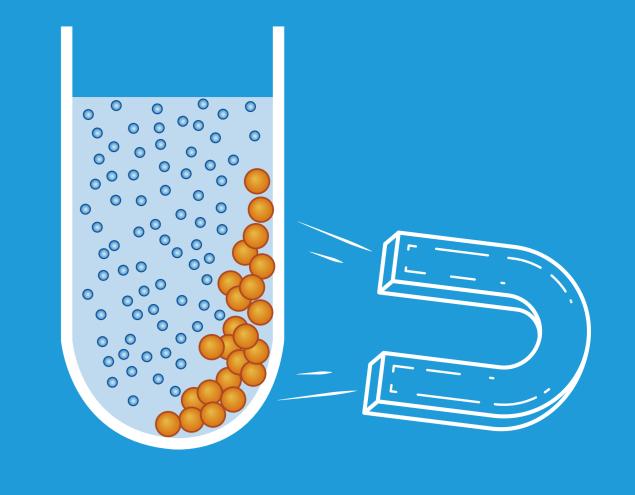
Novel Solutions for High Throughput Antibody Purification Using Magnetic Platform

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Abstract

High throughput purification is a critical step for antibody engineering and screening. Protein purification using traditional protein A resin columns is limited by throughput and a complicated sample preparation process, which makes it challenging to extend to high throughput antibody purification. Magnetic beads-based purification systems are simpler to operate as they eliminate the need to remove cells by centrifugation and sample filtration, and are easily applied to high throughput purification while providing significant savings in time and labor. Here we present novel solutions that enable high-throughput antibody purification using magnetic beads. The techniques thus described are expected to significantly speed up antibody purification and screening while increasing cost-effectiveness.

Background

Antibody drug discovery and development process



To make antibody purification and screening process faster and easier

Magnetic purification platform from GenScript







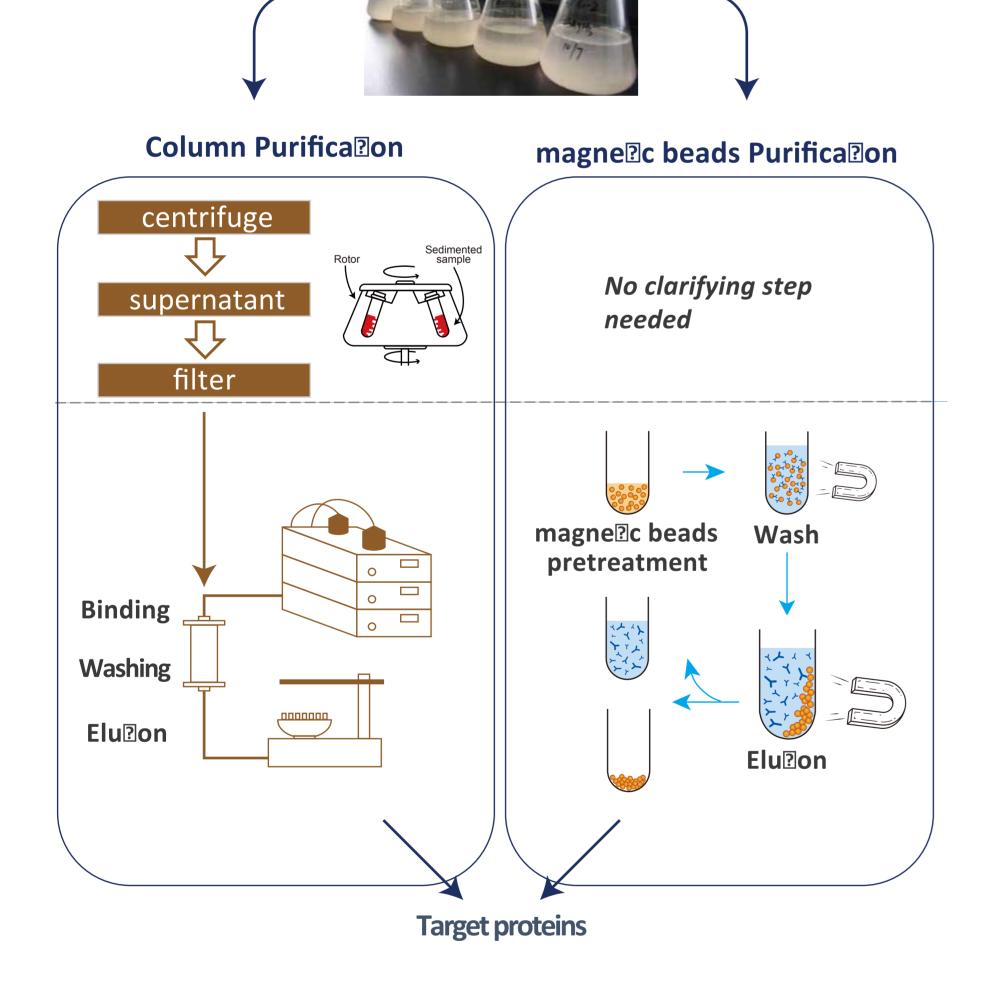


AmMag[™] MR AmMag[™] BOX
magnetic rack (15/50 ml tubes) (6-deep well plate / 50 ml tubes)

