

## Sometimes Different IS Better

The premier value-added Protein A affinity media for process development, clinical, and commercial scale manufacture of therapeutic antibodies.

CaptivA PriMAB is the first Protein A affinity chromatography media designed to significantly reduce cost of investment by offering excellent performance, high capacity, high flow rate, and low leaching for a fraction of the cost of traditional resins. CaptivA PriMAB combines an industry standard cross-linked agarose bead with recombinant native *Staphylococcal* Protein A (rSPA), manufactured by Repligen, the world's leading manufacturer of recombinant Protein A for over 20 years.



### Key Benefits Include:

- Exceptional value proposition at any scale
- High dynamic binding capacity
- Industry desired CIP/Sanitization options
- Low Protein A leaching
- Recognized manufacturing quality standards

As a direct result of improvements in titer, improved therapeutic potency and more targeted therapies many of today's monoclonals will be manufactured less frequently in smaller, multi-product facilities. In this scenario traditional Protein A resins designed for reusability at commercial scale are becoming less economically viable. CaptivA PriMAB reduces the direct cost of a Protein A capture step while retaining the desired performance characteristics of platformability, purity and ease of development as well as meeting the safety and quality standards accepted by regulatory bodies.

Whether for process development, clinical, commercial manufacturing, or single use applications **CaptivA PriMAB offers the simplicity of a Protein A capture step combined with compelling economics.**

## Product Overview

CaptivA PriMAB is a recombinant Protein A affinity chromatography media designed for end users who's processes need reliable resin performance but do not require cleaning with concentrated caustic and/or require significantly extended life cycles. CaptivA PriMAB combines a 4% highly cross-linked agarose base bead and Repligen's recombinant native *Staphylococcus* Protein A (rSPA). rSPA is a recombinant equivalent to the native Protein A and contains all five immunoglobulin binding domains (E,D,A,B,C). Additional product performance specifications are provided in Table 1.

table

1

## Product Performance Specifications

### Base Matrix

4% highly cross-linked agarose

### Particle Size

45-165 µm

### Ligand

Recombinant native *Staphylococcus* Protein A (rSPA) expressed in *E.coli*

### Ligand Attachment

Multipoint via reductive amination

### Total Binding Capacity (Static)

≥ 40 mg hlgG/ mL medium

### Recommended Flow Velocity

20-300 cm/hr

### Recommended pH

Working 3-10

Cleaning-in-Place 2-11

Temperature Stability 4-40°C

## Exceptional Value Proposition

Captiva PriMAB is the 1st cost competitive Protein A affinity resin that offers end-users performance features that are suitable for development through commercial scale processes. Significant reductions in Protein A resin investment are realized upfront for end users even without fully optimized processes. Captiva PriMAB is the first truly economical option for a disposable or limited campaign based Protein A capture step.

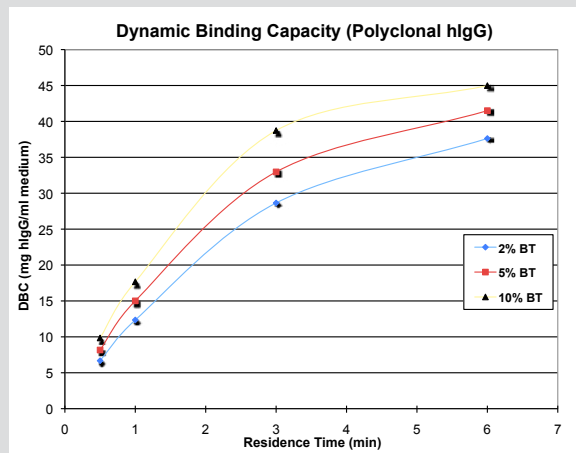
## Recognized Quality Standards and Secure Supply Chain

Captiva PriMAB is manufactured under a fully documented and auditable ISO9001 quality system. All manufacturing processes are fully validated. Details of product performance, quality and manufacturing systems are outlined in a product specific Regulatory Support File (RSF). The recombinant Protein A ligand rSPA is certified animal free and is manufactured using a high expression *E.coli* fermentation and high efficiency purification process. Captiva PriMAB manufacturing has been validated at large scale, which in combination with Repligen's formalized business continuity practices ensure a secure supply chain that will meet increased demand as therapeutic products move from clinical to commercial scale manufacturing.

