

CERTIFICATE OF ANALYSIS

Material	rCollagenase HI GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Animal origin free, aseptically dispensed mixture of purified recombinant Class 1 and recombinant Class 2 Collagenase expressed in <i>E. coli</i>		
Lot Number	131260204	Pack Size	1,600 Wünsch Units
Catalog Number	001-4010	Storage	-20±5°C
Date of Manufacture (DD MMM YYYY)	04FEB2026	Expiry Date (MMM YYYY)	FEB2028

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Identity¹	rC1 ± 1 min standard RT rC2 ± 1 min standard RT	+0.03 mins +0.18 mins
Purity²	> 90% AUC rC1 + rC2	93.85%
Total Wünsch Activity³	> 1,400 Units/bottle	1,658 Units/bottle
Endotoxin⁴ USP <85>	< 25.0 EU/mg	2.31 EU/mg
Total Collagen Degrading Activity⁵	Report Only (Units/bottle)	17,100,191 Units/bottle
Total Protein⁶	Report Only (mg/bottle)	464.5 mg/bottle

Printed Name & Title	Signature	Date (DD MMM YYYY)
Steve Epperson, Director, QA		26MAY2026

¹ Based on the Purity procedure described in USP <89.1> and <89.2> for peak retention time (RT)

² Integrated Area Under Curve for rC1 and rC2 based on the Purity procedure described in USP <89.1> and <89.2>

³ Based on the method Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>

⁴ Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

⁵ 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

⁶ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$