OMNIgene®·GUT Dx

Product handbook for OMD-200

DNAgenotek®

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Subsidiary of OraSure Technologies, Inc.

IVD Rx only

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IVD

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 statements

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

Summary and explanation of use

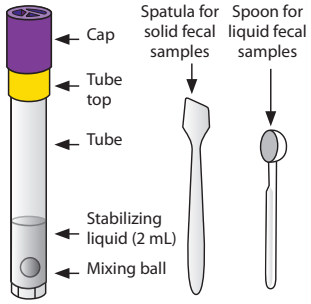
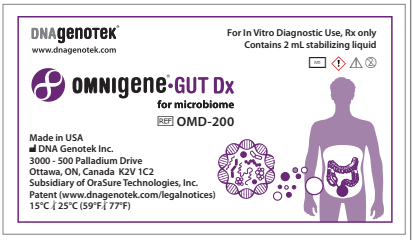
Use OMNIgene•GUT Dx for the collection, stabilization and room temperature storage of bacterial DNA from human fecal samples.

Features of the OMNIgene•GUT Dx

- Non-invasive and reliable for the collection of human fecal samples.
- Collected samples remain stable at room temperatures (20°C to 26°C) for 30 days, as evaluated using a validated metagenomic whole genome sequencing assay.
- Samples can be exposed to temperature fluctuation ranging from -20°C to 30°C (-4°F to 86°F) during storage.
- Standard volumetric sample input and point-of-collection sample homogenization reduce intra-sample variation and increase reproducibility.
- Collection kit provides the means to effectively collect and stabilize microbiome profiles of any fecal sample type (Bristol type 1 to 7).
- Sample provides bacterial DNA suitable for metagenomic whole genome sequencing.
- Bar code tracking to improve workflow efficiencies and sample traceability.

Materials

OMNIgene•GUT Dx kit includes the following:

Collection components	Instructions for Use
 Tube is NOT designed to stand upright.	

Materials not provided but available for use with OMNIgene•GUT Dx, if required.

1. Liquefaction Reagent (Models: OM-LQR-400; OM-LQR-1600)
   - Instruction for use (Lab Protocol) reference: https://www.dnagenotek.com/US/pdf/PD-PR-00855.pdf
2. Toilet Accessory (OM-AC1)
   - Instructions for use reference: https://www.dnagenotek.com/US/pdf/PD-PR-00684.pdf

WARNINGS AND PRECAUTIONS

- 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.
- Avoid contact with skin and eyes. Wash with water if stabilizing liquid comes in contact with eyes or skin. If irritation persists, seek medical advice.
- Safely clean and disinfect any areas if there is a spill.
- Small items may pose a choking hazard.
- Keep out of reach of children.
- Only use the components and accessories provided with the kit.
- During sample collection:
  - Handle device and stool sample in accordance with good personal or industrial hygiene and safety practice.
  - When using this collection device containing the stabilizing liquid, it is recommended to use gloves, protective eyewear and/or other personal protective equipment.
  - Wash hands thoroughly and after handling potentially infectious microbiological specimens such as stool.

- During lab processing:
  - Specimens collected by OMNIgene®•GUT Dx may contain viable infectious microorganisms; therefore, specimens should be processed with appropriate precautions for infectious materials and by trained personnel only. Gloves and/or other personal protective equipment should be used when handling stool. Protective eyewear and/or other personal protective equipment should be used when handling the stabilizing liquid.
  - Handle device and stool sample in accordance with good personal or industrial hygiene and safety practice. Wash hands thoroughly after handling potentially infectious microbiological specimens such as stool.
  - Decontaminate and dispose of all specimens, reagents and other potentially contaminated materials in accordance with local, state and federal regulations.
- See safety data sheet at www.dnagenotek.com

PRECAUTIONS

1. Carefully follow the instructions for use. Deviation from the instructions for the collection and storage of samples with the OMNIgene®•GUT Dx may affect test results.
2. 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.
3. This OMNIgene®•GUT Dx product is for single collection use only; re-use may cause a risk of infection and/or inaccurate results.

