

## CERTIFICATE OF ANALYSIS

Clzyme AS, Catalog # 005-1090  
GMP Grade – For *ex vivo* Use Only

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

Lot # 311190524	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Total Wünsch Activity <sup>1</sup>	30 – 40 Units/vial	36.4 Units/vial
Total Neutral Protease Activity <sup>2</sup>	220,000 – 350,000 Units/vial	344,695 Units/vial
Endotoxin EU/mg protein <sup>3</sup>	< 25.0 EU/OD 280 nm	1.6 EU/OD 280 nm
Total Collagen Degrading Activity <sup>4</sup>	Report Only	396,502 Units/vial

STORAGE: 2-8°C

DATE OF MANUFACTURE: 23 May 2019  
EXPIRY DATE: May 2021

Signature:



Andrew Breite, Director of Quality Assurance

3 Jun 2019

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- <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> Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54
- <sup>3</sup> Charles River Endosafe® PTS Endotoxin Assay
- <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