Praesto®
PROTEIN PURIFICATION

Protein A Resins

Modern, Advanced High-Flow,
Highly Cross-Linked Agarose Resins
For Improved Process Economics.

Purolite®
Life Sciences

www.purolite.com/life-sciences

Why Purolite®?

For over 35 years, Purolite has supplied specialty ion exchange resin technology to industries within complex regulatory environments, including biotechnology, pharmaceutical, food, fine chemical and electric power generation. Purolite is the only global company to focus 100% on resin technology.

Security of Supply

Ensuring reliable availability of products in case of emergency is vital to customers and of paramount importance to Purolite.

As a leading supplier of resin media to the world's most regulated industries, Purolite has a real-world security-of-supply system in place to support your process requirements for business continuity in the instance of natural disaster or emergency.

Purolite has manufacturing facilities at 3 strategic global locations in the USA, Asia and Europe, and is currently building its 4th manufacturing plant in the UK. This facility will be the second largest agarose manufacturing plant globally, with a capacity of 100,000 L per annum.

Currently, approximately 90% of all biopharmaceuticals approved by the U.S. Food and Drug Administration utilise a single source of agarose resins from a single manufacturing site, presenting a security of supply risk to long-term clinical trial material production.

Purolite have addressed this industry-wide concern by providing the first proven and reliable alternative source of agarose resins, allowing customers to dual-source their products to mitigate their supply risks.

Regulatory Support

Purolite Life Sciences provides customers with regulatory support documentation for ***Praesto*** products used by our customers in GMP regulatory environments.

Comprehensive regulatory support files are available for each ***Praesto*** resin, and are provided under a confidential disclosure agreement.

The purpose of this Regulatory Support File (RSF) is to provide assistance with:

- Process development of clinical and commercial purification processes
- Manufacturing validation
- Quality control tests
- Standard Operating Procedure (SOP) for cleaning in place (CIP) and sanitization
- Application for various regulatory licenses or compliance
- Plant and document audits

Quality

Global ISO 9001:2008 standards ensure consistent operating practices across each of our plants. Compliance is monitored and maintained through a quality assurance and regulatory team who conduct internal audits to ensure operations meet the guidelines and protocols for equipment and procedures.

Additionally, our production team is given continual training on quality processes to ensure batch-to-batch consistency, and we host numerous customer audits each year to make sure that we are in compliance with user expectations.

Purolite maintains a global Quality Management System (QMS) which supports BSI requirements of ISO 9001:2008.

Raw Materials

Our raw material suppliers are selected and qualified from leading manufacturers and are part of our global network of suppliers. Each key raw material has at least one alternative supplier and is managed through a globally coordinated inventory system to ensure security of supply.

Additionally, a quality control protocol is in place for testing new batches/lots of raw materials to confirm product specifications and lot-to-lot consistency.

Purolite Life Sciences also has long-term supply agreements in place for our Protein A ligands, which are sourced from Repligen Corporation.

Repligen provides dual-site supply for critical raw materials and has a long-standing history of successfully supplying a variety of Protein A ligands to the industry.

100% focused on resin technology.

The world's second largest agarose manufacturing facility.

De-risked long-term supply through dual-sourcing.

25+ years of regulatory experience from FDA inspected cGMP facility.

