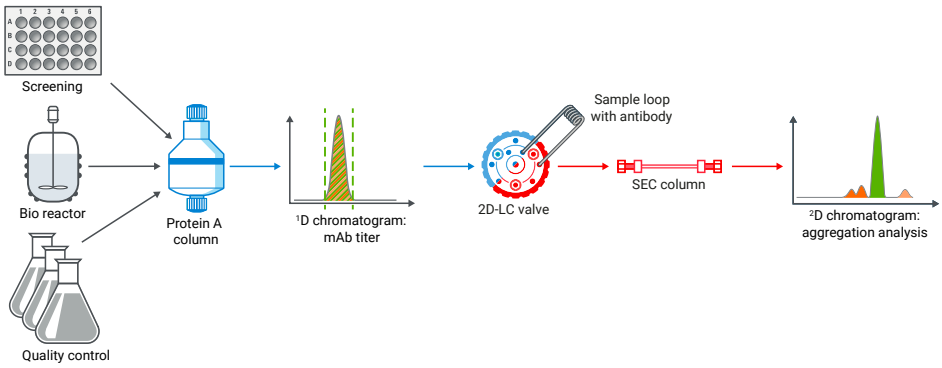
Data Sheet

The Agilent InfinityLab 2D-LC ProtA-SEC Kit and Service

An integrated workflow solution for titer and aggregation analysis of monoclonal antibodies with Agilent InfinityLab 2D-LC Solutions



Overview

The Agilent InfinityLab 2D-LC ProtA-SEC Kit is designed for rapid quantitative analysis of monoclonal antibodies, titer, and aggregation according to ICH Q6B specifications. The workflow enables the measurement of two critical quality attributes in one analysis with the Agilent 1290 Infinity II 2D-LC System:

- Titer determination for antibodies
- Quantitative aggregation analysis

It can be used in various stages of mAb development (clone selection, process development, or manufacturing process monitoring).

The use of this kit:

- Reduces analysis time by more than 80% (from 2 to 3 hours/sample to 15 minutes/sample)
- Achieves highly reproducible quantitative results
- Avoids high costs of batch failure in case of late analysis results
- Circumvents potential errors caused by manual handling through automation
- Minimizes the risk of mAb modification during ProtA purification

Kit contents and service

The InfinityLab 2D-LC ProtA-SEC Kit (G4245A) includes columns for both dimensions, tailored sample loops, and a NISTmAb standard for demonstrating and practicing this workflow.

For recommended system configurations and the standard, method files are ready to be loaded into 2D-LC Systems. For individual antibodies, optimization of method conditions is required. Data files show example results of NISTmAb. A workflow guide provides concepts, scope, and technical information. Sample and buffer preparation, system configuration, method setup, and data analysis are described in detail.

Agilent recommends an optional two-day 2D-LC ProtA-SEC Application Service (R3995C), for practicing this workflow with a certified engineer. The purchase of this service also includes the InfinityLab 2D-LC ProtA-SEC Kit (G4245A). Users who are experienced with handling of antibodies and the Agilent 2D-LC System can also implement the workflow on their own using the kit.

Typical results

With a system in good condition with the recommended configuration, the following typical results can be achieved/exceeded for the NISTmAb standard:

ProtA – Titer Analysis for Whole Antibody		SEC – Aggregation Analysis	
Parameter	**Typical Result**	**Parameter**	**Typical Result**
RT Repeatability	<0.5%	RT Repeatability	Monomer %RSD <1%
			HMW %RSD <1%
Area Repeatability	<2%	Area Repeatability	Monomer %RSD <3%
			HMW %RSD <3%

Typical results are not intended to be taken as specifications. Results depend on individual antibodies, system configuration, condition, performance, consumable quality, lab conditions, and operator routine.

Recommended system configurations

The following Agilent 1290 Infinity II 2D-LC System configurations are recommended:

- **^{1}D Pump:** 1260/1290 Infinity II Flexible Pump, 1290 Infinity II High-Speed Pump
- **^{2}D Pump:** 1290 Infinity II High-Speed Pump
- **Detectors**: 1260/1290 Infinity II VWD or DAD WR
- **Valve:** 2D-LC Standard and Active Solvent Modulation (ASM) valves
- **Software:** 2D-LC Software for Agilent ChemStation A.01.04 or later

Other valid 2D-LC System configurations may also work well, but may yield less-desirable results or may require method modifications. Alternate configurations can only be supported to a limited extent, especially if a service delivery is included.

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