



## CERTIFICATE OF ANALYSIS

Collagenase HA, Catalog # 001-1050  
GMP Grade – For *ex vivo* Use Only

**Product:** Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from *C. histolyticum*

Lot # 241170921	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Specific Wunsch Activity <sup>1</sup>	> 2.80 Units/mg	4.51 Units/mg
Total Wunsch Activity	175 – 225 Units/bottle	193.3 Units/bottle
Endotoxin EU/mg protein <sup>2</sup>	< 10.0 EU/mg	3.96 EU/mg
Specific Collagen Degrading Activity <sup>3</sup>	> 30,000 Units/mg	51,820 Units/mg
Total Collagen Degrading Activity	Report Only	2,221,420 Units/bottle
Total Protein <sup>4</sup>	Report Only	42.9 mg/bottle

**STORAGE:** < -20°C

**DATE OF MANUFACTURE:** 21 Sept 2017

**EXPIRY DATE:** September 2019

**Signature:**

Andrew Breite, Director of Quality Assurance

4 October 2017

<sup>1</sup> Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyleyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151

<sup>2</sup> Charles River Endosafe<sup>®</sup> PTS Endotoxin Assay

<sup>3</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>4</sup> Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon=1.41$

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