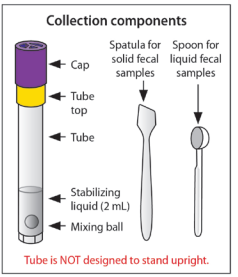
Product use limitations

1. The OMNIgene®•GUT Dx has been validated for collection and stabilization of bacterial DNA for the purpose of evaluating the bacterial community composition. Collecting samples for the evaluation of bacteria for the diagnosis of any specific disease requires validation of such assay. The OMNIgene®•GUT Dx is not for the detection of specific microbial pathogens.
2. OMNIgene•GUT Dx is intended for collection and stabilization of bacterial DNA from human fecal samples, it is NOT intended for the collection and stabilization of RNA, protein, metabolites or hormones.
3. Performance characteristics of the OMNIgene•GUT Dx kits were established using the QIAGEN® QIAamp® PowerFecal® Pro DNA Kit extraction protocol.
4. Performance of OMNIgene•GUT Dx was demonstrated using a validated metagenomic whole genome sequencing (WGS) assay for measurement of fecal microbiome profiles from a healthy donor cohort and was comprised of nucleic acid extraction, library preparation, sequencing and bioinformatics. For specific details of this validation process, please see the performance sections below. Room temperature stability performance of OMNIgene•GUT Dx was established in the range of 20°C to 26°C/68°F to 79°F for 30 days. All other temperatures and durations need to be validated by the end user.
5. Assays performed on specimens collected by the OMNIgene®•GUT Dx should be legally marketed and must be validated by the assay manufacturer for use with the OMNIgene®•GUT Dx.

Donor collection instructions for use

Product number	Donor collection instructions for use document number
OMD-200	PD-PR-01261

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. If irritation persists, seek medical advice.
- Safely clean and disinfect any areas if there is a spill.
- Small items may pose a choking hazard.
- Keep out of reach of children.
- Only use the components and accessories provided with the kit.
- It is recommended to use gloves, protective eyewear, and/or other personal protective equipment when handling this device.
- Handle device and stool sample in accordance with good personal or industrial hygiene and safety practice. Wash hands thoroughly and after handling potentially infectious microbiological specimens such as stool.
- Discard unused/misused devices in the garbage or in accordance with local guidelines. Excess sample should be flushed in the toilet.

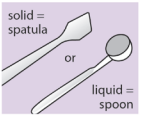
Important preparations:

A

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.

B



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):

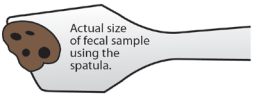
1

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.

2

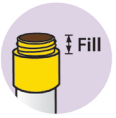
Use the **spatula** to collect a small amount of solid fecal sample.



3

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.



4

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.

5

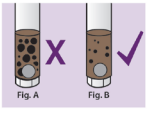
Pick up the purple cap and screw onto the yellow tube top until tightly closed.

6

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.

7



IMPORTANT: Continue shaking if **large** particles remain as shown in Figure A.

8

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):

1

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.

2

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.

Only 1 spoonful

3

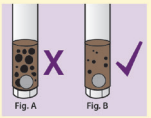
Pick up the purple cap and screw onto the yellow tube top until tightly closed.

4

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.

5



IMPORTANT: Continue shaking if **large** particles remain as shown in Figure A.

6

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

Storage of OMNIgene•GUT Dx

Pre-collection

Store OMNIgene•GUT Dx kits at room temperature (15°C to 25°C/59°F to 77°F) for up to 18 months.

Post-collection

Note: The recommended storage conditions of specimens should be validated for specific assays. The following post-collection recommendations were validated with a metagenomic whole genome sequencing assay.

Samples collected with OMNIgene·GUT Dx provide bacterial DNA suitable for downstream microbiome analysis.

Room-temperature storage: Fecal samples collected in OMNIgene•GUT Dx can be stored at room temperature (20°C to 26°C/ 68°F to 79°F) for up to 30 days after sample collection.

Storage at 4°C: We do not recommend storing OMNIgene•GUT Dx samples at 4°C/ 39°F

Freeze-thaw: Samples can be exposed to temperature fluctuations ranging from -20°C to 30°C (-4°F to 86°F). Up to 5 freeze-thaw cycles are recommended.

To achieve optimal sample preservation, collection tube must be closed tightly and sample fully homogenized with the stabilization liquid.

