reproducibility between the two devices. Videodrop-NTA linearity was assessed using a **ZetaView**® QUATT (PARTICLE METRIX) with usual standard operating procedure and parameters for EVs samples (11 positions).

Results

Videodrop Precision Assay Lab 1 Lab 2 **x1 Videodrop A Videodrop B** 1,0E+10(bart/m) 9,0E+09 8,0E+09 7,0E+09 6,0E+09 5,0E+09 Particle 4,0E+09 3,0E+09 2,0E+09 1,0E+09 •Lab 1 •Lab 2 **CV%:** 9.11% 10.19%

→ Both Videodrops showed a similar titer repeatability with approximately **10% of variation coefficient**, which demonstrates the instrument's reliability.

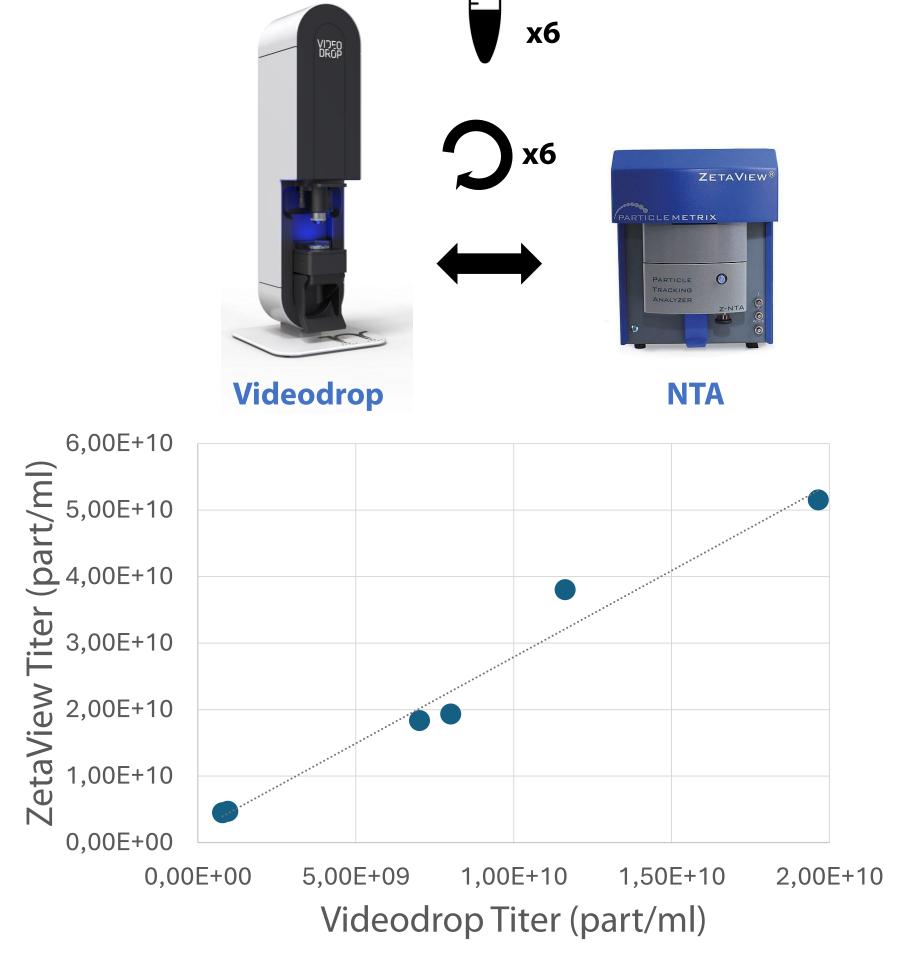
Videodrop Reproducibility Assay



ANOVA Gauge R&R test Reproducibility score = 0.0624%

→ EVs concentrations determined using Videodrops from 2 different labs showed excellent reproducibility results.

Biological samples Technical replicates Videodrop and NTA titers



Correlation coefficient $R^2 = 0.9560$

→ Videodrop titers were found to be **strongly correlated to NTA** results which confirms Videodrop titers relevance.

- Videodrop ensures high precision and reproducibility to control EVs Bioproduction quality.
- Videodrop and NTA EVs titers are linearly correlated.
- Videodrop is ideal for real-time monitoring of EVs Bioproduction.

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¹ Harnessing hydrodynamics for high-yield production of extracellular vesicles from stem cells spheroids with specific cargo profiling.