



## CERTIFICATE OF ANALYSIS

<b>Material</b>	Collagenase MA GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i>		
<b>Lot Number</b>	122250212	<b>Pack Size</b>	2.5 M CDA Units
<b>Catalog Number</b>	001-2030	<b>Storage</b>	-20±5°C
<b>Date of Manufacture (DD MMM YYYY)</b>	12 Feb 2025	<b>Expiry Date (MMM YYYY)</b>	Feb 2029

TEST	ACCEPTANCE CRITERIA	RESULT
<b>Appearance</b>	White lyophilized cake	Conforms
<b>Specific Collagen Degrading Activity<sup>1</sup></b>	15,000 – 30,000 Units/mg	29,454 Units/mg
<b>Total Collagen Degrading Activity<sup>1</sup></b>	2.25 – 2.75 M Units/bottle	2,498,665 Units/bottle
<b>Endotoxin<sup>2</sup> USP &lt;85&gt;</b>	< 10.0 EU/mg	3.5 EU/mg
<b>Total Protein<sup>3</sup></b>	Report Only	84.9 mg/bottle

Printed Name & Title	Signature	Date (DD MMM YYYY)
<b>Andrew Breite, Dir of Quality Assurance</b>		17 Mar 2025

<sup>1</sup> 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

<sup>2</sup> Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

<sup>3</sup> Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon^{0.1\%} = 1.41$