

## **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 Activity <sup>1</sup>		300,000 – 450,000 Units/vial			329, 845 Units/vial	
Total Neutral Protease Activity <sup>2</sup>		60,000 – 100,000 Units/vial			64,237 Units/vial	
Endotoxin EU/mg protein <sup>3</sup>		< 25.0 EU/OD 280 nm		2.3 EU/OD 280 nm		

## Signature:

Francis Dwulet, Acting Director of Quality Assurance

Francis & Dwelet

21 Aug 2023

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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

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

<sup>&</sup>lt;sup>3</sup> Charles River Endosafe® nexgen-PTS™ Endotoxin Assay