



## CERTIFICATE OF ANALYSIS

Collagenase MA, Catalog # 001-2020  
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 # 224190214	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Specific Wünsch Activity <sup>1</sup>	> 2.80 Units/mg	5.32 Units/mg
Total Wünsch Activity	1,000 – 1,400 Units/bottle	1,163 Units/bottle
Specific Collagen Degrading Activity <sup>2</sup>	15,000 – 30,000 U/mg	27,431 Units/mg
Endotoxin EU/mg protein <sup>3</sup>	< 10.0 EU/mg	4.18 EU/mg
Total Protein <sup>4</sup>	Report Only	218.6 mg/bottle

**STORAGE:** < -20°C

**DATE OF MANUFACTURE:** 14 Feb 2019  
**EXPIRY DATE:** Feb 2021

**Signature:**

Andrew Breite, Director of Quality Assurance

19 Feb 2019

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

<sup>2</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>3</sup> Charles River Endosafe® PTS Endotoxin Assay

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