

## **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 Protein⁴	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

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

Charles River Endosafe® PTS Endotoxin Assay

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

Based on absorbance at 280 nm using an extinction coefficient of  $\varepsilon$ =1.41

Mitchell WM, Harrington WF. Clostripain. Methods In Enzymology (1970) 19;635-642