DNAgenotek™

Product change notification

Products affected: OMNIgene®•ORAL

Catalog number/SKU: OM-505, OME-505
Description: OMNIgene®•ORAL

Effective date of change: January 1, 2021

Product description: OMNIgene•ORAL OM-505 and OMNIgene•ORAL OME-505 saliva collection devices are made from the same physical and chemical materials and are functionally equivalent in quality, safety and performance. The OME-505 device is CE marked for IVD use in Europe and is FDA authorized for emergency use (EUA).

OM-505

OME-505

Reason for change: Currently both OM-505 and OME-505 are available to fulfill OMNIgene•ORAL COVID-19 orders. In response to the increased demand for use of these devices for COVID-19 testing, DNA Genotek is implementing manufacturing efficiencies to focus on manufacturing one COVID-19 dedicated OMNIgene•ORAL saliva collection device. This implementation will allow for an increase in production lot sizes and an improved product supply to customers.

Change description: As of January 1, 2021, the OME-505 will be the designated product to fulfill orders of OMNIgene•ORAL for use in COVID-19 testing. A certificate of exclusivity and equivalency between OM-505 and OME-505 will be provided upon request.

Customer action: If you have any questions or want to discuss this product change notification, reach out to your account manager or email **info@dnagenotek.com**. As OM-505 and OME-505 are equivalent, there is no need to revalidate; the devices can be used interchangeably. If you are in the United States and have a granted or pending Emergency Use Authorization, you may need to amend your EUA request to also include the OME-505. Contact your FDA reviewer to confirm.