VitaCyte®
Unravelling Cell Isolation

CERTIFICATE OF ANALYSIS

Material	rCollagenase HI GMP Grade (For *ex vivo* Use Only)		
Description	Animal origin free, aseptically dispensed mixture of purified recombinant Class 1 and recombinant Class 2 Collagenase expressed in *E. coli*		
Lot Number	131260204	**Pack Size**	1,600 Wünsch Units
Catalog Number	001-4010	**Storage**	-20±5°C
Date of Manufacture (DD MMM YYYY)	04FEB2026	**Expiry Date** (MMM YYYY)	FEB 2028

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White lyophilized cake	Conforms
Identity[1]	rC1 ± 1 min standard RT rC2 ± 1 min standard RT	+0.03 mins +0.18 mins
Purity[2]	> 90% AUC rC1 + rC2	93.85%
Total Wünsch Activity[3]	> 1,400 Units/mg	1,658 Units/mg
Endotoxin[4] **USP <85>**	< 25.0 EU/mg	2.31 EU/mg
Total Collagen Degrading Activity[5]	Report Only (Units/bottle)	17,100,191 Units/btl
Total Protein[6]	Report Only (mg/bottle)	464.5 mg/btl

Printed Name & Title	Signature	Date (DD MMM YYYY)
Steve Epperson, Director QA	Steve Epperson Digitally signed by Steve Epperson Date: 2026.02.24 09:10:58 -05'00'	24FEB2026

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 the method Wünsch E, Heidrich H-G. Zur quantitativen bestimmung der kollagenase. *Hoppe-Seyler's Zeitschrift Physiologische Chemie* 333 (1963);149-151 in USP <89.2>
4 Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system
5 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
6 Based on absorbance at 280 nm using an extinction coefficient of $\varepsilon^{0.1\%}$ =1.41

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