

Biologics Workflow

AGGREGATE ANALYSIS

by Size Exclusion Chromatography



bioZen[™]
the bio series



New bioZen SEC columns provide:

- High efficiency on both HPLC and UHPLC
- Extreme inertness and robustness
- Finely tuned high and low MW separation windows

Ti PLUS!

Biocompatible titanium hardware minimizes priming and reproducibility concerns!

phenomenex[®]
...breaking with traditionSM

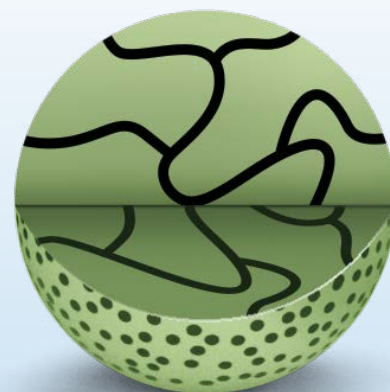
www.phenomenex.com/bioZen



One Particle Platform

With mAb aggregate often at very low levels (<0.1 % by peak area compared to monomer) and fragment separation a requirement, adequate resolution and peak shape have become even more crucial to method outcomes. To address this need, the robust set of bioZen SEC columns were developed with a combination of UHPLC efficiency and higher sensitivity, to drive resolution and identification of even lower level targets.

- High Efficiency
- Excellent Inertness
- Increased Sensitivity
- Exceptional Quality and Robustness



Thermally Modified Fully Porous



bioZen SEC-2
1.8 μ m

Extremely inert, high density fully porous particle with high efficiency and low molecular weight (LMW) separation range of 1 k–450 kDa.

Best choice for
HMW aggregates!



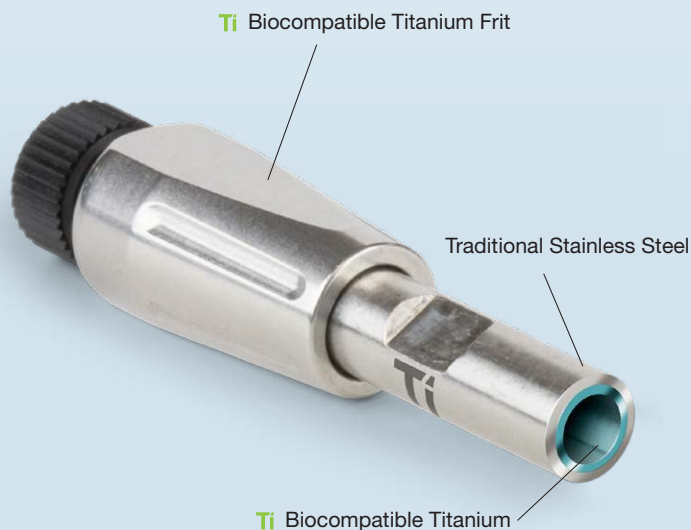
bioZen SEC-3
1.8 μ m

Extremely inert, high density fully porous particle with high efficiency and high molecular weight (HMW) separation range of 10 k–700 kDa.

Biocompatible Hardware

WOOHOO!

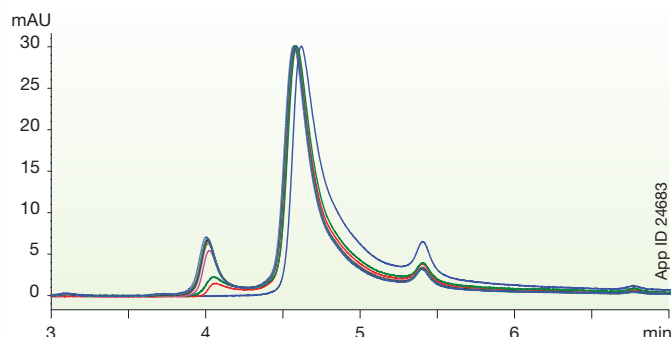
bioZen™ SEC columns come in titanium BioTi™ HPLC/UHPLC hardware that curtails lengthy priming steps, unwanted secondary interactions, problematic carryover, and recovery issues between injection to detection.



