RE•FEYN®
WEIGHING MOLECULES WITH LIGHT

PRODUCT SUMMARY

Karitro^{MP}: A new tool for rapid analysis of large viral vectors

The Karitro^{MP} characterizes viral vectors to inform process development in preclinical settings and early drug development. It analyzes samples of adenovirus and lentivirus within minutes. Offering essential capabilities for vector analysis, the Karitro^{MP} can assess sample stability and purity. It is particularly useful for process development and optimization.

The Karitro^{MP} provides useful vector analytics fast

The Karitro^{MP} instrument (Fig. 1) was designed to address the analytical challenges that arise in the development and production of larger viral vectors. It has been proven to give useful insights for assessing the purity and stability of adenovirus vectors (AdV) and lentivirus vectors (LVV).

The Karitro^{MP} performs single-particle analysis, enabling users to visualize the distributions of viral particle populations within their samples. Information from the Karitro^{MP} gives insights into vector purity and stability. The instrument can resolve distinct populations of vectors and reveal changes over time that may arise from degradation. This information allows users to decide whether a sample is suitable for further processing – saving valuable time and resources.

What the Karitro^{MP} offers

- **Fast, simple, qualitative AdV and LVV analysis**
  - Differentiation of multiple populations, even those with the same size
  - Evaluation of relative changes across samples, from crude to purified
- **The Karitro^{MP} allows you to**
  - Quickly assess purity and stability prior to next steps
  - Compare production or purification methods
  - Identify batch-to-batch variations

Fig. 1 Refeyn's Karitro^{MP} analyzes AdV and LVV on the benchtop. Simple sample prep and straightforward operation mean that the instrument can be easily incoroporated into existing workflows.

The Karitro^{MP} performs multiparametric analysis

For each particle, the instrument measures two distinct parameters: Contrast (a qualitative measure related to the particle's composition and mass) and size. Measuring these two parameters at once makes it possible to distinguish populations of particles with the same size but different mass. Such populations could not be distinguished based on size measurements alone.

Because the Karitro^{MP} can distinguish particles of the same size but different mass, it can resolve empty vs. full AdV capsids and quantify their proportions (Fig. 2). Its speed and excellent contrast resolution make the Karitro^{MP} the only instrument on the market that can quickly measure AdV empty-full ratios.

Karitro^{MP} analysis is also ideal for comparing vector purification methods. The instrument can be used, for example, to monitor the effectiveness of purification during LVV production (Fig. 3).

The Karitro^{MP} can be used to identify and assess vector degradation, for example in an AdV sample (Fig. 4). The data obtained using the instrument can also be used to identify batch-to-batch variations.

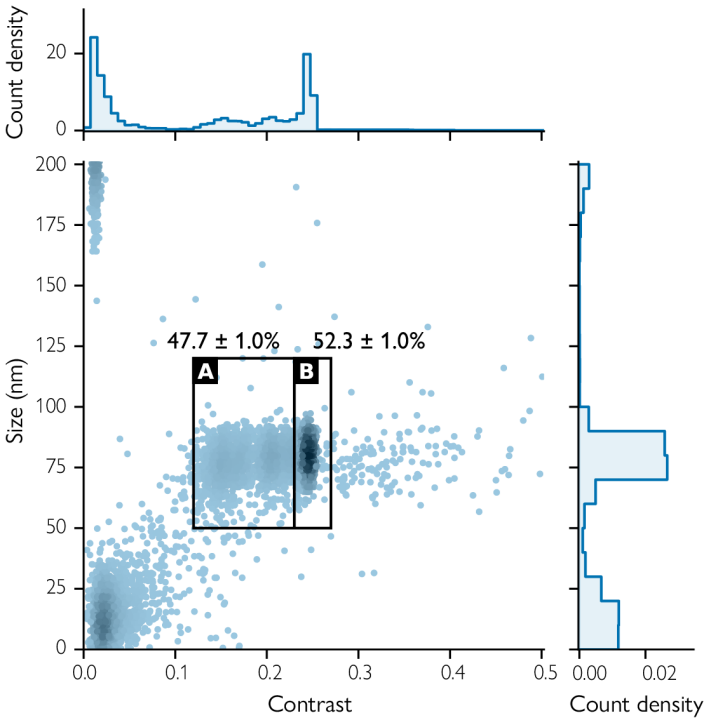

Fig. 2 The Karitro^{MP} measures purity, resolving empty vs. full AdV capsids. A mixture containing empty and fragmented capsids (confirmed by SDS page) plus full capsids was analyzed with the Karitro^{MP}. The instrument clearly resolved the full (gate A) and empty (gate B) populations. It measured the percentages of total particles within the gates (average ± standard deviation, SD), as indicated above each gate. The AdV samples were supplied by The Native Antigen Company Ltd. In all the data figures shown, the histograms display the distribution of contrasts measured for each viral vector in the sample (top histogram) and their size distribution (right histogram). The scatter plot shows the correlation between these two parameters.

