

## CERTIFICATE OF ANALYSIS

<b>Material</b>	Animal Origin Free Recombinant Collagenase HI GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed mixture of purified rColG (Class 1 Collagenase) and rColH (Class 2 Collagenase) expressed in <i>E. coli</i>		
<b>Lot Number</b>	131210729	<b>Pack Size</b>	1,600 Wünsch Units
<b>Catalog Number</b>	001-4010	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	29 Jul 2021	<b>Expiry Date</b>	31 Jul 2023
TEST	ACCEPTANCE CRITERIA		RESULTS
<b>Appearance</b>	White lyophilized cake		Conforms
<b>Identity<sup>1</sup></b>	rC1 ± 1 min standard RT rC2 ± 1 min standard RT		+0.05 min +0.11 min
<b>Purity<sup>2</sup></b>	> 90% AUC rC1 + rC2		98.3%
<b>Total Wünsch Activity<sup>3</sup></b>	> 1,400 Units/bottle		1,549 Units/bottle
<b>Total Collagen Degrading Activity<sup>4</sup></b>	Report Only		23,093,286 Units/bottle
<b>Endotoxin EU/mg protein USP &lt;85&gt;<sup>5</sup></b>	< 25.0 EU/mg		7.6 EU/mg
<b>Total Protein<sup>6</sup></b>	Report Only		380.6 mg/bottle

**Signature:**



Andrew Breite, Director of Quality Assurance

17 Aug 2021

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- <sup>1</sup> Based on the Purity procedure described in USP <89.1> and <89.2> for peak retention time (RT)  
<sup>2</sup> Integrated Area Under Curve for rC1 and rC2 based on the Purity procedure described in USP <89.1> and <89.2>  
<sup>3</sup> Based on the method Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>  
<sup>4</sup> 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>5</sup> Charles River Endosafe® nexgen-PTS™ Endotoxin Assay  
<sup>6</sup> Based on absorbance at 280 nm with an extinction coefficient of  $\epsilon^{0.1\%} = 1.41$