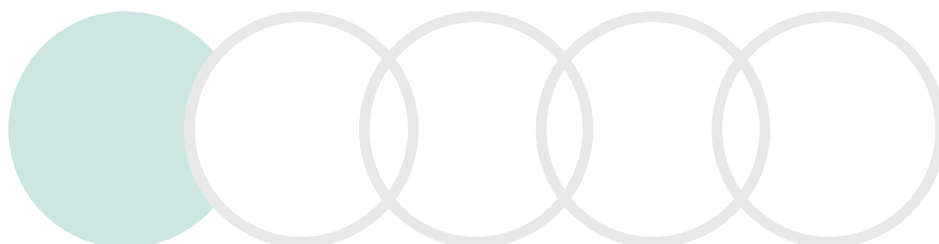
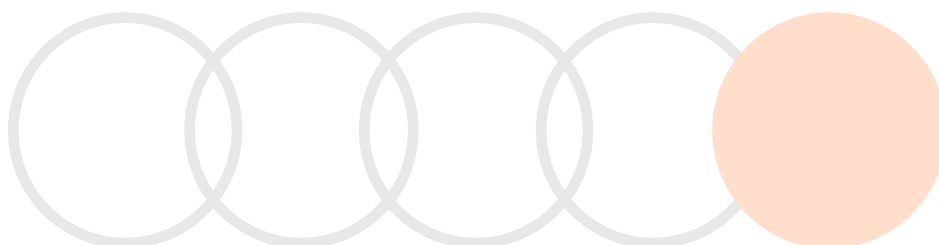
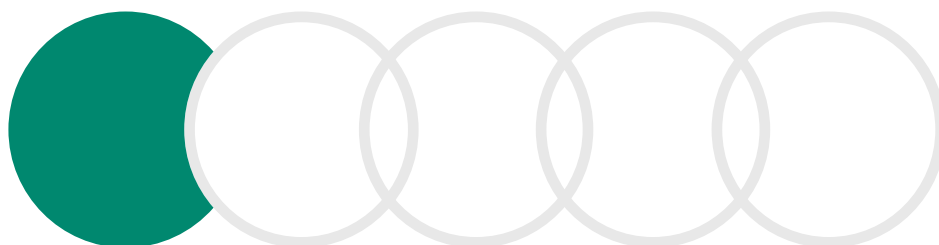


Process development

Guide to transition from MabSelect SuRe™ based resins to next-generation MabSelect™ Prisma resin



Introduction

MabSelect™ Prisma is a BioProcess™ affinity chromatography resin for capture of monoclonal antibodies (mAbs) and Fc-containing recombinant proteins. Like its predecessor resins MabSelect SuRe™ LX and MabSelect SuRe™, MabSelect™ Prisma is designed with a rigid, high-flow agarose base matrix and an alkaline-stabilized ligand derived from protein A. For MabSelect™ Prisma however, both the base matrix and the ligand have been further optimized for the resin to provide increased capacity and alkaline stability, allowing for improved productivity, facility fit, and bioburden control.

This guideline aims to support biopharmaceutical manufacturers in the transition from MabSelect SuRe™ LX or MabSelect SuRe™ resins to include MabSelect™ Prisma in the capture steps of new mAb development projects. Similarities and differences of MabSelect™ Prisma compared with its predecessor resins will be described.

When transitioning from one resin to another, our recommendation is to conduct thorough performance studies to identify differences between the resins. The impact of chemical and physical properties of the target molecule on purification parameters should also be considered. For a successful transfer to MabSelect™ Prisma, key steps to consider are:

- Upgrade immunoassay for quantitation of leached MabSelect™ Prisma ligand.
- Adjust column packing methods when necessary to adapt to the updated pressure-flow properties of MabSelect™ Prisma base matrix.
- With the improved capacity of MabSelect™ Prisma, ensure potential increased mass throughput and concentration of purified target molecule are addressed in further polishing steps.
- With the increased alkaline-stability of MabSelect™ Prisma, consider implementing new and improved cleaning and sanitization protocols.

The main characteristics of MabSelect™ Prisma and its predecessor MabSelect SuRe™ LX and MabSelect SuRe™ resins are summarized in Table 1. MabSelect™ Prisma is produced from the same agarose raw material as its predecessors, manufactured in the same facilities using similar manufacturing methods, and based on the same quality standards. Statements concerning the ingredients used in the manufacture of BioProcess™ chromatography resins are available from cytiva.com/rsf. These statements include but are not limited to: raw material of animal free-origin, metal catalysts or metal reagents, allergens, and melamine-free raw materials.

Table 1. Resin characteristics

Characteristics	MabSelect™ Prisma	MabSelect SuRe™ LX	MabSelect SuRe™
Matrix	Highly cross-linked agarose, spherical	Highly cross-linked agarose, spherical	Highly cross-linked agarose, spherical
Ligand	Alkaline-stabilized protein A-derived (<i>E. coli</i>) hexamer	Alkaline-stabilized protein A-derived (<i>E. coli</i>) tetramer	Alkaline-stabilized protein A-derived (<i>E. coli</i>) tetramer
Ligand coupling	Single-point attachment	Single-point attachment	Single-point attachment
Coupling chemistry	Epoxy	Epoxy	Epoxy
Particle size d_{50} *	~ 60 μm	~ 85 μm	~ 85 μm
Dynamic binding capacity Q_{B10} †	~ 80 mg human IgG/mL resin at 6 min residence time ~ 65 mg human IgG/mL resin at 4 min residence time	~ 60 mg human IgG/mL resin at 6 min residence time ~ 50 mg human IgG/mL resin at 4 min residence time	~ 50 mg human IgG/mL resin at 6 min residence time ~ 45 mg human IgG/mL resin at 4 min residence time
Maximum operating flow velocity‡	300 cm/h (4 min residence time)	500 cm/h (2.4 residence time)	500 cm/h (2.4 min residence time)
pH stability	3–12	3–12	3–12
Operational§	2	2	2
CIP¶	14	13.7	13.7
Cleaning agent	0.5 to 1 M NaOH	0.1 to 0.5 M NaOH	0.1 to 0.5 M NaOH
Chemical stability	Stable to commonly used buffers in protein A chromatography		
Delivery conditions	20% ethanol. On request, 2% benzyl alcohol		

* Median particle size at 50% of the cumulative volume distribution.

† DBC at 10% breakthrough by frontal analysis of a mobile phase velocity of 100 cm/h and 150 cm/h in a lab column at 10 cm bed height for human IgG at PBS at pH 7.4.

‡ Determined in an AxiChrom™ 300 with an inner diameter of 30 cm and bed height of 20 cm using buffers with the same viscosity as water at 20°C.

§ pH range where resin can be operated without significant change in function.

¶ pH range where resin can be cleaned in place without significant change in function.