AmMag[™] SA
(Semi automatic magnetic purification)

GenScript provides a fully automated solution for magnetic beads purification including Alkaline-resistant AmMag[™] beads, Magnetic rack and Box for small scale protein purification. The small-automatic purification system, AmMag SA, is designed to save time and labor by integrating the incubation, wash and elution steps together for a one-button operation.

The comparison between magnetic purification and traditional column purification



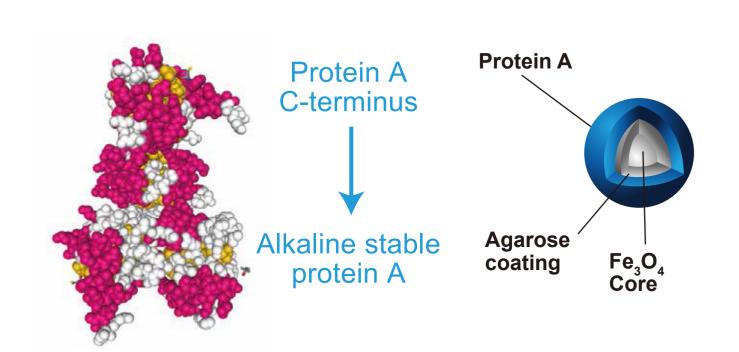
The advantages of magnetic beads purification

- No need for clarification process
- Works with up to 50 ml or even larger cell cultures
 Save time and labor (Save ~ 70% time of column purification)
- Higher throughput (2-3 times higher than column purification)

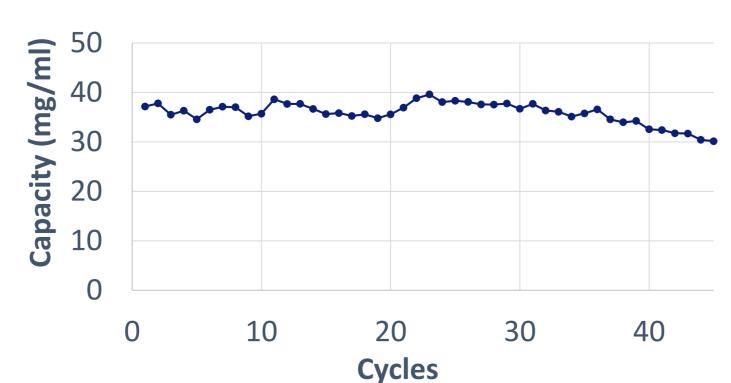
AmMag[™] protein A magnetic beads

AmMag[™] protein A magnetic beads are alkaline-resistant magnetic beads that can be re-used multiple times while maintaining low endotoxin levels during antibody purification. The high binding capacity minimizes the use of beads to further reduce the cost of purification. Cell viability assay demonstrated that the cell viability was not affected after beads were added to the cell culture, which allowed direct purification from cell culture without centrifugation and filtration.