## High Dynamic Binding

Captiva PriMAB offers Process developers and manufacturers of therapeutic and diagnostic antibodies high dynamic binding capacity at standard process flow rates and residence times (Figure 1.)

figure  
1



Dynamic binding capacity was determined for human polyclonal IgG at four different flow velocities providing residence times ranging from 0.5 to 6 minutes. A 5 x 50mm column was loaded with a 2 mg/ml hlgG solution in PBS pH 7.4. Capacity was determined and reported at 2, 5, and 10% breakthrough. A column bed height between 10-20 cm, loaded at 100 cm/hr provides 6-12 minutes of residence time.

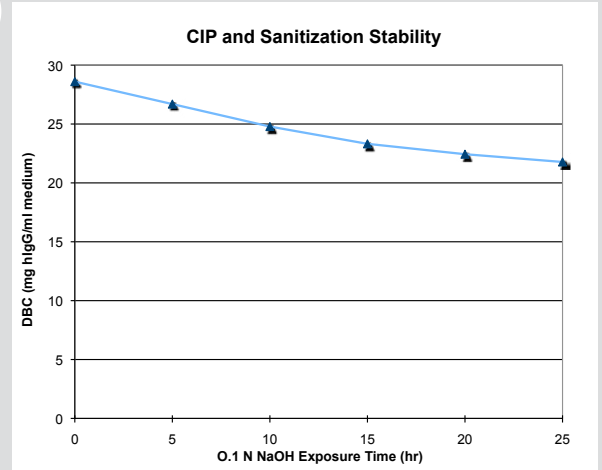
## Industry desired CIP/Sanitization options

Captiva PriMAB retains desired Dynamic Binding Capacities (DBC) (Figure 2) when exposed to stringent washing conditions that reduce standard feed stream contaminants. Captiva PriMAB's recombinant Protein A is attached to an agarose base bead via reductive amination chemistry. This creates multi-point attachment bonds between ligand and support that withstands alkaline conditions more favorably than single point attachment.

## Low Protein A leaching

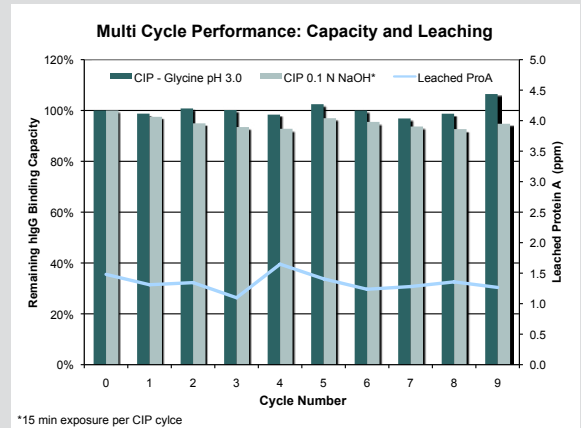
Captiva PriMAB's multi-point Protein chemistry results in low protein A leakage that is consistent from cycle to cycle (Figure 3). This results in a low and predictable protein A contamination in the monoclonal pool following the product elution step. Captiva PriMAB's low protein A leakage reduces contaminant load on the downstream polishing steps thus contributing to easier downstream polishing and better product quality.

figure  
2



The dynamic binding capacity was determined for human polyclonal IgG following 0.1 N NaOH exposure. A 5 x 50mm column was loaded with a 2 mg/ml hlgG solution in PBS pH 7.4. The loading residence time was 3 minutes. Capacity was determined and reported at 2% breakthrough. Each column elution was followed by a 5 hour exposure to 0.1 N NaOH. An exposure time of 25 hours represents 100 x 15 minute CIP cycles.

figure  
3



The human polyclonal IgG binding capacity was determined following each column cycle. CIP was performed between cycles with either extra volumes of Glycine pH 3.0 elution buffer or 0.1 N NaOH with a 15 min contact time. Contaminating Protein A was measured in the product pool from each cycle (0.1N NaOH CIP) using the Repligen Leached Protein A ELISA.



