

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 / 25 °C (59 °F / 77 °F).

Label legend:

- Flammable liquid
 - Exclamation mark (Warning)
 - Manufacturer
 - Collect sample by (Use by)
 - Catalog number
 - Lot number
 - CE marking
 - UKCA marking
 - Do not re-use
 - Consult package insert
 - In vitro diagnostic medical device
 - Caution, consult instructions for use
 - European Authorized Representative
 - Swiss Authorized Representative
 - Unique Device Identifier
 - Storage instructions
- 15°C / 25°C
59°F / 77°F

USER INSTRUCTIONS

Read all instructions prior to collection.

Other languages are available at www.dnagenotek.com

Procedure:



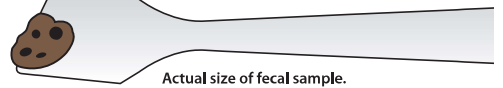
- 1 IMPORTANT PREPARATIONS:**
- Empty your bladder before beginning the collection.
 - Collect fecal sample free of urine or toilet water.
 - Utilize any toilet accessory which may be supplied with the collection device.
 - Toilet paper or tissues may be required.



- 2** 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.



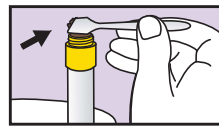
- 3** Use the spatula to collect a small amount of fecal sample.



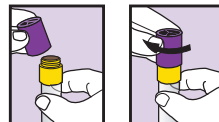
- 4** Transfer the fecal sample into the top portion of the yellow tube top. Repeat until the sample fills the yellow tube top.



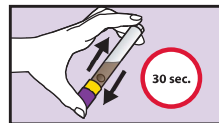
IMPORTANT: Do NOT push sample into the tube.



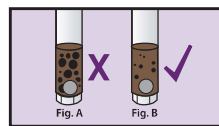
- 5** Scrape horizontally across the tube top to level the sample and remove any excess.
- Wipe exterior of tube and top with toilet paper or tissue as needed.



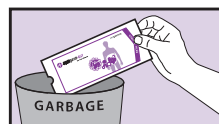
- 6** Pick up the purple cap and screw onto the yellow tube top until tightly closed.



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



- 8** 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.



- 9** 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.