- Unique Alkaline-resistant ligand
- Fast magnetic response

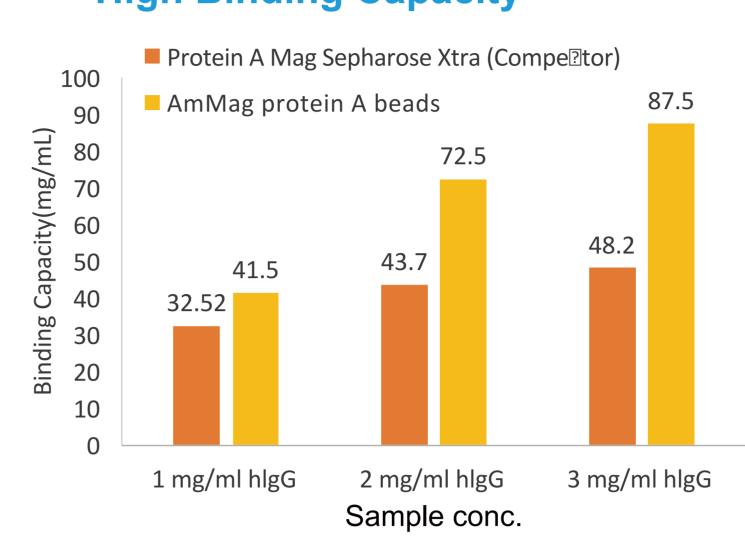


Reusability and Alkaline resistance

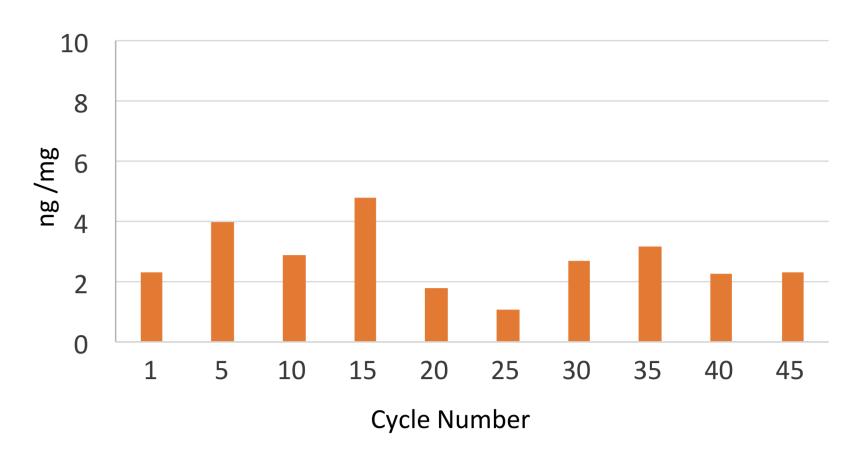


The capacity is reduced 20% after 45 cylces 0.1M NaOH treatment (1 h per cycle)

High Binding Capacity

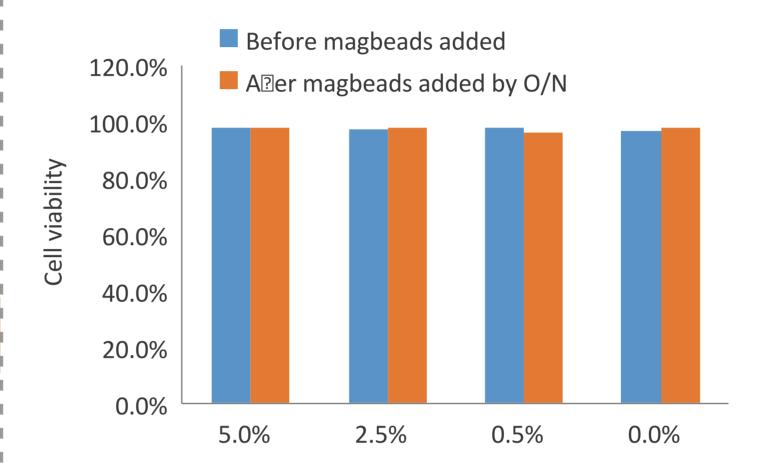


Protein A Leakage in Purified Sample



Protein A leakage is lower than 10 ng/mg after 45 cycles of magnetic beads use.

