

User instructions - For In Vitro Diagnostic Use

Intended use:

OMNIgene®-GUT Dx is intended for the non-invasive collection of human fecal samples and the stabilization of DNA from the bacterial community for subsequent assessment of the microbiome profile by an assay validated for use with OMNIgene®-GUT Dx.

SUMMARY AND PRINCIPLES:

The OMNIgene®-GUT Dx has been demonstrated to stabilize microbial DNA in a fecal sample, through the preservation of bacterial relative abundance profiles. Performance of OMNIgene®-GUT Dx has been validated using metagenomic whole genome sequencing, demonstrating stability and reproducibility of the representation of the *in vivo* fecal bacterial community composition. The OMNIgene®-GUT Dx is not for the detection of specific microbial pathogens.

Special conditions for use statement:

- For *in vitro* diagnostic use.
- For prescription use.

Contents: Kit contains 2 mL stabilizing liquid.

Warnings:

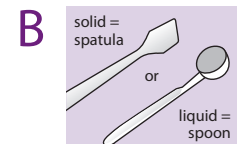
- FOR EXTERNAL USE ONLY.
- Do NOT remove the yellow tube top from the tube.
- Tube is not designed to stand upright.
- Do NOT ingest. Do NOT spill the stabilizing liquid in the tube.
- The OMNIgene®-GUT Dx should not be used if (1) there is evidence of damage or visible contamination to the product, (2) the expiration date has passed, (3) the package is open or damaged, or (4) there are other signs of deterioration.
- Avoid contact with skin and eyes. Wash with water if stabilizing liquid comes in contact with eyes or skin.

Important preparations:



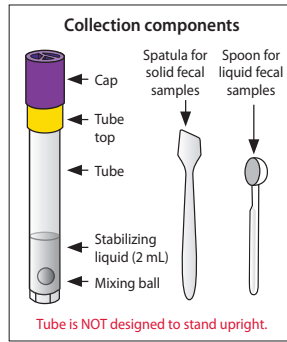
Read all instructions prior to collection.

- Empty your bladder before beginning the collection.
- Collect fecal sample free of urine or toilet water.
- Utilize any toilet accessory which may be supplied with the collection device.
- Toilet paper or tissues may be required.



Determine which collection tool to use based on the consistency of the fecal sample:

- If a **solid** fecal sample, use the **spatula**. Follow collection steps 1 to 8 shown on the next panel.
- If a **liquid** fecal sample, use the **spoon**. Follow collection steps 1 to 6 shown on the yellow panel.



Read all instructions prior to collection.

SOLID FECAL SAMPLE collection procedure (with spatula):

- While holding the yellow tube top, unscrew **ONLY** the purple cap and set aside for later use.
IMPORTANT: Do NOT remove the yellow tube top. Tube is not designed to stand upright. Do NOT spill the stabilizing liquid in the tube.
- Use the **spatula** to collect a small amount of solid fecal sample.
- Transfer the fecal sample into the top portion of the yellow tube top. **Repeat until the sample fills the yellow top.**
IMPORTANT: Do NOT push sample into the tube.
- Scrape horizontally across the tube top to level the sample and remove any excess. Wipe exterior of tube and top with toilet paper or tissue as needed.
- Pick up the purple cap and screw onto the yellow tube top until tightly closed.
- For a **minimum of 30 seconds**, shake the sealed tube as hard and fast as possible in a back and forth motion. The fecal sample will be mixed with the stabilizing liquid in the tube; not all particles will dissolve.
- IMPORTANT:** Continue shaking if **large** particles remain as shown in Figure A.
- Place spatula in original packaging or wrap in toilet paper and discard in garbage.
IMPORTANT: Send the sample for processing following the delivery instructions supplied separately by the test provider.

Read all instructions prior to collection.

LIQUID FECAL SAMPLE collection procedure (with spoon):

- While holding the yellow tube top, unscrew **ONLY** the purple cap and set aside for later use.
IMPORTANT: Do NOT remove the yellow tube top. Tube is not designed to stand upright. Do NOT spill the stabilizing liquid in the tube.
- Use the **spoon** to transfer **one spoonful of liquid sample** into the top portion of the yellow tube top. Do NOT transfer more than one spoonful.
- Pick up the purple cap and screw onto the yellow tube top until tightly closed.
- For a **minimum of 30 seconds**, shake the sealed tube as hard and fast as possible in a back and forth motion. The fecal sample will be mixed with the stabilizing liquid in the tube; not all particles will dissolve.
- IMPORTANT:** Continue shaking if **large** particles remain as shown in Figure A.
- Place spoon in original packaging or wrap in toilet paper and discard in garbage.
IMPORTANT: Send the sample for processing following the delivery instructions supplied separately by the test provider.

Complete sample collection instructions and troubleshooting are available at: www.dnagenotek.com/us/pdf/PD-HB-00023.pdf for OMD-200 Handbook

A free paper copy of the Handbook may be requested at:
Toll-free (North America): 1.866.813.6354 | info@dnagenotek.com
3000 - 500 Palladium Drive, Ottawa, ON, Canada K2V 1C2

Ship in accordance to applicable regulations covering transport of biological specimens. See MSDS at www.dnagenotek.com

DNAGENOTEK®
www.dnagenotek.com

For In Vitro Diagnostic Use, Rx only
Contains 2 mL stabilizing liquid

OMNIGENE-GUT DX
for microbiome
REF OMD-200

Made in USA
DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.
Patent (www.dnagenotek.com/legal/notices)
15°C / 25°C (59°F / 77°F)

Label legend:

	Manufacturer
	Consult package insert
	Collect sample by (Use by)
	Catalog number
	Rx Only
	For Prescription Use Only
	In vitro diagnostic medical device
	Lot number
	Do not reuse
	Caution, consult instructions for use
	May cause skin/eye irritation
15°C / 25°C	Pre-collection storage instructions
59°F / 77°F	
20°C / 26°C	Post-collection storage instructions
68°F / 79°F	

Storage:

Pre-collection:
15°C / 25°C (59°F / 77°F)
for up to 18 months.

Post-collection:
20°C / 26°C (68°F / 79°F)
for up to 30 days after
sample collection.

DNAGENOTEK®
www.dnagenotek.com

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