

# Waters™

## Aura Systems

High-throughput, fluidics-free aggregate and particle characterization and identification



# Choose the right Aura™ Particle Analyzer for your lab's needs



## Aura+ System

Everything in the box



## AuraBMI System

Biologics subvisible/  
visible particle analysis



## Aura System

Particle analysis with ID



## AuraGT System

Gene therapy



## AuraPTx System

Protein formulation  
development and screening



## AuraCL™ System

Cell therapy

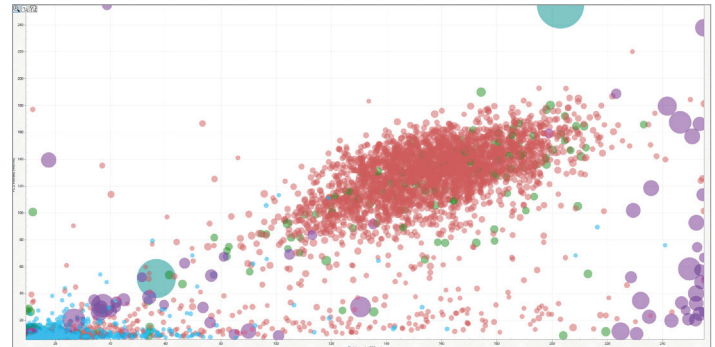
### All Aura Systems deliver:

- Visible and subvisible particle count
- Particle identification
- Particle morphology
- Flexible volume from microliters to milliliters
- Automation-ready performance
- Trustworthy data with minimal optimization
- Easy method transfer
- Continuous workflow from research to QC

# Aura Particle Analysis

## Take the Guesswork Out of Your Aggregate ID

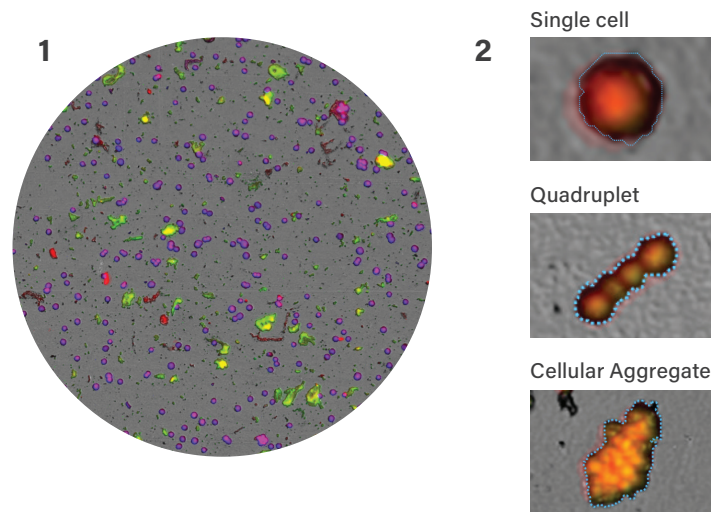
Don't waste time troubleshooting incorrectly identified aggregates in your therapeutic. Aura uses a combination of brightfield and fluorescent imaging to specifically ID and quantitate cell, viral capsid, protein, degraded excipients, and packaging contaminants so you'll know exactly what's in your sample.



Identify cell doublets and triplets (1), cellular aggregates (2), protein aggregates (3), and plastic contaminants (4) in a cell therapeutic sample.

## Make the Best Decisions About Your Therapeutic

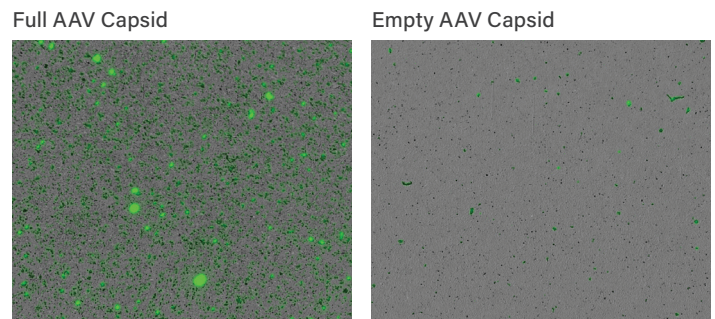
Know whether formulation or process modifications are needed to avoid aggregates that can affect the efficacy or safety of your drug therapeutics. Fluorescence Membrane Microscopy (FMM) uses specific fluorescent dyes or conjugated antibodies to help you visualize, quantitate, and ID aggregates, subvisible particles (SVP), and visible particles. Know for sure what is protein, viral capsid, cell, degraded polysorbate, plastic, or a fiber in your sample.



