

## CERTIFICATE OF ANALYSIS

<b>Material</b>	Collagenase Gold Plus GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed enriched <i>C. histolyticum</i>		
<b>Lot Number</b>	141220331	<b>Pack Size</b>	1,500 Wunsch Units
<b>Catalog Number</b>	011-2000	<b>Storage</b>	≤ 2-8°C
<b>Date of Manufacture</b>	31 Mar 2022	<b>Expiry Date</b>	Mar 2026
TEST	ACCEPTANCE CRITERIA		RESULT
<b>Appearance</b>	White lyophilized cake		Conforms
<b>Specific FALGPA Activity<sup>1</sup></b>	> 3.4 Units/mg		4.06 Units/mg
<b>Total FALGPA Activity<sup>1</sup></b>	> 1,500 Units/bottle		1,916 Units/bottle
<b>Endotoxin EU/mg protein<sup>2</sup> USP &lt;85&gt;</b>	< 10.0 EU/mg		4.2 EU/mg
<b>Total Collagen Degrading Activity<sup>3</sup></b>	> 30,000 Units/mg		53,080 Units/mg
<b>Total Protein<sup>4</sup></b>	Report Only		473.5 mg/bottle

**Signature:**



Andrew Breite, Director of Quality Assurance

25 Apr 2022

<sup>1</sup> Jackson, R.J., Dao, M.L. and Lim, D.V. *Journal of Microbiological Methods* (1995) 21;209-215

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

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