

NanoCoulter™ Particle Analyzer		Technical Specifications
Model		NanoCoulter Vertex Max
Principle		Resistive Pulse Sensing (RPS)
Channel		Dual-channel
Particle Size	Range	15 - 2000 nm
	Accuracy	100% ± 6%
	Precision	CV < 3%
Concentration	Range	2 × 10 ⁶ - 1× 10 ¹² particles/mL
	Accuracy	100% ± 10%
	Precision	CV < 5%
Zeta Potential	Range	± 100 mV
	Accuracy	± 3 mV
	Precision	CV < 5%
Testing Time Per Sample		2-3 (up to 15) min
Volume Per Sample		200 µL after dilution
Operating System		Windows 7+ Pro/Ent
GMP/GLP Management		IQ/OQ Option/FDA 21 CFR Part 11 Option
Dimensions (W x D x H)		28.5 cm x 35 cm x 45 cm
Weight		17.3 kg

NanoCoulter™

Vertex Max

Single-Nanoparticle Characterization Expert

TEM-Comparable
Resistive Pulse Sensing Technology



ADVANTAGES

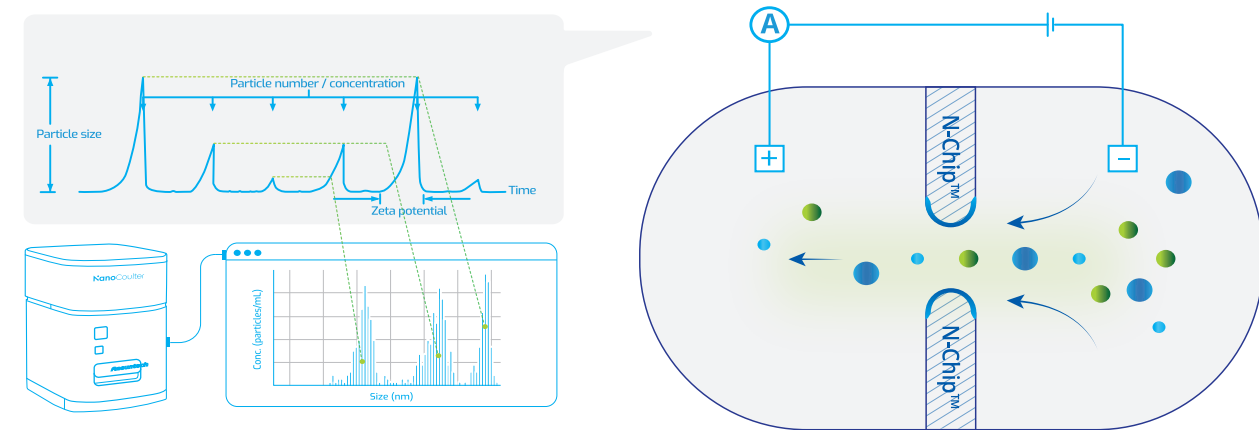
NanoCoulter™

World's first nanopore chip for RPS



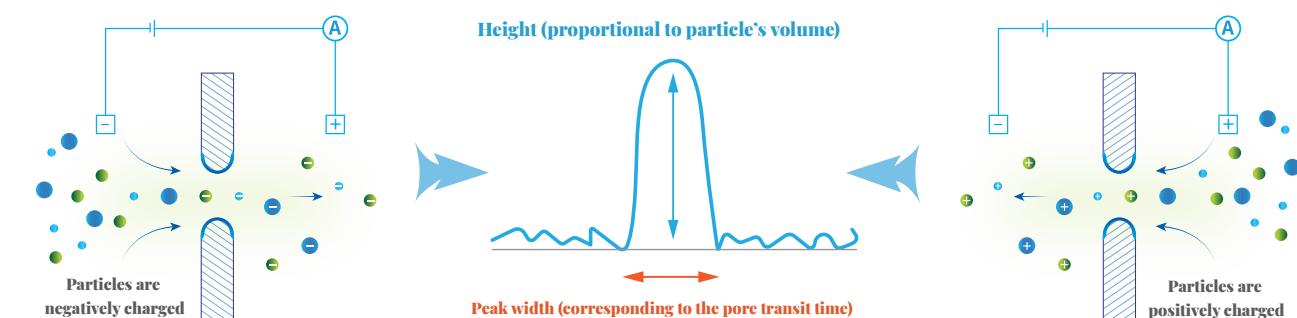
Resistive Pulse Sensing (RPS) Principle

NanoCoulter™ utilizes the resistive pulse sensing (RPS) principle, also known as the Coulter principle. When the voltage is applied in the electrolyte, as individual particles traverse the nano-aperture of the NanoCoulter™ N-Chip™, a transient change in electrical resistance is generated, forming a resistive pulse. These resistive pulses are accurately analyzed by NanoCoulter™ to yield multi-dimensional data, including particle size, concentration, and Zeta potential.



