



Aura

AGGREGATE AND PARTICLE
COUNTING, SIZING, AND ID

Protein vs Non-Protein ID
5 μ L - 10 mL Sample Volume
96 Sample Automation
Custom Fluorescence Assays

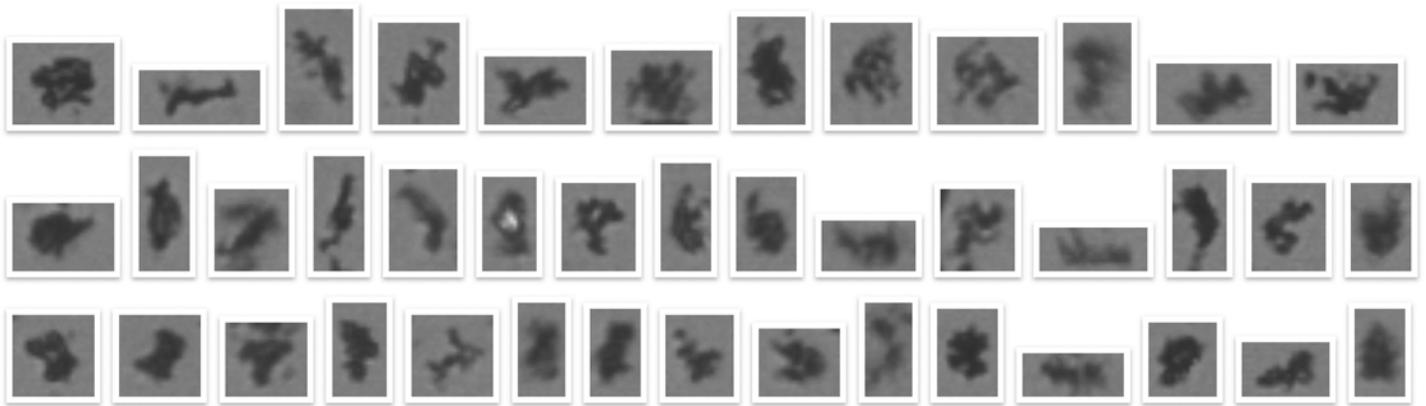
Particle Analysis Re-Imagined

Know your particles	Reproducible and quantitative count, size, morphology <i>and</i> particle ID in one system. Finally!
Find your best formulation	Distinguish protein from non-protein aggregates in your biotherapeutic and know exactly how to troubleshoot any stability issues.
Sample volumes that meet your needs	Use as little as 5 μ L of sample per analysis if you are sample limited. Or process an entire 10 mL sample if you want to leave no stone unturned. It's up to you.
Save time and money	Avoid costly downstream setbacks. Screen precious early-stage samples to gain key stability insights and make decisions about your protein drug sooner rather than later.
Fast answers...	Process a full 96 well plate in hours, not weeks. Why wait for answers?
... with no fuss	Get started right away — Aura™ is automated and always ready to go. Disposable membrane plates mean no cleaning between runs and no chance for cross-contamination.
Trust your data with minimal optimization	Measure 100% of your sample. Everything is counted without having to optimize image capture conditions.
No more method transfer	Use Aura from early development all the way through lot release. Membrane microscopy is an established USP method.
Automation ready	Increase your efficiency. Liquid handlers and robotics can automate your plate prep and assays.

