

Valita Aggregation Pure PROTEIN AGGREGATION DETECTION AND QUANTIFICATION ASSAY

SPEED • PERFORMANCE • SIMPLICITY AUTOMATION • 96-WELL FORMAT





Rapid Determination of Protein Aggregation in Pure Solution

Results in minutes not hours

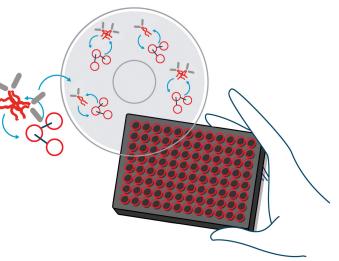
The Valita Aggregation Pure assay is a plate-based, 96-well screening tool that offers rapid, high throughput protein aggregation detection and quantification. The Valita Aggregation Pure assay is among the fastest and simplest aggregation detection tools on the market, and is compatible with high-performance microplate readers with Fluorescence Polarization functionality.

Workflow benefits

- No additional reagents (just the plate!)
- No wash steps required
- Reduce project timelines with rapid in-lab/in-house testing

Assay Benefits

- Simple: Add, mix, read
- Rapid: Results in less than 15 minutes
- Automation friendly: 3 steps in standard plates
- Cost effective: All that's needed is a plate reader



VALITA AGGREGATION PURE ASSAY TECHNICAL FEATURES

- Limit of detection: >/= 0.5 % at 1 g/L
- Plate format: 96-well format
- Accuracy: > 95 % for human IgG1 samples with levels of aggregation > 0.5 % at 1 g/L
- Assay time: Add, mix, read <15 minutes
- Fluorescent binding peptide: Proprietary molecule (Excitation max = 560 nm, Emission max = 590 nm)
- Validated protein constructs: Human IgG1, human IgG2, human IgG4, Fab, F(ab')², IgG hybrid, IgG Fc fusion, murine IgG, rabbit IgG
- Recommended sample concentration: 200 mg/L to 2 g/L
- Validated assay matrix: Purified solution

PROCESS DEVELOPMENT WORKFLOW



Quantify aggregation in minutes, not hours with the Valita Aggregation Pure assay

SCALE UP / MEDIA DEVELOPMENT

Develop the ideal production media while expanding cell culture volumes OPTIMIZATION Create a feed strategy to optimize yield and

product CQAs

FEED

HARVEST / SEPARATE

Singly deposit clones into culture and image to verify monoclonality

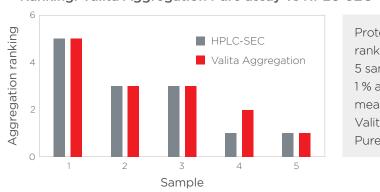
PURIFICATION

Test and select clones based on product CQAs

Other possible applications include: late cell line development, stability studies, formulation screening

Valita Aggregation Pure AssayDLS/SLSHPLC - SECAssay Time15 mins - 1-2 hours				
Assay Time Assay Time 1-2 hours Image: Throughput		Aggregation	DLS/SLS	HPLC - SEC
Throughput ++++ ++ + Automation Friendly Yes Semi-automatable No		15 mins		
Throughput +++ + Automation Friendly Yes Semi-automatable No	Assay Time		1-2 hours	
Throughput +++ + Automation Friendly Yes Semi-automatable No			· · · · · · · · · · · · · · · · · · ·	
Automation Friendly Yes Semi-automatable No				>6 nours
Automation Friendly Yes Semi-automatable No				
	Throughput	++++	++	+
Number of Reagents 1 >1 >2	Automation Friendly	Yes	Semi-automatable	No
	Number of Reagents	1	>1	>2
CAPEX \$ \$\$ \$\$	CAPEX	\$	\$\$	\$\$\$

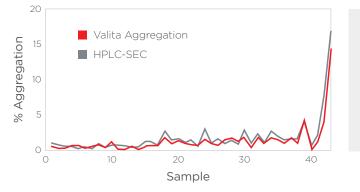
BENCHMARK DATA



Ranking: Valita Aggregation Pure assay vs HPLC-SEC

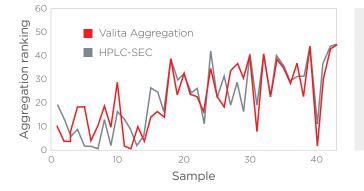
Protein Aggregation ranking, comparing 5 samples with < 1 % aggregation measured on both Valita Aggregation Pure and HPLC-SEC





Percentage Protein Aggregation, comparing 43 samples measured on both Valita Aggregation Pure and HPLC-SEC.





Protein Aggregation ranking, comparing 43 samples measured on both Valita Aggregation Pure and HPLC-SEC.



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