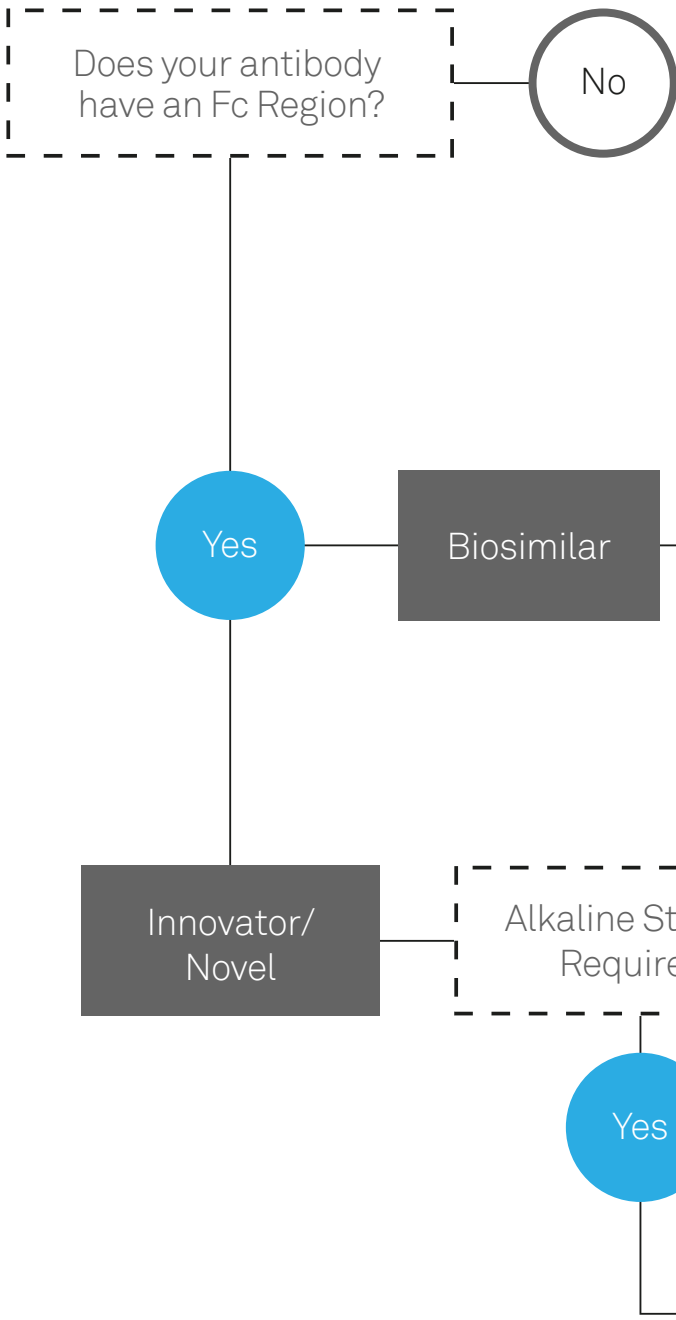
Over 35+ years of experience in solving advanced R&D and purification challenges.

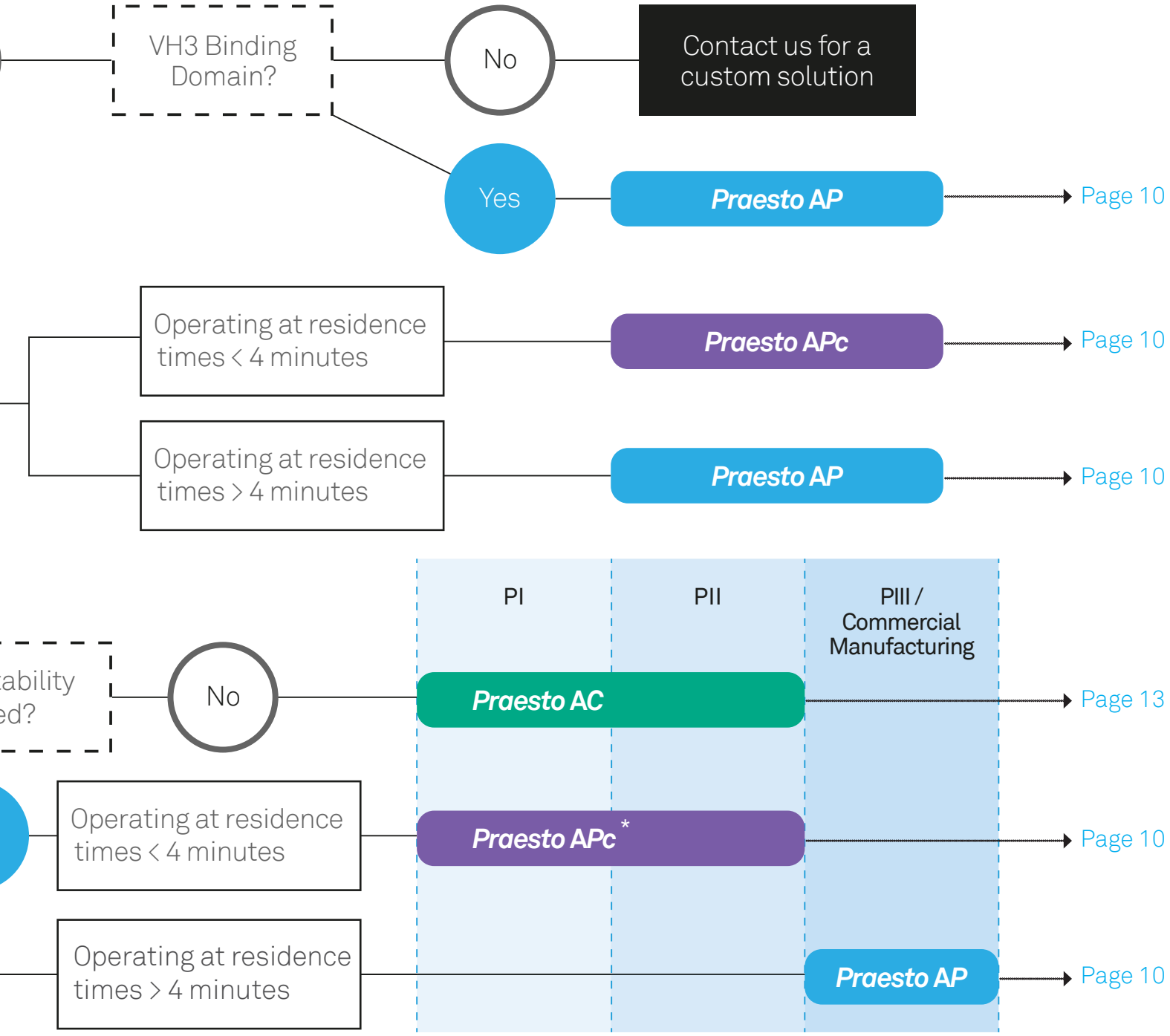
Reduce your clinical trial costs by up to 65% using *Praesto* resins

