

CERTIFICATE OF ANALYSIS

Material	Clzyme RI (Rodent Islet) For Research Use Only		
Description	Aseptically dispensed mixture of purified Class 1 and Class 2 Collagenase from <i>C. histolyticum</i> and purified Neutral Protease from <i>P. polymyxa</i>		
Lot Number	321250918	Pack Size	375k CDA + 75k NP Units
Catalog Number	005-1030	Storage	-20±5°C
Date of Manufacture (DD MMM YYYY)	18 Sept 2025	Expiry Date (MMM YYYY)	Sept 2027

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Total Collagen Degrading Activity¹	300,000 – 450,000 Units/bottle	406,164 Units/bottle
Total Neutral Protease Activity²	60,000 – 100,000 Units/bottle	75,879 Units/bottle
Endotoxin³ USP <85>	< 25.0 EU/OD 280 nm	2.1 EU/OD 280 m

Printed Name & Title	Signature	Date (DD MMM YYYY)
Andrew Breite, Dir of Quality Assurance		3 Oct 2025

- ¹ Based on the method 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 Based on the method of Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54
- ³ Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system