Potential Detection Principle (Electrophoresis Method)

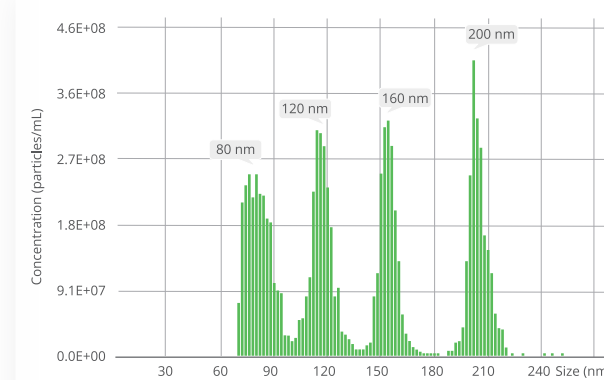
When particles are subjected only to the electric field force, their electrophoretic migration velocity is proportional to their surface charge, which is quantified as the Zeta potential. Under the action of an applied electric field, charged particles move toward the electrode of opposite charge, and their migration velocity is related to the magnitude of the Zeta potential.



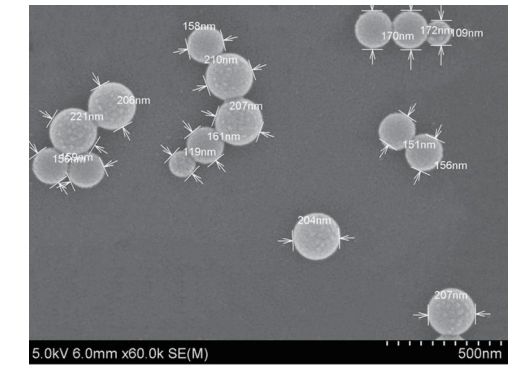
NanoCoulter™

Electron Microscopy-Comparable Particle Size Determination

NanoCoulter™ measures both the particle size and size distribution of polydisperse samples, delivering EM-consistent results with exceptional accuracy and precision.



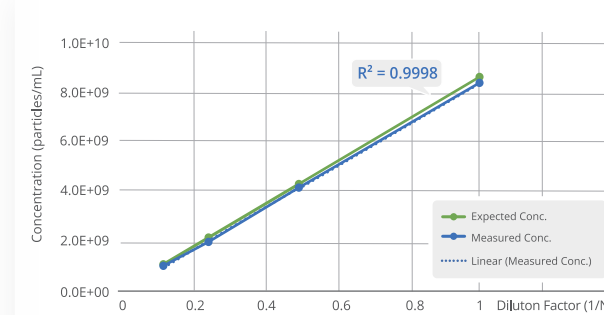
Particle Size Data Measured by NanoCoulter™



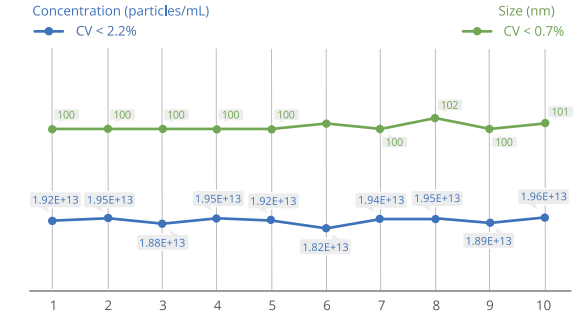
Electron microscopy results for the same sample

Measure Concentration with High Accuracy and Repeatability

Samples were serially diluted, and the concentration detection data demonstrated a strong linear correlation with the theoretical concentration ($R^2 > 0.999$). Across 10 repeated measurements, the coefficient of variation (CV) was less than 5%.



