



Product change notification

Products affected



Catalog number: OM-200

Description: OMNIGene®•GUT for Microbiome

Effective date of change: December 2016

Customer actions

Required only if:

- Barcodes are applied to OMNIGene•GUT after purchase
- Collection instruction layout impacts ethics approval
- Tube label changes impacts ethics approval

Change description

Based upon user feedback and additional performance data, DNA Genotek has made improvements to our OMNIGene•GUT product.

1. Pre-use OMNIGene•GUT shelf-life

We have extended the pre-use shelf-life of OMNIGene•GUT from 12 months to 18 months.

Kits manufactured with lot numbers starting with "TK" will be the first to have the 18 month "use by" date printed on the label.

Note: this change to the "collect sample by (use by)" date is retroactive for kits with the following lots, and therefore they can be used 6 months after the labeled "use by" date printed on the label.

Lot numbers beginning with	Use by date on label (year - month)	Extended use by date (year - month)
SE	2016-05	2016-11
SF	2016-06	2016-12
SG	2016-07	2017-01
SH	2016-08	2017-02
SI	2016-09	2017-03
SJ	2016-10	2017-04
SK	2016-11	2017-05
SL	2016-12	2017-06
TA	2017-01	2017-07
TB	2017-02	2017-08
TC	2017-03	2017-09
TD	2017-04	2017-10
TE	2017-05	2017-11
TF	2017-06	2017-12
TG	2017-07	2018-01
TH	2017-08	2018-02
TI	2017-09	2018-03
TJ	2017-10	2018-04



Change description (continued)

2. Improved instructions for use

The layout of the instructions for use (donor collection instructions) have been improved to increase ease of use. These changes highlight and clarify collection preparation and material disposal instructions by including them as collection steps.

3. Reduced tyvek packaging dimensions

The outer tyvek packaging will be reduced in size from 14 cm × 24.2 cm to 10.2 cm × 24.1 cm. The content on the package is unchanged.

4. Addition of barcodes to standard tube label

The tube label will include a unique 128C barcode with a human readable portion to facilitate sample traceability and handling.

Standard label



Reason for change

Pre-use shelf life change is based on additional performance data. Improved instructions for use, reduced size of tyvek packaging and the addition of barcodes on the tube label are based on user feedback.

Note

We recommend confirming with your ethics review board if the changes to the collection instruction layout or tube label impact protocol approval. Please contact info@dnagenotek.com or your **account manager** if you have any issues or concerns pertaining to this product change notification.