

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	112220127	Pack Size	200 Wunsch Units
Catalog Number	001-1050	Storage	-20±5°C
Date of Manufacture	27 Jan 2022	Expiry Date	Jan 2026
TEST	ACCEPTANCE CRITERIA	RESULT	
Appearance	White lyophilized cake	Conforms	
Specific Wunsch Activity¹	> 2.80 Units/mg	4.60 Units/mg	
Total Wunsch Activity¹	175 – 200 Units/bottle	192.8 Units/bottle	
Endotoxin EU/mg protein² USP <85>	< 10.0 EU/mg	2.4 EU/mg	
Total Collagen Degrading Activity³	> 30,000 Units/mg	51,118 Units/mg	
Total Collagen Degrading Activity³	Report Only	2,142,867 Units/bottle	
Total Protein⁴	Report Only	41.9 mg/bottle	

Signature:



Andrew Breite, Director of Quality Assurance

15 Mar 2022

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 $\epsilon^{0.1\%} = 1.41$

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