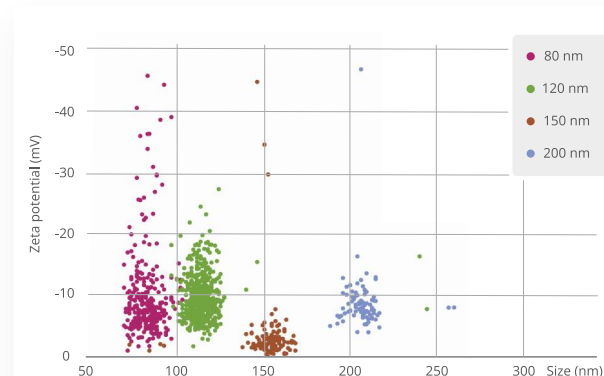
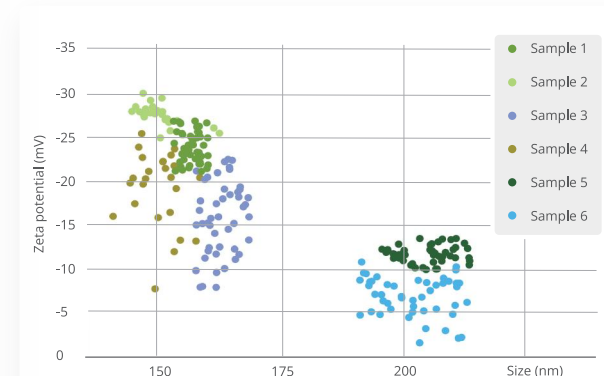
Linearity of concentration



10 Replicate Measurements of a 100 nm Standard Sample

Single-Particle Zeta Potential Measurement

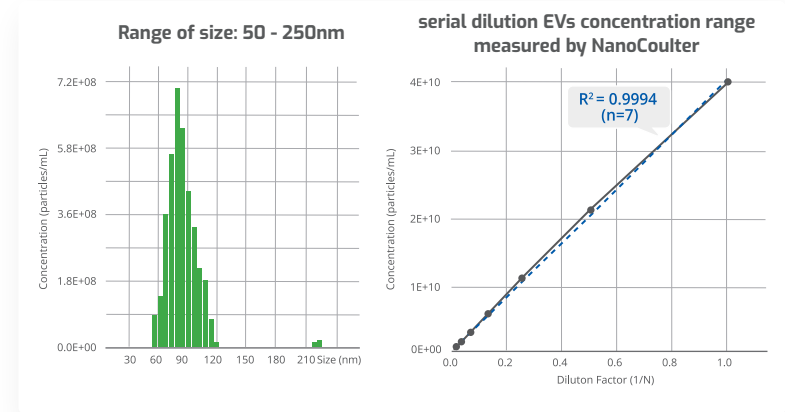
Zeta potential is an important indicator of the stability of dispersion systems. Under a constant electric field, the electrophoretic velocity of particles is directly proportional to the absolute value of their zeta potential. NanoCoulter™ measures the time it takes for particles to pass through a nanopore to obtain Zeta potential data, making it the only technology platform capable of simultaneously measuring single-particle size, Zeta potential, and concentration.



Extracellular Vesicles (EVs)

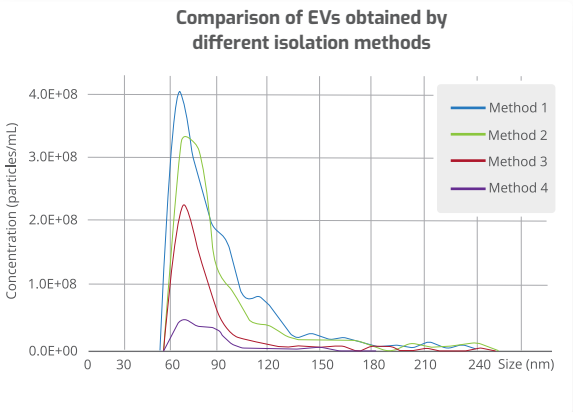
RPS measurements do have very high concordance with TEM data. — MISEV 2023

RPS technology, a non-optical method, well suited for orthogonal validating against TEM and flow cytometry. NanoCoulter™ offers accurate size distribution analysis with a defined LOD (50nm) and a wide concentration range (5×10^7 - 2×10^{11} particles/mL), making it indispensable for EV research."



