



Notification of Change

4 Jan 2021

Dear Valued Customer:

In accordance with VitaCyte's Quality Management System, this letter is to inform you of changes related to products you have purchased. VitaCyte is providing this information for your quality records and to communicate changes for impacted staff in your organization for future orders.

Specific Changes

Expiration dates for purified Collagenase products have been extended from 2 to 4 years from the date of manufacture. The change was justified by an extensive real-time stability study in which no statistically significant change in enzyme potency was observed on retention samples stored at -20°C in excess of 5 years by standard test methods used in final product release testing. The stability studies were a part of a Change Control plan that compiled a significant body of data and underwent a thorough review.

Products Impacted

This change notification only impacts purified collagenase products not formulated with protease(s).

Part (Catalog) Number	Product	Pack Size	Actions
001-1000	Collagenase HA	2,000 Wunsch	Expiry – 4 years from date of manufacture
001-1050	Collagenase HA	200 Wunsch	Expiry – 4 years from date of manufacture
001-2020	Collagenase MA	1,100 Wunsch	Expiry – 4 years from date of manufacture
001-2030	Collagenase MA	2.5 M CDA	Expiry – 4 years from date of manufacture

Effective Date

Batches manufactured after 28 Aug 2020 will be labeled with the new 4 year expiration date.

Quality Management System

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Unravelling Cell Isolation

We kindly request you share this information with your team's quality assurance, purchasing, shipping and receiving colleagues along with any other impacted individuals. VitaCyte understands any change to your incoming raw materials represents a risk to your processes. However, we are confident in these data and hope the stability of these collagenase products is beneficial to your processes. We remain committed to manufacturing the highest quality, most consistently performing cell recovery reagents and proactively seek solutions that limit the need to change our processes. Thank you for your continued business! We look forward to working with you in the future. Please feel comfortable to reach out to me directly with any specific questions or concerns.

Best regards,

A handwritten signature in blue ink, appearing to read "A. Breite".

Andrew Breite M.S., M.B.A.
Director of Quality Assurance