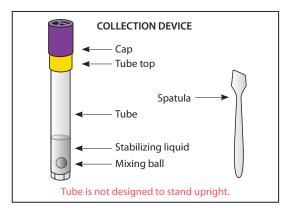


For microbiome **№ OM-200**



Intended use/purpose: Intended for the collection and stabilization of microbial DNA from human fecal samples.

Intended user: This product is intended for use by adults.

Contents: 1 kit containing stabilizing liquid.

Summary and explanation of the kit:

OMNIgene®•GUT provides the materials and instructions for collecting and stabilizing microbial DNA from a fecal sample.

Warnings and precautions:

- · FOR EXTERNAL USE ONLY.
- Do NOT remove the yellow tube top from the tube.
- Do NOT spill the stabilizing liquid in the tube.
- Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com.
- · If collecting a liquid fecal sample, see separately provided user instructions.
- Small items may pose a choking hazard.
- Report any serious incident to DNA Genotek and the competent authority in your country

Storage: Room temperature storage pre- and post-collection 15 °C 1/25 °C (59 °F 1/77 °F).

Flammable liquid

Label legend:

Exclamation mark (Warning) Manufacturer Collect sample by (Use by) Catalog number REF LOT Lot number CE CE marking **UKCA** marking CK (2) Do not re-use (Ii) Consult package insert ND In vitro diagnostic medical device \triangle Caution, consult instructions for use European Authorized Representative CH REP Swiss Authorized Representative

Unique Device Identifier UDI Storage instructions

59°F 1/77°F

For In Vitro Diagnostic Use

DNAgenotek[™]

Made in Canada

CE ™ K

Superior samples Proven performance

Toll-free (North America): 1.866.813.6354 Tel.: +1.613.723.5757 • Fax: +1.613.723.5057 DNA Genotek Inc. 3000 - 500 Palladium Drive info@dnagenotek.com Ottawa, ON, Canada K2V 1C2 www.dnagenotek.com

USER INSTRUCTIONS

Read all instructions prior to collection.

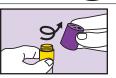
Other languages are available at www.dnagenotek.com

Procedure:



IMPORTANT PREPARATIONS:

- 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.



While holding the yellow tube top, unscrew ONLY the purple cap and set aside for later use.



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 fecal sample.





Transfer the fecal sample into the top portion of the yellow tube top. Repeat until the sample fills the yellow tube 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.



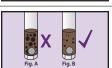


Pick up the purple cap and screw onto the yellow tube top until tightly closed.



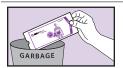


For a minimum of 30 seconds, shake the sealed tube as hard and fast as possible in a back and forth motion.



The fecal sample will be mixed with the stabilizing liquid 8 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 kit provider.

Ship in accordance to applicable regulations covering transport of biological specimens.

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OMNIgene-GUT (OM-200) is not available for sale in the United States.

OMNIgene is a registered trademark and DNA Genotek is a trademark of DNA Genotek Inc.

Some DNA Genotek products may not be available in all geographic regions; contact your sales representative for details. All DNA Genotek protocols, white papers and application notes are available in the support section of our website at www.dnagenotek.com.

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