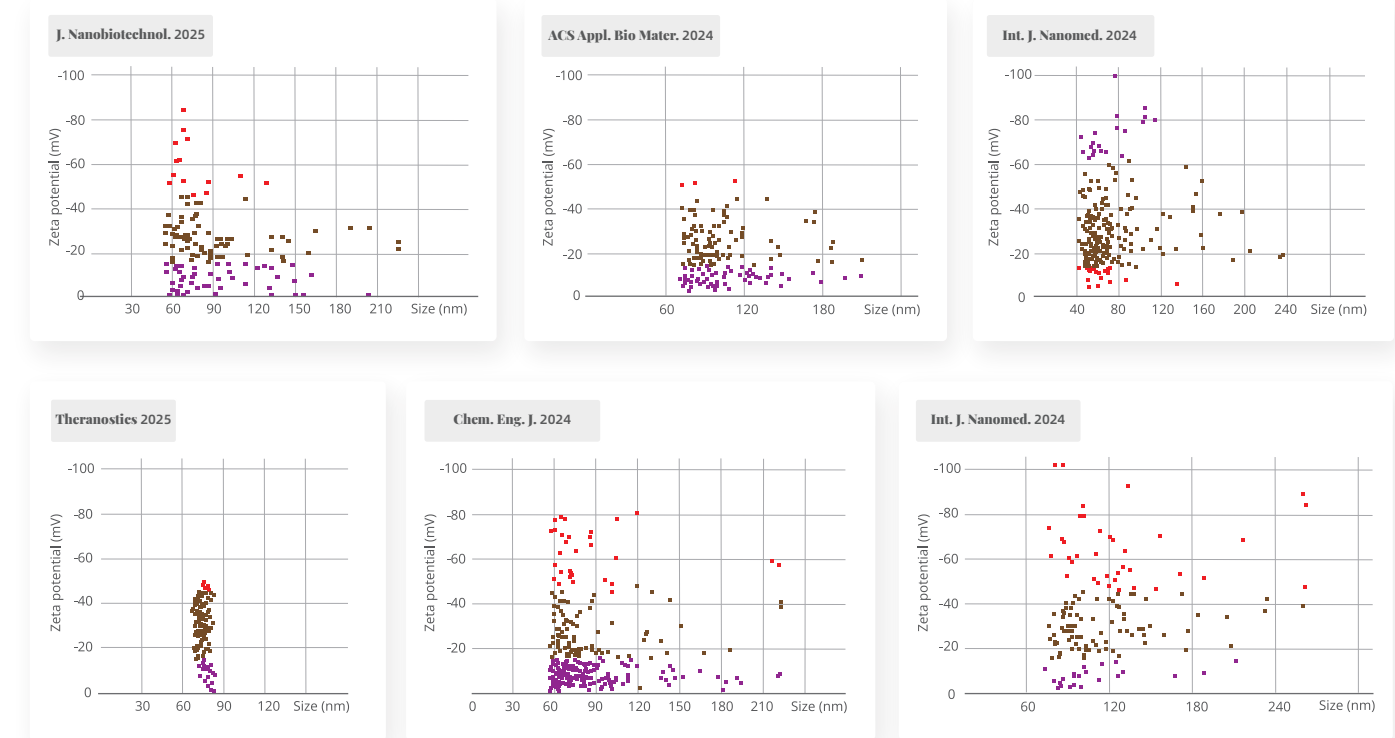
Investigation of EV Isolation Methods

Exosomes have complex origins and often require multiple isolation steps to obtain relatively pure exosomes. Different isolation methods can significant impact on the particle size and concentration of exosomes. The NanoCoulter™ enables rapid and accurate assessment of the advantages and disadvantages of different purification methods.



