



Notification of Change

15 Dec 2021

Dear Valued Customer:

In accordance with VitaCyte's Quality Management System, this letter is to inform you of changes related to the product packaging process and shipping conditions for 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

Pandemic triggered supply disruptions have put significant pressures on couriers to deliver packages in the target timeline. For this reason, VitaCyte had to resolve numerous delayed product shipments in the past 2 years which highlighted the risks associated with maintaining cold storage using dry ice. These issues along with the rapid increases in dry ice costs has prompted VitaCyte to evaluate different shipping containers and cold storage options.

Product integrity is the paramount consideration. After review of the extensive stability studies performed on purified enzyme products, the need to transport materials at -70°C (dry ice) is not required. All products are stable for a minimum of weeks to months at $+4^{\circ}\text{C}$ with most products showing no loss of potency as measured by internal assays up to $+37^{\circ}\text{C}$ for multiple weeks. In thoroughly evaluating the needs of product integrity, costs and shipping risks, VitaCyte has selected to use Enviro Ice in lieu of dry ice for most shipments that require cold storage. These Enviro Ice provide a number of benefits relative to dry ice including:

- Maintaining a temperature below 0°C for 48 hours minimum
- Significant material cost reduction (Dry ice costs 7x more than Enviro Ice for similar size cartons)
- Equal to or less shipping weight keeping shipping costs low
- No dry ice courier imposed hazard fees

In the event of a delayed shipment Enviro Ice offer additional benefits including:

- Keeping product below 0°C slightly longer than regular quantity of dry ice
- Significantly slower warming between 0°C and ambient temperature minimizes high temperature excursions



Products Impacted

This change will impact the packaging and shipping of all products that had been shipped on dry ice.

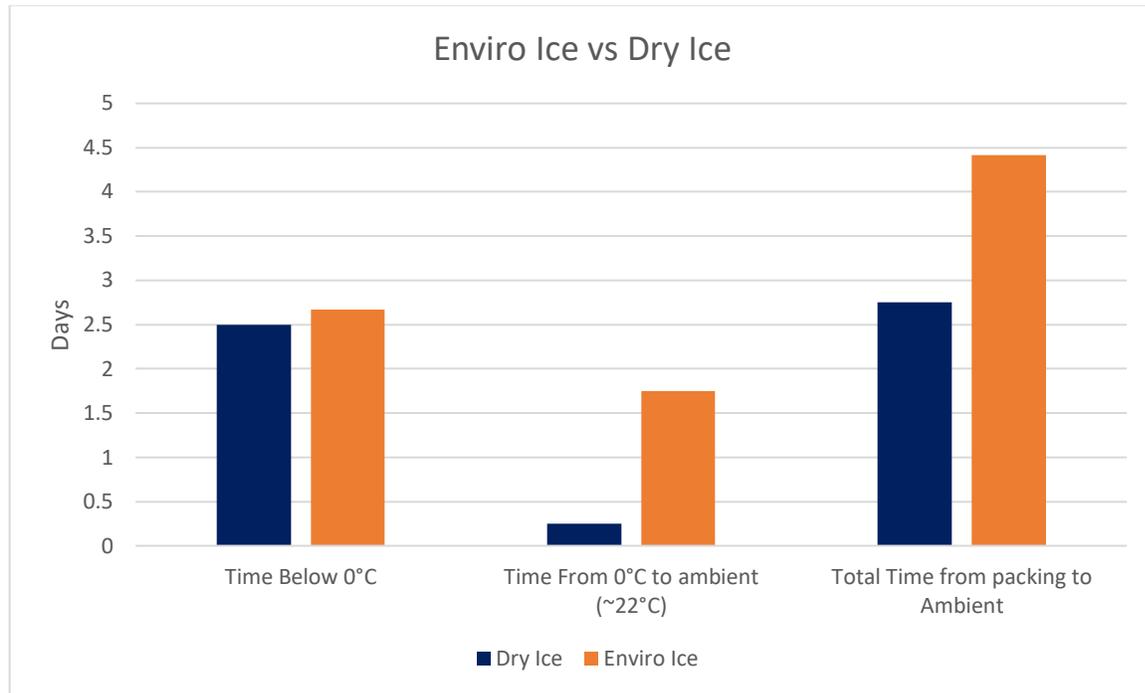
Product	Shipping Conditions
Collagenase HA/MA	Enviro Ice
Collagenase Gold	Ambient
Collagenase Gold Plus	Enviro Ice
BP Protease	Ambient
RI	Enviro Ice
Thermolysin	Enviro Ice
DE Collagenases	Ambient
AS/AS2	Ambient
Comingled Order	Enviro Ice (if at least 1 item is recommended to ship with Enviro Ice)

There has been no change made to manufacturing processes or product specifications related to this notification. This change only applies to shipping conditions.

Justification

Enviro Ice

The Enviro Ice were qualified by testing different combinations of cartons and frozen Enviro Ices for duration of cold storage. A comparison of cold storage duration for an average shipment is shown in the graph below. Additional product stability and cold storage data can be provided upon request.



Effective Date

Orders fulfilled after 31 Jan 2022 will be shipped according to the table above, unless you contact VitaCyte and articulate your organization’s preferences.

Dry ice will only be used for future orders if expressly communicated to VitaCyte and will result in higher packaging and shipping costs.

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 material shipping conditions creates a potential for confusion. For that reason, we will continue to fulfill shipments to your organization’s specific requirements. Please let VitaCyte know promptly if these changes conflict with your quality system and specify your organization’s preferences. 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