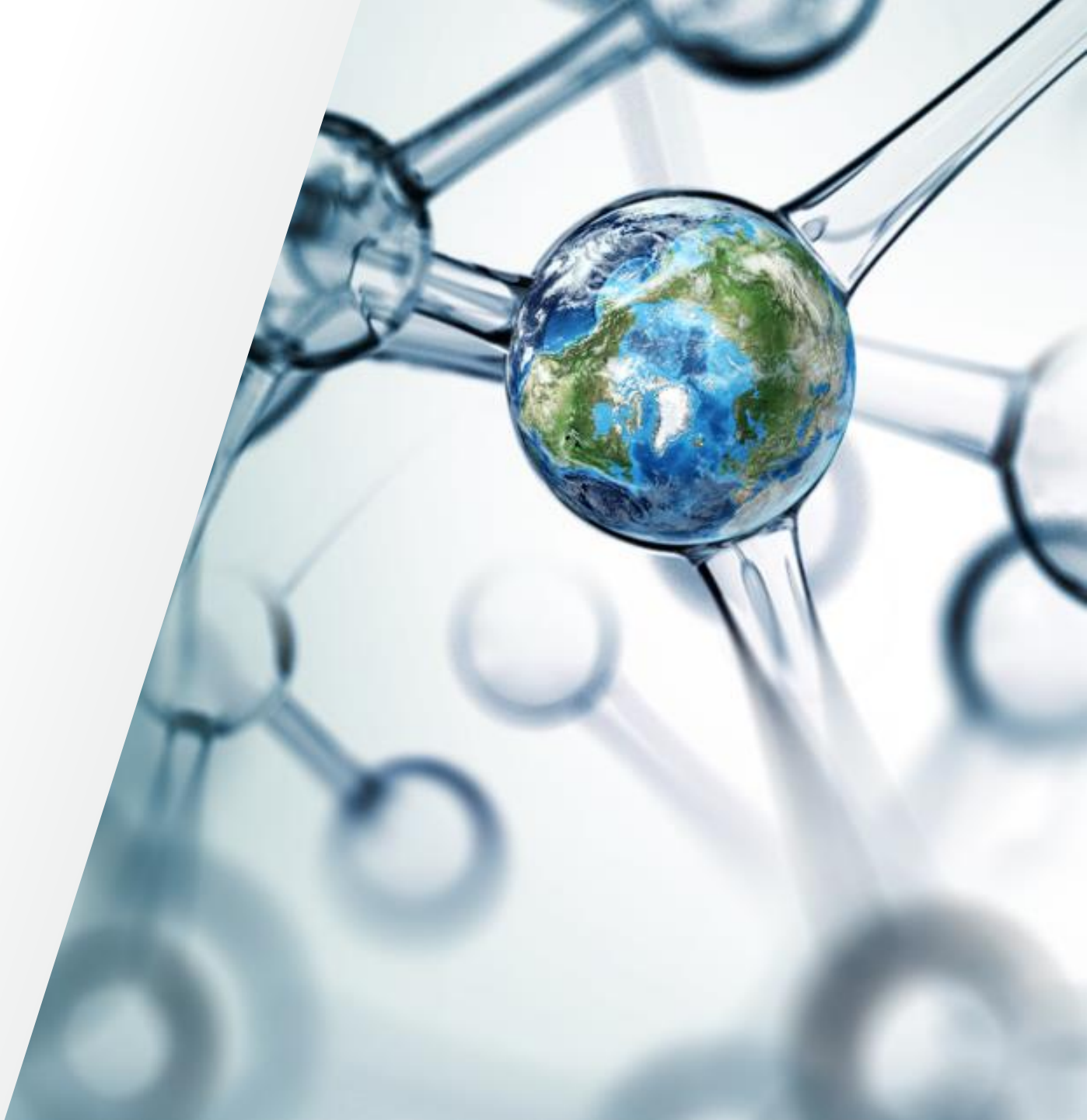
CaptureSelect™ FcXP Affinity Matrix

Product release – September 2020

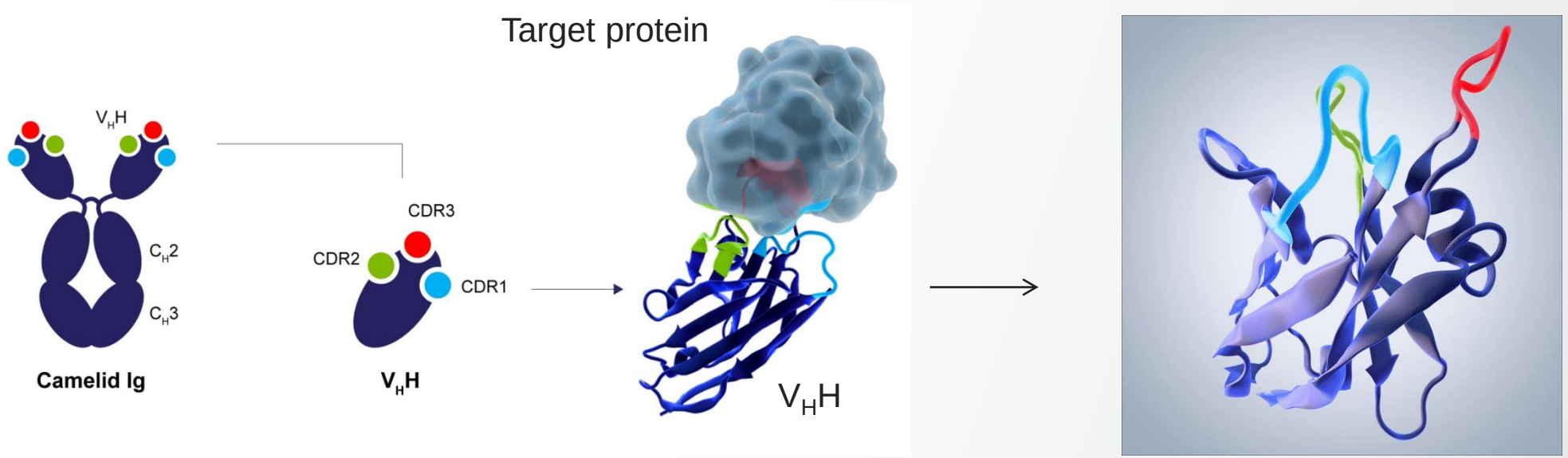