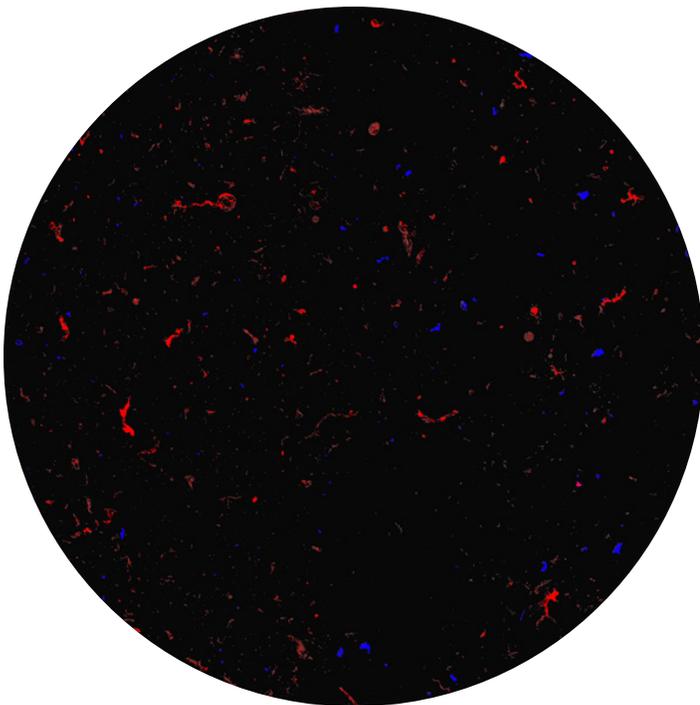


Take the Guesswork Out of Particle ID

Don't waste time troubleshooting incorrectly identified particles in your drug sample because you relied on undependable morphology and intensity filters to identify your particles. Tag particles in your sample with a fluorescent dye to know exactly which are protein aggregates. Need even more info? Tag hydrophobic proteins or other aggregates with a different dye for further insight.



Plastic particles that can easily be incorrectly identified as DP particles when using morphology and intensity filters only.



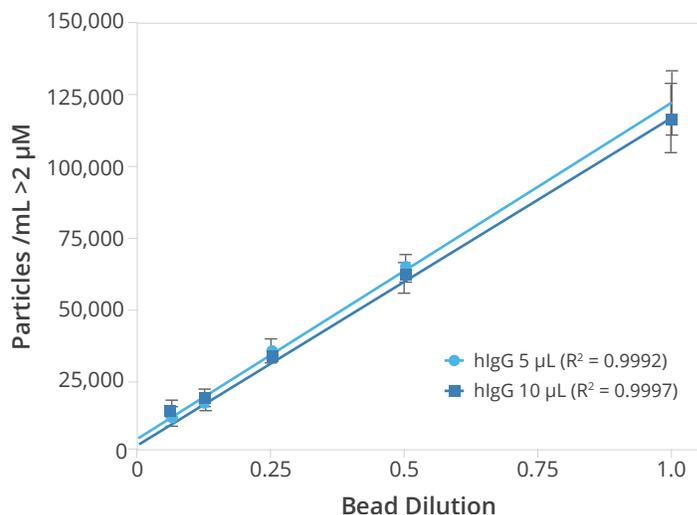
Aura clearly identifies protein aggregates (red) from non-protein particles (blue).

Easily figure out what's protein and what's not in less than 90 seconds. See exactly what your particles are with aligned images using Vue software. There's no calibration or spectral interpretation needed, removing all the ID guesswork.

Aura – definitive ID made simple!

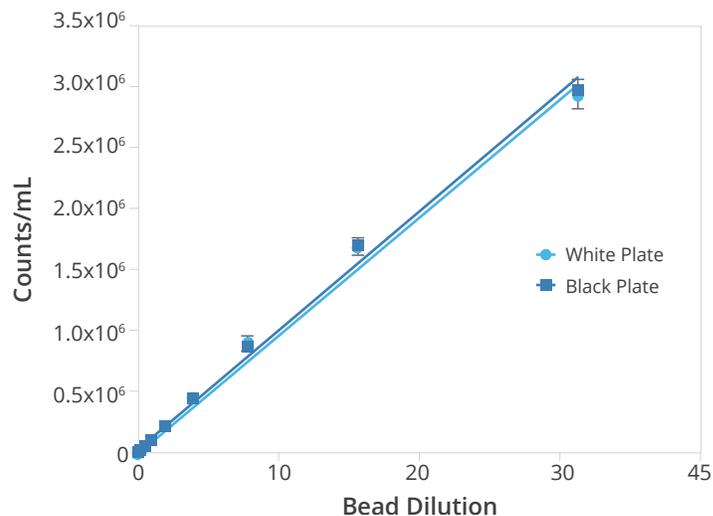
Reliable Data at the Volume You Need

Sample limited? No problem! The Aura system does more with less, delivering reproducible, quantitative data with as little as 5 μL of sample. 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 the summed data from Vue software for your entire sample lot.