Addressing update of protein A-based ligand

The MabSelect™ Prisma ligand is a recombinant protein derived from the B-domain of protein A (Fig 1). Although based on the same domain as MabSelect SuRe™ resins, the selected domain has been further alkaline-stabilized by site-directed mutagenesis, in which sensitive amino acids have been exchanged for more stable ones. Compared with the MabSelect SuRe™ ligand, which is based on a tetramer, the monomer domain is multimerized into a hexamer for the MabSelect™ Prisma ligand. As for the MabSelect SuRe™ ligand, the MabSelect™ Prisma ligand is attached to the base matrix through a C-terminal cysteine. MabSelect™ Prisma exhibits comparable antibody binding properties as its predecessor resins.

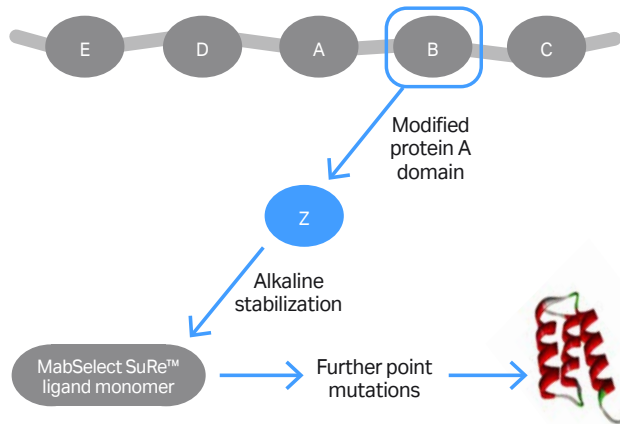


Fig 1. Development of the MabSelect™ Prisma ligand.

MabSelect™ Prisma ligand manufacture

The MabSelect™ Prisma ligand is produced in *E. coli*, and purified using conventional chromatography. The production is free of animal-derived components. For security of supply, dual sources of both the agarose base matrix and the ligand are used. The ligand is produced by two different suppliers where one of the suppliers is Cytiva. The other contract manufacturer uses Cytiva's developed process.

Elution conditions and specificity

Like the MabSelect SuRe™ ligand, the MabSelect™ Prisma ligand binds to the Fc domain of human IgG, with involved amino acids conserved. Although, enhanced binding to the antibody VH3 domain has been engineered into the MabSelect™ Prisma ligand, the specificity of the ligands is similar. The similarity in specificity also means similar elution pH and elution pool volumes (Fig 2).

Our inhouse data has also been confirmed in several customer evaluations (1). However, elution pH and elution pools should always be evaluated for the specific target molecule to be purified at relevant load. The significantly higher load for MabSelect™ Prisma compared with MabSelect SuRe™ resin can in some cases result in a higher elution pH for molecules as seen in Figure 3. In the same case study, lower host cell protein (HCP) concentration was observed in eluate with the higher elution pH (Fig 4).

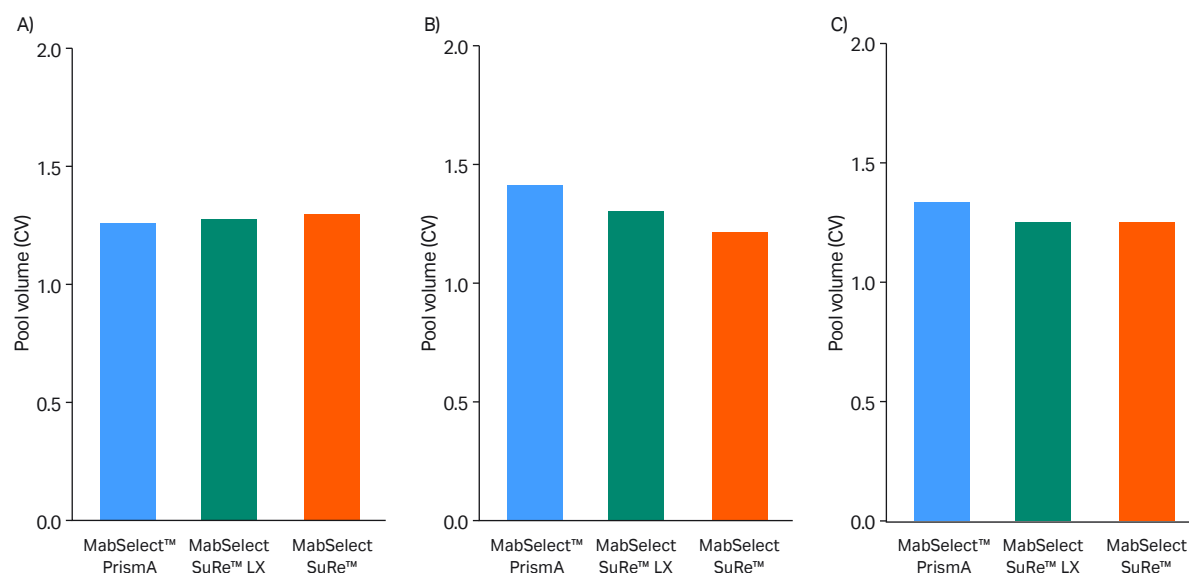


Fig 2. MabSelect™ Prisma elution pool volume in column volumes (CV) using 50 mM acetate, with pH 3.5 for elution of (A) mAb1 and (B) mAb2, and with pH 3.6 for elution of (C) mAb3 (2).

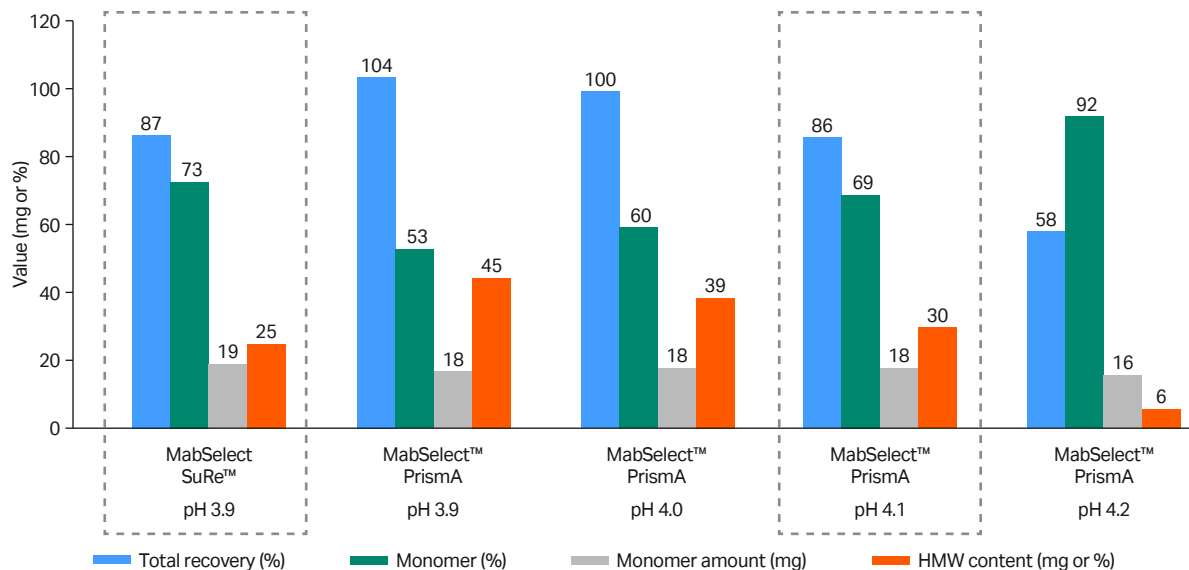


Fig 3. Optimal elution pH determined for MabSelect™ PrismaA as compared with MabSelect SuRe™ resin (2). Sample = Fc-based antibody construct CV = 2 mL (bed height 10 cm), residence time = 6 min.