The world leader in serving science

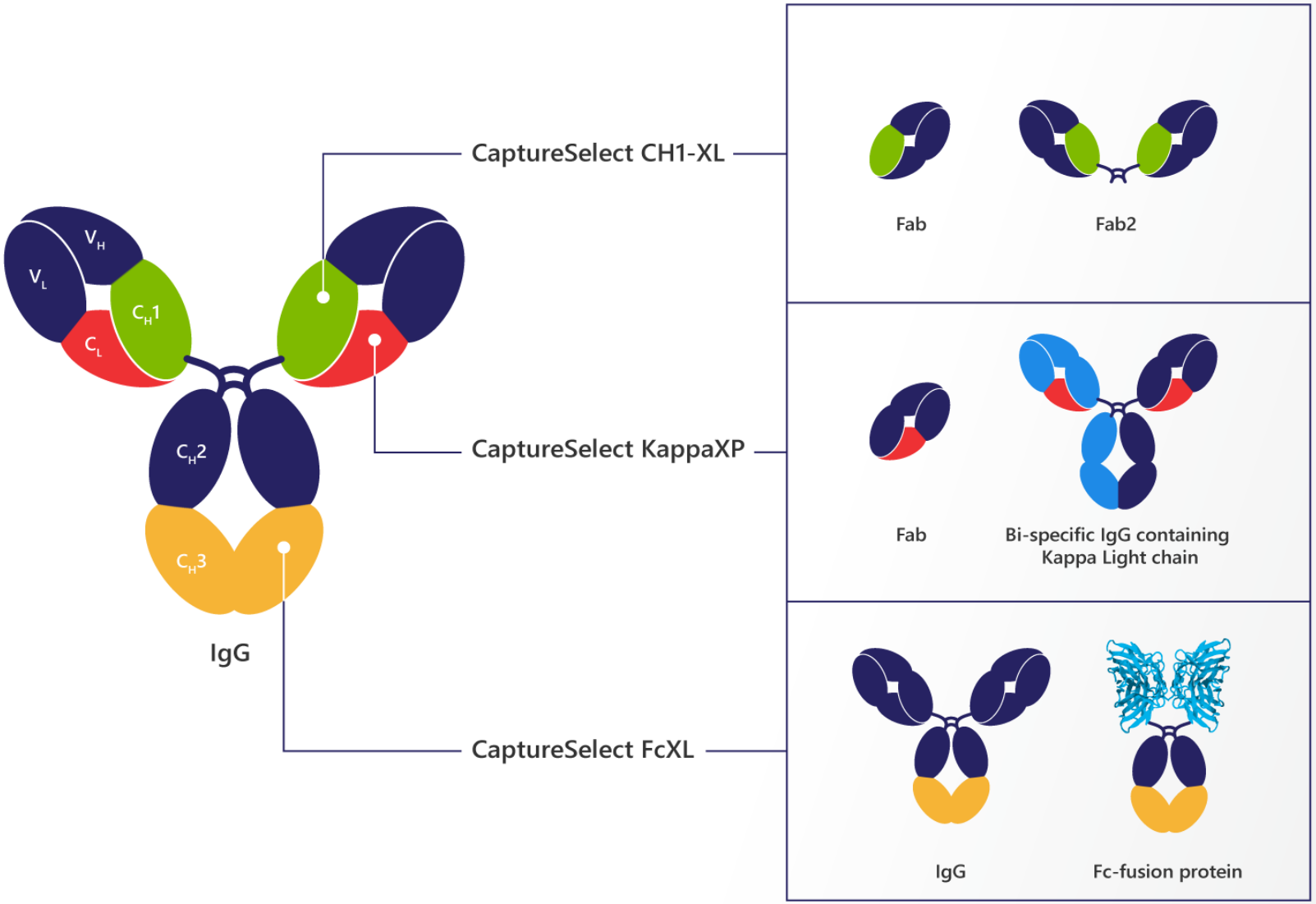
CaptureSelect™ Technology: Affinity Through Antibody Selectivity

