

CERTIFICATE OF ANALYSIS

| Material | Collagenase MA GMP Grade (For ex vivo Use Only) | | |
|---------------------|---|-------------|-----------------|
| Description | Aseptically dispensed mixture of purified Class 1 (60%) and Class 2 (40%) Collagenase from <i>C. histolyticum</i> | | |
| Lot Number | 122240502 | Pack Size | 2.5 M CDA Units |
| Catalog Number | 001-2030 | Storage | -20±5°C |
| Date of Manufacture | 02 May 2024 | Expiry Date | May 2028 |

| TEST | ACCEPTANCE CRITERIA | RESULT |
|--|----------------------------|------------------------|
| Appearance | White lyophilized cake | Conforms |
| Specific Collagen Degrading Activity ¹ | 15,000 – 30,000 Units/mg | 26,805 Units/mg |
| Total Collagen Degrading Activity ¹ | 2.25 – 2.75 M Units/bottle | 2,604,613 Units/bottle |
| Endotoxin ² USP <85> | < 10.0 EU/mg | 3.31 EU/mg |
| Total Protein ³ | Report Only | 97.2 mg/bottle |

Signature:

Aaron B. Craig

Director, Quality Assurance

14 May 2024

Date

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 Test performed on the Charles River nexgenEndosafe® PTS Endotoxin Assay system

Based on absorbance at 280 nm using an extinction coefficient of $\epsilon^{0.1\%}$ =1.41