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Reduce manufacturing cost of antibody-based therapeutics with an alternative-source Protein A resin

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Designed for cost-effective antibody purification

For decades Protein A chromatography has been the method of choice for the purification of monoclonal antibodies. Modifications to the first generation of Protein A ligands has given way to more robust and efficient purification resins allowing the design of antibody purification processes with greater flexibility. The introduction of Thermo Scientific[™] MabCaptureC affinity matrix offers an additional tool for process development and manufacturing of monoclonal antibodies. Featuring high capacity and a highly crosslinked agarose backbone, this Protein A resin is specifically designed to help improve the productivity and efficiency of antibody purification processes.

MabCaptureC affinity matrix – features and benefits

Our MabCaptureC resin is based on a new engineered and in-house produced protein A ligand, recombinantly expressed in yeast. It features:

- High binding capacity: ~60 g/L IgG at 5 min residence time
- Alkali stable ligand: >100 cycles at 0.2M NaOH
- Highly cross-linked agarose backbone (Praesto[™] jetted technology)
- O Uniform bead size (70 μm +/- 10 μm) offering improved performance characteristics
- Excellent scalability and free of animal components - allowing use in commercial manufacturing

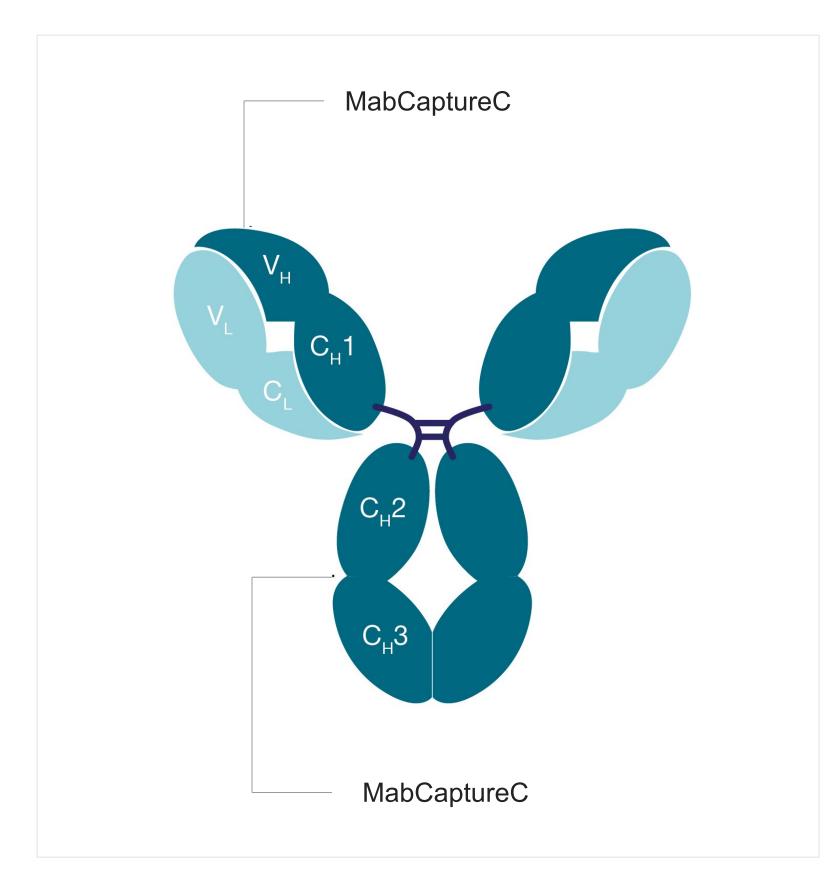


Figure 1: The MabcaptureC resin binds at the C_H2-**C**_H3 interface and **V**_H3 region of IgG