- Unique screening technology for target specificity, mild elution, and stability
- V_HH affinity ligands are produced in yeast (*S. cerevisiae*) in an animal origin-free production process
- Products in commercial purification processes;
  proven custom ligand development program

Combining antibody-based selectivity and process robustness



Supporting development of next generation antibody therapeutics



- Fab purification platform
- Binding the CH1 domain
- No binding of free light chains

- Developed for Fab fragments and bi-specifics
- Binding C_L- kappa domain
- High Dynamic Binding Capacity
- Mild elution

- Developed for Fc fusion proteins and non-protein A binding IgGs
- Binding the CH3 domain (Fc)
- Mild elution

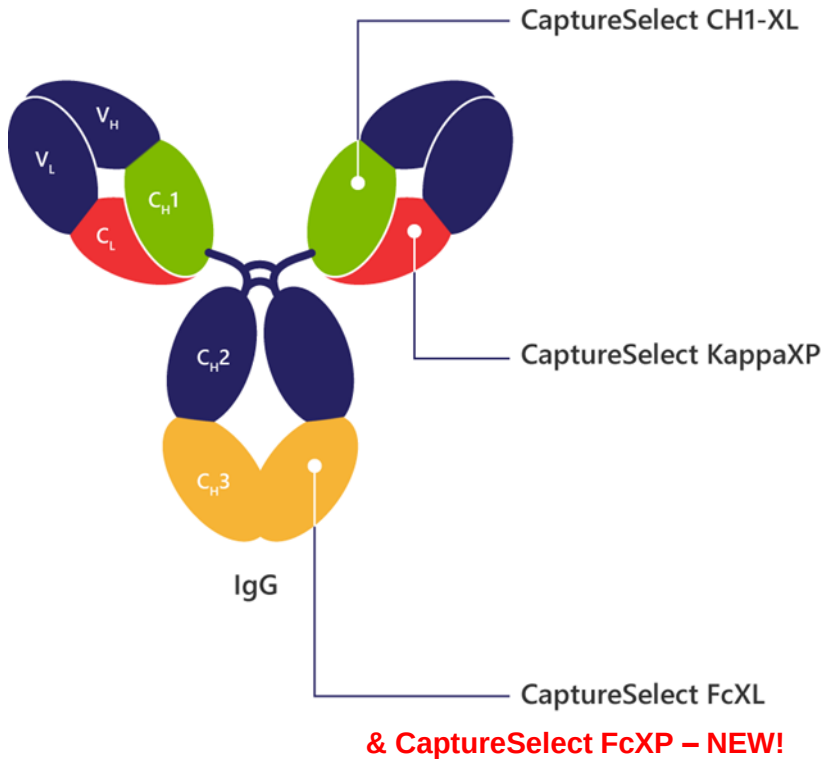
Products come with full regulatory support (RSF) enabling use in commercial manufacturing.