1. Distinguish cells (pink), protein aggregate (red), and particles labeled with a particle-specific conjugated antibody (yellow).
2. Cell aggregates can easily be mis-identified, but FMM can ID them with ease.

## Evaluate AAV and Payload-Related Stability of Your Gene Therapy

Quantitate the stability of different AAV serotypes. Monitor AAV DNA leakage using SYBR™ Gold and evaluate increases in subvisible particle formation, which can occur when nucleic acids leak from an unstable capsid. Assess the stability of your gene therapy across the entire development process — with only 5 µL of sample!



Label DNA with SYBR Gold (green) to monitor DNA leakage using FMM on Aura.

## Out of the Box ID

Using morphology to classify particles is notoriously unreliable and not everybody has the time or resources to build complicated machine learning libraries. Plus, these approaches just don't measure up when you have complex aggregates in your sample that are a combination of cell, protein, or plastic.

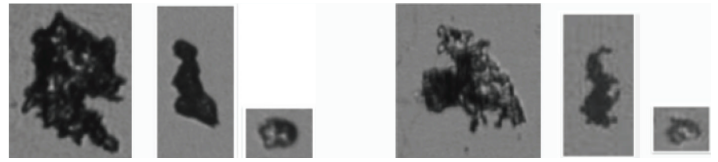
FMM makes it simple and straightforward to specifically ID cell from non-cell and protein from non-protein. Now, you can finally know what's in your sample without having to spend hours sorting through images. The specificity of FMM makes it easy to distinguish what's what in complex samples, so you'll never misidentify your aggregates again.

## Reliable Data at the Volume You Need

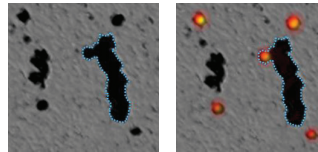
Aura Systems provide reproducible, quantitative data with any volume, so you can use the same method throughout the development of your product. Are you sample-limited? No problem! Aura Systems do more with less, so you can use 5  $\mu\text{L}$ , run triplicates, and still have plenty of material left for analysis using orthogonal methods. Working with larger volumes? Use the 24-well membrane format or split samples across multiple wells, then combine results in Particle Vue™ Software to obtain summed data for the entire sample lot.

## A Better Look with Side Illumination Membrane Imaging

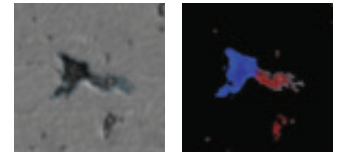
Got a non-biological particle in your sample and not sure what it is? Building on BMI particle analysis, Side Illumination Membrane Imaging (SIMI) provides additional information to clearly identify Dynabeads™, fibers, glass, and other unlabeled inorganic particles. Together, BMI and SIMI expand your particle analysis toolkit to support confidence in sample purity, safety, stability, and efficacy.



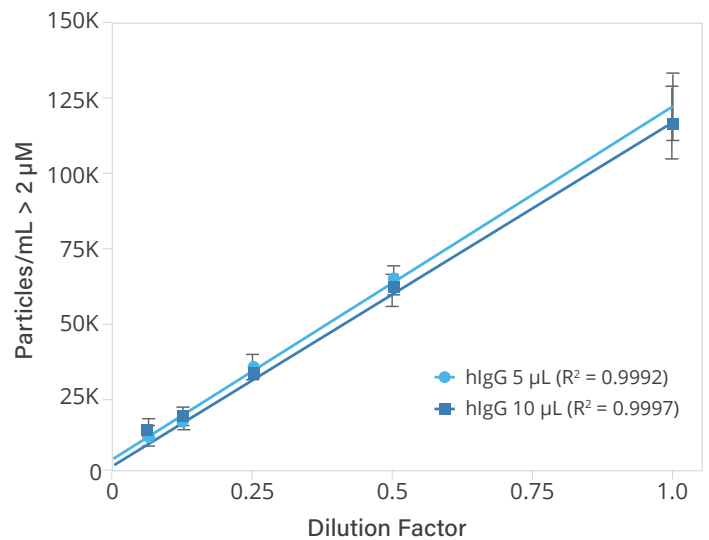
Protein aggregates (left) can easily be confused with plastic ETFE (right) when you rely on morphology and intensity filters. Avoid mis-identifying aggregates with FMM, only available with Aura.