Production of early phase (PI & PII) clinical trial material can be very costly when balanced against high failure rates. Much of this unnecessary expense results from utilizing Protein A resins optimized for 100+ cycles when, typically fewer than 20 purification cycles are performed.

One method of maximizing your cost efficiencies is to follow Purolite Life Sciences' recommended strategy of switching Protein A resins after PII, only utilizing a higher-cost resin optimized for 100+ cycles when your process requirements justify your cost of goods.

Our selection of highly-optimized Protein A resins deliver the highest possible performance. Follow our Protein A resin selection guide to find your ideal ***Praesto*** Protein A resin.





* Can also be implemented in PIII and Commercial Manufacture due to long lifetime

Protein A Resins
Praesto® APc & *Praesto* AP

Modern, high flow agarose-based, alkaline-stable Protein A resins for cost-effective, high productivity MAb capture.

Praesto Protein A Resins

Purolite Life Sciences has designed two alkaline-stable Protein A resins – ***Praesto*** *APc* and ***Praesto*** *AP*.

Both ***Praesto*** *APc* and ***Praesto*** *AP* are based on the same 85 µm agarose base matrix and identical Protein A ligand, differing only in the amount of Protein A immobilization required.

Praesto *APc* provides high capacities of over 40 mg/ml, at 4 minutes residence time. It is purpose-designed and evaluated for phase I and II clinical trials - where typically less than 20 reuse cycles are performed - but ***Praesto*** *APc* can be implemented across all phases due to long life time.

Praesto *AP* provides ultra-high capacities of over 50 mg/ml, particularly at residence times of 6 minutes or higher. It is purpose-designed and evaluated for the production of late phase clinical trial material and commercial manufacture, where typically hundreds of reuse cycles are performed.

Key Performance Benefits

- Reduces volume required and overall process times with ultra-high capacities
- Increased throughput due to excellent pressure/ flow performance
- Long lifetime due to alkaline-tolerant, modified Protein A
- Minimize non-specific binding due to hydrophilic agarose base matrix
- Minimal Protein A leaching via multi-point attachment
- Up to 50% cost savings compared to MabSelect SuRe/LX

