

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	122230112	Pack Size	2.5 million CDA Units
Catalog Number	001-2030	Storage	-20±5°C
Date of Manufacture	12 Jan 2023	Expiry Date	Jan 2027
TEST	ACCEPTANCE CRITERIA		RESULT
Appearance	White lyophilized cake		Conforms
Specific Collagen Degrading Activity¹	15,000 – 30,000 U/mg		22,810 Units/mg
Total Collagen Degrading Activity¹	2.25 – 2.75 M Units/bottle		2,338,875 Units/bottle
Endotoxin EU/mg protein² USP <85>	< 10.0 EU/mg		2.7 EU/mg
Total Protein³	Report Only		102.5 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

10 Feb 2023

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