

Notification of Change

9 Jan 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

The DE Collagenase product line will be discontinued to be replaced with two new purified define (PD) collagenase formulation products. The new PD collagenase products, PD Collagenase 100 and PD Collagenase 800 will have the same formulation as DE Collagenase 100 and DE Collagenase 800, respectively, as shown in the table below. The enzymes used in the new formulation are equivalent to the enzymes used to manufacture the DE Collagenase products and no other changes will be made to the manufacturing process other than a labeling name change.

Old Product	New Product	Pack Size	Enzyme Formulation
DE Collagenase 100	PD Collagenase 100	1 gram	55 mg collagenase + 18 mg BP Protease
Cat# 011-1010	Cat# 011-3010		
DE Collagenase 800	PD Collagenase 800	1 gram	440 mg collagenase + 18 mg BP Protease
Cat# 011-1050	Cat# 011-3020		

Products Impacted

This change notification only impacts purified defined collagenases and not the purified collagenases (ex. Collagenase HA, etc.)

Catalog Number	Product	Pack Size	Actions
011-3010	PD Collagenase 100	1 gram	New product replaces DE100 Cat# 001-1010
011-3020	PD Collagenase 800	1 gram	New product replaces DE800 Cat# 001-1050
011-1010	DE Collagenase 100	1 gram	Discontinued
011-1020	DE Collagenase 200	1 gram	Discontinued
011-1030	DE Collagenase 400	1 gram	Discontinued
011-1040	DE Collagenase 600	1 gram	Discontinued
011-1050	DE Collagenase 800	1 gram	Discontinued
011-1110	DE Collagenase 10	100 mg	Discontinued
011-1120	DE Collagenase 20	100 mg	Discontinued
011-1130	DE Collagenase 40	100 mg	Discontinued
011-1140	DE Collagenase 60	100 mg	Discontinued
011-1150	DE Collagenase 80	100 mg	Discontinued

VitaCyte, LLC

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Effective Date

DE Collagenases will be available until current inventories have been consumed. If DE Collagenase batches are exhausted prior to 1 Mar 2024, new batches of material labeled as PD Collagenase will be manufactured and made available after release testing. Any remaining DE Collagenase products will be removed from inventory on 1 Mar 2024 and replaced with new batches of PD Collagenase on or after that date.

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. 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,

Andrew Breite M.S., M.B.A. Director of Quality Assurance <u>abreite@vitacyte.com</u> 317-269-7143

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