

CERTIFICATE OF ANALYSIS

Material	Collagenase Gold Plus GMP Grade (For <i>ex vivo</i> Use Only)		
Description	Aseptically dispensed enriched <i>C. histolyticum</i>		
Lot Number	141220331	Pack Size	1,500 Wunsch Units
Catalog Number	011-2000	Storage	≤ 2-8°C
Date of Manufacture	31 Mar 2022	Expiry Date	Mar 2026
TEST	ACCEPTANCE CRITERIA		RESULT
Appearance	White lyophilized cake		Conforms
Specific FALGPA Activity¹	> 3.4 Units/mg		4.06 Units/mg
Total FALGPA Activity¹	> 1,500 Units/bottle		1,916 Units/bottle
Endotoxin EU/mg protein² USP <85>	< 10.0 EU/mg		4.2 EU/mg
Total Collagen Degrading Activity³	> 30,000 Units/mg		53,080 Units/mg
Total Protein⁴	Report Only		473.5 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

25 Apr 2022

¹ Jackson, R.J., Dao, M.L. and Lim, D.V. *Journal of Microbiological Methods* (1995) 21;209-215

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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