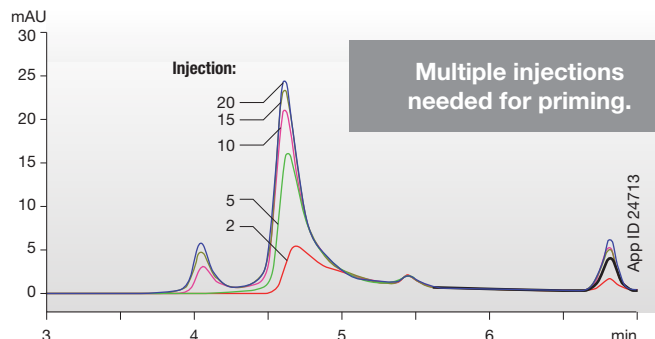
Overlaid Successive Injections

Protein Priming Comparison

bioZen™ Titanium BioTi™ Hardware



Traditional Stainless Steel



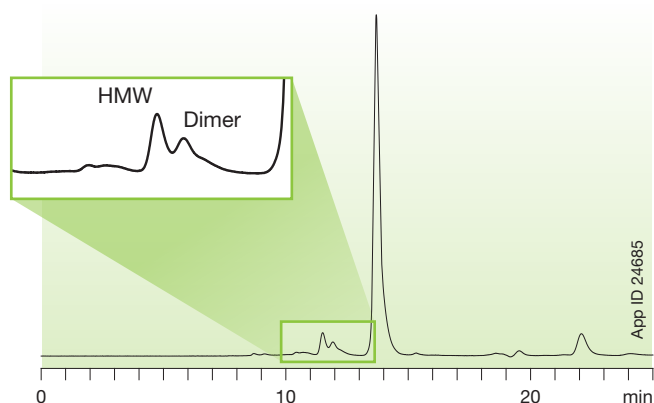
Conditions for both columns:

Column: bioZen 1.8 µm SEC-3
Dimension: 150 x 4.6 mm
Mobile Phase: 100 mM Sodium Phosphate Buffer (pH 6.8)
Flow Rate: 0.3 mL/min
Temperature: Ambient
Detection: UV @ 280 nm
Sample: 1. γ-Globulin
2. Ovalbumin