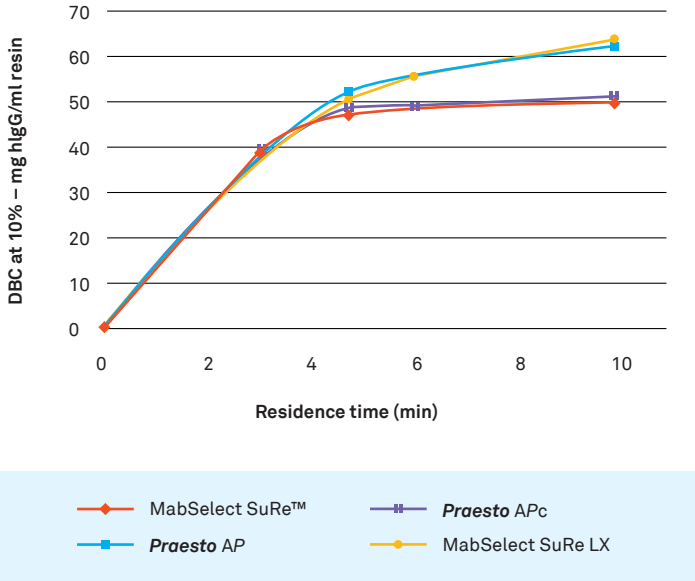
Praesto Protein A Ligand

The novel, alkaline-tolerant Protein A ligand was developed through protein engineering of a Protein A IgG-binding domain. The improved alkaline-stability permits the use of sodium hydroxide for CIP and sanitization whilst still achieving a functional lifetime of 100s of purification cycles.

Supply Agreement

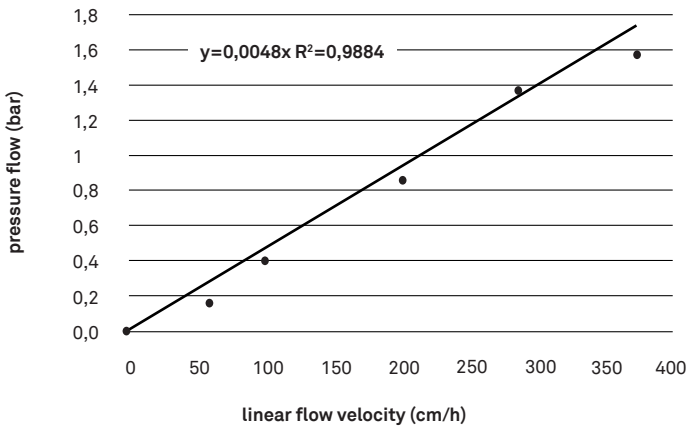
The Protein A ligand is provided under a supply agreement with Repligen Corporation, with the production process free from sources of mammalian origin.

Dynamic Binding Capacity

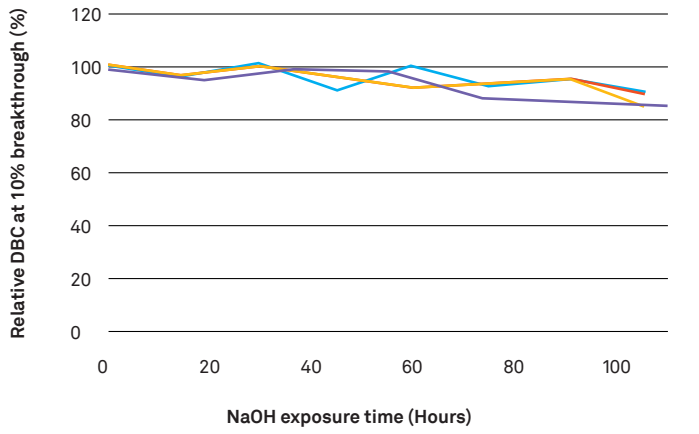


Pressure/Flow Performance

The ***Praesto*** high flow agarose base matrix provides a rigid, but open pore structure. This results in high productivities due to the ability to operate at high flow velocities at process-scale, compared to softer, cross-linked agarose resins with similar porosity.



Dynamic Binding Capacity After Cleaning In Place – 0.1 M NaOH



MabSelect SuRe™
Praesto *APc*
Praesto *AP*
MabSelect SuRe LX

Protein A Leakage

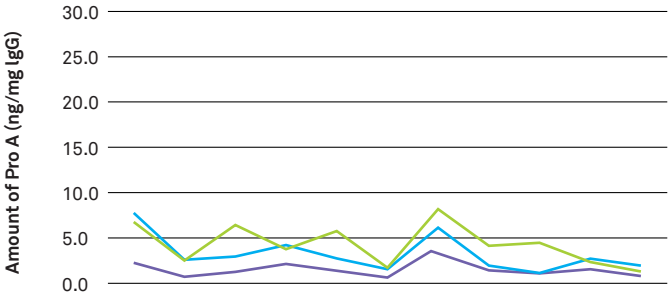
Protein A leakage occurs during:

- NaOH exposure
- Exposure to protease containing cell culture supernatants
- Spontaneous deamidation

The use of multipoint-attached alkaline-stable ***Praesto*** Protein A resins has a positive impact on each of these challenging factors.

