

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	122211014	Pack Size	2.5 million CDA Units
Catalog Number	001-2030	Storage	-20±5°C
Date of Manufacture	14 Oct 2021	Expiry Date	31 Oct 2025
TEST		ACCEPTANCE CRITERIA	RESULT
Appearance		White lyophilized cake	Conforms
Specific Collagen Degrading Activity¹		15,000 – 30,000 U/mg	25,488 Units/mg
Total Collagen Degrading Activity¹		2.25 – 2.75 M Units/bottle	2,572,249 Units/bottle
Endotoxin EU/mg protein² USP <85>		< 10.0 EU/mg	4.0 EU/mg
Total Protein³		Report Only	100.9 mg/bottle

Signature:



Andrew Breite, Director of Quality Assurance

26 Oct 2021

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