

## CERTIFICATE OF ANALYSIS

<b>Material</b>	Collagenase HA GMP Grade (For <i>ex vivo</i> Use Only)		
<b>Description</b>	Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i>		
<b>Lot Number</b>	112210930	<b>Pack Size</b>	200 Wunsch Units
<b>Catalog Number</b>	001-1050	<b>Storage</b>	-20±5°C
<b>Date of Manufacture</b>	30 Sept 2021	<b>Expiry Date</b>	Sept 2025
<b>TEST</b>	<b>ACCEPTANCE CRITERIA</b>	<b>RESULT</b>	
<b>Appearance</b>	White lyophilized cake	Conforms	
<b>Specific Wunsch Activity<sup>1</sup></b>	> 2.80 Units/mg	4.53 Units/mg	
<b>Total Wunsch Activity<sup>1</sup></b>	175 – 200 Units/bottle	200.2 Units/bottle	
<b>Endotoxin EU/mg protein<sup>2</sup> USP &lt;85&gt;</b>	< 10.0 EU/mg	3.3 EU/mg	
<b>Total Collagen Degrading Activity<sup>3</sup></b>	> 30,000 Units/mg	50,211 Units/mg	
<b>Total Collagen Degrading Activity<sup>3</sup></b>	Report Only	2,217,318 Units/bottle	
<b>Total Protein<sup>4</sup></b>	Report Only	44.2 mg/bottle	

**Signature:**



Andrew Breite, Director of Quality Assurance

8 Oct 2021

<sup>1</sup> Based on the method Wunsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>

<sup>2</sup> Test performed on the Charles River nexgenEndosafe<sup>®</sup> PTS Endotoxin Assay system

<sup>3</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>4</sup> Based on absorbance at 280 nm using an extinction coefficient of  $\epsilon^{0.1\%} = 1.41$

**VitaCyte, LLC**

1341 Sadlier Circle West Drive

Indianapolis, IN 46239

www.vitacyte.com

**Phone:** 317.917.3457

**Fax:** 317.917.3459