The figure below shows Protein A eluate levels assayed during a re-use study over 20 cycles.

The results are consistently below 10 mg Protein A /mg IgG in all twenty product pools. The feed stock was kindly provided by Alvotech Biopharmaceuticals.



	1	2	4	6	8	10	12	14	16	18	20
AP	2.2	0.7	1.3	2.1	1.4	0.6	3.5	1.4	1.1	1.5	0.8
APc	7.8	2.6	3.0	4.2	2.9	1.5	6.1	2.0	1.2	2.7	2.0
AC	6.8	2.5	6.4	3.8	5.8	1.7	8.1	4.1	4.4	2.4	1.3

Praesto AP & APc: Typical Physical & Chemical Characteristics		
	Praesto AP	Praesto APc
Application	MAb capture	
Polymer Structure	Highly cross linked agarose	
Appearance	Spherical beads	
Functional Group	Recombinant Protein A (*E. coli*)	
Dynamic Binding Capacity	>50 mg hIgG/mL resin	>40 mg hIgG/mL resin
Average Particle Size[2]	85 µm	
Pressure/Flow Specifications	> 500 cm/h at 3 bar in a 2.6 x 20 cm column	
pH Stability, Working Range	3 - 10	
pH Stability, CIP (Short-term)	2 - 13.7[3]	
Recommended Storage	2 to 8°C, 20% ethanol, supplied in 20% ethanol	

[1] Determined at 10% breakthrough by frontal analysis in a column with a bed height of 20 cm.

[2] $d_{50}v$ is the median particle size of the cumulative volume distribution.

[3] pH below 3 may be required to elute strongly bound species, but protein ligands can hydrolyse at very low pH.

Protein A Resins
Praesto® AC

Modern agarose-based Protein A affinity resin for cost-effective, high productivity MAb capture, designed to address today's early-phase clinical manufacturing challenges.

Praesto *AC* is purpose-designed and evaluated for production of early phase clinical trial material, where typically less than 20 cycles are run.

With capacity over 40 mg/mL at 4 minutes residence time or higher, ***Praesto*** *AC* combines high capacity, excellent pressure/flow performance, and NaOH CIP stability for over 20 cycles, thus meeting the common requirements for production of materials for PI and PII clinical trials. It is an excellent choice for the capture step in a typical MAb platform process.

Praesto *AC* can also be used in small scale MAb purification, in purification of MAbs for diagnostics, in process development and in pre-clinical processes.

Key Performance Benefits:

- Reduces volume required and overall process times with ultra-high capacities
- Increased throughput due to excellent pressure/flow performance
- Long lifetime due to alkaline-tolerant, modified Protein A
- Minimal Protein A leaching via multi-point attachment
- Up to 65% cost savings compared to MabSelect SuRe

Production Of Early Clinical Phase Material

Despite platform approaches to MAb processing, the production of materials for early-phase clinical trials can be costly.

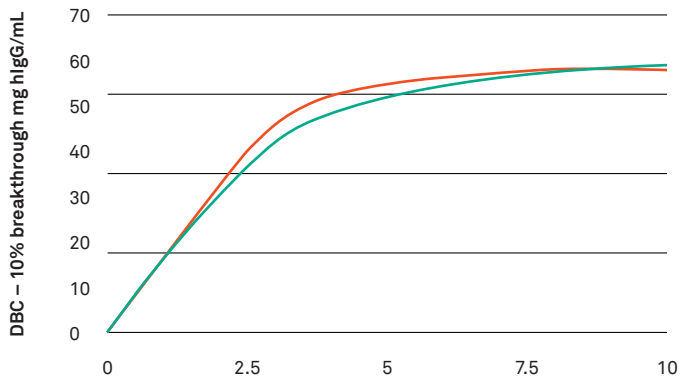
Much of the expense comes from using the same purification tools that are used later for many cycles in full scale production. Particularly for more expensive resins like Protein A, the cost/cycle or cost/g product looks prohibitive when the resin is used for only a few cycles in clinicals production, instead of the 100s of cycles it is designed for.

