DNAgenotek™

Product change notification

Products affected: OMNIgene™·ORAL

Catalog numbers/SKUs: OME-505

Change description: The OME-505 is currently labeled as an In Vitro Diagnostic (IVD) device for use under Emergency Use Authorization (EUA) within the United States for SARS-CoV-2. Given the demand for diagnostic SARS-CoV-2 testing has significantly declined following the pandemic, the device labeling will be updated to remove the EUA labeling. As a result of this change, the OME-505 device will no longer be available within the United States.

In countries outside of the United States, the OME-505 device will remain available as a CE/IVD labeled device.

Customer action:

- For customers in the United States, OME-505 will be available for purchase until December 26, 2026, or until current inventory is depleted, whichever occurs first. Contact your account manager to place a final order, as required, and to discuss alternate device options.
- If you are purchasing OME-505 devices from a country outside of the United States, no action is required.

For any issues or concerns pertaining to this product change notification, email **info@dnagenotek.com**.

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