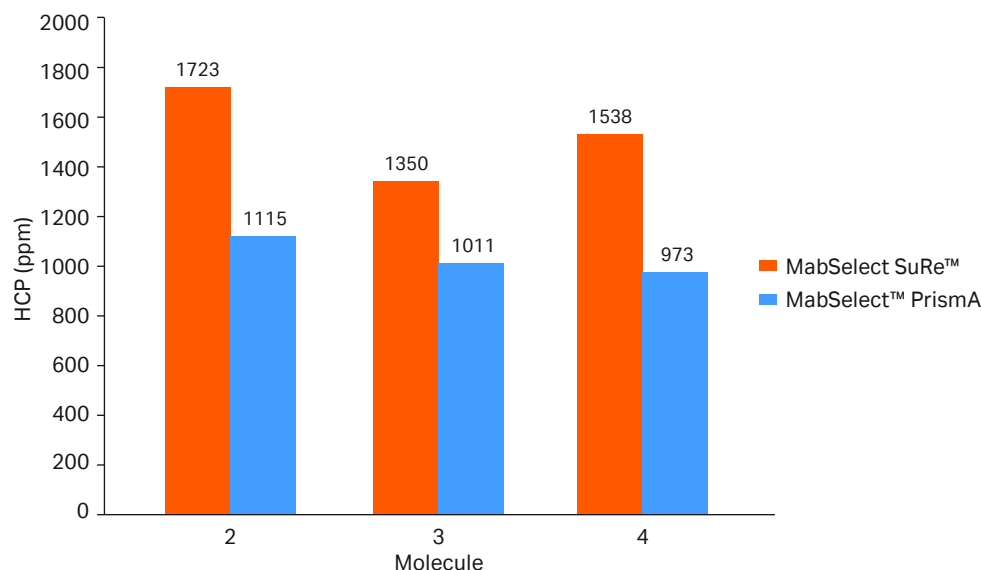


Fig 4. HCP reduction content in samples with different Fc-based antibody constructs using either MabSelect™ PrismaA or MabSelect SuRe™ resin.

Toxicity data

Toxicology studies performed on the MabSelect™ PrismaA ligand show toxicity levels comparable with the MabSelect SuRe™ ligand. For more detailed information, please refer to the regulatory support file for MabSelect™ PrismaA, cytiva.com/rsf.

Ligand leaching

The ligand concentration of MabSelect™ PrismaA is higher than for MabSelect SuRe™. Although having a positive impact on binding capacity, the increased length and ligand concentration of MabSelect™ PrismaA can also mean an increased amount of leached ligand to remove in subsequent polishing steps. Figure 5 compares ligand leaching from MabSelect™ PrismaA, MabSelect SuRe™ LX, and MabSelect SuRe™ resins for three mAb molecules. Although levels were as low as 20 ppm, an increased ligand leaching could be observed for MabSelect™ PrismaA.

Studies have been performed to demonstrate the ability of subsequent polishing steps to remove the increased ligand content in the MabSelect™ Prisma elution pool. Figure 6 shows the results from a study, where MabSelect™ Prisma ligand spiked in the MabSelect™ Prisma elution pool to a final concentration of 1000 ppm was reduced using Capto™ S ImpAct ion exchange resin run in bind-elute mode. Analysis of the elution peak from the Capto™ S ImpAct polishing step showed that MabSelect™ Prisma ligand was found in the tail of the peak together with the aggregates, as well as in the cleaning-in-place (CIP) fraction. Fractions containing the target mAb were pooled based on aggregate content. In the pooled fractions, mAb recovery was high and the amount of ligand was found to be below 1 ppm. Using unspiked sample, ligand content was reduced from 25 ppm to below 1 ppm over the Capto™ S ImpAct polishing step.

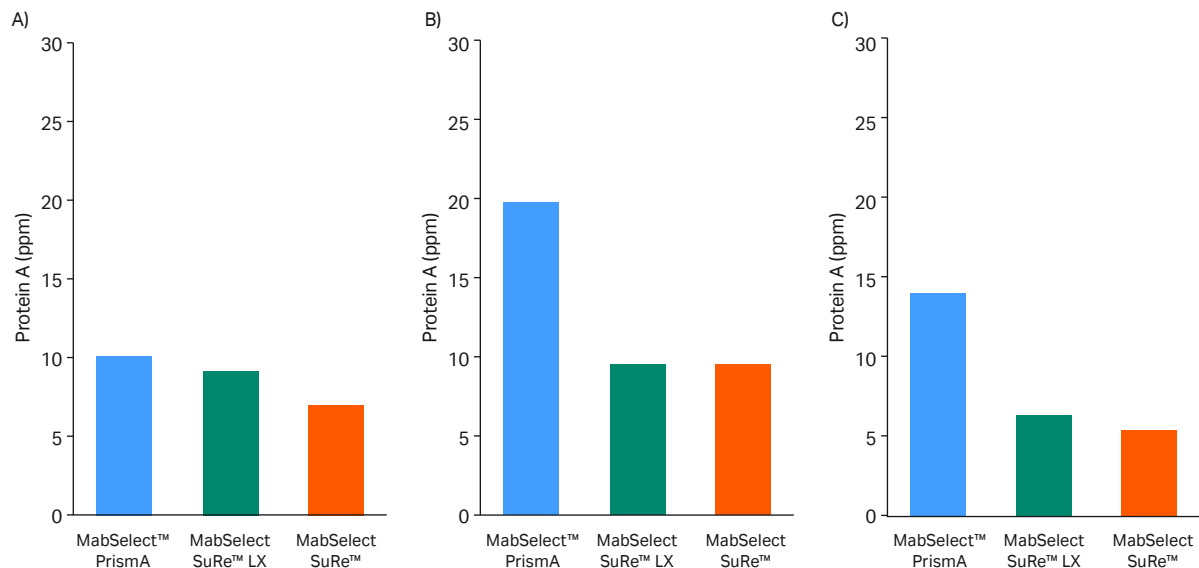


Fig 5. Leached protein A in elution pool of (A) mAb1, (B) mAb2, and (C) mAb3 (2).

