AURA SYSTEMS

HIGH-THROUGHPUT, FLUIDICS-FREE AGGREGATE AND PARTICLE CHARACTERIZATION AND IDENTIFICATION

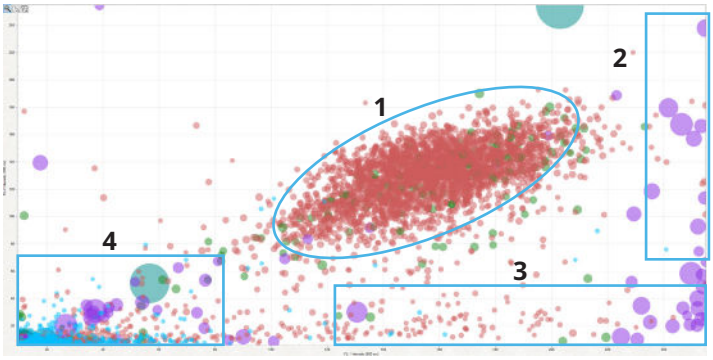
- Particle ID
- Subvisible Aggregate Analysis
- DNA Leakage
- Polysorbate Degradation
- Product Purity
- 5 µL – 10 mL Sample Volume

An Aura For You

- Automation Ready
- Know Your Aggregates
- Sample Volumes That Meet Your Needs
- Fast Answers
- Fluidics-Free Peace of Mind
- Trustworthy Data with Minimal Optimization
- Easy Method Transfer
- Machine-Learning Free Aggregate ID

Take the Guesswork Out of Your Aggregate ID

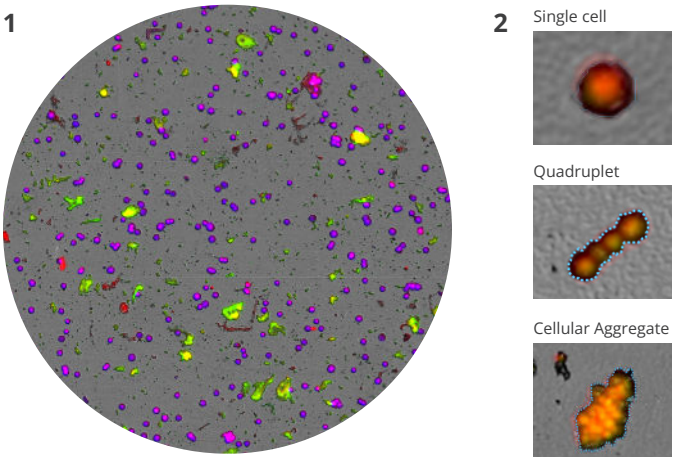
Don't waste time troubleshooting incorrectly identified aggregates in your therapeutic. Aura uses a combination of brightfield and fluorescent imaging to specifically ID and quantitate cell, viral capsid, protein, degraded excipients, and packaging contaminants so you'll know exactly what's in your sample.



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.

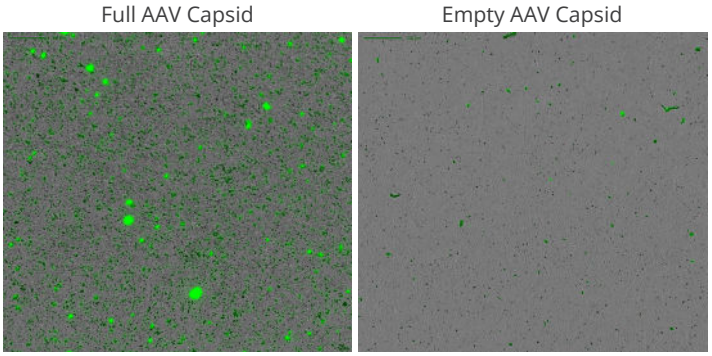


1: Distinguish cells (pink), protein aggregate (red), and particles labeled with a particle-specific conjugated antibody (yellow).

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 stabilty of different AAV serotypes under several conditions. Or label free DNA with SYBR™ Gold to monitor increased subvisible particle formation that can occur when nucleic acids leak out of an instable capsid. Assess the stability of your gene therapy throughout the entire development process – with just 5 µL of sample!

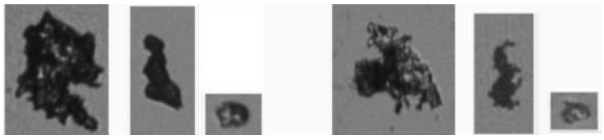


Label DNA with SYBR Gold (green) to monitor DNA leakage using FMM on Aura.