CaptureSelect™ FcXP Affinity Resin

Next generation Fc-binder

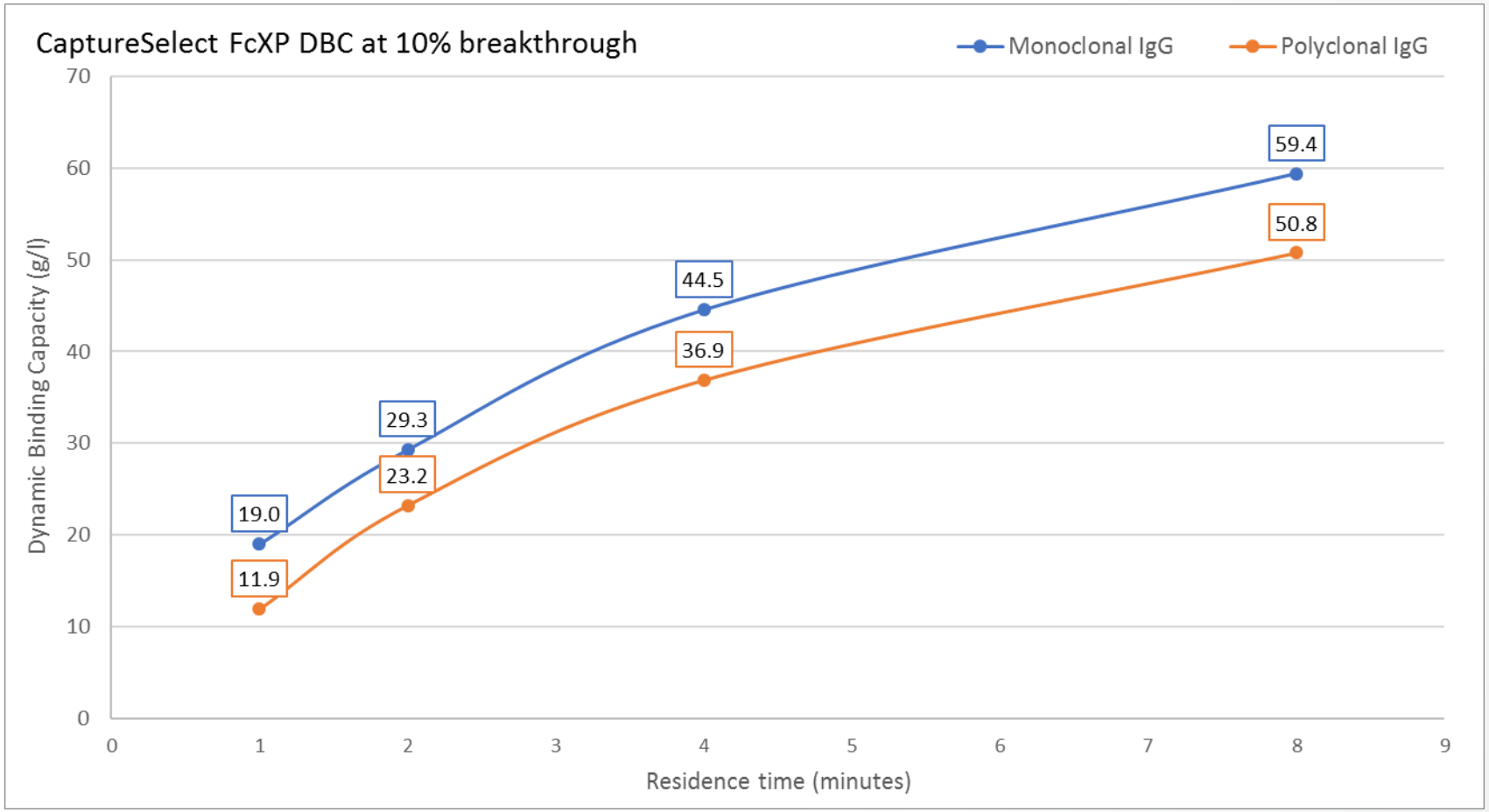
- Purification of recombinant human IgG, Fc fusion proteins and plasma derived IgG
- One step purification from crude material with high purity and yield
- Highly selective, binding occurs through the CH3 domain of human IgG
- Recognizes all human IgG classes (IgG1-4)
- High DBC: >40 g/L (10% breakthrough / 5 min residence time)
- Mild elution at pH 4.0 – 4.5, making it suitable for Fc fusion proteins
- Excellent scalability
- Non-animal-derived

