

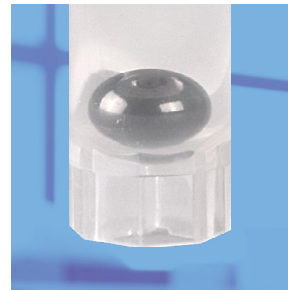
FDA-authorized device for gut microbiome profiling

Reduce validation time, experimental bias and failed collections by leveraging the only validated and FDA-authorized device for *in vitro* diagnostic use.

OMNigene®·GUT Dx is setting the standard in collection, homogenization and stabilization of fecal bacterial DNA for microbiome-based diagnostic applications.



Adopting a standardized and fully validated collection method creates workflow consistency and enables transferability across laboratories and projects.



IVD FDA De Novo authorized

Standardization

Volumetric sample input to improve reproducibility.

High validity

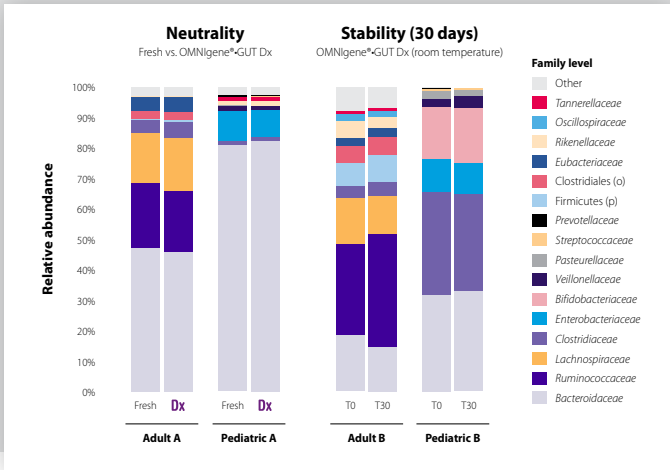
Homogenization and stabilization to ensure reliable results.

Scalability

Barcode tracking to improve workflow efficiencies and sample traceability.

A microbiome benchmark for reproducibility, reliability and efficiency.

Accurate profile, from time of collection to DNA extraction

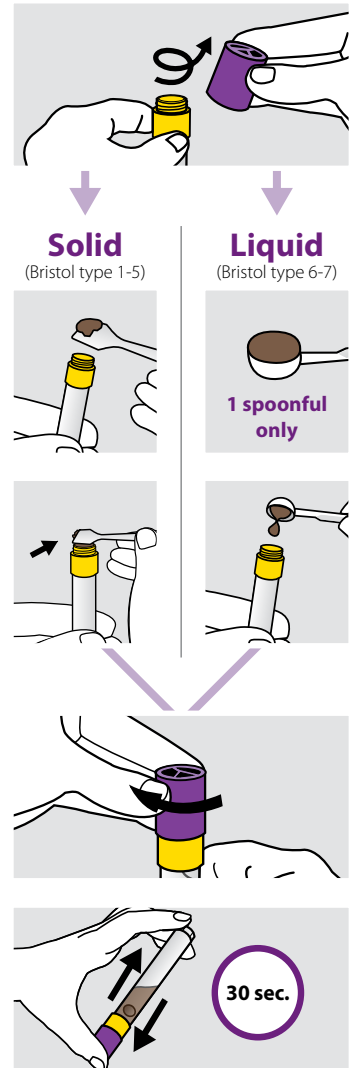


A true snapshot

Capture an unbiased view of the relative abundance of the bacterial community at time of collection while maintaining sample integrity for **30 days at room temperature**.

Relative abundance bar plots representing % abundance for top 10 family-level classifications for Adult (A/B) and Pediatric (A/B) donors between fresh samples (Fresh) and OMNIGENE-GUT Dx (Dx) at time of collection (Neutrality) and stabilized samples (Dx) held for 30 days at room temperature (Stability). Family-level classification is presented, or lowest taxonomy where family was not assignable, as indicated in the brackets.

Collection instructions



Specifications and attributes¹

Fecal sample collected per kit (median)	545 mg
Number of extractions per kit (250 µL per extraction)	8
DNA yield per 250 µL extraction (median)	8.1 µg
Freeze-thaw and temperature fluctuation stability	-20°C to +30°C
Validated with guanidinium-based extraction kits	✓
Validated with liquefaction reagent OM-LQR	✓
Microbiome profile stability at room temperature	30 days
Validated with metagenomic WGS assay	✓
Suitable for long-term storage and biobanking ²	✓
Barcoded for full sample traceability (128C and 2D)	✓

Packaged product:

Dimensions: 24.2 cm x 10.2 cm
Weight: 25.96 g

Collection device:

Height: 118.9 mm
Tube height: 92.5 mm
Tube diameter: 15.25 mm
Cap diameter: 18 mm

Storage conditions:

Pre-collection:
15°C to 25°C (59°F to 77°F)

Maximize compliance and minimize failed collections

A validated collection method combining an intuitive design and clear concise instructions drives cost reduction and time saving through a higher percentage of successful sample collections.

Comprehension and execution*

Collection instructions	
Successfully understood and performed critical steps ¹	94.0%
Collection results (extracted DNA per 250 µl aliquot)	
Successfully provided more than 120 ng of DNA ¹	99.9%

*Validation study on a subset of 118 naive users representing the general population.



Your partner in streamlining your assay development and standardizing your workflow.

¹ Product handbook for OMD-200, DNA Genotek, PD-HB-00023 (2022)

² DNA Genotek, internal validation

Some DNA Genotek products may not be available in all geographic regions.

OMNIGENE-GUT Dx (OMD-200) has been granted FDA De Novo classification for in vitro diagnostic use (DEN200040).

OMNIGENE and DNA Genotek are registered trademarks of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners.



For the collection of bacterial DNA from human fecal samples

Superior samples • Proven performance