### Captiva™ PriMAB Bottled Slurry

Formulated as a 52% ± 1% slurry in 18.5% ± 1% ethanol and bottled volumes from 5mLs to 1 Liter

Catalog Number	Description
CA-PRI-0005	Captiva PriMAB - 5mL
CA-PRI-0025	Captiva PriMAB - 25mL
CA-PRI-0100	Captiva PriMAB - 100mL
CA-PRI-1000	Captiva PriMAB - 1000mL

NOTE: Bulk sizes >5L are available. Please contact Repligen for pricing and availability.

## Coming Soon

### Captiva™ PriMAB Development Mini Columns

Small pre-packed process development columns packed formulated in 18.5% ± 1% ethanol.

Catalog Number	Description	Quantity	Availability
BA-CPRI-001	<ul style="list-style-type: none"> <li>Captiva PriMAB Mini Column 5mm diameter</li> <li>5cm Bed Height</li> <li>1mL Resin Volume</li> </ul>	1 column	Call for price and availability
BA-CPRI-005	<ul style="list-style-type: none"> <li>Captiva PriMAB Mini Column 11.3mm diameter</li> <li>5cm Bed Height</li> <li>5mL Resin Volume</li> </ul>	1 column	Call for price and availability

Ordering and  
Product Range

Call today:  
781 250-0111

Contact details:

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Captiva™ PriMAB Opus™ Pre-Packed Columns

Larger columns from the Repligen Opus™ run ready product line

Catalog Number	Description	Availability
BS-012-CPRI-010	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 12mm diameter</li> <li>• 10cm Bed Height</li> <li>• ~11mL Resin Volume</li> </ul>	Available
BS-012-CPRI-020	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 12mm diameter</li> <li>• 20cm Bed Height</li> <li>• ~23mL Resin Volume</li> </ul>	Available
BS-025-CPRI-010	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 25mm diameter</li> <li>• 10cm Bed Height</li> <li>• ~49mL Resin Volume</li> </ul>	Available
BS-025-CPRI-020	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 25mm diameter</li> <li>• 20cm Bed Height</li> <li>• ~98mL Resin Volume</li> </ul>	Available
BS-050-CPRI-010	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 50mm diameter</li> <li>• 10cm Bed Height</li> <li>• ~196mL Resin Volume</li> </ul>	In Development Call for Availability
BS-050-CPRI-020	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 50mm diameter</li> <li>• 20cm Bed Height</li> <li>• ~393mL Resin Volume</li> </ul>	In Development Call for Availability
BS-080-CPRI-010	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 80mm diameter</li> <li>• 10cm Bed Height</li> <li>• ~503mL Resin Volume</li> </ul>	Available
BS-080-CPRI-020	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 80mm diameter</li> <li>• 20cm Bed Height</li> <li>• ~1005mL Resin Volume</li> </ul>	Available
BS-200-CPRI-010	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 200mm diameter</li> <li>• 10cm Bed Height</li> <li>• ~3142mL Resin Volume</li> </ul>	In Development Call for Availability
BS-200-CPRI-020	<ul style="list-style-type: none"> <li>• Captiva PriMAB Opus Column</li> <li>• 200mm diameter</li> <li>• 20cm Bed Height</li> <li>• ~6284mL Resin Volume</li> </ul>	In Development Call for Availability

Note: Customized bed height packing (3 - 20mm) is available for Captiva PriMAB and other resins. Call Repligen for details