EV Zeta Potential Characterization

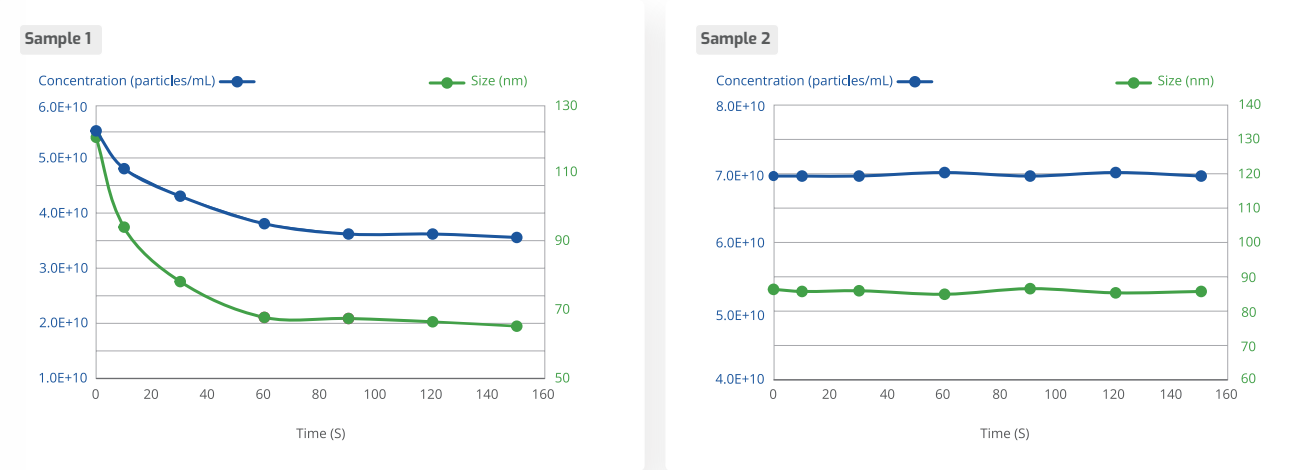
Zeta potential is a key parameter for evaluating EV stability, surface charge characteristics, and in vivo interactions. It directly influences adsorption, targeted delivery, and circulation time within biological systems. Traditional optical methods (DLS/LNT), can only provide an ensemble-averaged potential, failing to capture sample heterogeneity. NanoCoulter™ enables single-particle Zeta potential measurement, offering precise insights into EV population heterogeneity, thereby advancing research and applications in EV-based therapeutics.



