



## PRODUCT SPECIFICATIONS

Version Apr 2024

<b>Material</b>	Clzyme RI (Rodent Islet) For Research Use Only		
<b>Description</b>	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>		
<b>Lot Number</b>	<i>Lot Specific</i>	<b>Pack Size</b>	375k CDA + 75k NP Units
<b>Catalog Number</b>	005-1030	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	<i>Lot Specific</i>	<b>Expiry Date</b>	2 years from date of manufacture

TEST	ACCEPTANCE CRITERIA	RESULT
<b>Appearance</b>	White lyophilized cake	<i>Lot Specific</i>
<b>Total Collagen Degrading Activity<sup>1</sup></b>	300,000 – 450,000 Units/bottle	<i>Lot Specific</i>
<b>Total Neutral Protease Activity<sup>2</sup></b>	60,000 – 100,000 Units/bottle	<i>Lot Specific</i>
<b>Endotoxin<sup>3</sup> USP &lt;85&gt;</b>	< 25.0 EU/OD 280 nm	<i>Lot Specific</i>

Electronically signed in Qualio® eQMS

<sup>1</sup> 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

<sup>2</sup> Based on the method of Breite AG, et. al. Tissue Dissociation Enzyme Neutral Protease Assessment. *Transplantation Proceedings* 42 (2010);2052-54

<sup>3</sup> Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system