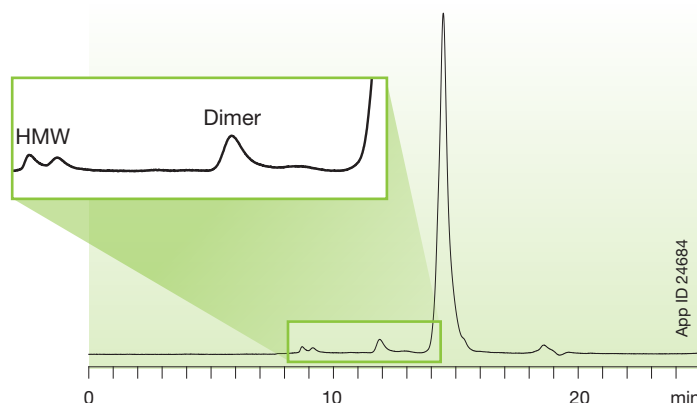
Aggregate Analysis

by Size Exclusion

Adalimumab



Trastuzumab

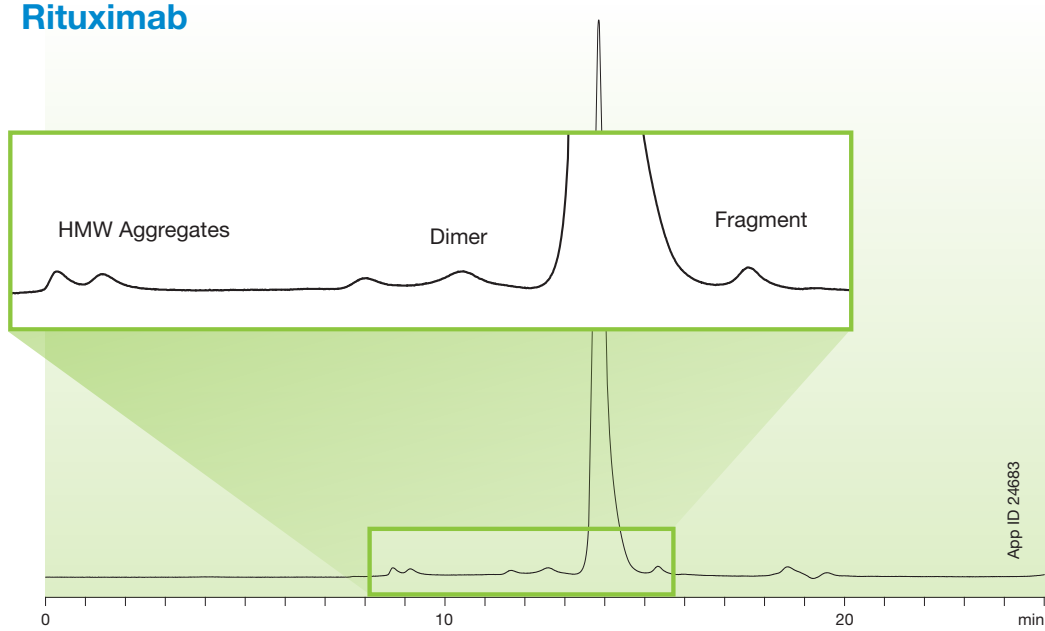


Conditions same for both samples:

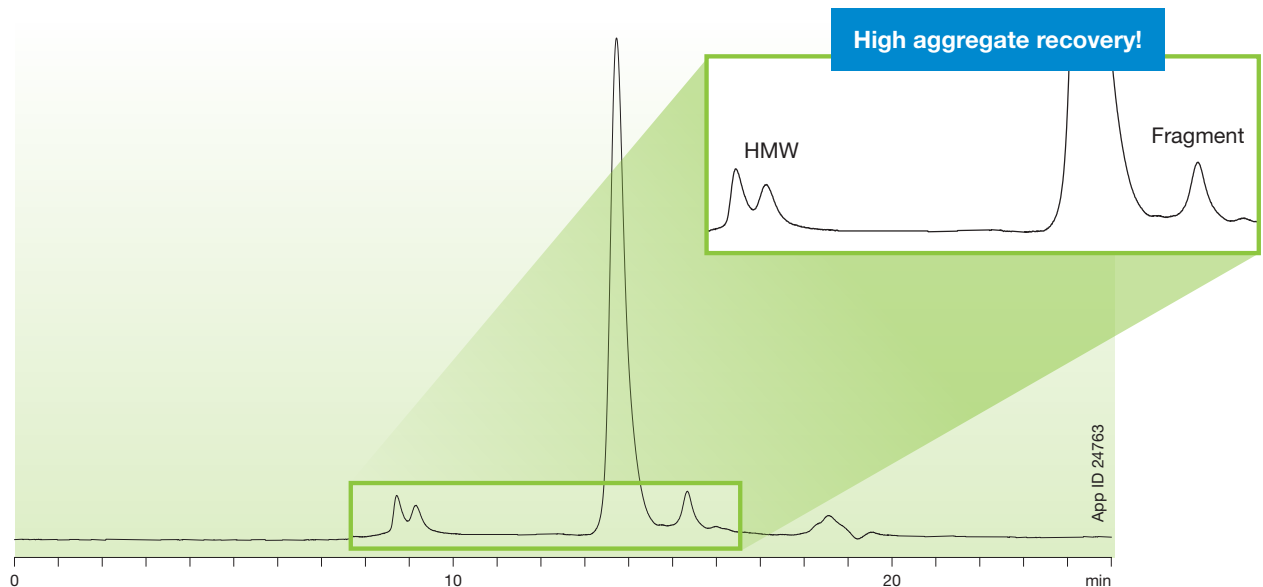
Column: bioZen 1.8 µm SEC-3
Dimension: 300 x 4.6 mm
Part No.: 00H-4772-E0
Mobile Phase: 50 mM Dipotassium phosphate + 100 mM Sodium sulphate (pH 6.8)
Flow Rate: 0.2 mL/min
Temperature: 25 °C
Detection: UV @ 280 nm
Sample: As Noted