MabCaptureC resin binding capacity and elution properties

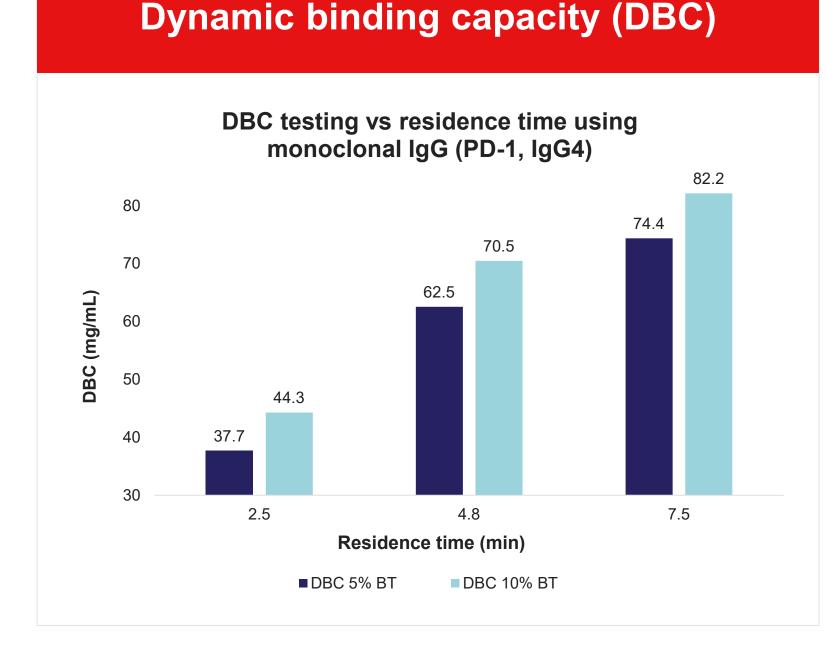


Figure 2: MabCaptureC resin dynamic binding capacity measured at 5 & 10% breakthrough at 2.5-, 4.8- and 7.5-min residence time using monoclonal IgG (load density 70mg/mL)

Elution performance at pH 3.0-3.5 **Elution performance of MabCaptureC at pH 3.0-3.5** 700 0.1 M Citric acid pH 3.0 0.05 M Na Acetate pH 3.3 0.05 M Na Acetate pH 3.5 **CVs**

Figure 3: MabCaptureC was tested in a 2cm 0.4mL column and displayed efficient elution at pH 3.0 – 3.5

- The MabCaptureC resin demonstrates high dynamic binding capacity
- The resin shows efficient elution (>98%) at pH 3.0-3.5

Dynamic binding capacity comparison at increased residence times

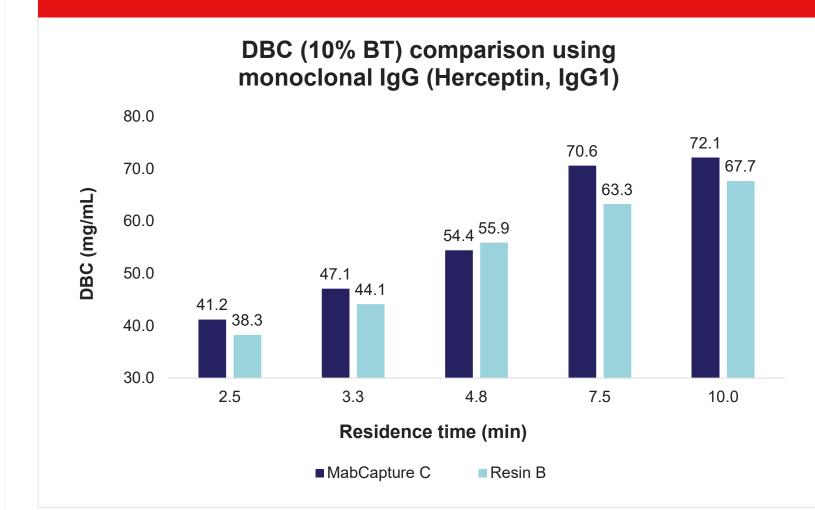


Figure 4: Comparison study of dynamic binding capacity measured at 10% breakthrough with increasing residence times using MabCaptureC and a comparative resin.

