



GORE™ Protein Capture Devices

WITH PROTEIN A

For rapid purification of monoclonal antibodies

High binding capacity and short residence time

GORE™ Protein Capture Devices with immobilized Protein A are intended for affinity purification of monoclonal antibodies. GORE Protein Capture Devices use a unique expanded polytetrafluoroethylene (ePTFE) membrane composite that provides a binding capacity advantage at high flow rates and improves the speed of purification.

In addition, GORE Protein Capture Devices produce highly concentrated elution pools, which may eliminate a downstream concentration step during the antibody purification process. These unique membrane devices are offered in 1.0 mL (≥ 30 mg capacity) and 3.5 mL (≥ 105 mg capacity).

Common Applications

Affinity purification and screening of monoclonal antibodies in drug discovery markets and production of antibodies for research and development.

Improved Performance

The Gore Protein Capture device is pre-packed. The unique ePTFE membrane bed provides high capacity at short residence time without causing collapse, channeling, or alteration of the membrane bed.

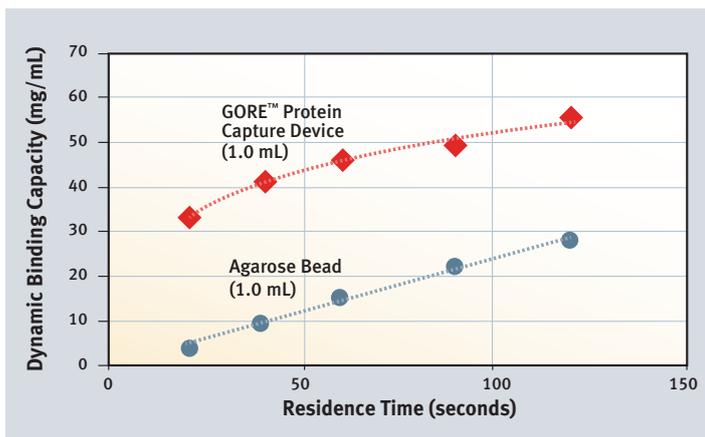
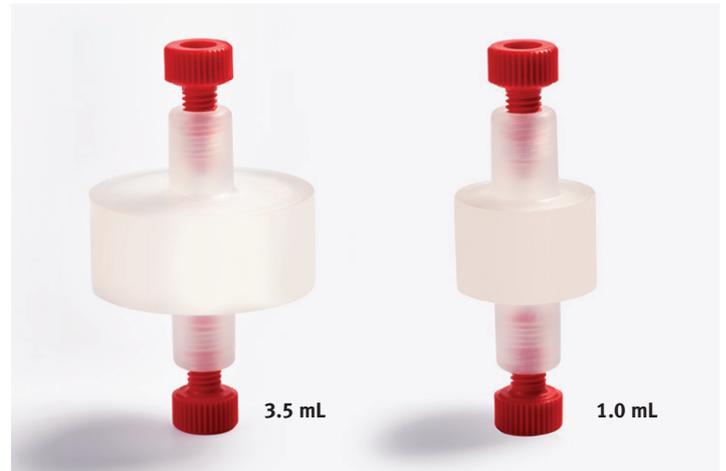


Figure 1. Typical dynamic binding capacity of GORE Protein Capture Devices versus a standard agarose bead based technology. The difference between Performance Data (back page) and this DBC curve (above) curve reflects different techniques to assess overall binding capacity.



Key Features and Benefits

Key features

- High dynamic binding capacity (≥ 30 mg/mL)
- Short residence time (20 seconds)
- Stable membrane bed
- Durable to repeated cleaning cycles
- Pre-packed column

Key benefits

- Improved throughput and productivity
- Increased concentration of antibody in the elution pool
- Potential to eliminate downstream concentration step
- Reduced set-up time

Regulatory Compliance

GORE Protein Capture Devices are manufactured following the appropriate material and regulatory requirements. Please contact W. L. Gore & Associates for current compliance statements.

Quality Statement:

GORE Protein Capture Devices are manufactured in a manner that adheres to relevant Good Manufacturing Practices as defined in the Gore PharmBIO Products' quality system which is certified to ISO 13485.



