

Product change notification

Products affected:  **OMNigene-ORAL**

Catalog number: OM-501 and OM-505

Description: OMNigene-ORAL is intended for the collection and stabilization of microbial DNA (OM-501) or microbial DNA and RNA (OM-505) from saliva. For research use only, not for use in diagnostic applications.

Effective date of change: As stated in the change description below.

Product change descriptions:

Change #1: The purple dot insert on the small screw cap has been removed from the OM-501 and OM-505 (See Figure 1).

From: Coloured purple dot

To: Clear (no purple dot)

Effective date of change: April 1, 2020

Reason for change: To improve manufacturing efficiencies

Change #2: A standard 14-digit scannable barcode (128C format) has been added to the tube label for the OM-501 and OM-505 (see Figure 2).

From: No barcode

To: 14-digit, 128C format scannable barcode

Effective date of change: April 17, 2020

Reason for change: To better support workflow scalability and improve sample traceability.

Change #3: Step #5 on the printed Instructions For Use (IFU) and on the collection video (see Customer action on page 2), have been updated across all languages for OM-501 and OM-505 (see Figure 3).

From: *Shake the capped tube for 10 seconds.*

To: *Shake the capped tube for 5 seconds.*

Effective date of change: May 13, 2020

Reason for change: To keep the Instructions For Use consistent across all DNA Genotek's saliva collection devices.

Change #4: The standard 14-digit scannable barcode (128C format) for the OM-501 and OM-505 has been modified in format and positioning since Change #2 above (see Figure 2).

From: NNNNYMMLLSSSS

To: NNYYMMLLLSSSS

Effective date of change: September 1, 2020

Reason for change: To improve manufacturing efficiencies and automation capabilities

Customer action:

To obtain the latest version of the video instructions, visit the following website links provided below.

Note: Any existing links referring to the video instructions for the OM-505 and OM-501 obtained and used prior to May 13, 2020 will return an error page.

a. **North America:**

<https://www.dnagenotek.com/US/support/collection-instructions/omnigene-oral/OM-505.html>

b. **Outside North America:**

<https://www.dnagenotek.com/ROW/support/collection-instructions/omnigene-oral/OM-505.html>

Figure 1: Purple dot insert on the small screw cap (Change #1)

OM-501 /OM-505



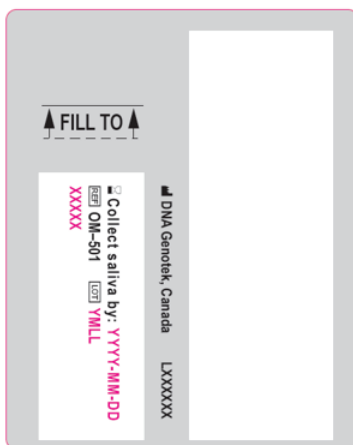
Before April 1, 2020



After April 1, 2020

Figure 2: Tube label (Change #2 and #4)

OM-501



Before April 17, 2020



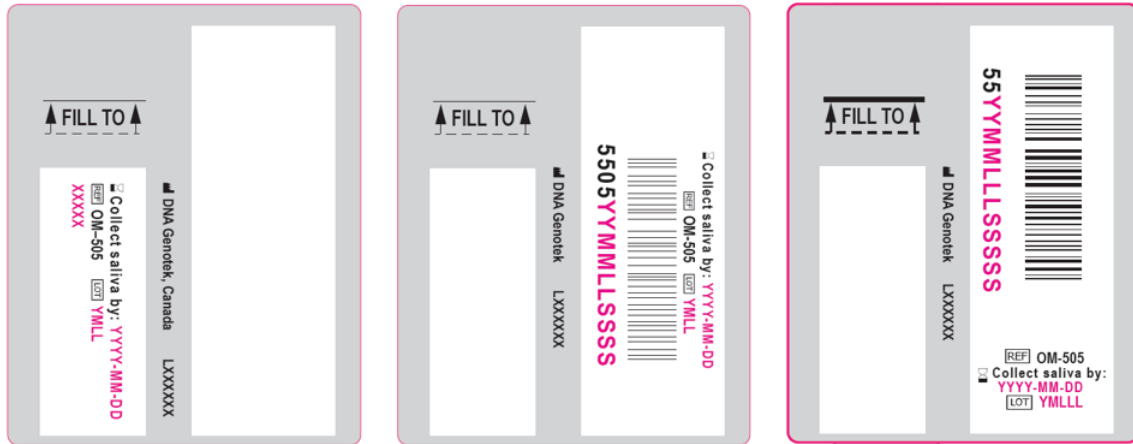
Between April 17 and September 1, 2020



After September 1, 2020

Figure 2 continued: Tube label change (Change #2 and #4)