Praesto *AC* is an example of a purpose-designed resin, specified and evaluated for production of early-phase clinical trial material. It delivers both process and cost efficiencies.

Praesto AC: Typical Physical & Chemical Characteristics	
Application	MAb capture
Polymer Structure	Highly cross linked agarose
Appearance	Spherical beads
Functional Group	Recombinant Protein A (*E. coli*)
Dynamic Binding Capacity	>40 mg hIgG/mL resin at 4 minutes residence time[1]
Average Particle Size[2]	85 µm
Pressure/Flow Specifications	> 500 cm/h at 3 bar in a 2.6 x 20 cm column
pH Stability, Working Range	3 - 10
pH Stability, CIP (Short-term)	2 - 13[3]
Recommended Storage	2 to 8ºC, 20% ethanol, supplied in 20% ethanol

[1] Determined at 10% breakthrough by frontal analysis in a column with a bed height of 20 cm.
[2] $d_{50}v$ is the median particle size of the cumulative volume distribution.
[3] pH below 3 may be required to elute strongly bound species, but protein ligands can hydrolyse at very low pH.

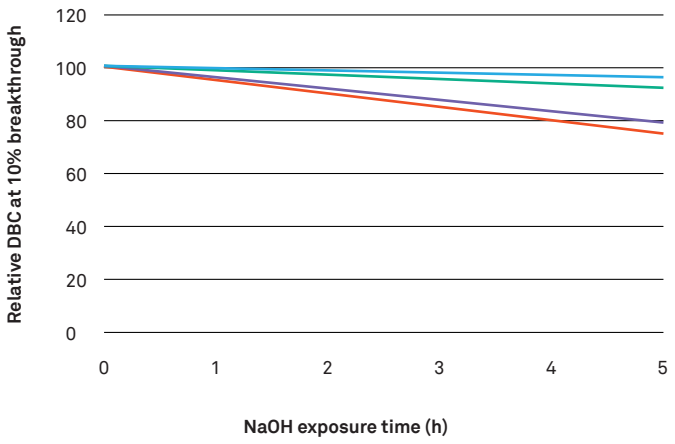
Dynamic Binding Capacity



DBC at 10% breakthrough at various residence times measured with a 5 mg hIgG/mL solution, pH 7.4

MabSelect SuRe™
Praesto AC

Dynamic Binding Capacity After Cleaning In Place – 0.1 M NaOH and 0.5 M NaOH



CIP study over 5 hour exposure time using 0.1 M and 0.5 M NaOH. DBC measured with a 5 mg hIgG/mL solution, pH 7.4.

0.1 M MabSelect
0.5 M MabSelect
0.1 M *Praesto* AC
0.5 M *Praesto* AC

Praesto® Formats

All *Praesto* resins are available in a variety of formats to suit your process needs, from high-throughput to full-scale commercial manufacture. Process development and up-scaling is further streamlined by using our pre-packed and pre-qualified formats.

Bulk Resins

Bulk resins are available in 10 ml, 25 ml, 100 ml, 500 ml, 1 L, 5 L and 10 L volumes. All ***Praesto*** Protein A resins are bottled in 20% ethanol.

HT Columns

For quick and easy separation offers pre-packed HT columns columns are available containing ***Praesto*** Protein A and Ion Exchange high-flow resins. The HT range of columns are available in 1 ml and 5 ml bed volumes and are compatible will all common chromatography systems.

RoboColumns®

For HTPD work, ***Praesto*** resins are available in RoboColumn volumes of 8 x 200 µL and 8 x 600 µL. They are 100% quality checked for HETP and asymmetry.

MiniChrom Columns

Praesto MiniChrom pre-packed columns provide a small bed volume for fast results and minimal sample and buffer consumption, as well as convenience in media screening and easy, direct connection to chromatography systems. They are 100% quality checked for HETP and asymmetry.

Ordering Information

Ordering Information

To place your order simply contact us via email or telephone using the information on the back page of this brochure and quote your order number from the table below.

If you wish to discuss your purification challenges with a specialist, we have dedicated experts on-hand across the globe to provide knowledgeable, same-day technical assistance.