CaptureSelect antibody selectivity



& CaptureSelect FcXP – NEW!

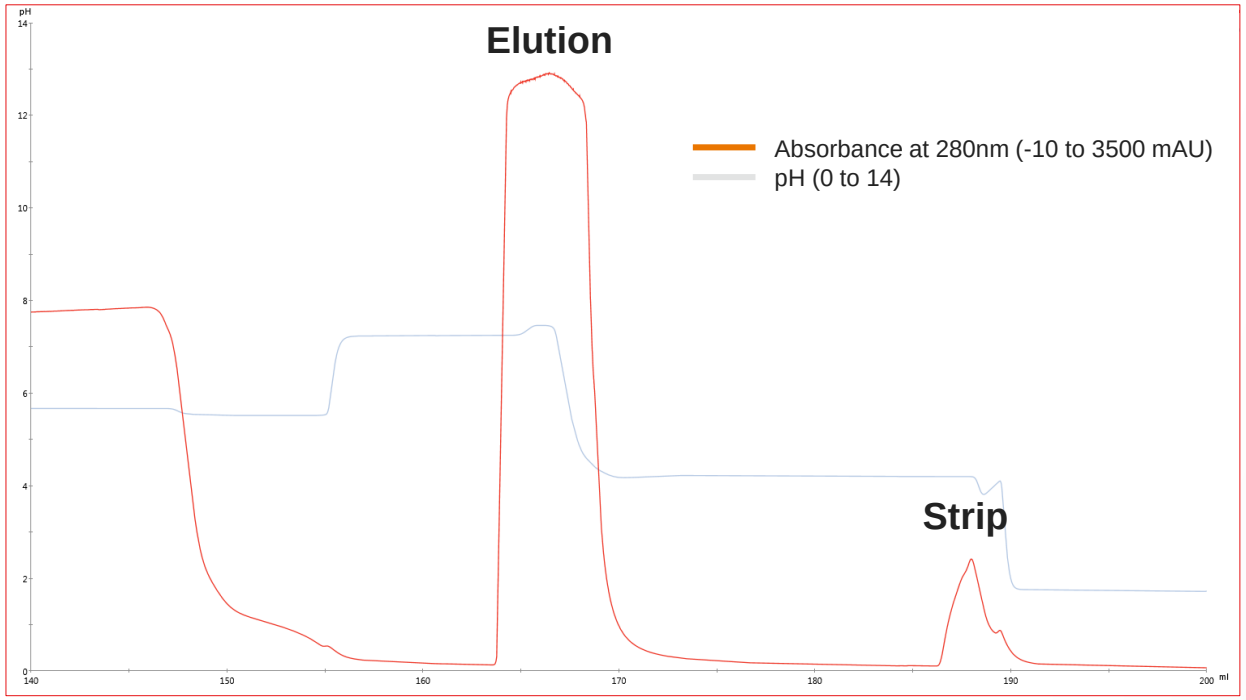
Dynamic Binding Capacity at 10% breakthrough