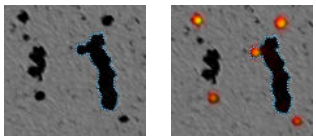
Out of the Box ID

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.

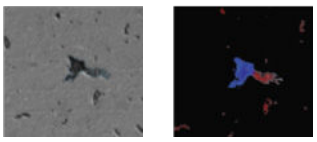
FMM makes it simple and straightforward to specifically ID cell from non-cell and protein from non-protein. Now, you can finally know what's in your sample without having to spend hours sorting through images. The specificity of FMM makes it easy to distinguish what's what in complex samples, so you'll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



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.



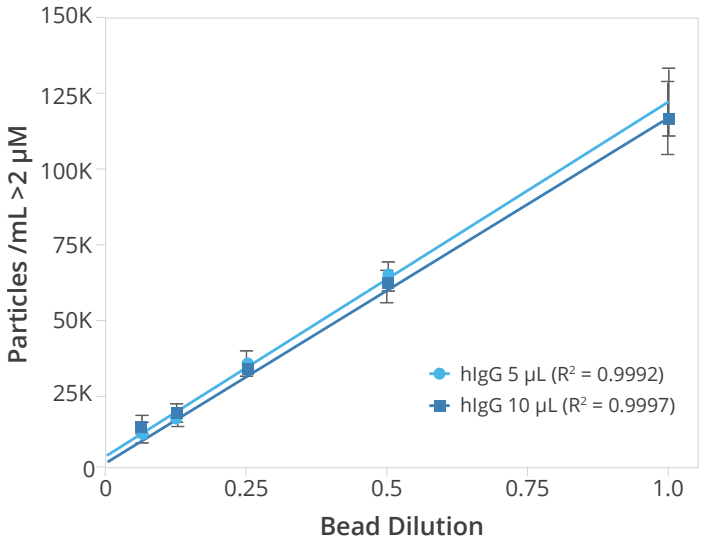
Easily identify what's cell (orange) and non-cell (black).



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

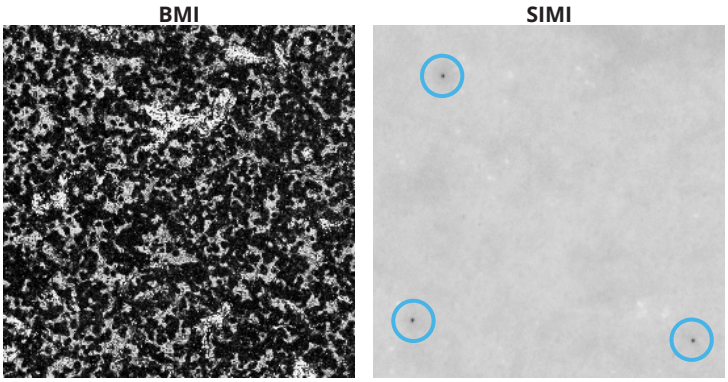
Reliable Data at the Volume You Need

Aura delivers reproducible, quantitative data with any volume so you can use the same method throughout the development of your product. Sample limited? No problem! Aura systems does more with less so you can use 5 µL, run triplicates and still have plenty of material left for analysis using orthogonal methods. Need to analyze 10 mL or more? Split samples into multiple wells and get summed data from Particle Vue software for your 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? Only using BMI for your particle analysis and need more information to determine what is what? Clearly identify Dynabeads™, fibers, glass and other unlabeled inorganic particles in your sample with Side Illumination Membrane Imaging (SIMI) adding another tool to your arsenal for ensuring sample purity, safety, stability, and efficacy.



BMI reveals cells and Dynabeads vs. SIMI reveals Dynabeads only

“

After evaluating all of the options for subvisible particle instruments, I concluded there really is no other choice besides getting an Aura. Nothing else can match its capabilities.

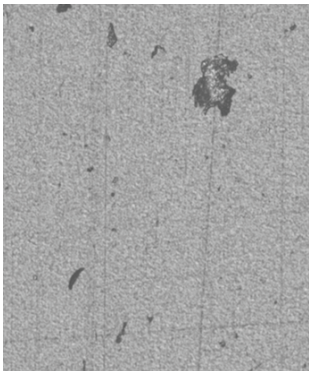
— Analytical Scientist, Major Biopharmaceutical Company

How It Works

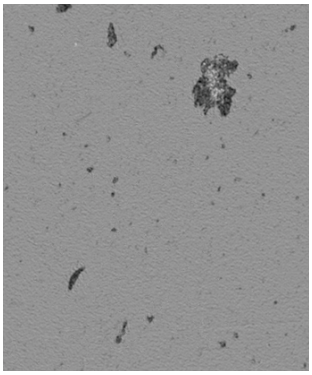
BACKGROUNDED MEMBRANE IMAGING (BMI)

BMI is an analytical technique with roots in membrane microscopy, a USP 788 subvisible particle lot release method. A background image of the membrane is first 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.

