



CERTIFICATE OF ANALYSIS
Revised for Extended Expiry

Material	Collagenase Gold Plus GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed enriched Collagenase from <i>C. histolyticum</i>		
Lot Number	141220331	Pack Size	1,500 Wunsch Units
Catalog Number	011-2000	Storage	2-8°C
Date of Manufacture (DD MMM YYYY)	31MAR2022	Expiry Date (MMM YYYY)	MAR 2027

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Specific FALGPA Activity¹	> 3.4 Units/mg	4.29 Units/mg
Total FALGPA Activity¹	> 1,500 Units/bottle	1,785 Units/bottle
Endotoxin² USP <85>	< 25.0 EU/mg	3.89 EU/mg
Specific Collagen Degrading Activity³	> 30,000 Units/mg	58,406 Units/mg
Collagenase Purity⁴	> 90% AUC C2 + C1	92.6%
Total Protein⁵	Report Only (mg)	416.1 mg

Printed Name & Title	Signature	Date (DD MMM YYYY)
Steve Epperson, Director of QA		23 FEB 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 As measured by strong anion exchange analytical chromatography method based on USP <89.1> and <89.2>
- ⁵ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$