

# Technical Notes

## Collagenase AF-1 GMP Grade Neutral Protease AF GMP Grade Safe, Gentle & Free of Animal-Derived Materials



### Animal-free GMP Grade Collagenase and Neutral Protease for Cell Isolation

Since 2015 Nordmark has offered the world's first highly purified collagenase and purified neutral protease **completely free of any animal-based components**.

Using raw materials from animal origin often causes concerns regarding the introduction of potential animal-derived pathogens. To rule out these concerns, Collagenase AF-1 GMP Grade and Neutral Protease AF GMP Grade are derived from *Clostridium histolyticum* grown in a medium containing carefully selected plantbased ingredients.



Dedicated collagenase GMP facility

By design, the sophisticated production process ensures that there is no crosscontamination with any animal-derived materials.

As a result, these enzymes provide the **highest level of safety and reduced regulatory hurdles**.

### Manufactured According to GMP Guidelines

Our animal-free enzymes are produced with the expertise of one of the world's largest manufacturers of collagenase, the pharmaceutical company Nordmark. Compliance with GMP guidelines guarantees the highest quality and a reliable lot-to-lot consistency.



### Highly Purified for Exact Dosage and Enzyme Stability

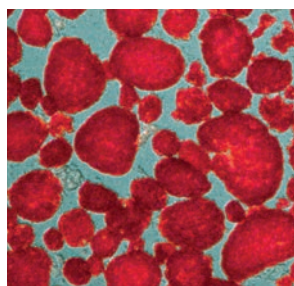
Additional enzymatic side activities are often essential for efficient cell isolation. For this reason, chromatographically purified Neutral Protease AF GMP Grade is provided separately, which offers the benefit of:

- > Individual and precise dosage
- > Greater stability of the enzymes
- > Optimized yield and viability

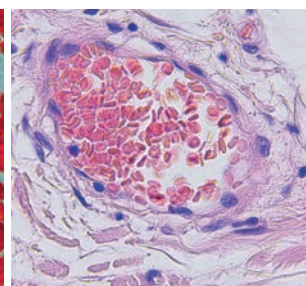
Collagenase AF-1 GMP Grade and Neutral Protease AF GMP Grade are highly active and designed to isolate especially sensitive cells from tissues such as liver, pancreas and solid tumors.

### Tested for Islet, Tumor & SVF Isolation

The efficacy and reliable performance of these animal-free enzymes have been confirmed by leading experts in various fields. For example, isolation of solid tumors and islet cells requires an effective but gentle breakdown of the connective tissue, especially when cell surface receptor integrity is crucial.



Islets isolated with AF enzymes, Greg Szot, UCSF



Colon cancer microscopic photograph

Collagenase AF-1 with Neutral Protease AF has been shown to be exceptionally gentle where sensitive conditions are required. Individual dosing of both products also allows for adjustment to specific applications, such as isolation of stromal vascular fraction from lipoaspirate.

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## Product Information

Enzyme	Collagenase AF-1 GMP Grade		Neutral Protease AF GMP Grade	
Origin	<i>Clostridium histolyticum</i>		<i>Clostridium histolyticum</i>	
Composition	Collagenase class I and class II		Neutral Protease	
Molecular weight	70 – 120 kDa (collagenases)		34 kDa	
Special features	Manufactured free from animal components & according to international GMP guidelines		Manufactured free from animal components & according to international GMP guidelines	
Characters	White to off-white, 0.2 µm filtered, chromatographically highly purified, lyophilisate		Beige to brown, 0.2 µm filtered, chromatographically highly purified, lyophilisate	
Protein content	Lowry assay	> 95 %	Lowry assay	> 85 %
Identification	SDS-PAGE	Position of main bands must comply	SDS-PAGE	Position of main bands must comply
Test	Water	≤ 15 % (w/w)	Water	≤ 15 % (w/w)
Microbiological examination	TAMC (Total Aerobic Microbial Count)	≤ 10/Vial	TAMC (Total Aerobic Microbial Count)	≤ 10/Vial
	TYMC (Total Yeasts/Moulds Count)	≤ 10/Vial	TYMC (Total Yeasts/Moulds Count)	≤ 10/Vial
	Absence of Clostridia	Must comply	Absence of Clostridia	Must comply
Activities	Collagenase (PZ activity according to Wünsch, 25 °C)	≥ 150 U/Vial or ≥ 2000 U/Vial	Neutral Protease (DMC assay)	≥ 100 U/Vial
	Collagenase (PZ activity according to Wünsch, 25 °C)	≥ 3.000 U/mg lyophilisate	Neutral Protease (DMC assay)	≥ 0.50 U/mg lyophilisate
	Neutral Protease (DMC assay)	≤ 0.050 U/mg lyophilisate		
	Trypsin-like activities (BAEE assay)	Status		
	Clostripain, native state (BAEE assay)	Status		
Bacterial endotoxins	LAL assay	≤ 10.0 EU/mg lyophilisate	LAL assay	≤ 100.0 EU/mg lyophilisate
Long term storage	+2 to +8 °C		+2 to +8 °C	
Long term stability data	5 °C ± 3 °C 5 years (after manufacture)*		5 °C ± 3 °C 5 years (after manufacture)	

\*available for N0003554, ongoing ICH study for N0003855

## Ordering Information

Enzyme	Cat. No.	Size
Collagenase AF-1 GMP Grade from <i>C. histolyticum</i>	N0003855	≥ 150 PZ U/Vial
	N0003554	≥ 2000 PZ U/Vial
Neutral Protease AF GMP Grade from <i>C. histolyticum</i>	N0003553	≥ 100 DMC U/Vial



For information and samples please contact the Nordmark Biochemicals Team

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