Column: Capto™ S ImpAct in Tricorn™ 5/100
Sample: Elution pool from mAb capture step spiked with MabSelect™ Prisma ligand (~ 1000 ppm)
Sample load: 60 g mAb/L resin at 5.4 min residence time
Binding buffer: 50 mM sodium acetate, pH 5.3
Elution buffer: 50 mM sodium acetate, pH 5.3 + 0 to 350 mM NaCl in 20 CV

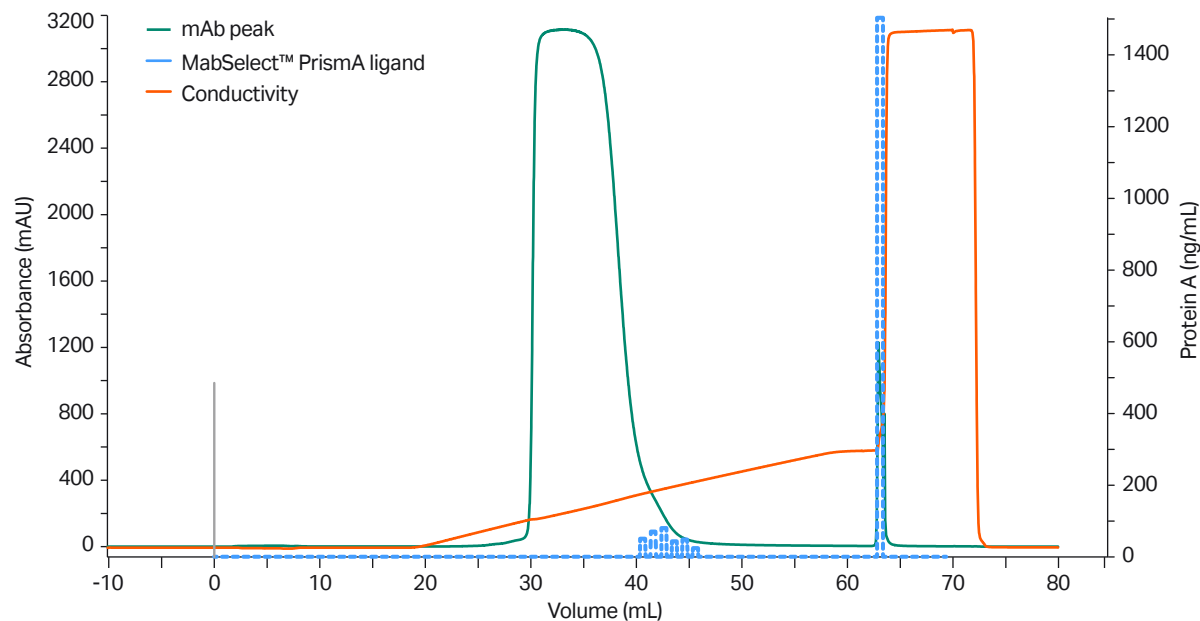


Fig 6. Analysis of MabSelect™ Prisma ligand content (light blue) in the elution peak from Capto™ S ImpAct polishing step.

Updating immunoassays for quantitation of leached MabSelect™ Prisma ligand

Regulatory agencies demand control and quantitation of ligand leaching throughout purification of biopharmaceuticals. Quantitation of leached protein A ligand can be performed using commercially available immunoassay kits.

Five commercially available immunoassay kits have been evaluated in detection and quantitation of ligand leaching from MabSelect™ Prisma:

- Abcam™ (ab133036)
- Cygnus (#F400)
- GenScript™ (L00430)
- Gyrolab™ (P0020456)
- Repligen™ (9000-1)

Assay performance was compared using both included standard and MabSelect™ Prisma ligand as standard. The results show that the antibodies included in the kits recognize the MabSelect™ Prisma ligand and, hence, all five immunoassays can be used to quantitate leached MabSelect™ Prisma ligand (Fig 7). Although MabSelect™ Prisma ligand could be quantitated using both included standard and MabSelect™ Prisma ligand as standard, MabSelect™ Prisma ligand is recommended to be used as standard to increase accuracy of the assay. In general, using MabSelect™ Prisma ligand as standard resulted in higher ligand concentrations compared with using the included kit standard. MabSelect™ Prisma ligand can be purchased with a restricted license from Cytiva. Please contact your local Cytiva sales representative for more information.

