

CERTIFICATE OF ANALYSIS

Material	Collagenase MA 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	122240502	Pack Size	2.5 M CDA Units
Catalog Number	001-2030	Storage	-20±5°C
Date of Manufacture	02 May 2024	Expiry Date	May 2028

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Specific Collagen Degrading Activity¹	15,000 – 30,000 Units/mg	26,805 Units/mg
Total Collagen Degrading Activity¹	2.25 – 2.75 M Units/bottle	2,604,613 Units/bottle
Endotoxin² USP <85>	< 10.0 EU/mg	3.31 EU/mg
Total Protein³	Report Only	97.2 mg/bottle

Signature:



Aaron B. Craig
Director, Quality Assurance

14 May 2024

Date

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- ¹ 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
- ² Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system
- ³ Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%} = 1.41$