

Product change notification

Products affected:  **ORAGENE-DNA**

Catalog numbers/SKUs: OG-500, OG-510, OG-575, OG-600, OG-610, OG-675

Effective date of change: May 15, 2024

Final purchase date: April 30, 2025

Change description: The Oragene™•DNA saliva collection devices will be discontinued. Oragene™•DNA devices will be replaced with the equivalent Oragene™•Dx saliva collection devices. Oragene™•Dx devices are made from the same physical and chemical materials and are functionally equivalent in safety, performance and price. A Certificate of Exclusivity and Equivalency is available for download at <https://dnagenotek.com/globaldocs/PD-1057.pdf>.

Below is a comparison summary for the Oragene™•DNA and Oragene™•Dx devices.

	Oragene 500 Series: Classic design		Oragene 600 Series: New design with automation features and shorter tube to reduce carbon footprint	
	Discontinued devices	Replacement devices	Discontinued devices	Replacement devices
	 ORAGENE-DNA	 ORAGENE-Dx	 ORAGENE-DNA	 ORAGENE-Dx
Catalog number/SKU	OG-500, OG-510, OG-575	OGD-500, OGD-510, OGD-575	OG-600, OG-610, OG-675	OGD-600, OGD-610, OGD-675
Regulatory labeling	CE/IVD, Class I	FDA 510(k) cleared, CE/IVD, Class I	CE/IVD, Class I	FDA 510(k) cleared, CE/IVD, Class I
Device components				
Self-collection devices:				
Assisted collection devices:				
Volume of saliva collected	OG-500: 2 mL OG-510: 1 mL OG-575: 0.75 mL	OGD-500: 2 mL OGD-510: 1 mL OGD-575: 0.75 mL	OG-600: 2 mL OG-610: 1 mL OG-675: 0.75 mL	OGD-600: 2 mL OGD-610: 1 mL OGD-675: 0.75 mL
Stabilization chemistry	Same. See safety data sheet at www.dnagenotek.com/ROW/pdf/PD-MSDS-00004.pdf			

Reason for change:

DNA Genotek will be discontinuing the Oragene™•DNA saliva collection devices to streamline its portfolio to improve operations globally.

Customer action:

Your last order for Oragene™•DNA devices must be placed no later than **April 30, 2025**. Contact your account manager for information on the appropriate replacement devices or email info@dnagenotek.com to ensure you've transitioned to the Oragene™•Dx saliva collection devices prior to the final purchase date.

DNA Genotek recommends you review the following for additional guidance:

1. You have unused Oragene™•DNA devices:
 - No action is required. The Oragene™•DNA devices can be used until the specified expiration date.
2. You have placed an order for Oragene™•DNA devices but have not received delivery:
 - No action is required. The Oragene™•DNA devices will be shipped and delivered. Once received, the devices can be used until the specified expiration date.
3. You will place an upcoming order for Oragene™•DNA devices:
 - Contact your account manager to discuss transitioning to Oragene™•Dx saliva collection devices; you may want to request Oragene™•Dx device samples or request a quote.
4. You would like to receive Oragene™•Dx device sample(s):
 - Contact your account manager to request an Oragene™•Dx device sample or complete the online sample request form <https://dnagenotek.com/ROW/products/request-trial-kit.html>.
5. You hold company-specific marketing authorizations and/or import permits for the Oragene™•DNA devices:
 - Contact your account manager to discuss available marketing authorizations for the replacement Oragene™•Dx saliva collection devices in your region.