

## CERTIFICATE OF ANALYSIS

<b>Material</b>	Collagenase HA 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>	111210415	<b>Pack Size</b>	2,000 Wunsch Units
<b>Catalog Number</b>	001-1000	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	15 Apr 2021	<b>Expiry Date</b>	30 Apr 2025
TEST	ACCEPTANCE CRITERIA		RESULT
<b>Appearance</b>	White lyophilized cake		Conforms
<b>Specific Wunsch Activity<sup>1</sup></b>	> 2.80 Units/mg		4.80 Units/mg
<b>Total Wunsch Activity</b>	> 1900 Units/bottle		2,186 Units/bottle
<b>Endotoxin EU/mg protein<sup>2</sup> USP &lt;85&gt;</b>	< 10.0 EU/mg		0.8 EU/mg
<b>Total Collagen Degrading Activity<sup>3</sup></b>	Report Only		27,052,582 Units/bottle
<b>Total Protein<sup>4</sup></b>	Report Only		455.4 mg/bottle
<b>Trypsin Like Activity (BAEE Unactivated)<sup>5</sup></b>	Report Only		0.005 U/mg
<b>Clostripain (BAEE Activated)<sup>5</sup></b>	Report Only		0.062 U/mg

**Signature:**



Andrew Breite, Director of Quality Assurance

10 May 2021

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- <sup>1</sup> Based on the method Wunsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>
- <sup>2</sup> Test performed on the Charles River nexgenEndosafe<sup>®</sup> PTS Endotoxin Assay system
- <sup>3</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>4</sup> Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon^{0.1\%} = 1.41$
- <sup>5</sup> Mitchell WM, Harrington WF. Clostripain. *Methods in Enzymology* (1970) 19;635-642