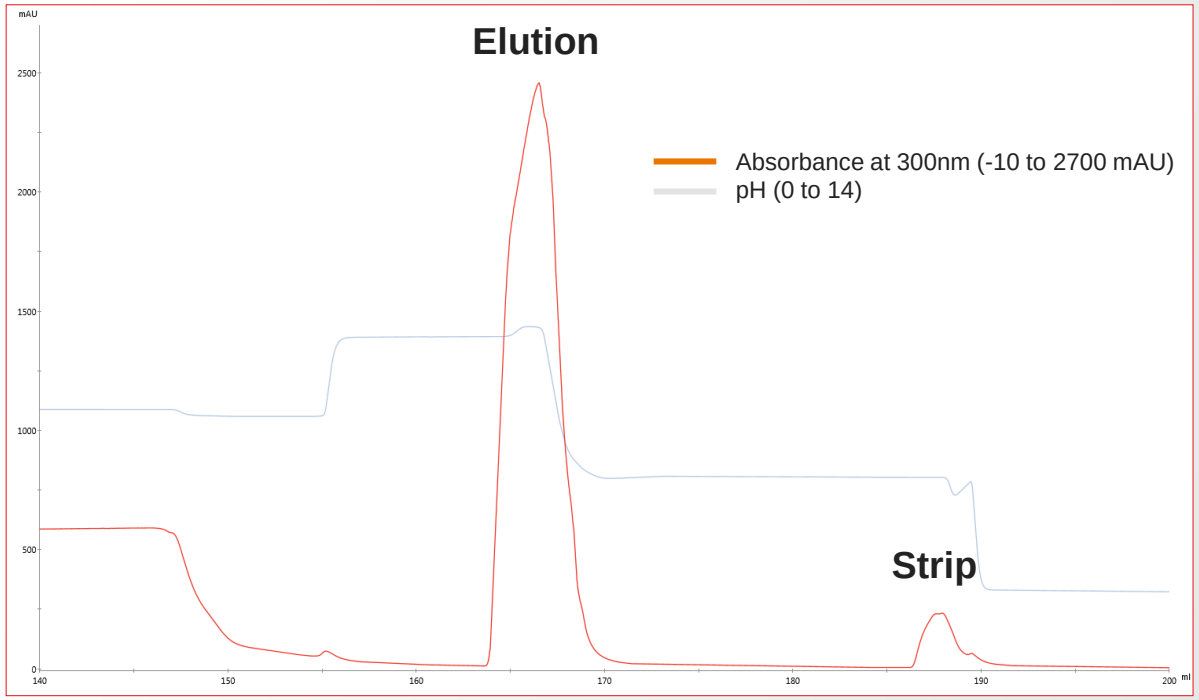


Capacities measured with monoclonal Rituximab (titer: 5 g/l) and Polyclonal IgG (titer: 7g/l) on 4 ml columns (0.5 x 20 cm). Bound protein eluted using 20 mM Citric Acid pH 4.0

CaptureSelect FcXP affinity resin shows high binding capacity with both monoclonal and polyclonal IgG

Elution conditions



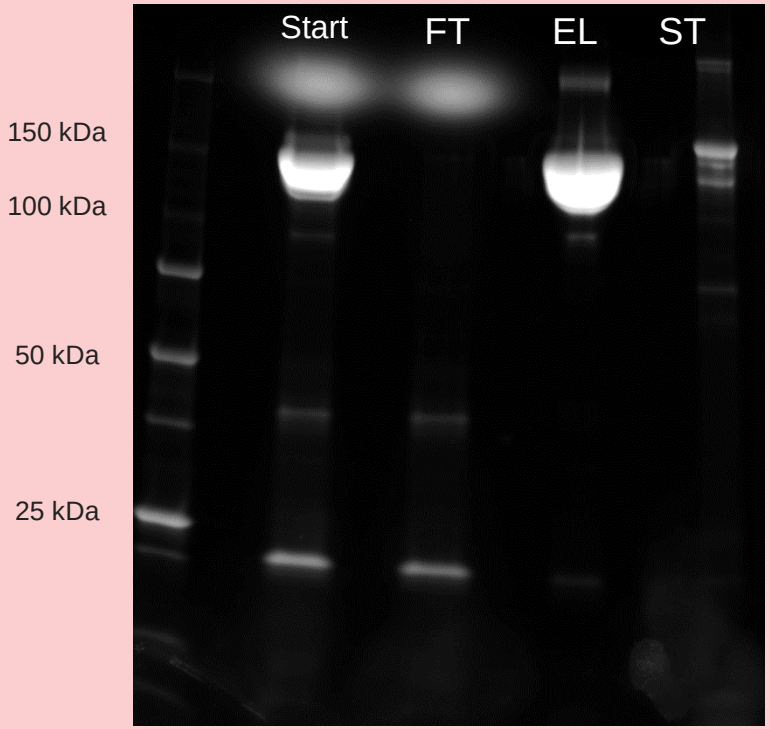


Elution efficiency with monoclonal antibody feed (Rituximab, titer 1.7 g/l) at 8 min residence time. Bound mAb eluted using 20 mM Acetic Acid pH 4.0 and stripped with 100 mM Glycine pH 2.0.