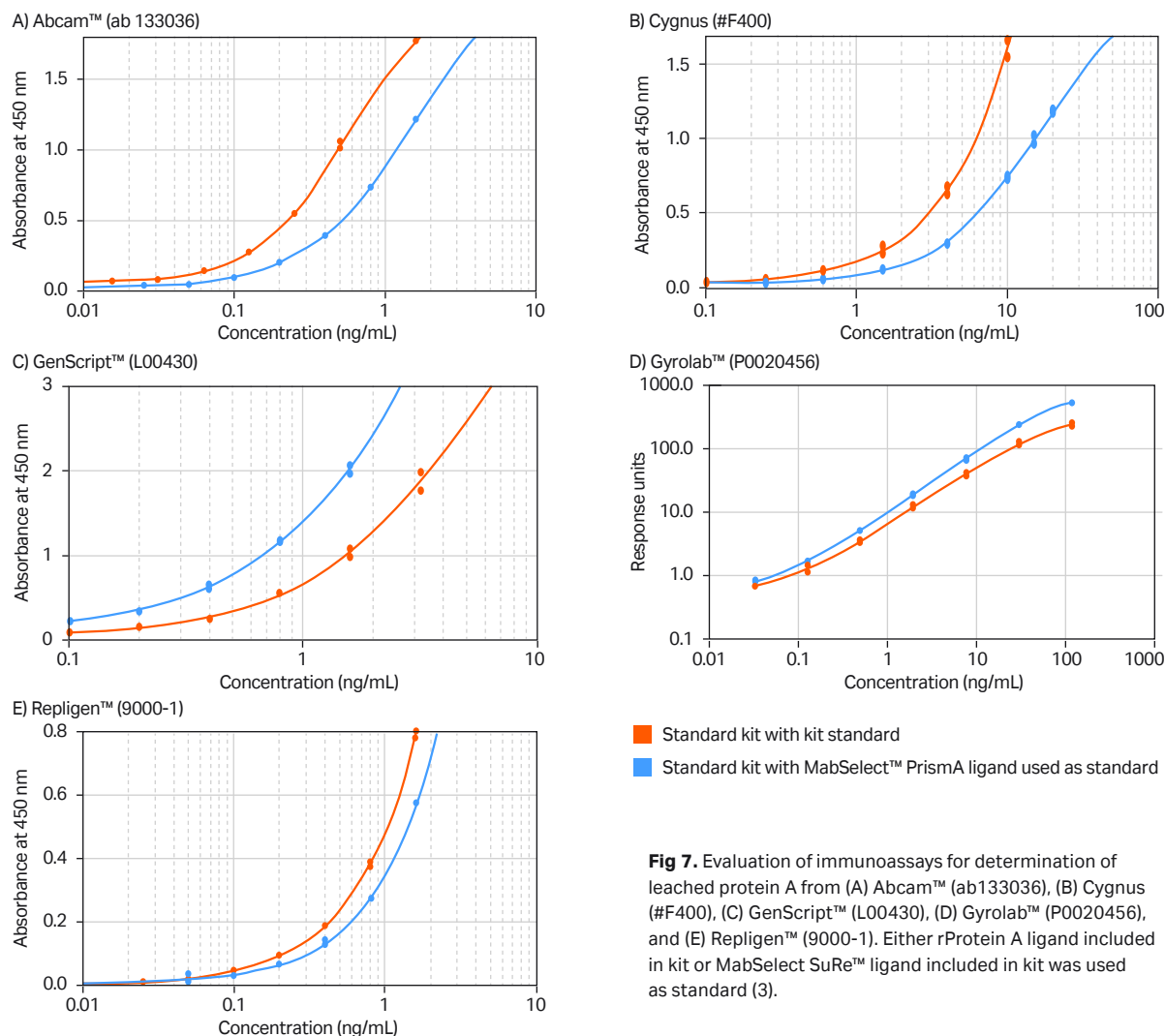


Fig 7. Evaluation of immunoassays for determination of leached protein A from (A) Abcam™ (ab133036), (B) Cygnus (#F400), (C) GenScript™ (L00430), (D) Gyrolab™ (P0020456), and (E) Repligen™ (9000-1). Either rProtein A ligand included in kit or MabSelect SuRe™ ligand included in kit was used as standard (3).

Impact of updated resin base matrix on column packing procedures and recommended flow rates

As the bead size and porosity of MabSelect™ Prisma is different than of MabSelect SuRe™ and MabSelect SuRe™ LX, column packing factors, compression factors and pressure-flow properties are also slightly different. Figure 8 shows the recommended combinations of bed height and operational nominal flow velocity for MabSelect™ Prisma, MabSelect SuRe™ LX, and MabSelect SuRe™. As MabSelect SuRe™ and MabSelect SuRe™ LX are based on the same base matrix, their pressure-flow curves are identical. Figure 8 also shows the resulting residence time in the interval 1 to 15 min for any bed height and flow velocity, where pressure drop and packing limitations at large scale are also considered. As shown, the maximum recommended flow velocity for MabSelect™ Prisma is lower than for MabSelect SuRe™ LX and MabSelect SuRe™ resins, but still as high as 300 cm/h at a 20 cm packed bed height. The recommendation is based on extensive experimentation in large-scale AxiChrom™ columns.

The updated base matrix of MabSelect™ Prisma, as compared with MabSelect SuRe™ and MabSelect SuRe™ LX, will have a slight impact on column packing methods. The optimal column packing factor for packing of MabSelect™ Prisma in different columns will differ from the ones for MabSelect SuRe™ LX and MabSelect SuRe™ resins and needs to be adjusted for both small, laboratory-scale column and larger BioProcess™ columns. For detailed descriptions of the packing factors and column packing methods, please refer to the instruction for each product, which can be found for each resin on cytiva.com. More information can be found in the additional documents listed in the Ordering information. For additional questions on column packing, please contact your local sales representative.

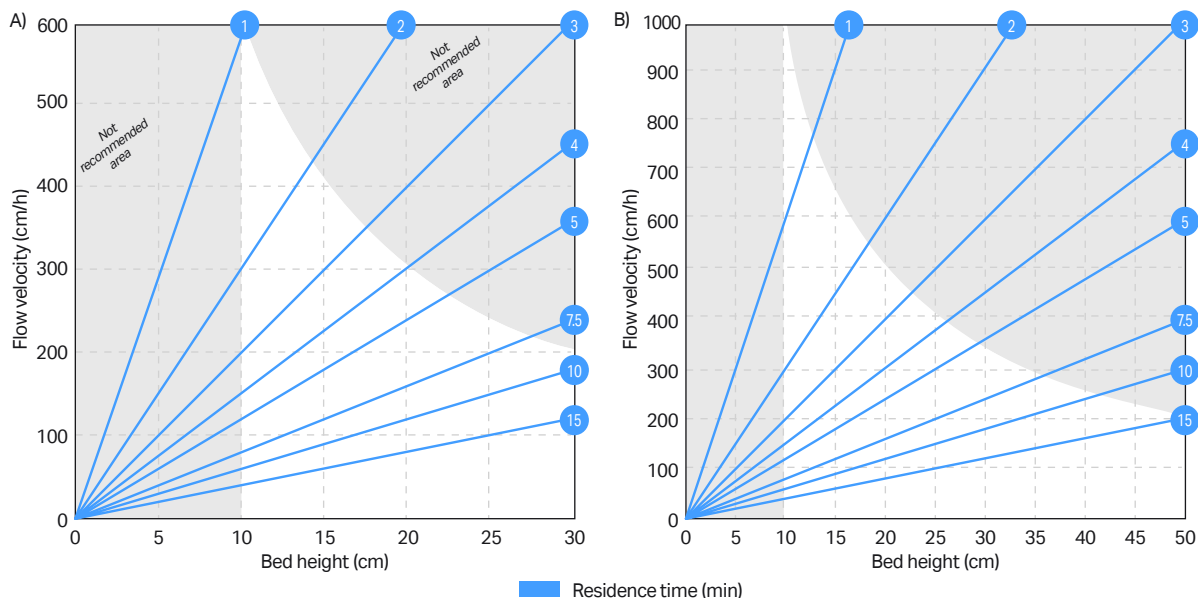


Fig 8. Operating window (white area) for (A) MabSelect™ Prisma as well as for (B) MabSelect SuRe™ and MabSelect SuRe™ LX as determined in an AxiChrom™ 300 column (i.d. 30 cm) using water at 20°C.

Considerations regarding increased binding capacity

Impact on facility fit and processing times

The increased dynamic binding capacity of MabSelect™ Prisma (up to 40% higher than MabSelect SuRe™ LX depending on selected residence time) enables higher mass throughput per time unit and per column. This means, a specified sample feed volume can be processed in shorter time for a given column volume as compared with MabSelect SuRe™ or MabSelect SuRe™ LX (Fig 9).

With the increased mass throughput, mass balance needs to be considered in subsequent purification steps and columns for polishing steps 2 and 3 need to be sized accordingly. The increased mass throughput also means less cycles required for processing of a certain amount of bioreactor harvest as compared with MabSelect SuRe™ and MabSelect SuRe™ LX, impacting number of batches that can be purified by one packed column.