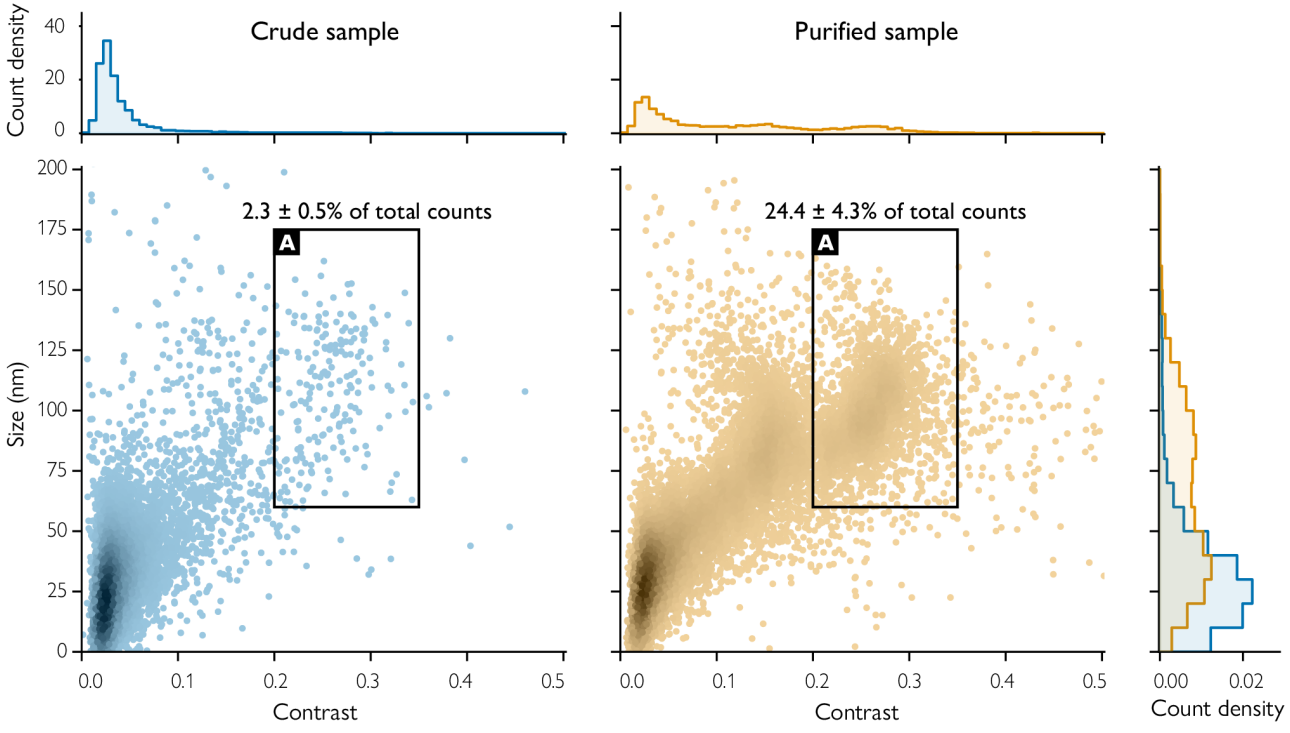

Fig. 3 The Karitro^{MP} assesses the effectiveness of sample purification processes. A sample that was analyzed before and after purification showed a ten-fold increase in the percentage of particles within gate A, which was assigned to be LVV capsids. This increase corresponds to an increase in the infectious titer. The percentages of total particles within the gate (average ± SD), is indicated above each gate. The LVV samples were manufactured by Revvity Gene Delivery (formerly SIRION Biotech). See the caption of Fig. 2 for more details on interpreting the figure.