Liposome/LNP

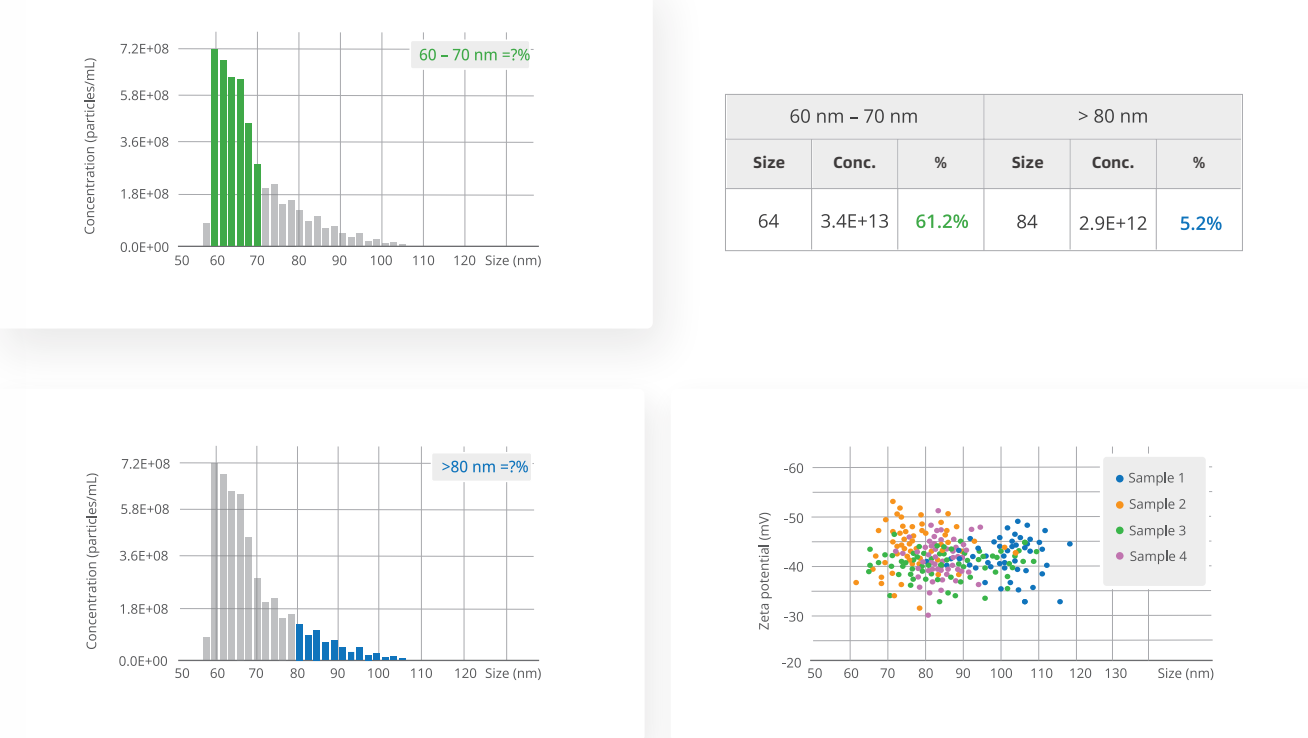
Liposome Stability Study

The stability of liposomal drugs directly affects their storage and in vivo delivery performance. The NanoCoulter™ enables precise evaluation of stability differences among various liposomes. The figure below shows the concentration changes of two liposome samples after different durations of simulated agitation, indicating that Sample 2 exhibits superior stability.



