



## CERTIFICATE OF ANALYSIS

Collagenase HA, Catalog # 001-1000  
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 # 111200206	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Specific Wunsch Activity <sup>1</sup>	> 2.80 Units/mg	4.48 Units/mg
Total Wunsch Activity	> 1900 Units/bottle	2,182 Units/bottle
Endotoxin EU/mg protein <sup>2</sup>	< 10.0 EU/mg	2.5 EU/mg
Total Collagen Degrading Activity <sup>3</sup>	Report Only	24,528,571 Units/bottle
Total Protein <sup>4</sup>	Report Only	487.2 mg/bottle
Trypsin Like Activity (BAEE Unactivated) <sup>5</sup>	Report Only	0.006 U/mg
Clostripain (BAEE Activated) <sup>5</sup>	Report Only	0.029 U/mg

**STORAGE:** -20±5°C

**DATE OF MANUFACTURE:** 6 Feb 2020

**EXPIRY DATE:** February 2022

**Signature:**

Andrew Breite, Director of Quality Assurance

18 Feb 2020

- <sup>1</sup> Wunsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151
- <sup>2</sup> Charles River Endosafe® 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  $\epsilon=1.41$
- <sup>5</sup> Mitchell WM, Harrington WF. Clostripain. *Methods In Enzymology* (1970) 19;635-642

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