- The MabCaptureC resin shows excellent binding capacity compared to comparative resins
- High dynamic binding capacity is shown at increased residence times, allowing processing of high-titer feedstocks

MabCaptureC resin cleaning, reusability and impurity removal

Advised cleaning strategy

- Acid strip after every run: Up to 0.5 M Citric acid or Acetic acid
- Additional cleaning/sanitization steps Process optimization mainly depending on type of feed
 - Cleaning after every run with 0.2 M NaOH
 - If needed, cleaning with 0.4 M NaOH after every 5th or 10th run

Reusability: Life cycle study with CIP 0.2M NaOH for 200 caustic cycles

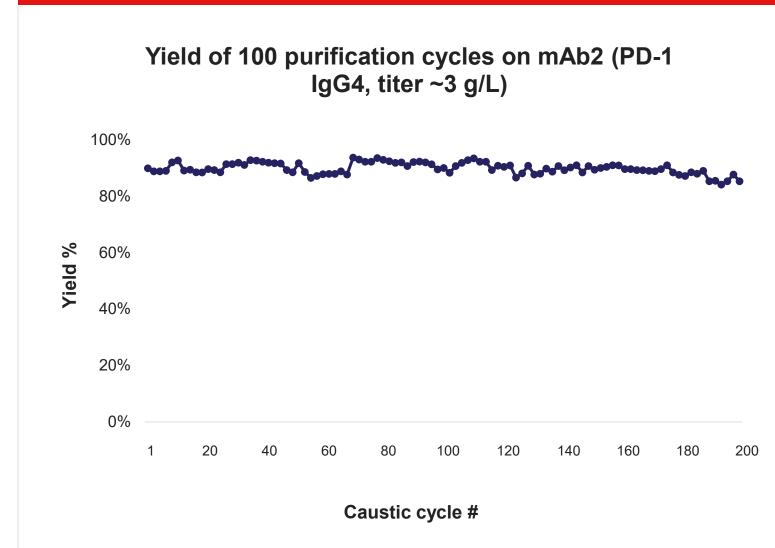


Figure 5: Stable yield (~90%) during 100 purification cycles using 2x 15min 0.2M NaOH per run (equivalent to 200 caustic cycles)

Reusability: Life cycle study with CIP 0.2M NaOH for 200 caustic cycles (cont.)