Aggregate Analysis by Size Exclusion

Rituximab



Cetuximab

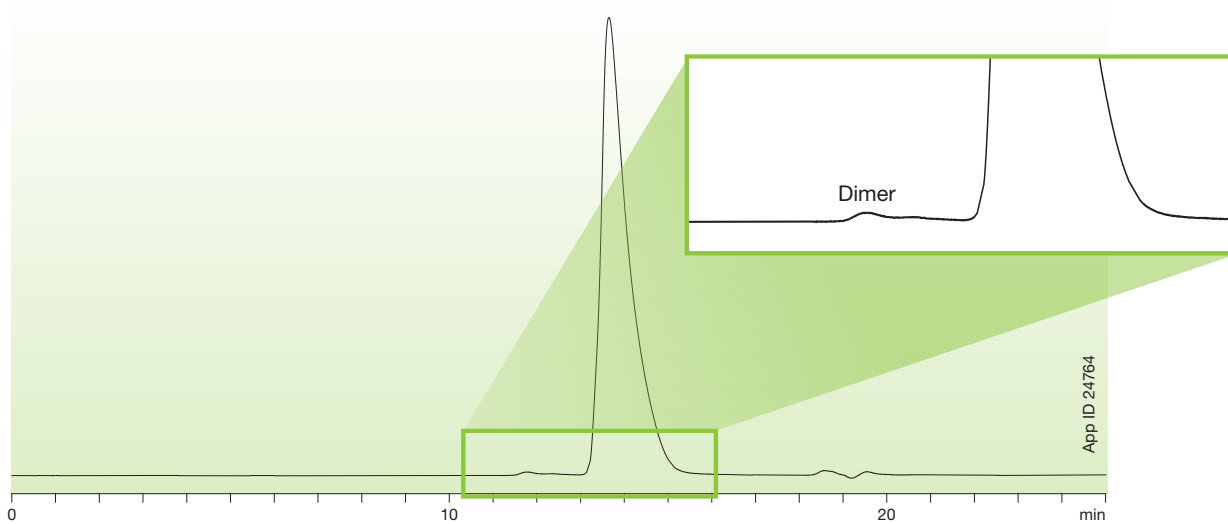


Conditions same for all samples:

Column: bioZen™ 1.8 µm SEC-3
Dimension: 300 x 4.6 mm
Part No.: 00H-4772-E0
Mobile Phase: 50 mM Dipotassium phosphate + 100 mM Sodium sulphate (pH 6.8)
Flow Rate: 0.2 mL/min
Temperature: 25 °C
Detection: UV @ 280 nm
Sample: As Noted

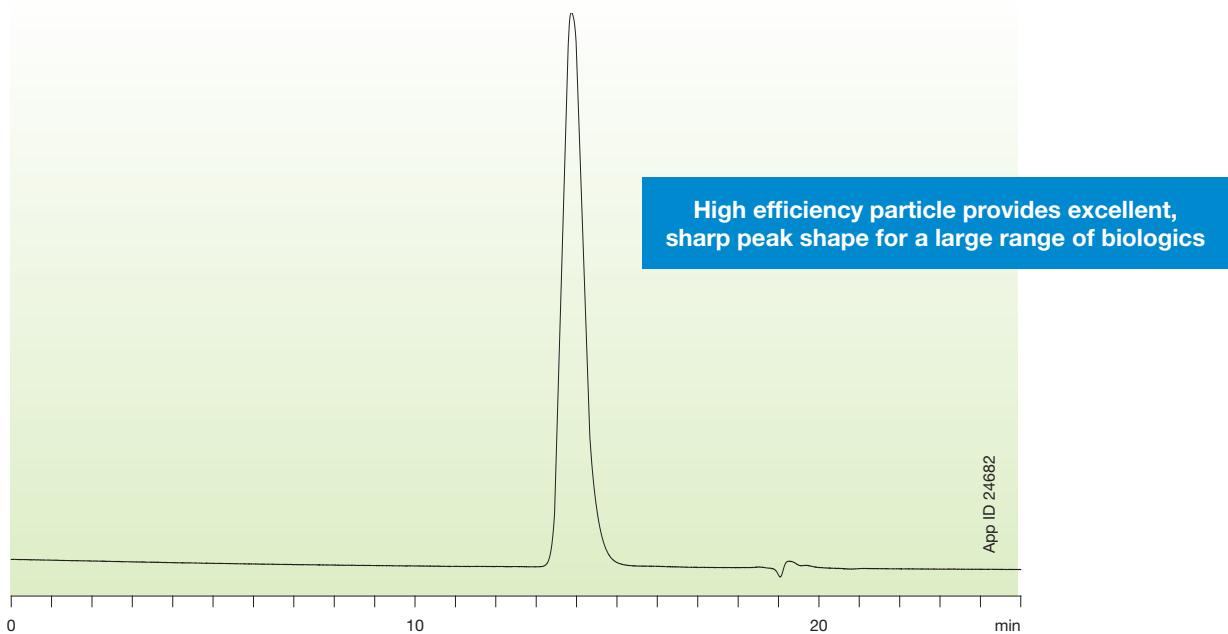
Aggregate Analysis by Size Exclusion

Infliximab



ADC Analysis

Herceptin - mcMMAF



Conditions same for all samples:

