



## PRODUCT SPECIFICATIONS

Version Apr 2024

<b>Material</b>	Collagenase Gold Plus GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed enriched Collagenase from <i>C. histolyticum</i>		
<b>Lot Number</b>	<i>Lot Specific</i>	<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>	<i>Lot Specific</i>	<b>Expiry Date</b>	4 years from date of manufacture

TEST	ACCEPTANCE CRITERIA	RESULT
<b>Appearance</b>	White lyophilized cake	<i>Lot Specific</i>
<b>Specific FALGPA Activity<sup>1</sup></b>	> 3.4 Units/mg	<i>Lot Specific</i>
<b>Total FALGPA Activity<sup>1</sup></b>	> 1,500 Units/bottle	<i>Lot Specific</i>
<b>Endotoxin<sup>2</sup> USP &lt;85&gt;</b>	< 25.0 EU/mg	<i>Lot Specific</i>
<b>Specific Collagen Degrading Activity<sup>3</sup></b>	> 30,000 Units/mg	<i>Lot Specific</i>
<b>Collagenase Purity<sup>4</sup></b>	> 90% AUC C2 + C1	<i>Lot Specific</i>
<b>Total Protein<sup>5</sup></b>	Report Only (mg)	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

<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® 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> As measured by strong anion exchange analytical chromatography method based on USP <89.1> and <89.2>

<sup>5</sup> Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon^{0.1\%} = 1.41$