

CERTIFICATE OF ANALYSIS

Material	Collagenase HA GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i>		
Lot Number	111230622	Pack Size	2,000 Wunsch Units
Catalog Number	001-1000	Storage	-20±5°C
Date of Manufacture	22 Jun 2023	Expiry Date	Jun 2027
TEST	ACCEPTANCE CRITERIA	RESULT	
Appearance	White lyophilized cake	Conforms	
Specific Wunsch Activity¹	> 2.80 Units/mg	4.46 Units/mg	
Total Wunsch Activity	> 1900 Units/bottle	2,075 Units/bottle	
Endotoxin EU/mg protein² USP <85>	< 10.0 EU/mg	1.0 EU/mg	
Total Collagen Degrading Activity³	Report Only	24,509,313 Units/bottle	
Total Protein⁴	Report Only	465.5 mg/bottle	
Trypsin Like Activity (BAEE Unactivated)⁵	Report Only	0.010 U/mg	
Clostripain (BAEE Activated)⁵	Report Only	0.101 U/mg	

Signature:



Andrew Breite, Director of Quality Assurance

25 Jul 2023

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- ¹ Based on the method Wunsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>
 - ² Test performed on the Charles River nexgenEndosafe[®] PTS Endotoxin Assay system
 - ³ Based on the method McCarthy RC, et. al. Development and Characterization of a Collagen Degradation Assay to Assess Purified Collagenase Used in Islet Isolation. *Transplantation Proceedings* 40 (2008); 339-342
 - ⁴ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$
 - ⁵ Mitchell WM, Harrington WF. Clostripain. *Methods in Enzymology* (1970) 19;635-642