All other temperatures and conditions need to be validated by the end user.

Purification

OMNIgene•GUT Dx performance has been established using the following protocol:

OMNIgene®•GUT Dx collection device - bacterial DNA purification protocol using QIAGEN® QIAamp® PowerFecal® Pro DNA Kit (PD-PR-00968)

Purification protocol is available at www.dnagenotek.com.

Performance characteristics

The following data are representative of OMNIgene•GUT Dx performance and were generated using the purification and extraction methods described above as well as through a validated metagenomic whole genome sequencing (WGS) assay on an Illumina based sequencing system.

OMNIgene•GUT Dx device performance

Data obtained from the validation studies, including a total of 552 samples collected using the OMNIgene•GUT Dx device, is used in support of the performance characteristics. Performance of the device was determined using a metagenomics whole genome sequencing assay, which was validated using a diverse panel of 15 bacteria representing bacterial families within healthy fecal microbiomes. Validation involved evaluating assay limits and ranges as part of determining a linear dynamic range; additionally, carryover, contamination, and reproducibility of the process (e.g., extraction, library prep, sequencing, analysis) were tested. Minimum number of samples and validation parameters were determined based on recommendations from Clinical and Laboratory Standards Institute (EP17-A. Vol. 24 No. 34. 2004.).

The microbial species composing the microbiome panel were selected based on the following criteria:

- High prevalence (≥ 40%) in representative donor population
- Abundance (≥ 0.05%) in donors where species is present
- Panel members are representative of Adult (12/15) and Pediatric (3/15) cohorts
- Representative species from major commensal and clinically relevant pathogenic bacterial families on the gut microbial community phylogenetic tree: Bacteroidaceae, Ruminococcaceae, Rikenellaceae, Tannerellaceae, Lachnospiraceae, and Peptostreptococcaceae
- Gram negative (6/15) and Gram positive (9/15) bacteria are represented
- Genomes range in GC content from 38% to 56%

Overall data

As summarized in the Table 1 and in Figure 1, sufficient DNA for sequencing was consistently obtained from a 250 µL extraction aliquot across all 552 OMNIgene•GUT Dx collected samples.

Table 1: Summary of DNA concentration and yield from OMNIgene•GUT Dx collected samples (552 samples)

	DNA concentration (ng/µL)	Aliquot DNA yield (µg)*	Total DNA yield (µg)
Mean ± SD	98.95 ± 54.96	9.89 ± 5.50	79.16 ± 43.96
Median	87.25	8.72	69.80
95% of samples	≥ 29.57	≥ 2.96	≥ 23.66

*DNA yield from a 250 µL aliquot.

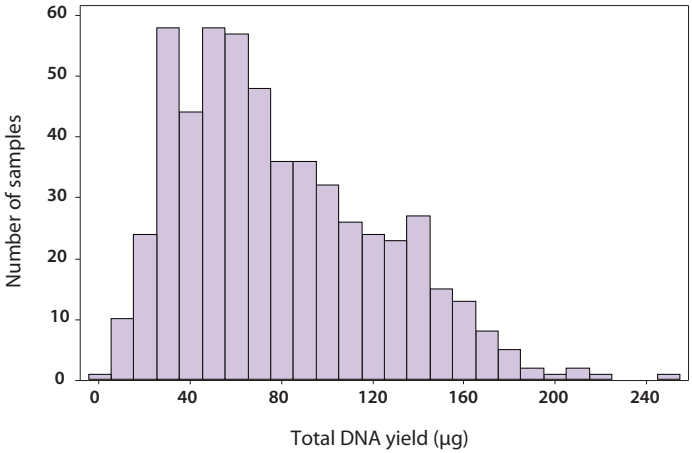


Figure 1: Summary plot for total DNA yield (µg) from an OMNIgene•GUT Dx collected device*. The frequency of total DNA yield (µg) across collected OMNIgene•GUT Dx devices (n = 552) from validation datasets.*

Sample stability

Samples were stored at room temperature (20°C to 26°C/68°F to 79°F) for > 30 days (T30) with and without the addition of OMNIgene liquefaction reagent (OM-LQR). Additional samples were subjected to freeze (-20°C/-4°F)/thaw (30°C/86°F) cycles. At the study time point, DNA was extracted, quantified and analyzed using metagenomic whole genome sequencing (WGS). Samples were assessed for stability by comparing read counts between OMNIgene•GUT Dx baseline and test samples (within a pre-determined acceptable range). Two donor cohorts were collected; adults of 18+ years and pediatrics between the ages of 3 and 46 months.

