



CERTIFICATE OF ANALYSIS

Animal Origin Free Recombinant Collagenase HI, Catalog # 001-4010
GMP Grade – For *ex vivo* Use Only

Product: Aseptically dispensed mixture of purified recombinant ColG (Class 1 Collagenase) and recombinant ColH (Class 2 Collagenase) expressed in *E. coli*

Lot # 131200521	SPECIFICATION	RESULT
Appearance	White lyophilized cake	White lyophilized cake
Identity ¹	rC1 ± 1 min standard RT rC2 ± 1 min standard RT	-0.11 min +0.05 min
Purity ²	> 90% AUC rC1 + rC2	97.8%
Total Wünsch Activity ³	> 1,400 Units/bottle	1,775 Units/bottle
Total Collagen Degrading Activity ⁴	Report Only	20,335,910 Units/bottle
Endotoxin USP <85> ⁵	< 25.0 EU/mg	7.5 EU/mg
Total Protein ⁶	Report Only	402.5 mg/bottle

STORAGE: -20±5°C

DATE OF MANUFACTURE: 21 May 2020

EXPIRY DATE: May 2022

Signature:

Andrew Breite, Director of Quality Assurance

9 Jun 2020

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- ¹ Based on the Purity procedure described in USP <89.1> and <89.2> for peak retention time (RT)
 - ² Integrated Area Under Curve for rC1 and rC2 based on the Purity procedure described in USP <89.1> and <89.2>
 - ³ Based on USP <89.1> and <89.2> and Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151
 - ⁴ 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
 - ⁵ Charles River Endosafe[®] nexgen-PTS[™] Endotoxin Assay
 - ⁶ Based on absorbance at 280 nm with 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