Easily identify what's cell (orange) and non-cell (black).

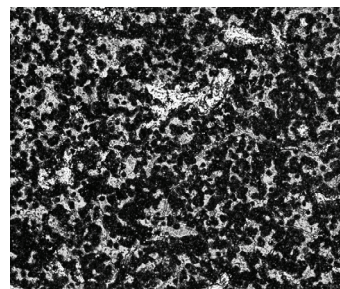


Easily identify what's protein (red) and non-protein (blue).

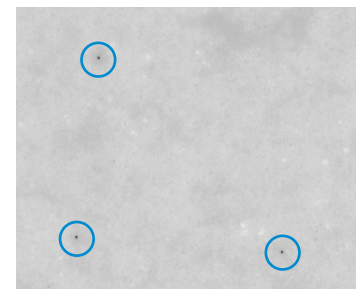


Excellent linearity ( $R^2 > 0.99$ ) across serial dilutions.

BMI



SIMI

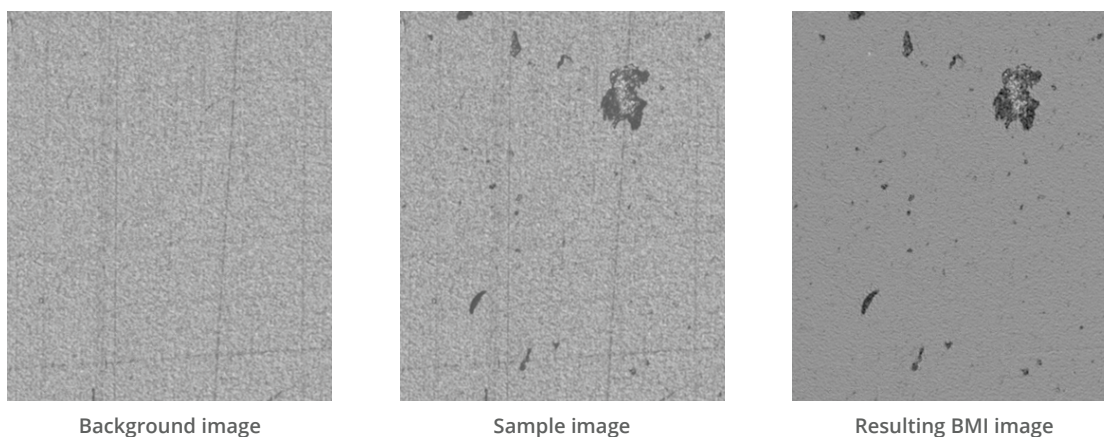


BMI reveals cells and Dynabeads vs. SIMI reveals Dynabeads only.

