

May 29, 2025

TO: Customers of the Visby Medical Sexual Health Test

RE: Update to External Controls for Visby Medical Sexual Health Test

Dear Valued Visby Customer,

We're writing to inform you of an important update regarding the external controls used with the **Visby Medical Sexual Health Test**.

As part of our ongoing commitment to quality improvement and in response to customer feedback, we are transitioning to a new SKU and configuration for external controls. These controls continue to be manufactured by **Zeptomatrix™**, now under a new item number: **NATCTNGTV-ERCK-IVD**.

What's Changing?

The new external control kit offers a simplified configuration, combining both positive and negative controls in a single kit:

	Item #	Details
OLD	Pos Controls: NATCTNGTV-POS-IVD Neg Controls: NATCTNGTV-NEG-IVD	Separate Positive and Negative Controls. 6 x 1 mL vials of control per SKU
NEW	NATCTNGTV-ERCK-IVD	One kit includes: 2 x 1 mL Positive Control vials and 2 x 1 mL Negative Control vials

What This Means For You

- You now only need to order one item number to receive both control types.
- External controls should continue to be run with every shipment received.
- Controls may be ordered as needed, based on your testing volume.

Supporting Materials

We've updated both the Quick Reference Guide and Instructions for Use to reflect this change. You can access and download the latest versions [here](#).

Customer Support
Hours: Mon-Fri 8:00 am - 4:00 pm PST
Email: support@visby.com
Phone: 1-833-GoVisby (1-833-468-4729)

PL-000338 Rev A



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Transition Guidance

You will continue to receive Visby Sexual Health Tests containing the old QRG while we deplete inventory.

We recommend utilizing any current stock of the previous controls while they remain within their expiration dates. Moving forward, please use the new SKU **NATCTNGTV-ERCK-IVD** for all future orders.

If you have any questions or need further assistance, please don't hesitate to contact Visby Customer Support at **1-833-468-4729** or via email at **support@visby.com**.

Thank you for your continued partnership.

Sincerely,

The Visby Medical Team

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