Alternatively, a specified bioreactor harvest volume can be processed using lower resin volume than is possible with MabSelect SuRe™ and MabSelect SuRe™ LX (Fig 10). The possibility of using a smaller column size will impact equipment footprint and required capital investments.

A more detailed discussion and evaluation of productivity and process economy, comparing MabSelect™ PrismA with MabSelect SuRe™ and MabSelect SuRe™ LX, can be found in reference 4 or from the [protein A resins web page](#).

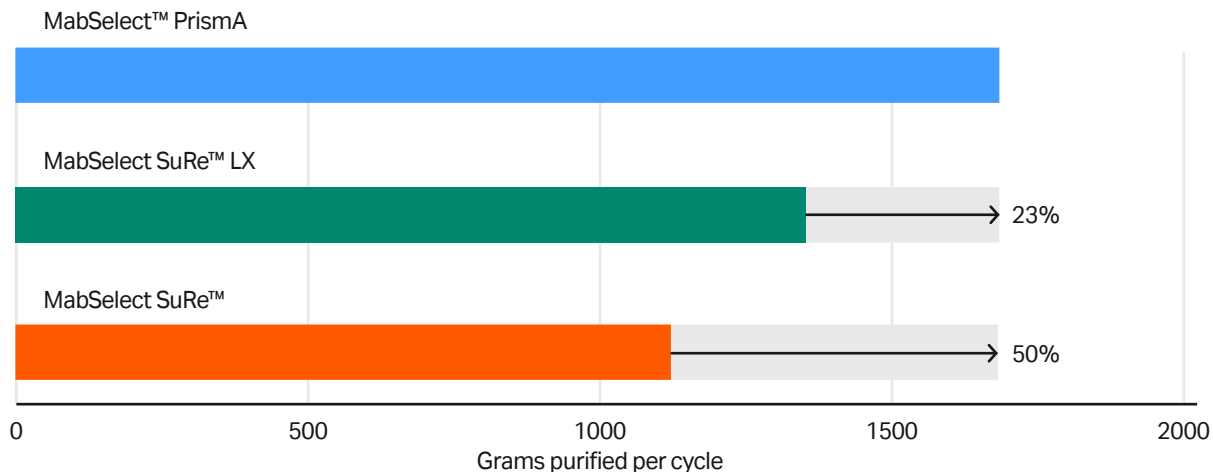


Fig 9. Example of the mass throughput increase enabled by using MabSelect™ PrismA in comparison with MabSelect SuRe™ and MabSelect SuRe™ LX. Assumptions in both graphs: Fixed column size 32 L (450/200), processing titer 4 g/L from a 2000 L bioreactor, 20% safety factor (loading to 80% of Q_{B10}), resin cycled five times per batch.

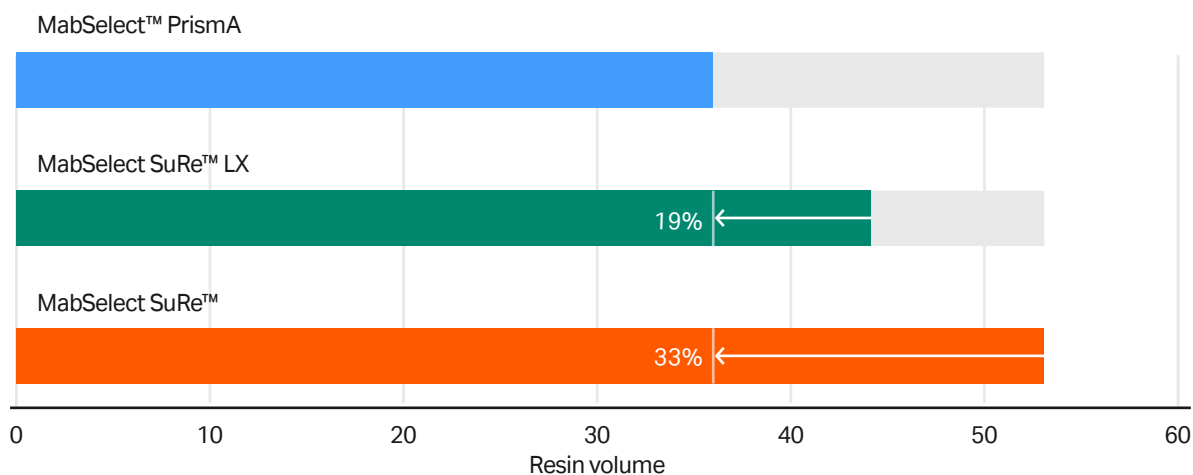


Fig 10. Example of the resin volume savings enabled by using MabSelect™ PrismA in comparison with MabSelect SuRe™ and MabSelect SuRe™ LX.

Impact of increased antibody concentrations in eluates

MabSelect™ Prisma exhibits a significantly higher binding capacity than its predecessors MabSelect SuRe™ and MabSelect SuRe™ LX. This means, higher sample loads are allowed with the packed column and also higher mAb concentrations in the elution pool. Aggregate levels will depend on characteristics and concentration of the purified mAb, and pH for elution needs to be monitored and evaluated. Figure 11 shows a comparison between aggregate levels in eluate pool from MabSelect™ Prisma and its predecessor resins. The observed increased aggregate level for one of the mAbs is associated with the higher mAb load, however, in most cases the aggregates levels are similar independent of load (1).

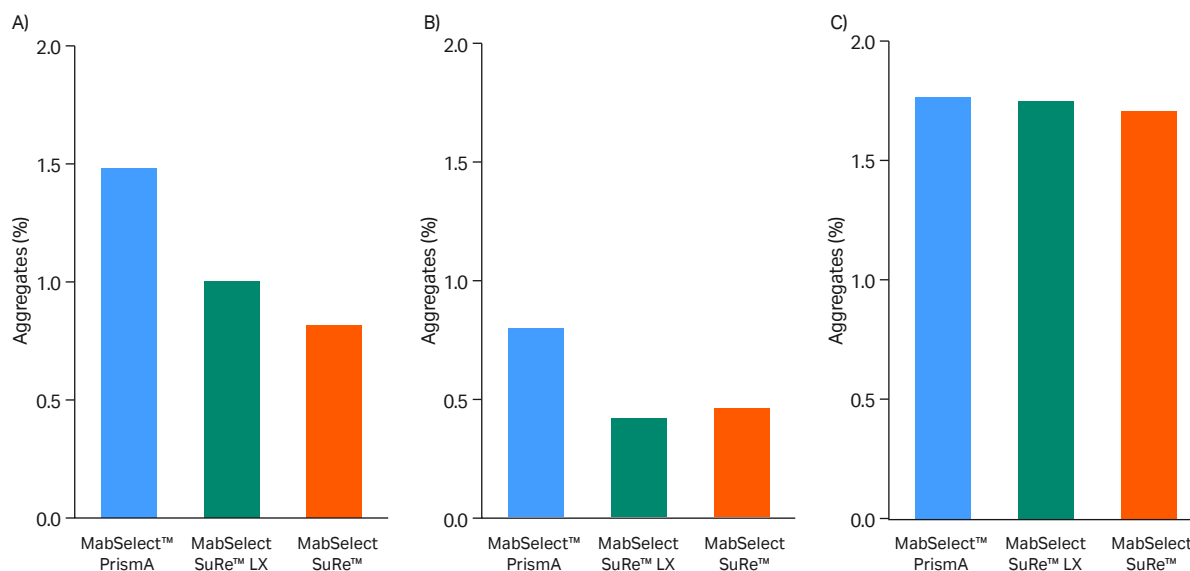


Fig 11. Aggregate content in eluate of (A) mAb1, (B) mAb2, and (C) mAb3. Bar graphs show remaining mAb aggregates (%) in elution pool.