# How It Works

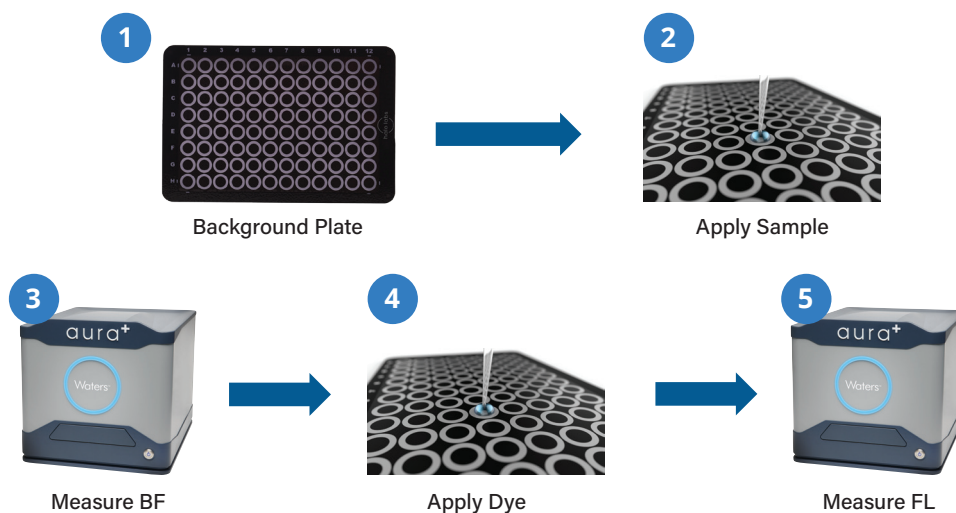
## Lipid Nanoparticles

BMI is an analytical technique with roots in membrane microscopy, a USP <788> subvisible particle lot release method. First, a background image of the membrane is taken before samples are filtered through and particles captured. The same membrane is then re-imaged – this time with particles on the surface. The background image is subtracted so that the background texture is eliminated, revealing particles. Contrast is 10x greater than measurements performed in liquid, sizes are calibrated to an ASTM glass slide microscope, and analysis is fully automated.



## Fluorescence Membrane Microscopy (FMM)

FMM works with BMI to deliver a level of particle analysis and identification not possible with any other particle analysis system. Particles can be rapidly labeled with fluorescent dyes or antibodies, either in solution or directly on the membrane in just a few seconds. BMI first identifies particle locations, then FMM, with flexible fluorescence channel options, detects and distinguishes multiple biomarkers simultaneously, enabling unrivaled, high-resolution discrimination of complex and heterogeneous populations.





Aura Systems set a new standard in visible and subvisible particle analysis. Powered by BMI, SIMI, and FMM, Aura Systems deliver complete particle characterization with insights beyond legacy techniques. From early-stage development to late-stage QC, Aura Systems provide seamless continuity across your entire development cycle.

## Which Aura is Right for You?



### SVP/Visible Particle Biologics Analysis

Aura+, Aura GT, Aura PTx, Aura CL, Aura and Aura BMI Systems



### Particle Analysis and Identification

Aura+, Aura GT, Aura PTx, Aura CL, and Aura Systems



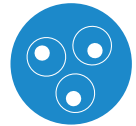
### Protein Therapy / Biologics

Aura+ and Aura PTx Systems



### Gene Therapy

Aura+ and Aura GT Systems



### Cell Therapy

Aura+ and Aura CL Systems

Application	Aura BMI	Aura	Aura PTx	Aura GT	Aura CL	Aura+
Particle detection/quantitation	✓	✓	✓	✓	✓	✓
Extrinsic particles	✓	✓	✓	✓	✓	✓
Protein ID		✓	✓	✓	✓	✓
Polysorbate ID			✓			✓
Cell aggregate ID					✓	✓
Capsid aggregate ID				✓		✓
DNA leakage				✓		✓
Immunoassays			✓	✓		✓
Cellular assays					✓	✓
High magnification microscopy					✓	✓
Custom FL applicants		✓				

# Product Specifications

Imaging area	24.6 mm <sup>2</sup>
Brightfield illumination (BF)	LED 455 nm
Side Scatter illumination	LED 465 nm
Fluorescence illumination (FL)	LED
FL channel 1	Ex: 440/40 nm, Em: 500/40 nm (Aura, Aura CL, Aura PTx, Aura GT, Aura+) Ex: 376/30 nm, Em: 440/40 nm (Aura CL, Aura+)
FL channel 2	Ex: 482/35 nm, Em: 524/24 nm (Aura PTx) Ex: 488/50 nm, Em: 544/24 nm (Aura GT) (optional) additional custom excitation and emission channel
FL channel 3	Ex: 482/35 nm, Em: 524/24 nm (Aura+)
Sampling efficiency	100%
Minimum sample volume	5 µL (assay dependent)
Resolution	1.0 pixel/µm
Particle size range (detection and quantitation)	>1 µm
Maximum particle concentration (1.6 µm particle size)	>3,000,000 particles/mL
Brightfield read time (BMI)	1 minute/sample
Fluorescence read time (FMM)	15–30 seconds/sample
Sample format	24-well or 96-well filter membrane
Membrane type 1 (brightfield)	White — polycarbonate track etched
Membrane type 2 (fluorescence)	Black — polycarbonate track etched
Robotic compatibility	Yes





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office, please visit  
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