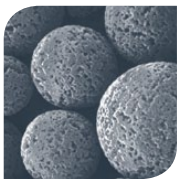

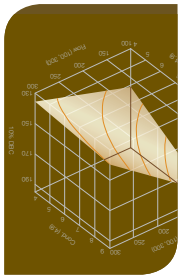

CHROMATOGRAPHY

Nuvia™ S Cation Exchange Media

- Ultra-high binding capacity for biomolecules at high flow rates
- Chemical stability to withstand repetitive clean-in-place cycles
- High binding performance over a wide operating window
- Flexibility in use for capture or polish steps
- Full support for regulatory submission

Ultra-High Binding Capacity for Downstream Processes

Introduction

Nuvia S is an ultra-high capacity, innovative cation exchange media built on the industry-proven UNOsphere™ base matrix technology. Nuvia S is a next-generation media that provides a unique combination of properties designed to meet current and future process needs. Nuvia S delivers superior binding capacity over a broad range of pH, conductivity, and flow rates, providing a flexible process design for both capture and polishing of therapeutic proteins. This exceptional combination of performance characteristics makes Nuvia S the tool of choice for a wide range of downstream processes.

Nuvia S delivers value and flexibility by allowing users to achieve high binding capacity at fast flow rates, and by using less media and smaller columns to purify a given amount of product. Nuvia S can significantly improve productivity while contributing to reduced capital costs, buffer consumption, space requirements, and cycle time for downstream processes.

Ultra-High Binding Capacity

Nuvia S is designed with proprietary surface extender technology and tuned for optimized charge, flow, and binding kinetics. The unique media design gives Nuvia S best-in-class dynamic binding characteristics (see Figures 1 and 2).

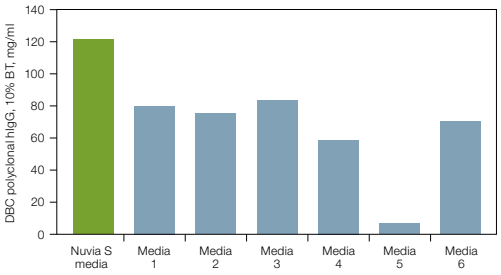

Fig 1. Binding of polyclonal human IgG (hIgG) by Nuvia S media. Comparison of Nuvia S and other commercially available CEX media. Column size, 0.7 x 5.5 cm. The sample was loaded onto the column in 40 mM NaOAc, pH 5.0 + 30 mM NaCl, washed, and then eluted with 40 mM NaOAc, pH 5.0 + 1 M NaCl. BT, breakthrough; DBC, dynamic binding capacity.

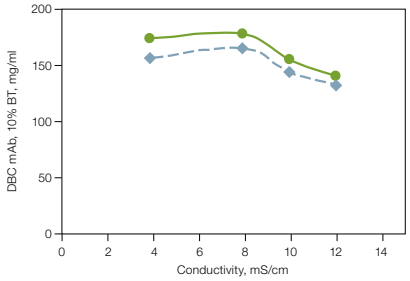

Fig. 2. Binding of a monoclonal antibody (mAb) by Nuvia S media. Column size, 1.1 x 10 cm. The sample mAb (4.5–5.0 mg/ml) was loaded onto the column in 20 mM NaOAc, pH 5.0 + NaCl (adjusted for conductivity) until 5% (◆) and 10% (●) breakthrough capacity were observed. BT, breakthrough; DBC, dynamic binding capacity.

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Superior Flow Properties for Bioprocess

Nuvia S is designed to meet the pressure-flow requirements of today's as well as tomorrow's demanding purification processes. With optimized bead size distribution and mechanical properties, Nuvia S consistently delivers very high binding capacity at fast linear velocities, while maintaining low column pressure (Figure 3). The wide operating window allows users to operate at increasingly higher flow rates without compromising binding capacity.

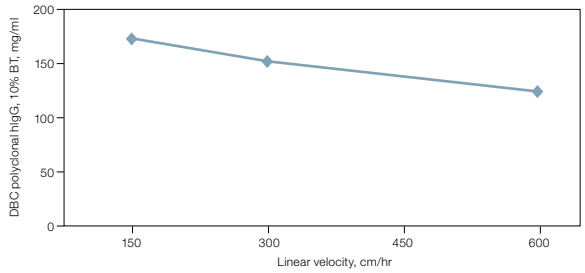

Fig. 3. Dynamic binding capacity vs. flow velocity. A 1.1 cm diameter column was packed to a 20 cm bed height with Nuvia S media. 4.5 mg/ml polyclonal human IgG in 40 mM NaOAc and 30 mM NaCl, pH 5.0, was loaded until 10% breakthrough was observed. BT, breakthrough; DBC, dynamic binding capacity.