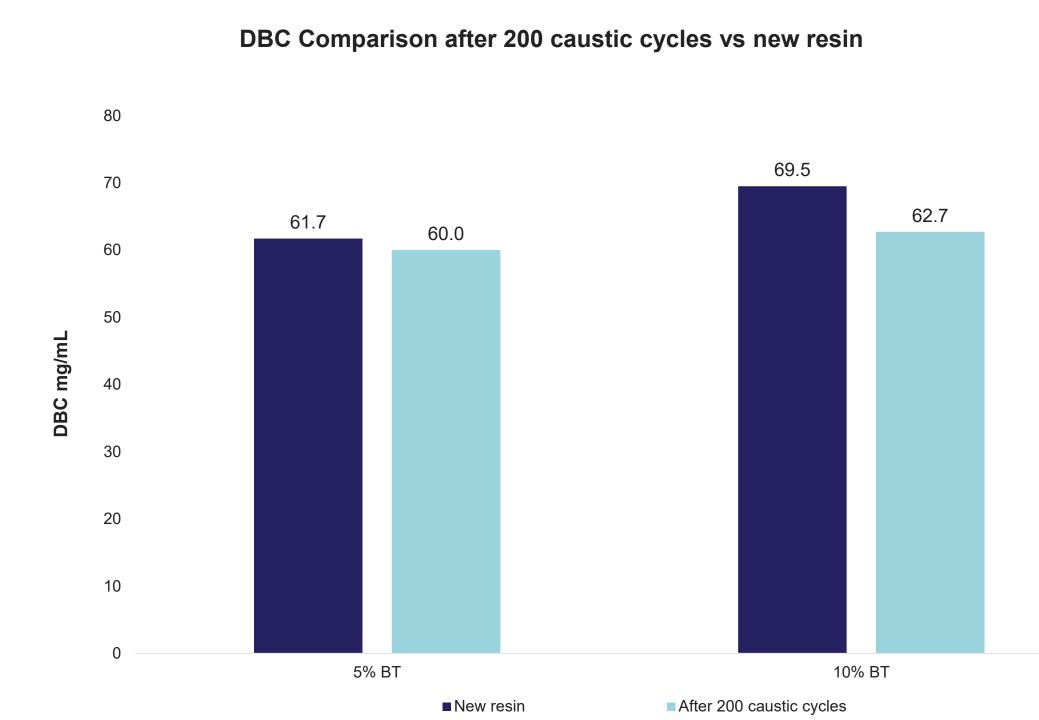
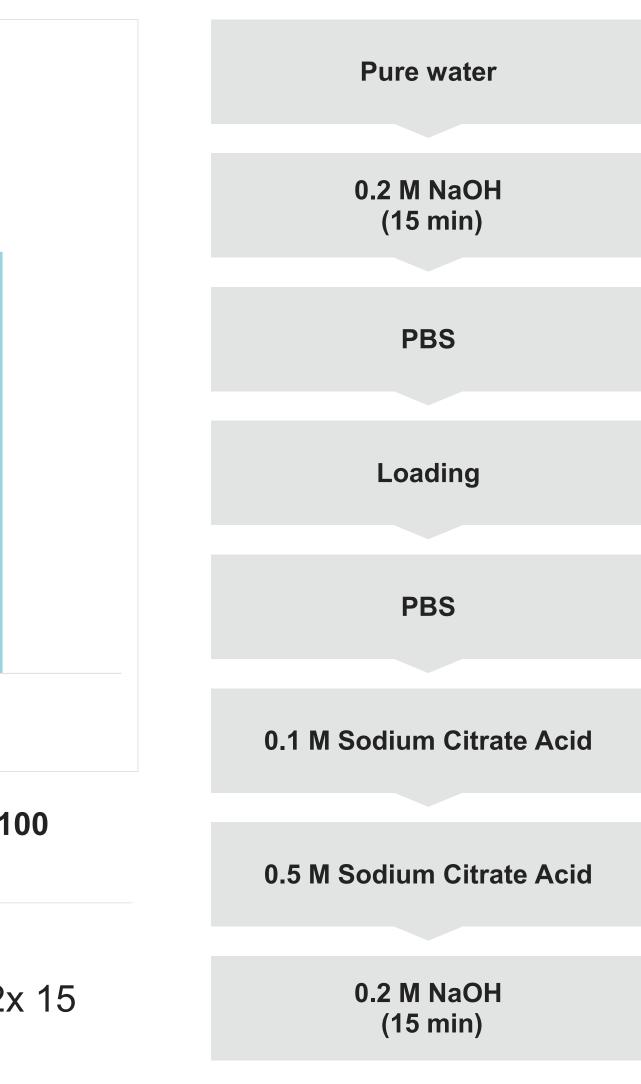


Figure 6. Excellent reusability: less than 10% capacity loss after 100 purification cycles (200 caustic cycles)

Excellent alkaline stability –

High capacity is observed after cleaning with 0.2M NaOH (2x 15 min/cycle) for 200 caustic cycles



