

## 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>	122220728	<b>Pack Size</b>	2.5 million CDA Units
<b>Catalog Number</b>	001-2030	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	28 Jul 2022	<b>Expiry Date</b>	Jul 2026
TEST	ACCEPTANCE CRITERIA		RESULT
<b>Appearance</b>	White lyophilized cake		Conforms
<b>Specific Collagen Degrading Activity<sup>1</sup></b>	15,000 – 30,000 U/mg		25,580 Units/mg
<b>Total Collagen Degrading Activity<sup>1</sup></b>	2.25 – 2.75 M Units/bottle		2,350,709 Units/bottle
<b>Endotoxin EU/mg protein<sup>2</sup> USP &lt;85&gt;</b>	< 10.0 EU/mg		7.4 EU/mg
<b>Total Protein<sup>3</sup></b>	Report Only		91.9 mg/bottle

**Signature:**



Andrew Breite, Director of Quality Assurance

9 Aug 2022

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