

## 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 # 311190607	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Total Wünsch Activity <sup>1</sup>	30 – 40 Units/vial	34.8 Units/vial
Total Neutral Protease Activity <sup>2</sup>	220,000 – 350,000 Units/vial	342,734 Units/vial
Endotoxin EU/mg protein <sup>3</sup>	< 25.0 EU/OD 280 nm	3.3 EU/OD 280 nm
Total Collagen Degrading Activity <sup>4</sup>	Report Only	407,362 Units/vial

**STORAGE:** 2-8°C

**DATE OF MANUFACTURE:** 6 Jun 2019

**EXPIRY DATE:** June 2021

**Signature:**



Andrew Breite, Director of Quality Assurance

25 Jun 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> 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