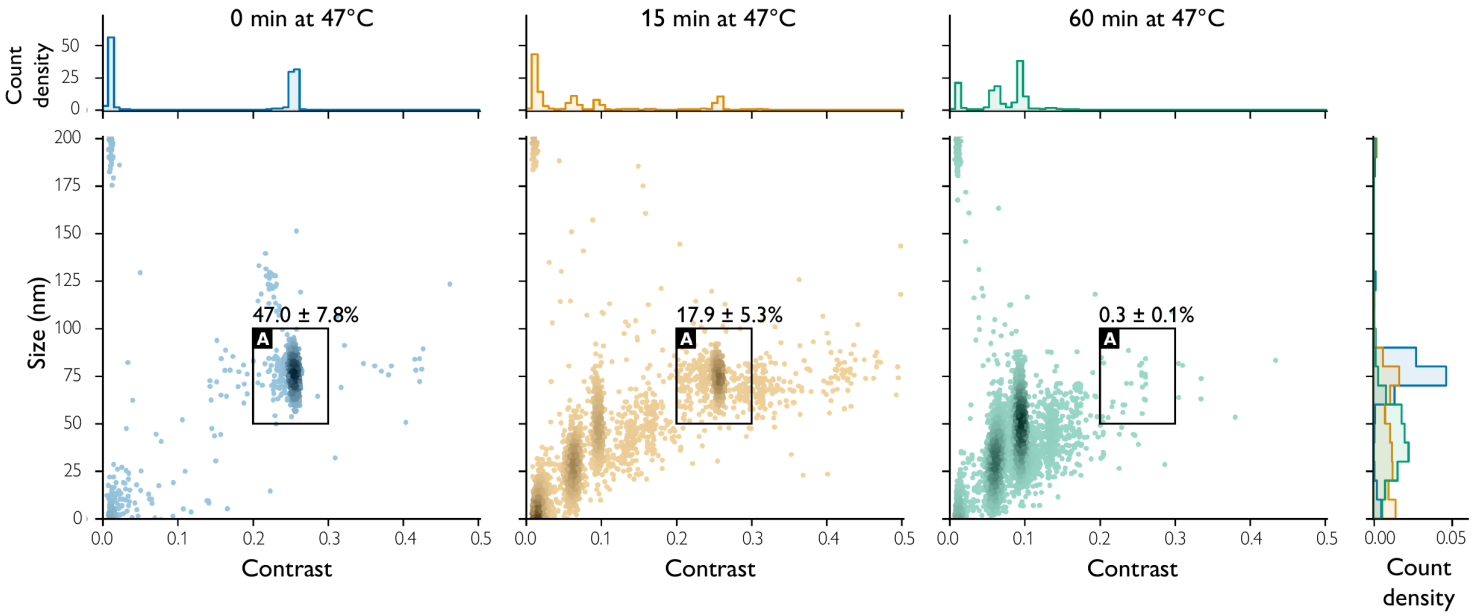

Fig. 4 The Karitro^{MP} measures AdV degradation. An AdV sample was exposed to heat (47°C) and analyzed with the Karitro^{MP} at the three indicated timepoints. The analysis showed that the population of intact AdV capsids (marked by gate A) clearly decreased over time, consistent with heat-induced degradation. Meanwhile, distinct new populations appeared with lower contrast (mass) values and smaller sizes. The percentages of total particles within the gate (average ± SD), is indicated above each gate. The AdV samples were supplied by The Native Antigen Company Ltd. See the caption of Fig. 2 for more details on interpreting the figure.

Semiautomatic workflow using little sample

The Karitro^{MP} uses little sample (5 µL at 10^8 – 10^9 particles/mL concentration), with minimal sample preparation and requiring no labels. After a simple dilution step, up to 13 samples plus a calibrant can be loaded onto a sample carrier (available from Refeyn) for analysis. The instrument gives results quickly (6 min/sample) and fits easily on a lab benchtop.

The Karitro^{MP} features a semiautomatic workflow that frees up operator time. The user manually adds the samples to the sample carrier. Then, the instrument runs the measurements autonomously and automatically analyzes the data using custom-built software.

The Karitro^{MP} builds on a disruptive analytical technology

The technology behind the Karitro^{MP} is macro mass photometry, a further evolutionary step beyond Refeyn's related technology, mass photometry. In mass photometry, the mass of biomolecules of up to 6 MDa is calculated from a precise measurement of the light scattered by each biomolecule.

Macro mass photometry, which is used by the Karitro^{MP}, measures the light scattered by larger particles using a vertically moving stage plus advanced data analysis. Macro mass photometry analysis returns the contrast of each vector particle – a qualitative measure that depends on the particle's composition and mass – along with its diameter.

Karitro^{MP} key specifications

Approx. size range	40 – 150 nm (diameter)
Optimal concentration	10^8 – 10^9 particles/mL
Sample volume	5 µL
Sample carrier capacity	14 wells
Time to result	6 min/sample
Contrast resolution	<5% (SD/mean, as measured for AdV particles)
Contrast precision	<2% (SD/mean)
Size resolution	<30 nm (FWHM, as measured for virus-like particles and silica nanoparticle standards)
Size precision	<5 nm (SD)
Laser wavelength	450 nm
Instrument dimensions	502.5 x 312.5 x 153.25 mm (WxDxH)
Instrument weight	25 kg

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