

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 # 311191121	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Total Wünsch Activity ¹	30 – 40 Units/vial	35.4 Units/vial
Total Neutral Protease Activity ²	220,000 – 350,000 Units/vial	286,374 Units/vial
Endotoxin EU/mg protein ³	< 25.0 EU/OD 280 nm	3.4 EU/OD 280 nm
Total Collagen Degrading Activity ⁴	Report Only	442,861 Units/vial

STORAGE: 2-8°C

DATE OF MANUFACTURE: 21 Nov 2019

EXPIRY DATE: Nov 2021

Signature:



Andrew Breite, Director of Quality Assurance

12 Dec 2019

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

² Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54

³ Charles River Endosafe® PTS Endotoxin Assay

⁴ 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