LNP Particle Size Distribution and Zeta Potential Analysis

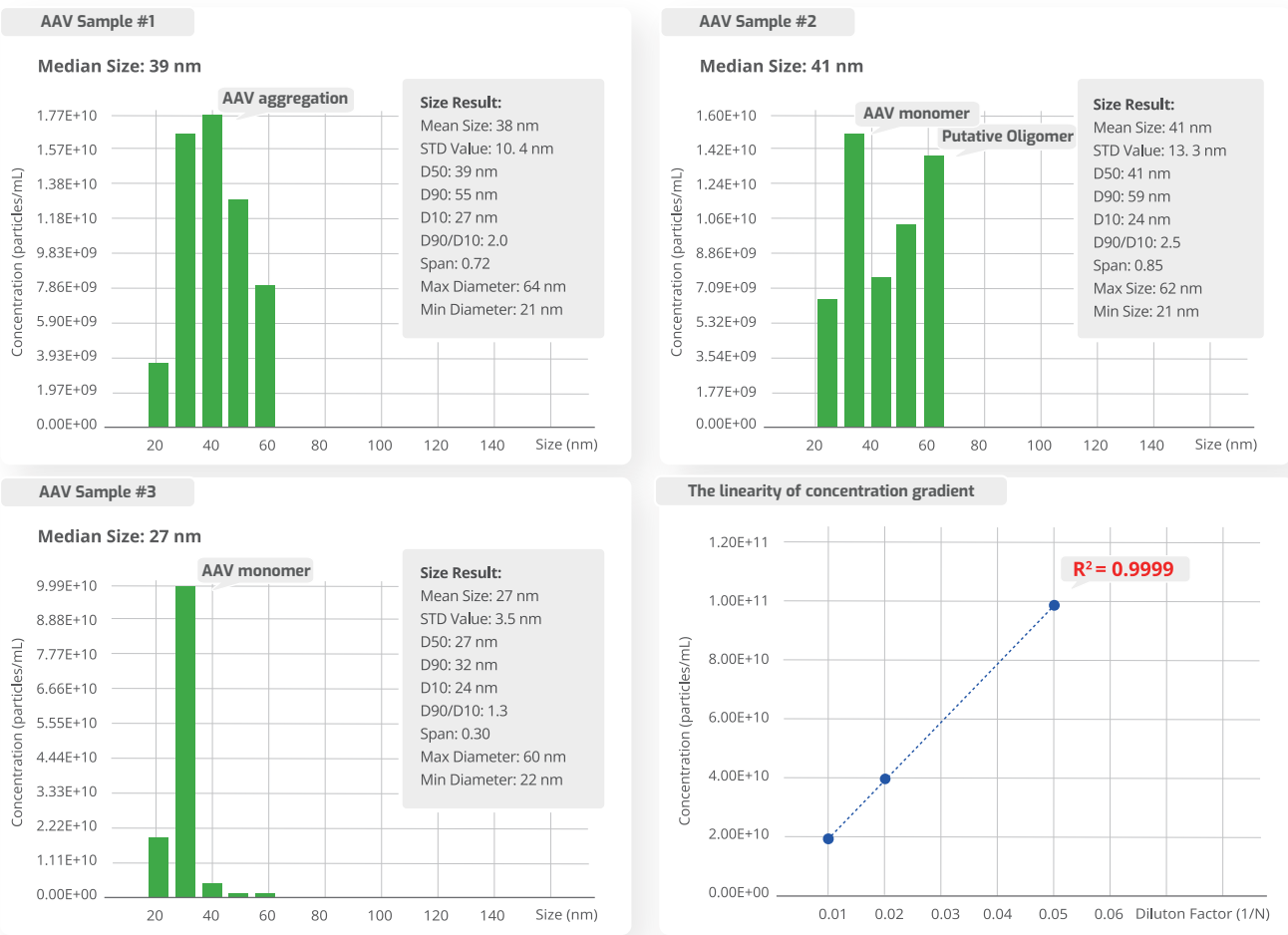
Particle size and size distribution are among the key Critical Quality Attributes (CQAs) parameters for LNPs. LNPs prepared by different methods may exhibit different size distributions, which are often overlooked by DLS measurements. The NanoCoulter™ can resolve the size distribution of LNP particle populations while providing concentration and component proportions within user-defined size ranges, along with the correlation between Zeta potential and particle size for each individual nanoparticle.



Virus Particles

Quantification of Adeno-Associated Virus (AAV) Particle Concentration

In addition to infectious titer, parameters such as physical titer (total particle concentration), particle size and distribution, purity, particle integrity, and aggregation status are also essential critical quality attributes for AAV gene therapy drug products. The NanoCoulter™ overcomes industry barriers, achieving single-particle nanoscale characterization for particles below 20 nm for the first time. It is particularly well-suited for high-sensitivity particle size analysis and high-precision concentration quantification of small viruses such as AAV.



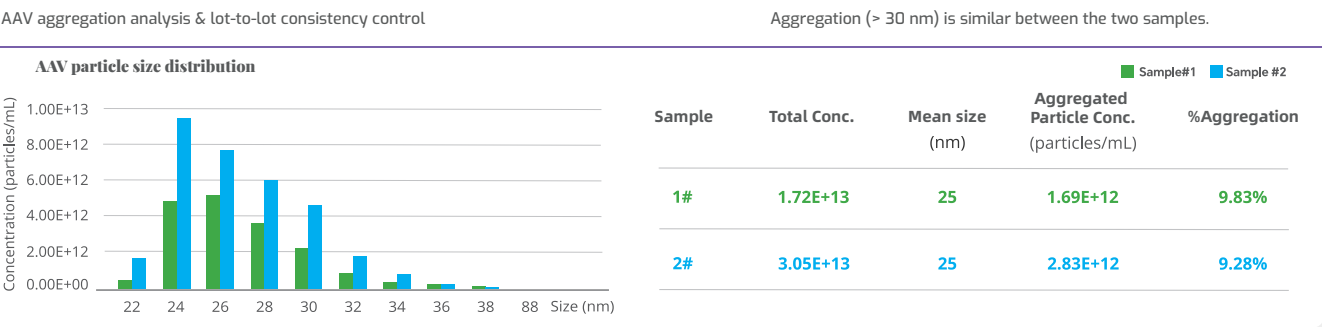
Three typical patterns of particle size distribution were observed for AAV samples:

Sample #1: A relatively broad normal distribution with evidence of particle aggregation.