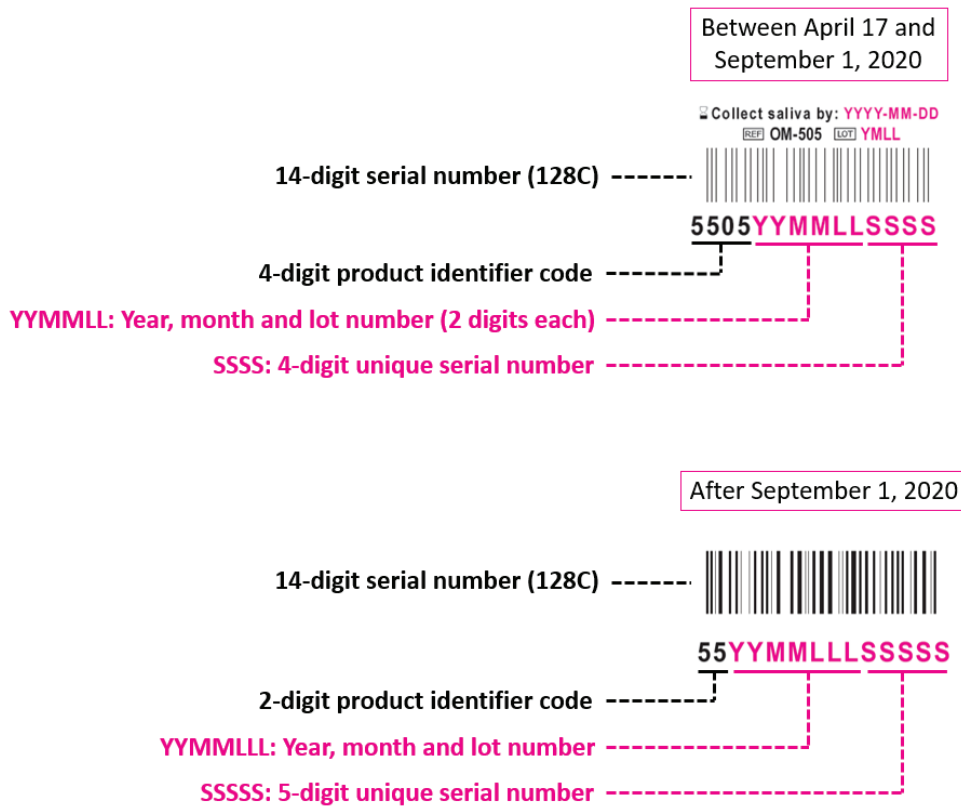
OM-505



Before April 17, 2020

Between April 17 and September 1, 2020

After September 1, 2020



*Pink indicates variable information. The final label is black.

Figure 3: Instructions For Use (Change #3)

OM-501 / OM-505

Before May 13, 2020

Procedure:

Most people take between 2 and 5 minutes to deliver a sample following steps 1 to 5.

- 1 Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.
- 2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.
- 3 Hold the tube upright. Unscrew the funnel from the tube.
- 4 Use the small cap to close the tube tightly.
- 5 Shake the capped tube for 10 seconds. Discard or recycle the funnel.

After May 13, 2020

Procedure:

Most people take between 2 and 5 minutes to deliver a sample following steps 1 to 5.

- 1 Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.
- 2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.
- 3 Hold the tube upright. Unscrew the funnel from the tube.
- 4 Use the small cap to close the tube tightly.
- 5 Shake the capped tube for 5 seconds. Discard or recycle the funnel.

Please contact info@dnagenotek.com if you have any issues or concerns pertaining to this product change notification.