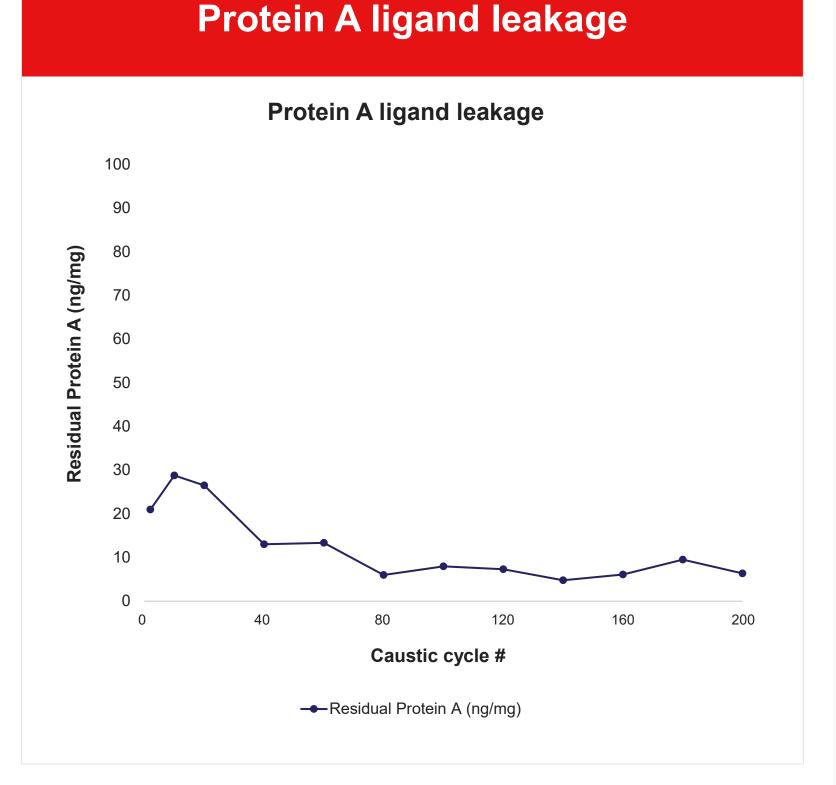


Figure 7: Ligand leakage (ppm) was measured over a 100 cycles using the Cygnus rec. Protein A ELISA kit demonstrating leakage on average of 12ppm over 100 cycles

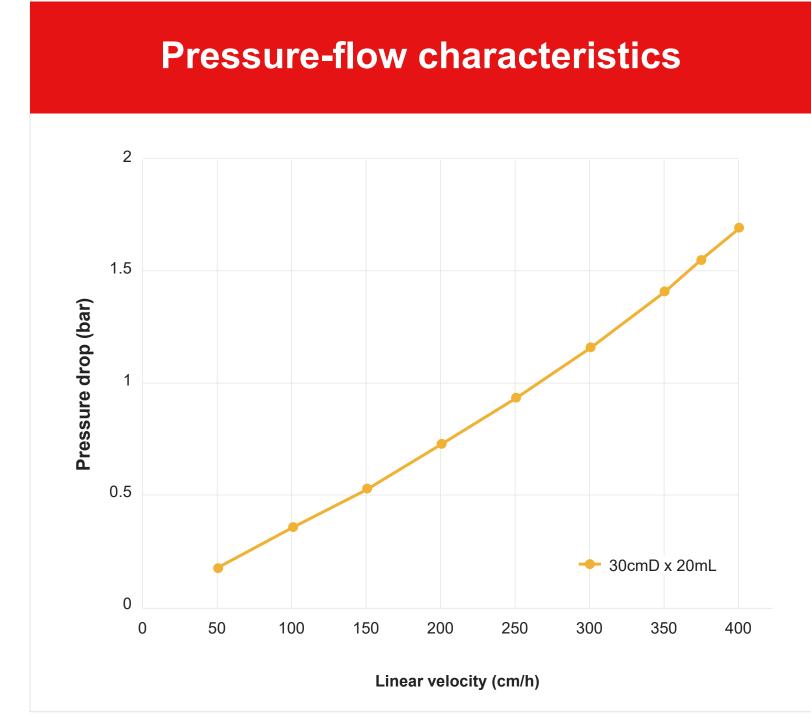


Figure 9: The MabCaptureC resin demonstrates high permeability - <2 bar at 400 cm/h in a 30 cm diameter column x 20 cm bed height