Column: bioZen™ 1.8µm SEC-3
Dimension: 300 x 4.6 mm
Part No.: 00H-4772-E0
Mobile Phase: 50 mM Dipotassium phosphate + 100 mM Sodium sulphate (pH 6.8)
Flow Rate: 0.2 mL/min
Temperature: 25 °C
Detection: UV @ 280 nm
Sample: As Noted



Acknowledgment

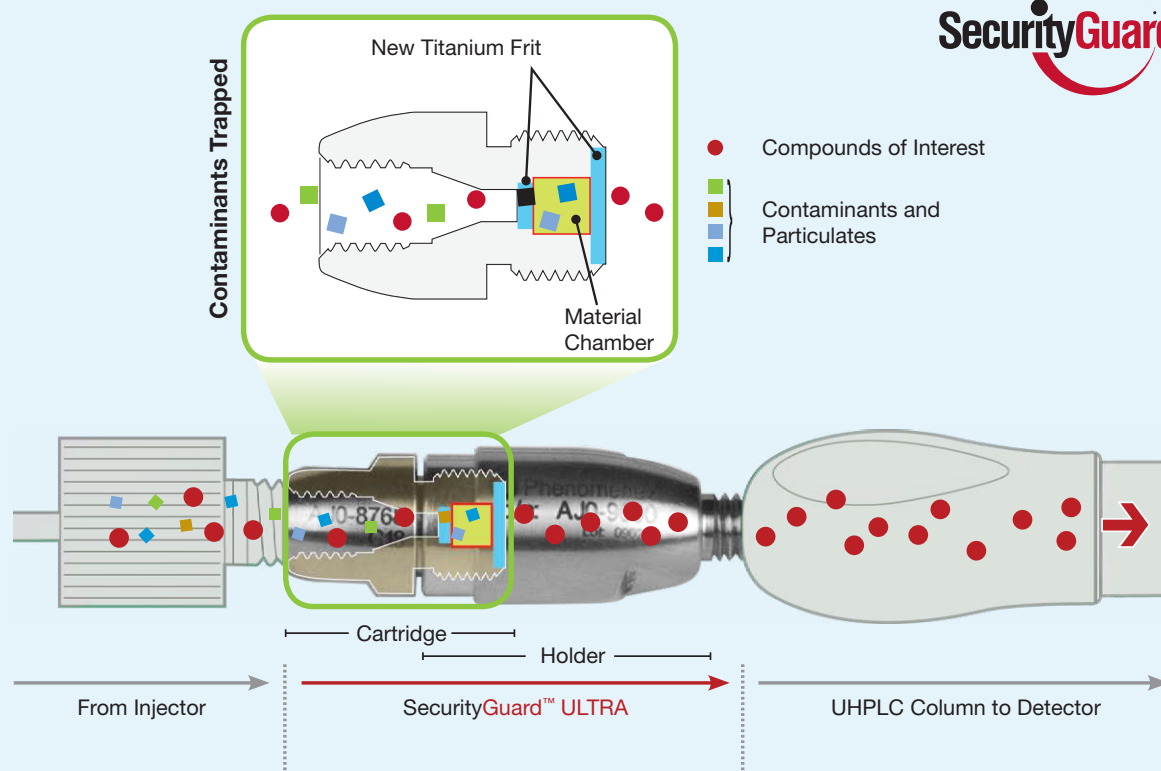
We would especially like to thank Colin McKee and ADC Biotechnology LTD for their support and ADC samples for this application.

Biocompatible Column/System Protection



The easiest way to extend column performance and minimize costly system and detector upkeep is to prevent contaminants and particulates from getting into and past your LC column with a guard system. SecurityGuard guard cartridge systems provide this protection and truly make it easy to acquire this benefit on both HPLC and UHPLC systems.