CaptureSelect FcXP affinity resin demonstrates efficient elution at mild pH (>95% at pH4.0)

Purity analysis

Rituximab one-step purification



Overexpressed light chain and light chain dimers present in flow through, not in elution

Start - Rituximab, monoclonal human/mouse chimeric IgG1 (1.7 g/l)

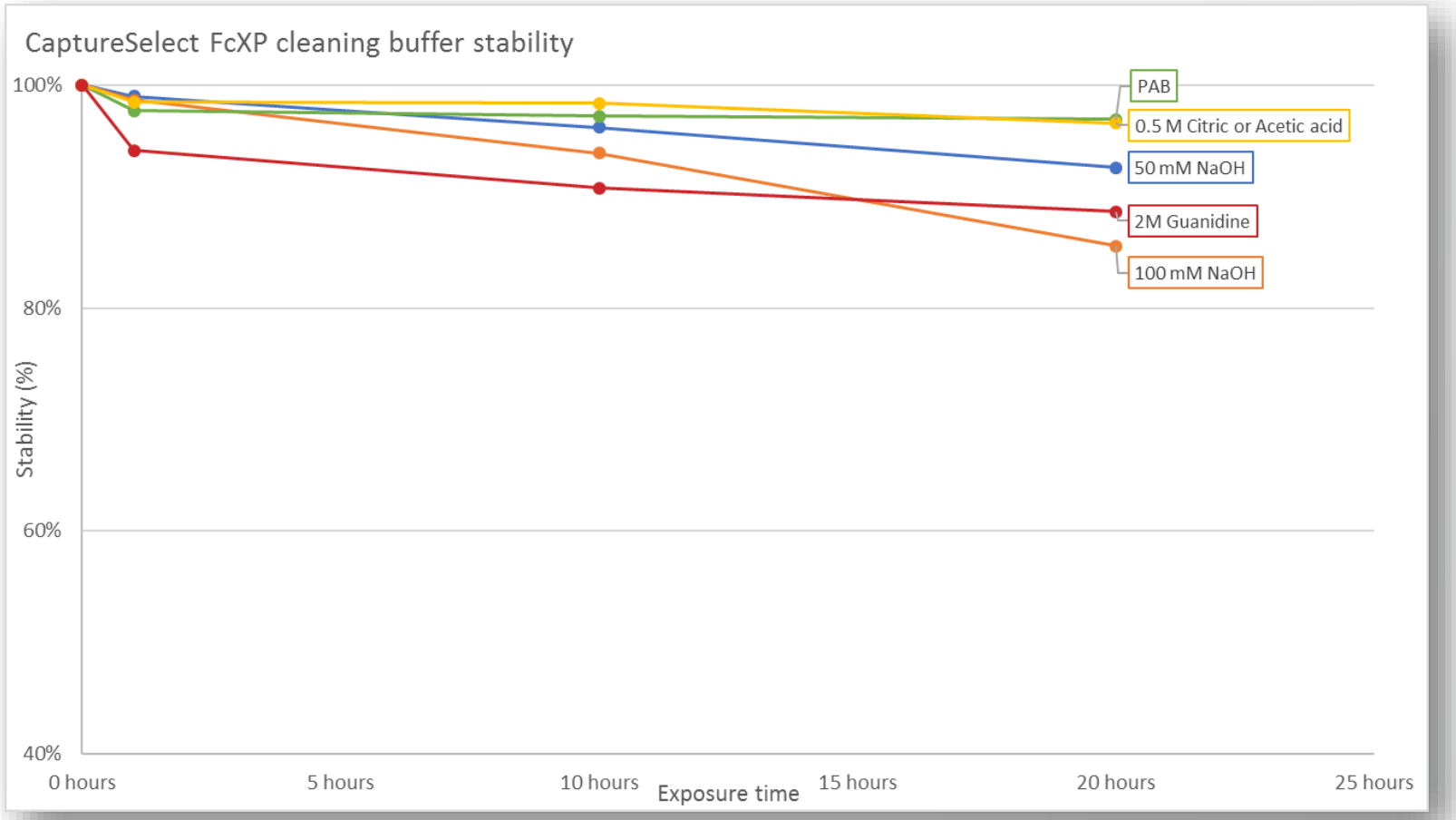
FT – flowthrough fraction

EL – 10 x diluted pH 4.0 elution fraction

ST – pH 2.0 strip

One step purification from crude material with high purity and yield

Cleaning buffer stability



Cleaning buffer exposure using a static hold for 1, 10 and 20 hours. Saturated capacities measured with Polyclonal IgG at 0.8 min residence time. Bound IgG Eluted using 20 mM Citric Acid pH 4,0 (>95%).