Cleaning and sanitization procedures

The enhanced alkaline stability of the MabSelect™ Prisma ligand enables more efficient cleaning of the resin using higher concentration of sodium hydroxide (NaOH). The recommended CIP solution is 0.5 to 1.0 M NaOH compared with the 0.1 to 0.5 M NaOH CIP solution recommended for MabSelect SuRe™ LX and MabSelect SuRe™ resins. Depending on the nature of the contaminants, different protocols might need to be combined, for example, using 0.5 M NaOH each cycle and 1.0 M NaOH every 10th cycle.

Figure 12 shows relative remaining DBC at 10% breakthrough (Q_{B10}) for MabSelect™ Prisma as compared with MabSelect SuRe™ and MabSelect SuRe™ LX over repeated CIP cycles. MabSelect™ Prisma retains more than 90% of its initial DBC after 150 cycles with 1.0 M NaOH while only 50% of the initial DBC of MabSelect SuRe™ LX remains after an equivalent number of CIP cycles. Using 0.5 M NaOH, MabSelect™ Prisma retains more than 93% of its initial DBC after 300 cycles (5).

The enhanced tolerance to high concentrations of NaOH allows streamlined use of the same cleaning solutions for MabSelect™ Prisma as for the subsequent polishing step. MabSelect™ Prisma creates an opportunity to extend the number of cycles to be validated for a specific process and, hence, column lifetime in commercial manufacturing. In addition to allowing for higher sample loads, the high remaining DBC of MabSelect™ Prisma over multiple cycles, in which cleaning with high concentrations of NaOH in each cycle is included, can allow the use of lower safety factors.

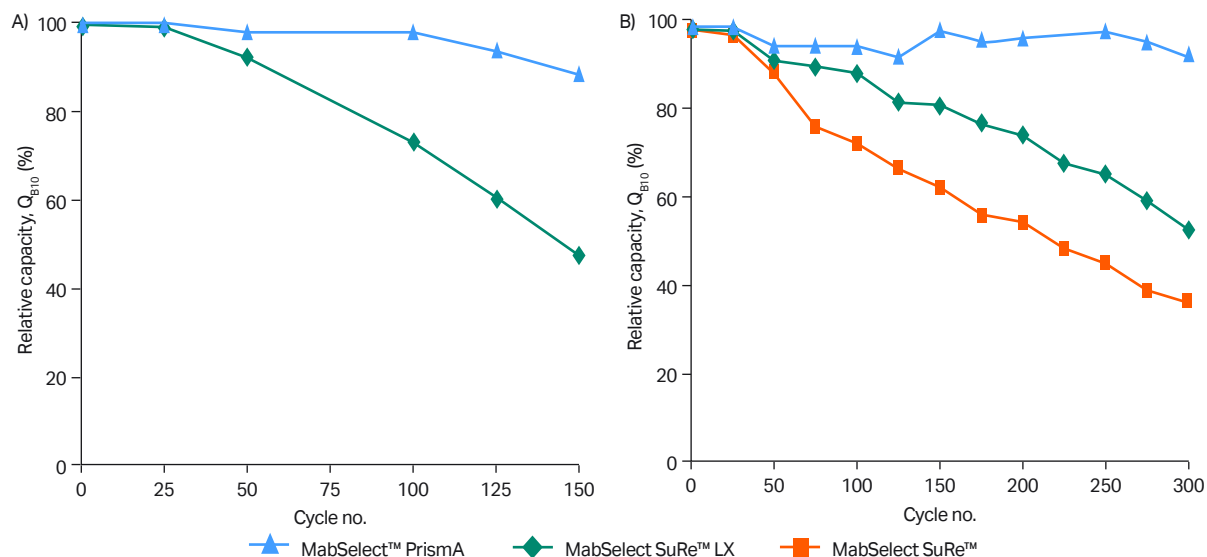


Fig 12. (A) Relative remaining Q_{B10} for 150 cycles, including CIP with 1.0 M NaOH for 15 min/cycle. (B) Relative remaining Q_{B10} for 300 cycles, including CIP with 0.5 M NaOH for 15 min/cycle. Cycling was performed with buffer only (no mAb-containing sample).

Start-up guidance for development of a capture step

This quick start guide provides a starting point that can be employed for use of MabSelect™ PrismaA in purification of the majority of mAbs produced in mammalian cells. Tables 2 to 4 provide general guidance for development of processes including MabSelect™ PrismaA, MabSelect SuRe™ LX, or MabSelect SuRe™ resins in the capture step. As shown, the proposed starting point for the methods are similar between the three resins. Note that the sample should be clarified prior to loading onto the column. A sterile filter should be used and an adsorptive depth filter is typically placed before the sterile filter. The chromatography run should be carried out as soon as possible after cell culture harvest. If the cell culture harvest needs to be stored before the run, it should be sterile filtered and kept at 4°C or frozen, if possible.

Table 2. Outline of typical mAb capture process using MabSelect™ PrismaA

Step	CV	Residence time (min)/linear flow velocity (cm/h) at 20 cm height	Buffer
Equilibration	3	4/300	20 mM sodium phosphate, pH 7.4 + 150 mM NaCl
Load	70% to 80% of Q_{B10}	4 or 6 / 300 or 200	As required
Wash 1	5	1.5 CV 4 or 6/300 or 200	20 mM sodium phosphate, pH 7 + 500 mM NaCl
Wash 2	1	4/300	50 mM sodium acetate, pH 6
Elution step	3	4/300	50 mM sodium acetate, pH 3.5
Strip	2	4/300	100 M acetic acid, pH 2.9
CIP	3 (15 min contact time)	5/240	0.5 M NaOH to 1.0 M NaOH
Re-equilibration	3	4/300	20 mM sodium phosphate, pH 7.4 + 150 mM
Only after last run/ for storage	4	7.5/160	20% ethanol