SecurityGuard ULTRA Guard Cartridge System with Titanium



* Cartridge schematic not drawn to scale

Ensure Protein Recovery with Biocompatible Accessories!



Phenex Syringe Filters

PES membranes offer fast-flow and ultra-low protein binding

www.phenomenex.com/SFfinder



Verex Vials, Caps, and Kits

Wide-range of certified vial and cap products to ensure precision

www.phenomenex.com/VialFinder



bioZen Column Selection

Peptide Mapping

- bioZen Peptide PS-C18
- bioZen Peptide XB-C18

Glycan Analysis

- bioZen Glycan

Intact and Fragment Analysis

- bioZen Intact C4
- bioZen Intact XB-C8

Peptide Quantitation

- bioZen Peptide PS-C18
- bioZen Peptide XB-C18

Aggregation

- bioZen SEC-3

Total mAb

- bioZen SEC-2
- bioZen SEC-3

Intact Mass

- bioZen Intact C4
- bioZen Intact XB-C8

Average DAR ADC

- bioZen Intact XB-C8

Product Ordering Information

bioZen™ Products - Powered by Biocompatible Hardware



bioZen Columns (mm)							Biocompatible Guard Cartridges		
	100 x 2.1	150 x 2.1					for 2.1 mm	Holder	
bioZen 2.6 µm Glycan	00D-4773-AN	00F-4773-AN					/3pk	ea	
	50 x 2.1	150 x 2.1					AJO-9800	AJO-9000	
bioZen 1.6 µm Peptide PS-C18	00B-4770-AN	00F-4770-AN					for 2.1 mm	Holder	
	50 x 4.6	150 x 4.6					/3pk	ea	
bioZen 3 µm Peptide PS-C18	00B-4771-E0	00F-4771-E0					AJO-9803	AJO-9000	
	50 x 2.1	150 x 2.1					for 4.6 mm	Holder	
bioZen 1.7 µm Peptide XB-C18	00B-4774-AN	00F-4774-AN					/10pk	/kit	
	50 x 2.1	150 x 2.1					AJO-7606	KJO-4282	
bioZen 2.6 µm Peptide XB-C18	00B-4774-AN	00F-4774-AN					for 2.1 mm	Holder	
	50 x 2.1	150 x 2.1	250 x 2.1	50 x 4.6	150 x 4.6	/3pk	ea		
bioZen 3.6 µm Intact C4	00B-4774-AN	00F-4774-AN					AJO-9806	AJO-9000	
	50 x 2.1	150 x 2.1	50 x 4.6	150 x 4.6		for 2.1 mm	Holder		
bioZen 3.6 µm Intact XB-C8	00B-4768-AN	00F-4768-AN	00G-4768-AN	00B-4768-E0	00F-4768-E0	/3pk	ea		
	50 x 2.1	150 x 2.1	50 x 4.6	150 x 4.6		AJO-9806	AJO-9808		
bioZen 1.8 µm SEC-2	00B-4767-AN	00F-4767-AN	00B-4767-E0	00F-4767-E0				AJO-9809	AJO-9811
	00B-4766-AN	00F-4766-AN	00B-4766-E0	00F-4766-E0				AJO-9812	AJO-9814
bioZen 1.8 µm SEC-3	00B-4766-AN	00F-4766-AN	00B-4766-E0	00F-4766-E0				for 4.6 mm	Holder
	150 x 4.6	300 x 4.6					/3pk	ea	
bioZen 1.8 µm SEC-2	00F-4769-E0	00H-4769-E0					AJO-9850	AJO-9000	
bioZen 1.8 µm SEC-3	00F-4772-E0	00H-4772-E0					AJO-9851	AJO-9000	

guarantee

If bioZen columns in this brochure do not provide at least equivalent separations to a competing column of the same phase, particle size, and dimensions, send in your comparative data within 45 days and keep the column for FREE!

AGGREGATE ANALYSIS

by Size Exclusion Chromatography



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Trademarks

bioZen, BioTi, SecurityGuard, Phenex, and Verex are trademarks of Phenomenex.

SecurityGuard is patented by Phenomenex. U.S. Patent No. 6,162,362

CAUTION: this patent only applies to the analytical-sized guard cartridge holder, and does not apply to SemiPrep, PREP or ULTRA holders, or to any cartridges.

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