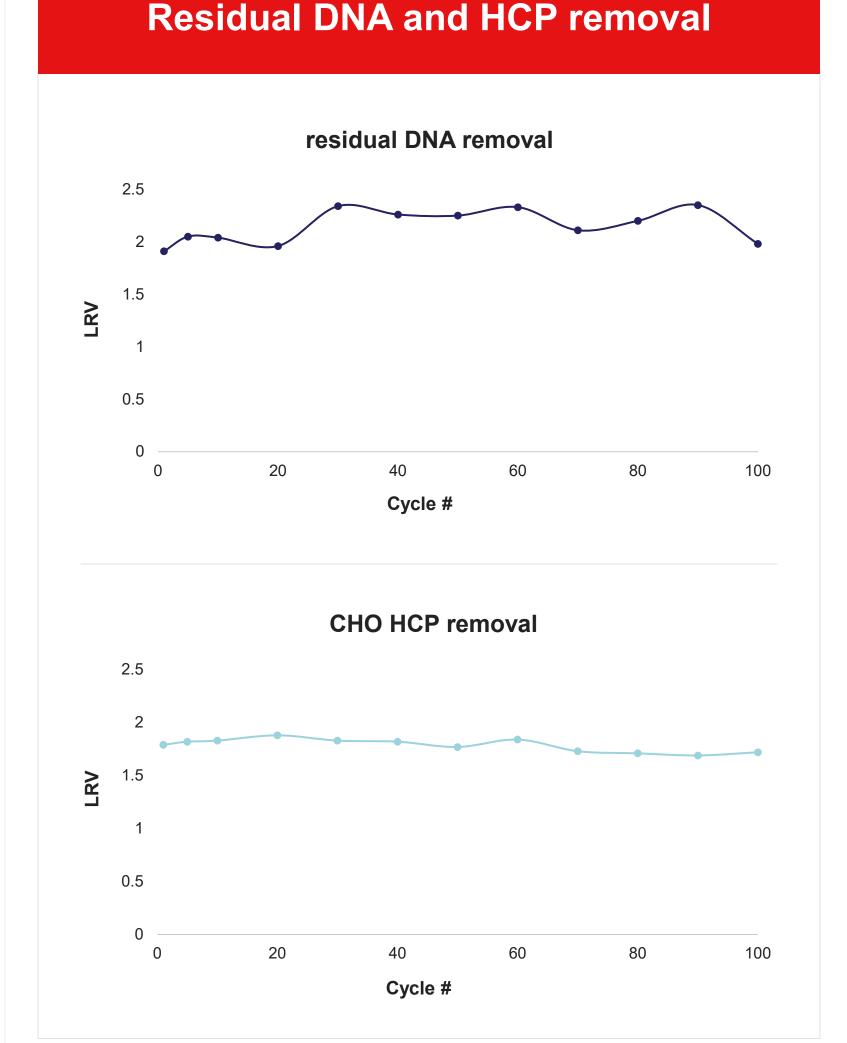


Figure 8: Consistent residual DNA and CHO HCP removal over a 100 purification cycles

Available products Product 1963662250* MabCaptureC Affinity Matrix 250ml MabCaptureC Affinity Matrix 1L 196366201L*

MabCaptureC Affinity Matrix 5L

MabCaptureC MiniChrom 1 ml

MabCaptureC MiniChrom 5 ml

MabCaptureC RoboColumn 200 ul

* Products come with regulatory support (RSF)

Conclusion

Cat nr.

196366205L*

5943662001

5943662005

5943662200

Featuring high capacity, excellent alkaline stability and increased productivity, the MabCaptureC affinity matrix can be an excellent protein A resin in the monoclonal antibody purification workflow.

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