Background image



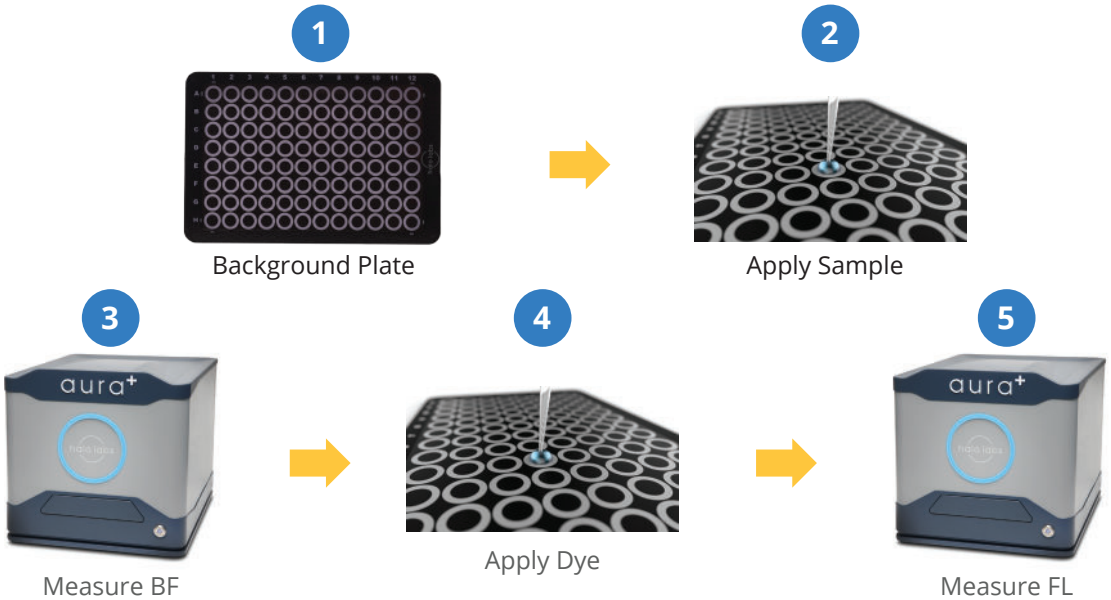
Sample image



Resulting BMI image

FLUORESCENCE MEMBRANE MICROSCOPY (FMM)

FMM works with BMI to give you a level of analysis not possible with any other particle analysis system. Targets are labeled using specific fluorescent dyes or antibodies using flexible protocols that easily fit into your workflow. Either label the particles on the membrane itself or in solution – either way it only takes a few seconds. Membranes are first imaged with BMI to mark where particles are present. After the membrane is imaged with FMM, particles introduced from the dye itself are excluded from analysis so you don't need to worry about particles introduced from the dye.



Which Aura is Right for You?

SVP/Visible Particle Biologics Analysis

Aura+, Aura GT, Aura PTx, Aura CL, Aura, Aura BMI

Particle Analysis & Identification

Aura+, Aura GT, Aura PTx, Aura CL, Aura

Protein Therapy/ Biologics

Aura+, Aura PTx

Gene Therapy

Aura+, Aura GT,

Cell Therapy

Aura+, Aura CL

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 Applications		✓				

> …backgrounded membrane imaging (BMI)… low volume option for particle characterization while providing significantly increased sensitivity compared to classical particle characterization methods such as light obscuration.
>
> — *Merck*

Product Specifications

Imaging area	24.6 mm^2
Brightfield illumination (BF)	LED 455 nm
Side Scatter illumination (SIMI)	LED 465 nm
Fluorescence illumination (FL)	LED
FL channel 1 (protein/non-protein)	Ex: 440/40 nm, Em: 500/40 nm
FL channel 2 options	Ex: 376/30 nm, Em: 440/40 nm Ex: 482/35 nm, Em: 524/24 nm Ex: 488/50 nm, Em: 544/24 nm Ex: 540/50 nm, Em: 600/37 nm Ex: 605/50 nm, Em: 670/50 nm Custom excitation and emission
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

Instrument Product Codes

Aura BMI	50–1000	**Aura GT**	50–1005
Aura	50–1001	**Aura CL**	50–1100
Aura PTx	50–1006	**Aura+**	50–1101

Rev H