Table 3. Outline of typical mAb capture process using MabSelect SuRe™ LX

Step	CV	Residence time (min)/linear flow velocity (cm/h) at 20 cm height	Buffer
Equilibration	3	4/300	20 mM sodium phosphate, pH 7.4 + 150 mM NaCl
Load	70% to 80% of Q_{B10}	6 /200	As required
Wash 1	5	1.5 CV 6/200 3.5 CV 3.4/350	20 mM sodium phosphate, pH 7.0 + 500 mM NaCl
Wash 2	1	3.4/350	50 mM sodium acetate, pH 6
Elution step	3	3.4/350	50 mM sodium acetate, pH 3.5
Strip	2	5/240	100 M acetic acid, pH 2.9
CIP	3 (15 min contact time)	5/240	0.1 M NaOH to 0.5 M NaOH
Re-equilibration	3	3.4/350	20 mM sodium phosphate, pH 7.4 + 150 mM
Only after last run/ for storage	4	7.5/160	20% ethanol

Table 4. Outline of typical mAb capture process using MabSelect SuRe™

Step	CV	Residence time (min)/linear flow velocity (cm/h) at 20 cm height	Buffer
Equilibration	3	4/300	20 mM sodium phosphate, pH 7.4 + 150 mM NaCl
Load	70% to 80% of Q_{B10}	2.4 or 4/500 or 300	As required
Wash 1	5	1.5 CV 6/200 3.5 CV 3.4/350	20 mM sodium phosphate, pH 7.0 + 500 mM NaCl
Wash 2	1	3.4/350	50 mM sodium acetate, pH 6
Elution step	3	3.4/350	50 mM sodium acetate, pH 3.5
Strip	2	5/240	100 M acetic acid, pH 2.9
CIP	3 (15 min contact time)	5/240	0.1 to 0.5 M NaOH
Re-equilibration	3	3.4/350	20 mM sodium phosphate, pH 7.4 + 150 mM
Only after last run/ for storage	4	7.5/160	20% ethanol

Simplified process development for MabSelect™ Prisma

Run 0. Blank run: should be performed prior to the first cycle on MabSelect™ Prisma to remove noncovalently immobilized ligand, and thus decrease the ligand leaching during chromatography. All phases in the chromatography method listed in Table 2 should be used, with two alterations: (i) the equilibration buffer should be used during the load phase (i.e., no protein load); and (ii) the elution phase in the blank run should be set to 3 CV and not controlled by a watch function.

Run 1. Load conditions: the next run should be performed to determine DBC of the column for your specific mAb at recommended residence time. Follow the procedure in Table 2 and overload the column up to stated maximum DBC, collect the flow through fractions and determine the mAb concentration in the pooled fractions and calculate the 10% breakthrough.

Run 2. Set load conditions to 70% to 80% of 10% breakthrough and follow all steps in Table 2. The process used here can be locked if this run leads to acceptable purity, quality, and yield levels.

Step durations. All the step durations mentioned here are only indicative. The actual step durations may be shortened if the chromatograms and fraction data in the specific step warrant it.

Elution conditions. Various elution conditions, instead of acetate, may be considered, such as citrate buffer (10–100 mM), or glycine. When optimizing elution conditions for better impurity clearance, determine the highest pH that allows efficient desorption of antibody (this can, however, increase pool volumes). Alternatively, design the elution condition to match the pH required for virus inactivation, as discussed below.

Analysis. Purity and quality must be analyzed for the capture step after titrating up to load conditions for the next step and filtering through a sterile filter. Additionally, purity and quality must be analyzed after the two or three chromatographic steps based on the platform process. If this process leads to low recovery or high host cell protein content in the elution pool, further development must be conducted as the wash and elution conditions will need to be optimized.

Virus inactivation. The pH in the elution pool should be kept at a pH of 3.8 or lower for at least 30 min for appropriate virus inactivation (6). If the elution pool has a higher pH, it needs to be titrated by addition of acid or decreased through further optimization of the elution buffer volume. After virus inactivation, the pH must be immediately adjusted to match loading conditions for the next step (e.g., pH 5–6 for cation ion exchangers or pH 6–8 for Capto™ adhere) by addition of 0.1 M NaOH. Precipitation might occur during elution and commonly occurs after pH titration and subsequent to the low-pH virus inactivation. It can be assumed that the precipitate contains mainly lipids and only trace amounts of mAb, host cell protein, and leach ligand. This precipitate can be safely removed by filtration using a sterile filter, but note that correct filter size should be used. Filters typically used in manufacturing are usually large enough for this step.

Further optimization. To optimize the process conditions for scale up, we recommend using high-throughput process development (HTPD). During HTPD, a large number of conditions (for binding, elution, and wash steps) can be evaluated in a short amount of time using PreDicator™ 96-well filter plates and PreDicator™ RoboColumn™ units. Information gained during HTPD can be used to set the parameters for a robustness study at laboratory scale before scaling up to the pilot plant and manufacturing. This strategy is especially useful when using a quality by design (QbD) approach.

This simplified process development approach can also be used for MabSelect SuRe™ LX and MabSelect™ resins using the methods listed in Tables 3 and 4.

Summary

MabSelect™ Prisma is designed and manufactured using the same basic raw materials as its predecessors MabSelect SuRe™ and MabSelect SuRe™ LX resins. However, both the base matrix and ligand of MabSelect™ Prisma have been optimized for increased capacity and alkaline-stability. The upgraded feature of MabSelect™ Prisma enables improved productivity and bioburden control.

The common heritage and design platform with its predecessor products make upgrade of current protein A capture platforms with the next-generation MabSelect™ Prisma resin straightforward for new preclinical projects.

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2. Application note: Capacity and performance of MabSelect™ Prisma protein A chromatography resin. Cytiva, CY14008-02Jun20-AN (2020).
3. Poster: Evaluation of five commercial immunoassays for quantification of leached ligand from a new protein A resin. Cytiva, CY14404-12Jun20-PT (2020).
4. Application note: Process economy simulation showing impact of using a high-capacity protein A chromatography resin with enhanced alkaline-stability in the mAb capture step. Cytiva, CY14070-03Jun20-AN (2020).
5. Application note: Lifetime performance study of MabSelect™ Prisma during repeated cleaning-in-place cycles. Cytiva, CY14006-02Jun20-AN (2020).
6. Brorson, K. *et al.* Bracketed generic inactivation of rodent retrovirus by low pH treatment for monoclonal antibodies and recombinant proteins. *Biotech. Bioeng.* **82**, 321–329 (2003).

Related documents

Product	Product code
Data file: MabSelect™ Prisma	CY553-17Sep20-DF
Instruction: MabSelect™ Prisma	29262586
Instruction: MabSelect SuRe™ LX	28976500
Instruction: MabSelect SuRe™	11002601
Whitepaper: Efficient cleaning-in-place methods for protein-based antibody affinity chromatography resins	CY14402-12Jun20-WP



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