Base-Stable, Consistent Performance

The chemical stability of Nuvia S allows the media to withstand repeated exposure to commonly used sanitization and clean-in-place protocols. Nuvia S exposed to 840 hr of 1.0 M NaOH showed no decreases of dynamic binding capacity or recovery (Figure 4). Nuvia S delivers value and process stability by maintaining peak performance over an extended life.

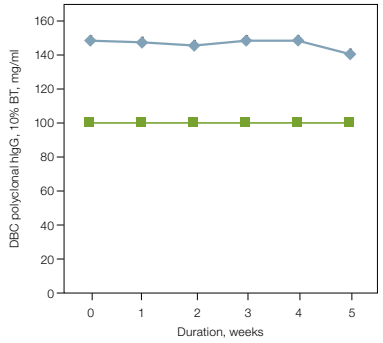

Fig. 4. Stability of Nuvia S media. Results from an accelerated storage study (in 1.0 M NaOH) show no loss in dynamic binding capacity and recovery. ◆, hIgG binding capacity, 10% breakthrough; ■, recovery (%). BT, breakthrough; DBC, dynamic binding capacity.

Reproducible Performance

Nuvia S is designed with demanding downstream processes in mind. Produced in a validated manufacturing process, the strict specifications of Nuvia S ensure batch-to-batch consistent performance. A dedicated application team with extensive experience in process development is available to answer questions and assist in process separation design.

Properties of Nuvia S Media

Type of ion exchanger	Strong cation
Functional group	$-SO_3^-$
Total ionic capacity	90–150 µeq/ml
Dynamic binding capacity*	
300 cm/hr	≥110 mg/ml
Shipping counterion	Na^+
Median particle size	85 ± 15 µm
Recommended linear flow rate range**	50–600 cm/hr
Chemical stability	
1.0 N NaOH (20°C)	Up to 1 week
0.1 N NaOH (20°C)***	Up to 5 years
Gel bed compression ratio	1.15–1.18 (settled bed volume/packed bed volume)
pH stability***	
Short-term	2–14
Long-term	4–13
Shipping solution	20% ethanol + 0.1 M NaCl
Regeneration	1–2 M NaCl
Sanitation	0.5–1.0 N NaOH
Storage conditions	20% ethanol or 0.1 N NaOH

* 10% breakthrough capacity determined with 4.5 mg/ml human IgG in 40 mM NaOAc + 30 mM NaCl, pH 5.0.
** Recommended elution flow rates are <150 cm/hr to minimize viscosity-induced backpressure.
*** Data derived under accelerated conditions at 60°C.

Technical Assistance

Regulatory support files are available upon request. Bio-Rad Laboratories is an ISO 9001 registered corporation. For additional information and technical assistance, contact your local Bio-Rad office.

For more information about Bio-Rad's complete line of process chromatography media, please visit us at **www.bio-rad.com/nuvia**.

Ordering Information

Catalog#	Description
156-0311	**Nuvia S Media**, 25 ml
156-0313	**Nuvia S Media**, 100 ml
156-0315	**Nuvia S Media**, 500 ml
156-0317	**Nuvia S Media**, 10 L
732-4701	**Foresight™ Nuvia™ S Plates**, 20 µl*
732-4801	**Foresight Nuvia S RoboColumn Unit**, 200 µl**
732-4802	**Foresight Nuvia S RoboColumn Unit**, 600 µl**
732-4720	**Foresight Nuvia S Column**, 1 ml
732-4740	**Foresight Nuvia S Column**, 5 ml

* Package size: 2 x 96-well plates.
** Package size: one row of eight columns.

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Life Science Group

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France *01 47 95 69 65* ***Germany*** *089 31 884 0* ***Greece*** *30 210 9532 220* ***Hong Kong*** *852 2789 3300* ***Hungary*** *36 1 459 6100* ***India*** *91 124 4029300*
Israel *03 963 6050* ***Italy*** *39 02 216091* ***Japan*** *03 6361 7000* ***Korea*** *82 2 3473 4460* ***Mexico*** *52 555 488 7670* ***The Netherlands*** *0318 540666*
New Zealand *64 9 415 2280* ***Norway*** *23 38 41 30* ***Poland*** *48 22 331 99 99* ***Portugal*** *351 21 472 7700* ***Russia*** *7 495 721 14 04*
Singapore *65 6415 3188* ***South Africa*** *27 861 246 723* ***Spain*** *34 91 590 5200* ***Sweden*** *08 555 12700* ***Switzerland*** *026 674 55 05*
Taiwan *886 2 2578 7189* ***Thailand*** *800 88 22 88* ***United Kingdom*** *020 8328 2000*