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Performance Data

| Characteristic | Antibody Purification Device* | | |
|----------------------------|--------------------------------------|-------------------|----------------------------|
| | GORE Protein Capture Device (1.0 mL) | | Agarose bead 1.0 mL device |
| | (Initial) | (Post 20th cycle) | |
| | 20 seconds residence time | | 60 seconds residence time |
| Average DBC (mg/mL)** | 39.4 ± 2.2 | 36.5 ± 1.7 | 21.3 |
| Protein A leaching (ppm) | 5.96 ± 1.74 | 3.77 ± 1.05 | 2.2 ± 0.9 |
| Yield (%) | 101.4 ± 4.2 | 101 ± 3.4 | 96.9 ± 3.6 |
| HCP (ppm)**** | 1010 ± 371 | 1155 ± 281 | 765 ± 306 |
| Ligand stability | 0.1 N NaOH (maximum) | | 0.1 N to 0.5 N NaOH*** |
| Maximum operating pressure | 5 bar | | 5 bar |

* GORE devices represent mean of 12 devices per size

** Determined using polyclonal human IgG at 10% breakthrough.

*** Agarose bead technology has stability to 0.5N NaOH; the user should refer to instructions for use for specific information

**** From CHO cell harvest.

DBC – dynamic binding capacity; HCP – host cell protein; NaOH – sodium hydroxide; ppm – parts per million

Data for the 3.5 mL device is available in the GORE Protein Capture Device Validation Guide.

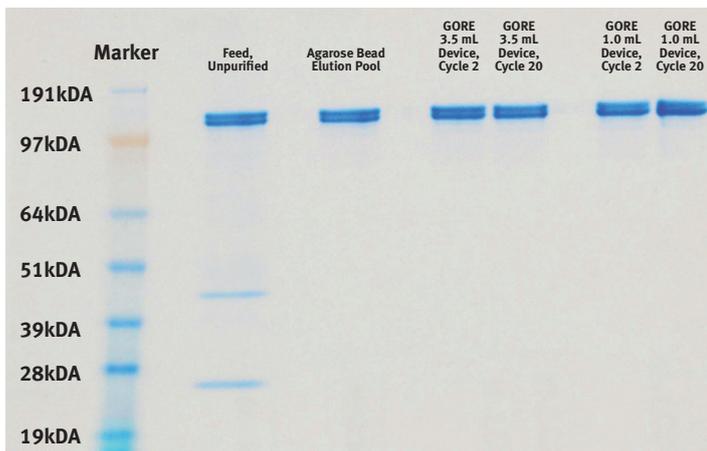


Figure 3. SDS-PAGE of eluent recovered from the GORE Protein Capture Device versus a standard agarose bead-based technology. GORE device residence time 20 seconds; competitor device 60 seconds. The purity of the eluents recovered from both purification devices was similar. Therefore, a short residence time did not negatively affect the purity of the antibody eluted from the GORE Protein Capture Device.

Part number/Ordering Information

| Part Number | Description | Quantity |
|-------------|---------------|----------|
| PROA101 | 1.0 mL Device | 1/box |
| PROA102 | 3.5 mL Device | 1/box |

Technology

Unlike traditional support matrices, the membrane bed in the GORE Protein Capture Device provides a near linear pressure drop at a wide range of flow rates (Figure 2).

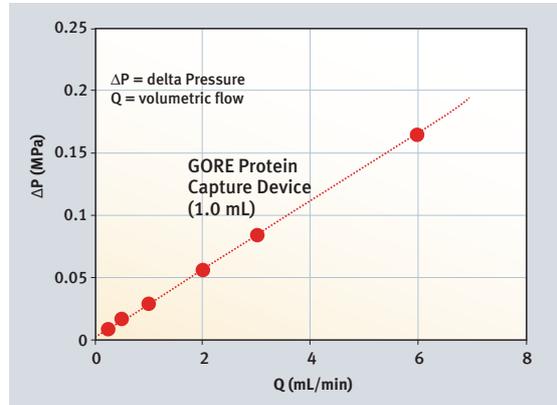


Figure 2. Column pressure drop (ΔP) of GORE Protein Capture Device (1.0 mL) at various flow rates.

Operating conditions

The typical flow rate at a residence time of 20 seconds is 3 mL/min for the 1.0 mL device and 10.5 mL/min for the 3.5 mL device.

Packaging/Storage information

Store device in the refrigerator at 2–8°C (35–46°F), in 20% ethanol solution in deionized water. Device has one year shelf life as determined by accelerated aging tests. Refer to the *Operating Instructions* for detailed operating and handling guidelines.

Device Characteristics

| Description | Material/Characteristic |
|---|---|
| Column, flow distributors, frits, and plugs | Polypropylene |
| Membrane bed | Proprietary polytetrafluoroethylene composite |
| Protein A | Recombinant Protein A |
| Connectors | 10/32" threaded fittings |

Intended Use

GORE Protein Capture Devices are intended for research use only and should not be used for clinical or diagnostic procedures.

See *GORE Protein Capture Device Validation Guide* for detailed test information.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE Protein Capture Devices, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

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