Sample #2: Two distinct normal distribution peaks, with large-particle impurities potentially indicating Oligomer or residues from upstream processing.

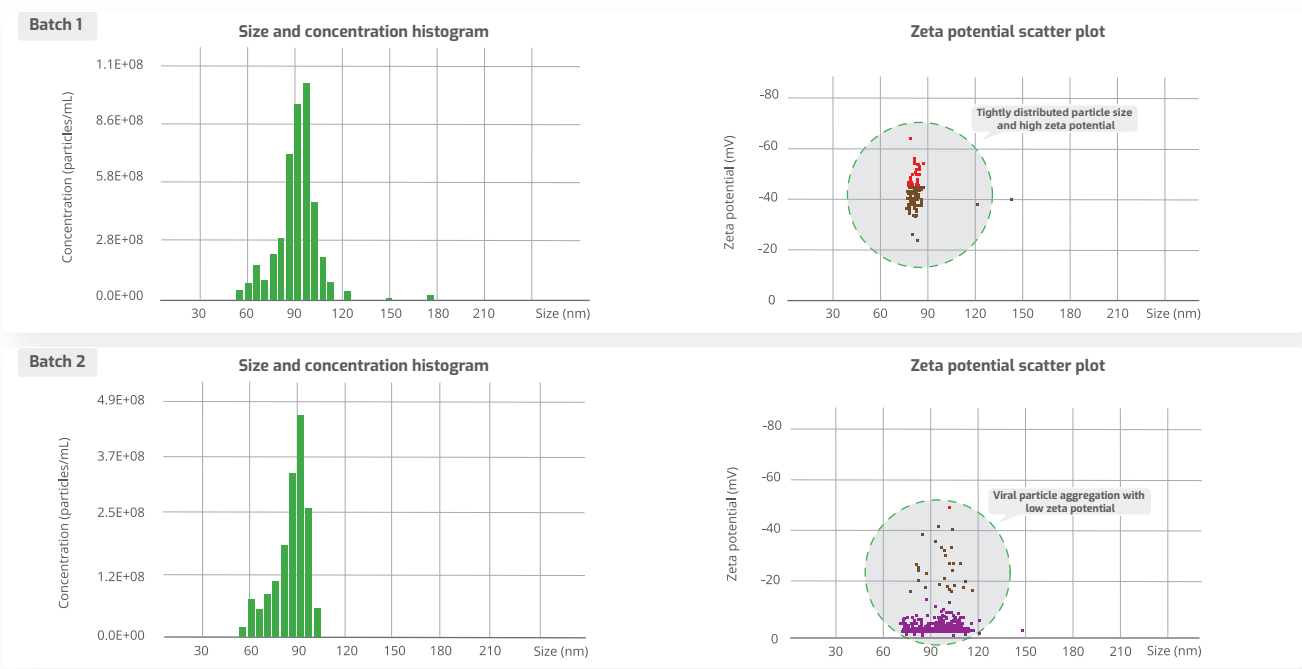
Sample #3: A relatively narrow normal distribution, consistent with the typical size distribution of AAV.

The NanoCoulter™ enables precise quantification of total AAV particle concentration, demonstrating a linear calibration curve with $R^2 = 0.999$.



Batch-to-Batch Quality Control in Adenovirus Production

Cell culture conditions, including medium composition, temperature, and pH, influence adenovirus production efficiency. NanoCoulter™ enables real-time monitoring of virus concentration, size distribution, and Zeta potential, facilitating rapid batch assessment and process optimization.



Magnetic Nanobeads & Microspheres

NanoCoulter™ enables precise analysis of nanosphere size and Zeta potential changes before and after antibody coating, effectively monitoring aggregation. Ultrasonication or other treatments can be used to address this issue.