Cell viability not affected after magnetic beads added



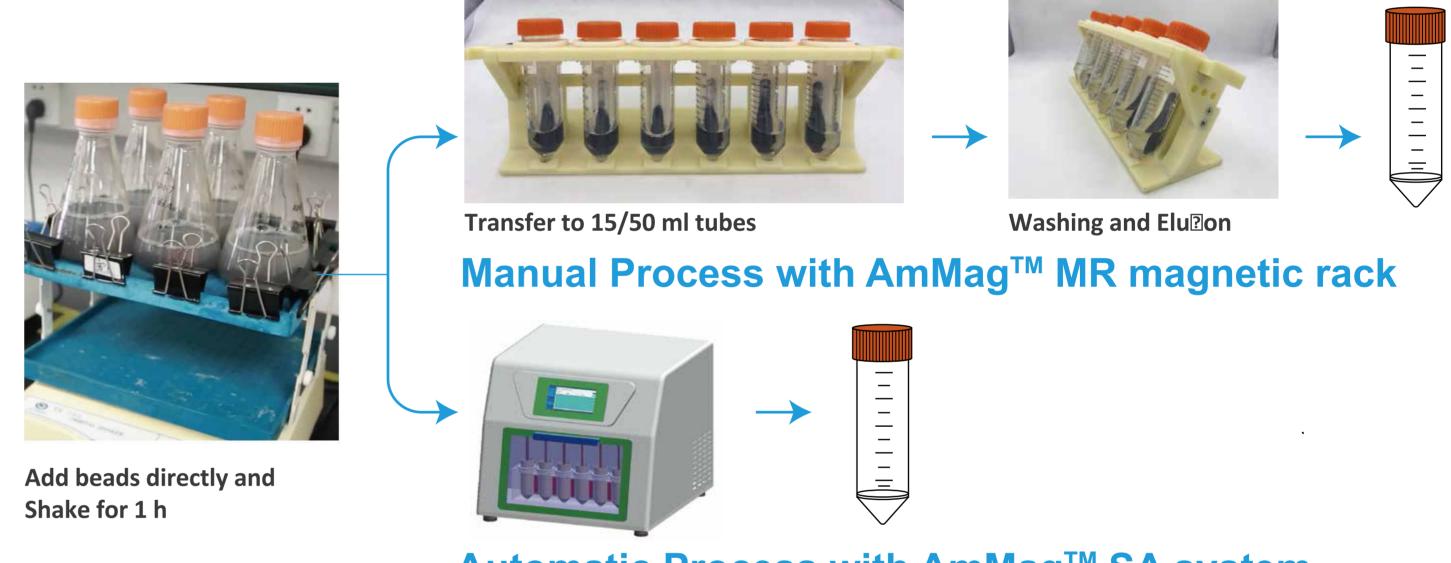
HCP and Endotoxin Comparison

Sample	AdjConc (ug/mL)	HlgG1 (mg/ml)	HCP (ug/mg)
magne?c beads	42.201	20.7	2.039
AKTA/Resin	54.408	18.9	2.879

Endotoxin detection:

Samples	magne?c beads	Resin	
#1	<1 EU/mg	<1 EU/mg	
#2	<1 EU/mg	<1 EU/mg	
#3	<1 EU/mg	<1 EU/mg	
#4	<1 EU/mg	<1 EU/mg	

AmMag™ Purification System



Automatic Process with AmMag™ SA system

AmMag[™] SA can purify 6 samples per batch with auto-washing and elution process. It allows for an easier high-throughput compared with manual process.

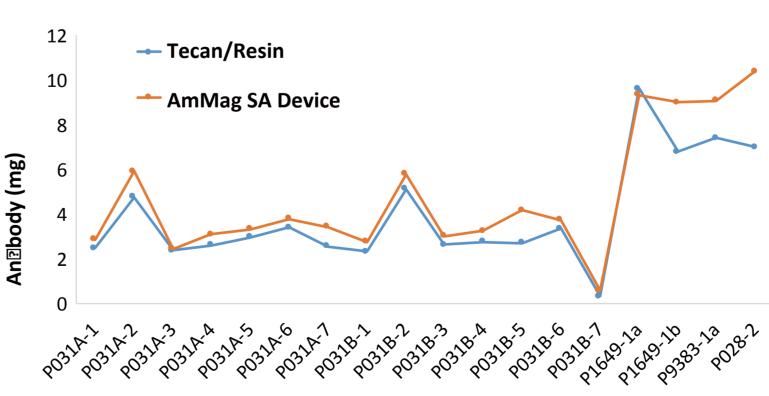
Compared with Tecan Freedom, it provides more flexibility, faster process time, and much more economical in cost, but comparable result.

AmMag[™] SA vs 8-channel Tecan-Freedom

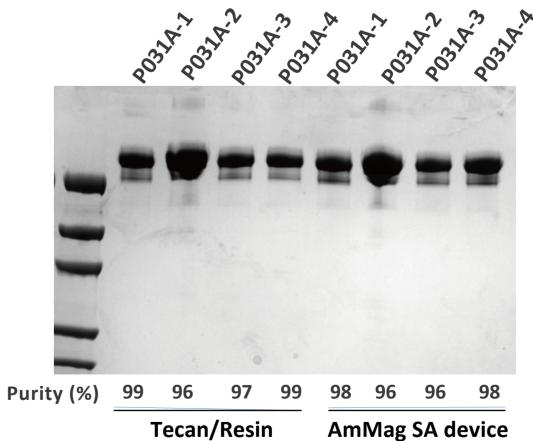
To compare antibody purification between AmMag SA and Tecan-Freedom, 18 antibody-expressed cell culture samples (20 ml/samples) were tested and analyzed as below.

	Device prepare (h)	Samples pretreat (Centrifuge and filter) (h)	Prepare before binding (h)	Binding (Incubaion) (h)	Washing and elu⊡on (h)	Total 2me (h)
Tecan 18 Samples	1	0.5	0.5	5.5	1.5	9 h
AmMag SA 18 Sampl	es 0.5	0	0.5	1	1	3 h

Higher antibody recovery rate



Comparable purity



Summary

- ► Magnetic beads platform eliminates the needs for centrifugation and filtration and significantly simplifies the purification process.
- ► Magnetic beads platform reduces both time and labor by more than 3-fold compared to column process.
- ► Antibody quality after magnetic bead purification is comparable with resin method.
- AmMag protein A magnetic beads are resistant to alkaline treatment and offer high capacity and reusability.