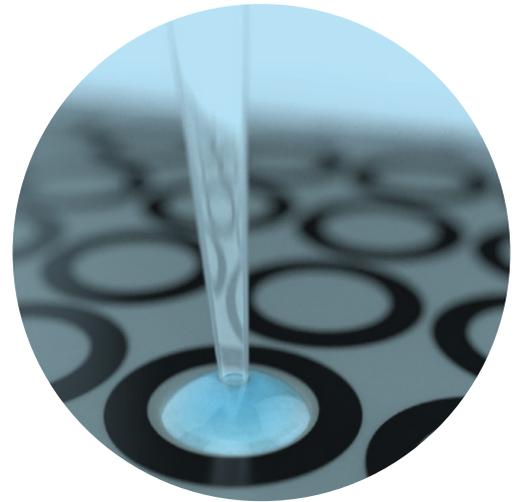
Wide Linear Range for Sensitive, Dilution Free Analysis

The Aura system is the only method that images 100% of your sample. Translation? A wide linear range that gives you confidence that both stressed stability studies and late stage lot release samples are measured accurately. Plus, all of the particles are in the plane of focus so you don't miss particles if your flow rates aren't perfectly tuned.



Get the Whole Picture

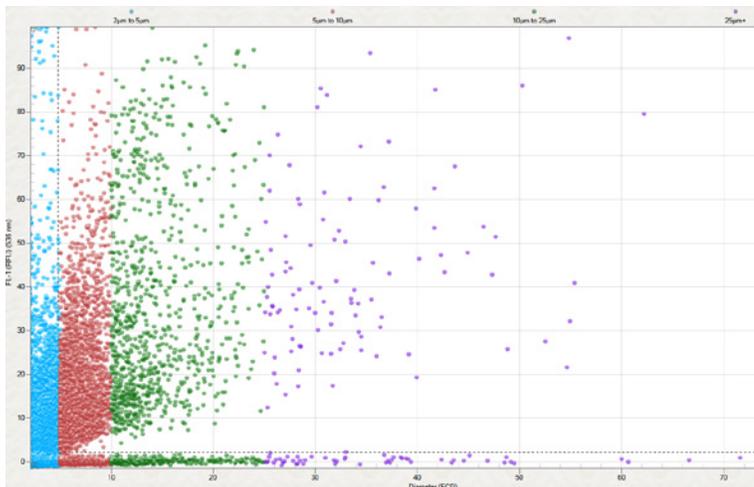
Aura detects aggregates and particles, even dim and translucent ones, in the 1 μm to 5 mm range so you'll see aggregates that can be missed by dynamic light scattering (DLS) and size exclusion chromatography (SEC). This can reveal stability issues you'd miss with other methods. Aura also takes measurements with the matrix removed so, unlike flow imagers, it benefits from a high refractive index contrast.



Deep Insights with a Simple Click

Vue software features help you take a dive deep into your analysis. You can:

- Set thresholds manually or using integrated expression engines. Quickly find specific particle populations with parameters like fluorescence intensity and size and determine which populations need a formulation fix and which require a process change.
- Easily overlay aligned brightfield, Side Scatter Illumination (SIMI), and fluorescent channels.
- Plot results, automatically averaging replicates and calculating error bars.
- Sum multiple wells for split samples.
- Search for specific measured parameters.
- Combine multiple detection, methods, and visualize your entire experiment in one window.

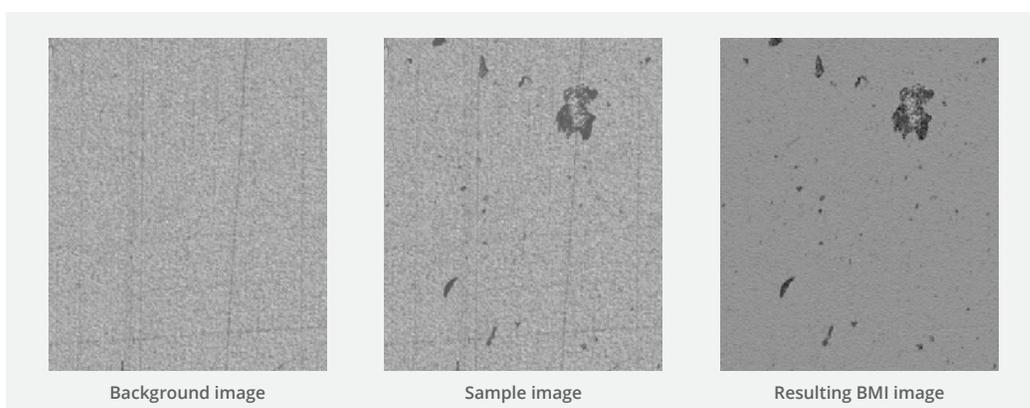


Sample	ECD >5 $\mu\text{m}/\text{mL}$	Particles Above Threshold	% >5 μm Above Threshold
Plastic	15857	244	1.5%
IgG	43494	43396	99.8%
IgG + Plastic	66343	58223	87.8%

Backgrounded Membrane Imaging (BMI)

Aura utilizes Backgrounded Membrane Imaging (BMI), an analytical technique with roots in membrane microscopy, to collect brightfield and SIMI data.