CaptureSelect FcXP resin demonstrates good stability with acidic cleaning solutions, chaotropic solutions and caustic up to 100mM NaOH

CaptureSelect FcXP advised cleaning strategy

Acidic strip after every run

- 0.1-0.5 M Citric Acid pH 2 (has chelating properties)
- When preferred, other acids can be used

Additional cleaning/sanitization steps (when needed)

- Process optimization mainly depending on type of feed
    - Cleaning after every run, or after 2-5 runs with 50-100 mM NaOH
- Acidic cleaning with PAB (phosphoric acid, acetic acid, benzyl alcohol as alternative for NaOH

Suggested protocol to start resin evaluation

Equilibration buffer

- PBS or Tris buffered saline (TBS)

Load

- Clarified cell culture harvest or plasma

Intermediate wash

- Wash out the load with equilibration buffer
- Additional wash step: equilibration buffer with additives or combinations of additives:
  - NaCl: up to 1.0 M
  - Arginine: up to 0.5 M
  - Detergent: 0.05% Tween 20

Elution

- 20 mM acetic acid pH 4

Strip

- 0.5 M acetic or citric acid

CIP

- 50-100 mM NaOH or PAB (120 mM phosphoric acid, 167 mM acetic acid and 2.2% (v/v) benzyl alcohol)

CaptureSelect FcXP resin characteristics and available products

MAIN RESIN CHARACTERISTICS

Matrix: agarose-based, epoxide activated
Average particle size: 65 ± 10 µm
Ligand: CaptureSelect™ FcXP affinity ligand
Ligand immobilization method: Epoxide immobilization of the ligand
Binding capacity: 40-50 g/L resin depending on flow rate, column height and contact time
Elution conditions: 20 mM acetic acid, pH 4.0-4.5
Flow characteristics: 50-200 cm/h (up to 2 bar)
Formulation buffer: 20%(v/v) ethanol

* Regulatory support package available (RSF) on request, enabling use in commercial manufacturing

Cat. No	Product	Size
1943712005	CaptureSelect FcXP Affinity Matrix	5 mL
1943712010	CaptureSelect FcXP Affinity Matrix	10 mL
1943712050	CaptureSelect FcXP Affinity Matrix	50 mL
1943712250	CaptureSelect FcXP Affinity Matrix	250 mL *
194371201L	CaptureSelect FcXP Affinity Matrix	1L *
194371205L	CaptureSelect FcXP Affinity Matrix	5L *
810371201	CaptureSelect FcXP Ligand Leakage ELISA kit	1 assay
810371210	CaptureSelect FcXP Ligand Leakage ELISA kit	10 assays
7103262100	CaptureSelect Biotin FcXP conjugate	100 µg
7103262500	CaptureSelect Biotin FcXP conjugate	500 µg
5943712200	CaptureSelect FcXP RoboColumn™	200 µl
5943712001	CaptureSelect FcXP MiniChrom Column	1 mL
5943712005	CaptureSelect FcXP MiniChrom Column	5 mL
6943712071	CaptureSelect FcXP EvolveD™ column	385 mL, 7x10 cm *
6943712072	CaptureSelect FcXP EvolveD™ column	770 mL, 7x20 cm *
6943712101	CaptureSelect FcXP EvolveD™ column	785 mL, 10x10 cm *
6943712102	CaptureSelect FcXP EvolveD™ column	1570 mL, 10x20 cm *
6943712201	CaptureSelect FcXP EvolveD™ column	3142 mL, 20x10 cm *
6943712202	CaptureSelect FcXP EvolveD™ column	6284 mL, 20x20 cm *

"For Research Use or Further Manufacturing. Not for use in diagnostic use or direct administration into humans or animals"