

## Notification of Change

15 Aug 2024

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

Products may be manufactured with plastic flip cap tear-off seal enclosure. Previously, VitaCyte products were sealed with an aluminum crimp. This aluminum seal served two purposes.

- First, the crimp seal keeps the butyl rubber septum firmly seated in the amber bottle containing the lyophilized product. This ensures the vacuum seal is maintained and moisture from the ambient environment is excluded.
- Second, the crimp seal provides a security feature that ensures the bottle containing the enzyme has not been tampered with since the time of manufacture.

While the scoring on the aluminum crimp seals is designed for easy pull-off at the time of use, the ease of access to the bottles, especially in an aseptic environment, is cumbersome and inconvenient. An alternate version of this seal uses the same aluminum crimp seal to keep the butyl rubber septum firmly sealed, but is covered by a plastic cap designed to more easily break the aluminum seal and cleanly tear-off the bottle. This enclosure is intended to be easier and more convenient for use in aseptic environments. The images below show the enclosure sealed (left) and in the process of tear-off (right).





## Products Impacted

This change notification impacts the catalog items listed in the table below. This change does not impact those products with screw top lid enclosures (PD Collagenases) or custom products.

Product	Catalog Number	Pack Size	Actions
Collagenase HA	001-1000 001-1050	2,000 Wünsch Units 200 Wünsch Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
Collagenase MA	001-2030	2.5 M CDA Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
AOF Collagenase rHI	001-1040	1,600 Wünsch Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
Collagenase Gold Plus	011-2000	1,500 FALGPA Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
BP Protease	003-1000 003-2000	1.1 M NP Units 2.3 M NP Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
AF Thermolysin	002-3000	6 mg	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
Clzyme RI	005-1030	375k CDA Units + 75k NP Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal
Clzyme AS	005-1090	35 Wünsch + 280k NP Units	Aluminum crimp seal replaced with Red Flip Cap Tear-Off Seal

## Effective Date

Batches manufactured on or after 01 Sept 2024 could be manufactured with the new plastic flip cap tear-off seal enclosure. If plastic flip cap tear-off seal enclosures aren't available, we reserve the option to use standard aluminum crimp seals.

## Quality Management System

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 changes to your incoming raw materials represents a risk 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.

Please feel comfortable to reach out with any specific questions or concerns or feedback to [orders@vitacyte.com](mailto:orders@vitacyte.com). Thank you for your continued business! We look forward to working with you in the future.

Best regards,

Aaron B. Craig, Director Quality Assurance

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