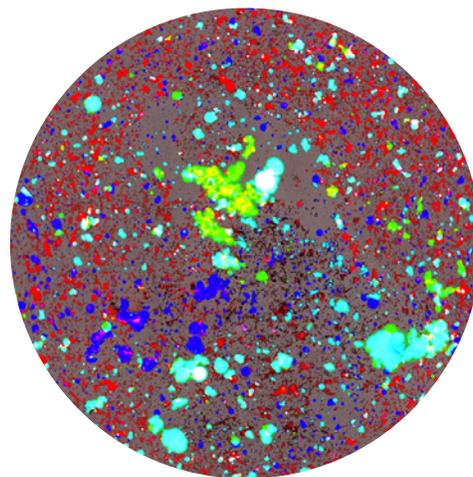
BMI uses sophisticated image-processing techniques to analyze images and acquire particle data. First, a background image of the membrane is taken. After samples are filtered through and particles are captured, the same membrane is re-imaged — this time with particles on the surface. The background image is precisely aligned with the sample image and then subtracted so that the background texture is eliminated, revealing particles. Contrast is 10x greater than measurements performed in liquid, sizes are calibrated to an ANSI calibration slide, and analysis is fully automated.



Fluorescence Membrane Microscopy (FMM)

FMM works with BMI to give you data you can't get with any other particle analysis system. Samples can be labeled with protein aggregate dyes (Thioflavin) and hydrophobic dyes (TMA, Bodipy, and DII) for detection with up to two fluorescence channels. Particles can be labeled 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, eliminating false positives.



Combine multiple fluorescence signals with brightfield and SIMI to understand what's in your sample. In this image, protein aggregates (red), non-protein particles (black), degraded excipient (green), and SIMI (blue) are all observed in one sample

Key Advantages of Aura

	Aura	Flow Imaging	Raman/FTIR
Counting and sizing	✓	✓	✗
Particle ID	✓	✗	✓
100% sampling	✓	✗	✗
Reproducible data	✓	✗	✗
Low volume	✓	✗	✗
Air bubbles not counted as particles	✓	✗	✓
Minimal optimization/single plane of focus	✓	✗	✓
Zero cross-contamination	✓	✗	✓
High refractive index contrast	✓	✗	✓
Fluidics free	✓	✗	✓
High Throughput	✓	✗	✗
Calibration-free measurements	✓	✗	✗
Automation	✓	✓	✗

Available Aura Configurations

	BMI	FMM
Brightfield system	✓	✗
1 FL channel system (ThT)	✓	✓
2 FL channel system (ThT + channel of your choice)	✓	✓



Product Specifications

Technology	Backgrounded Membrane Imaging (BMI) and Fluorescence Membrane Microscopy (FMM)
Imaging area	24.6 mm ²
Brightfield illumination (BF)	LED 455 nm
Side Scatter illumination (SIMI)	LED 465 nm
Fluorescence illumination (FL) - optional	LED
Fl channel 1 (option A)	Ex: 440/40 nm Em: 500/40 nm (Thioflavin T)
Fl channel 2 (option B)	Ex: 376/30 nm Em: 440/40 nm (e.g. TMA-DPH)
Fl channel 2 (option C)	Ex: 605/50 nm Em: 670/50 nm (e.g. BODIPY)
Fl channel 2 (option D)	Ex: 540/50 nm Em: 600/37 nm (e.g. Dil)
Fl channel 2 (option E)	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 – 5 mm (ECD)
Maximum particle concentration (1.6 µm particle size)	>3,000,000 particles/mL
Brightfield read time (BMI)	1 minute/sample
Fluorescence read time (FMM)	30 seconds/sample
Sample format	96-well filter membrane
Membrane type 1 (brightfield)	White — Polycarbonate track etched 0.4 µm or 0.8 µm pores
Membrane type 2 (fluorescence)	Black — Polycarbonate track etched 0.4 µm or 0.8 µm pores
Robotic compatibility	Yes