***Praesto* APc**		
BULK RESIN	**PACK SIZE**	**ORDER NUMBER**
***Praesto* APc**	10 ml	PR00310-163
***Praesto* APc**	25 ml	PR00310-166
***Praesto* APc**	100 ml	PR00310-164
***Praesto* APc**	500 ml	PR00310-165
***Praesto* APc**	1 L	PR00310-310
***Praesto* APc**	5 L	PR00310-311
***Praesto* APc**	10 L	PR00310-312
PRE-PACKED COLUMNS		
***Praesto* APc MiniChrom Column (8 x 20 mm)**	1 x 1 ml	PR00310-175
***Praesto* APc MiniChrom Column (8 x 100 mm)**	1 x 5 ml	PR00310-176
***Praesto* APc RoboColumn® (5 x 10 mm)**	8 x 200 µl	PR00310-174
***Praesto* APc RoboColumn® (5 x 10 mm)**	8 x 600 µl	PR00310-279
***Praesto* APc HT Column**	1 ml	PR00310-275
***Praesto* APc HT Column**	5 x 1 ml	PR00310-575
***Praesto* APc HT Column**	5 ml	PR00310-276
***Praesto* APc HT Column**	5 x 5 ml	PR00310-576

***Praesto* AP**		
BULK RESIN	**PACK SIZE**	**ORDER NUMBER**
***Praesto* AP**	10 ml	PR00300-163
***Praesto* AP**	25 ml	PR00300-166
***Praesto* AP**	100 ml	PR00300-164
***Praesto* AP**	500 ml	PR00300-165
***Praesto* AP**	1 L	PR00300-310
***Praesto* AP**	5 L	PR00300-311
***Praesto* AP**	10 L	PR00300-312

Praesto AP Continued...		
PRE-PACKED COLUMNS		
***Praesto* AP MiniChrom Column (8 x 20 mm)**	1 x 1 ml	PR00300-175
***Praesto* AP MiniChrom Column (8 x 100 mm)**	1 x 5 ml	PR00300-176
***Praesto* AP RoboColumn® (5 x 10 mm)**	8 x 200 µl	PR00300-174
***Praesto* AP RoboColumn® (5 x 10 mm)**	8 x 600 µl	PR00300-279
***Praesto* AP HT Column**	1 ml	PR00300-275
***Praesto* AP HT Column**	5 x 1 ml	PR00300-575
***Praesto* AP HT Column**	5 ml	PR00300-276
***Praesto* AP HT Column**	5 x 5 ml	PR00300-576

Praesto AC		
BULK RESIN	PACK SIZE	ORDER NUMBER
***Praesto* AC**	10 ml	PR00200-163
***Praesto* AC**	25 ml	PR00200-166
***Praesto* AC**	100 ml	PR00200-164
***Praesto* AC**	500 ml	PR00200-165
***Praesto* AC**	1 L	PR00200-310
***Praesto* AC**	5 L	PR00200-311
***Praesto* AC**	10 L	PR00200-312
PRE-PACKED COLUMNS		
***Praesto* AC MiniChrom (8 x 20 mm)**	1 x 1 ml	PR00200-175
***Praesto* AC MiniChrom (8 x 100 mm)**	1 x 5 ml	PR00200-176
***Praesto* AC RoboColumn® (5 x 10 mm)**	8 x 200 µl	PR00200-174
***Praesto* AC RoboColumn® (5 x 10 mm)**	8 x 600 µl	PR00200-279
***Praesto* AC HT Columns**	1 ml	PR00200-275
***Praesto* AC HT Columns**	5 x 1 ml	PR00200-575
***Praesto* AC HT Columns**	5 ml	PR00200-276
***Praesto* AC HT Columns**	5 x 5 ml	PR00200-576

The *Praesto*® Range

The ***Praesto*** range offers a selection of modern, high-flow Affinity and Ion Exchange agarose resins, delivering exceptional results from Protein A to high-resolution polishing steps. The range also includes a full selection of ***Praesto*** Pure base matrices, and pre-activated resins in a variety of source chemistries.

All ***Praesto*** products provide an advanced, high-flow, highly cross-linked agarose base matrix. The entire range benefits from excellent pressure/flow characteristics and stability for optimal recovery of active proteins.

Discover ***Praesto*** at: **www.purolite.com/life-sciences**

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Uzbekistan

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