

CERTIFICATE OF ANALYSIS

Material	Clzyme RI, For Research Use Only		
Description	Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i> and purified Neutral Protease from <i>B. polymyxa</i>		
Lot Number	321230810	Pack Size	375k CDA U + 75k NP U
Catalog Number	005-1030	Storage	-20±5°C
Date of Manufacture	10 Aug 2023	Expiry Date	Aug 2025
TEST	ACCEPTANCE CRITERIA		RESULT
Appearance	White lyophilized cake		Conforms
Total Collagen Degrading Activity¹	300,000 – 450,000 Units/vial		329, 845 Units/vial
Total Neutral Protease Activity²	60,000 – 100,000 Units/vial		64,237 Units/vial
Endotoxin EU/mg protein³	< 25.0 EU/OD 280 nm		2.3 EU/OD 280 nm

Signature:



Francis Dwulet, Acting Director of Quality Assurance

21 Aug 2023

¹ 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

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

³ Charles River Endosafe[®] nexgen-PTS[™] Endotoxin Assay