

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	112251106	Pack Size	200 Wunsch Units
Catalog Number	001-1050	Storage	-20±5°C
Date of Manufacture (DD MMM YYYY)	6 Nov 2025	Expiry Date (MMM YYYY)	Nov 2029

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Specific Wunsch Activity¹	> 2.8 Units/mg	4.04 Units/mg
Total Wunsch Activity¹	175 – 225 Units/bottle	182.9 Units/bottle
Endotoxin² USP <85>	< 10.0 EU/mg	1.7 EU/mg
Specific Collagen Degrading Activity³	> 30,000 Units/mg	50,850 Units/mg
Total Collagen Degrading Activity³	Report Only (Units/bottle)	2,302,081 Units/bottle
Total Protein⁴	Report Only (mg/bottle)	45.27 mg/bottle

Printed Name & Title	Signature	Date (DD MMM YYYY)
Andrew Breite, Dir of Quality Assurance		6 Jan 2026

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