The Aitchison distance was used to measure the difference in total bacterial microbiome composition and relative abundance between paired samples. Figures 2 (adult) and 4 (pediatric) show the Aitchison distances for the stability validation dataset where each point is a donor sample at baseline (T0) compared to the same sample after storage (T30) at room temperature with (RTL) or without (RT) OMNIgene liquefaction reagent (OM-LQR). For statistical comparison, the final box shows the between-donor distance at T0 (each donor against every other donor). The magnitude of change (distance) and the variability for each time point group is far lower than the between-donor change (T0_btwndonor), suggesting the microbiome profiles are stable over 30 days in the OMNIgene•GUT Dx device. Additionally, there is no significant difference between samples with or without OM-LQR.

Figures 3 (adult) and 5 (pediatric) show compositional principal component analysis (PCA) biplots for the stability validation dataset. Sample points colored by Donor ID show strong inter-donor clustering, regardless of condition.

Table 2: Summary of post-collection sample stability results

	Temperature	RT with OM-LQR	RT without OM-LQR	Freeze (-20°C)/ thaw (30°C)
	Time (days)	30	30	Multiple cycles (5)
Adult cohort	Yield	●	●	●
	Microbiome stability	●	●	●
Pediatric cohort	Yield	●	●	●
	Microbiome stability	●	●	●

● Summary of post-collection sample stability results (room temperature = RT, OMNIgene liquefaction reagent = OM-LQR)

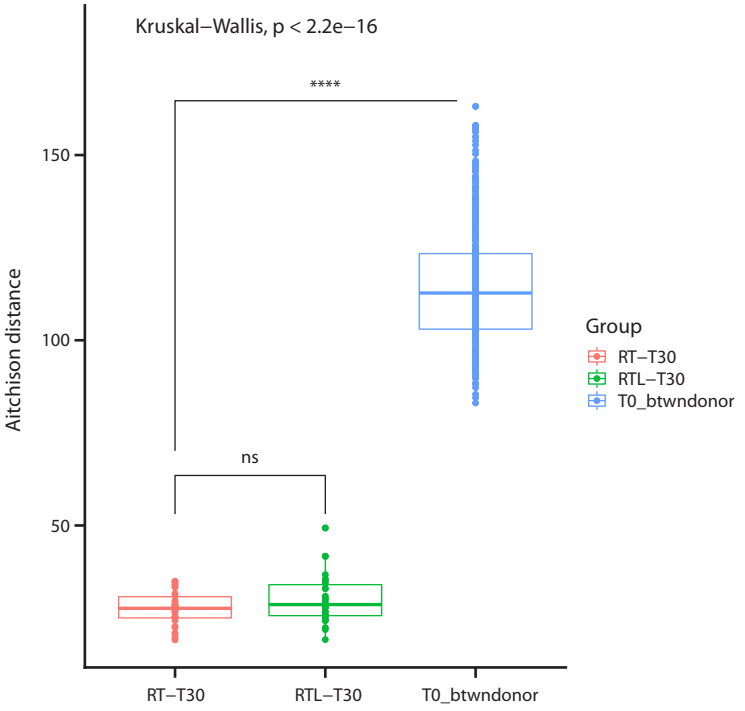


Figure 2: Group-wise comparison of Aitchison distance for the stability validation dataset (adult cohort; n = 30)*. Each point is a donor sample at baseline (T0) compared to the same sample after storage at room temperature with (RTL) or without (RT) OMNIgene liquefaction reagent (OM-LQR) for > 30 days (T30). For statistical comparison, the final box shows the between-donor distance at T0 (each donor against every other donor). Kruskal-Wallis non-parametric test was applied between groups, and two-group comparisons using a t-test from RT-T30 vs. the remaining groups. 'ns': P > 0.05, '****': P ≤ 0.0001.*

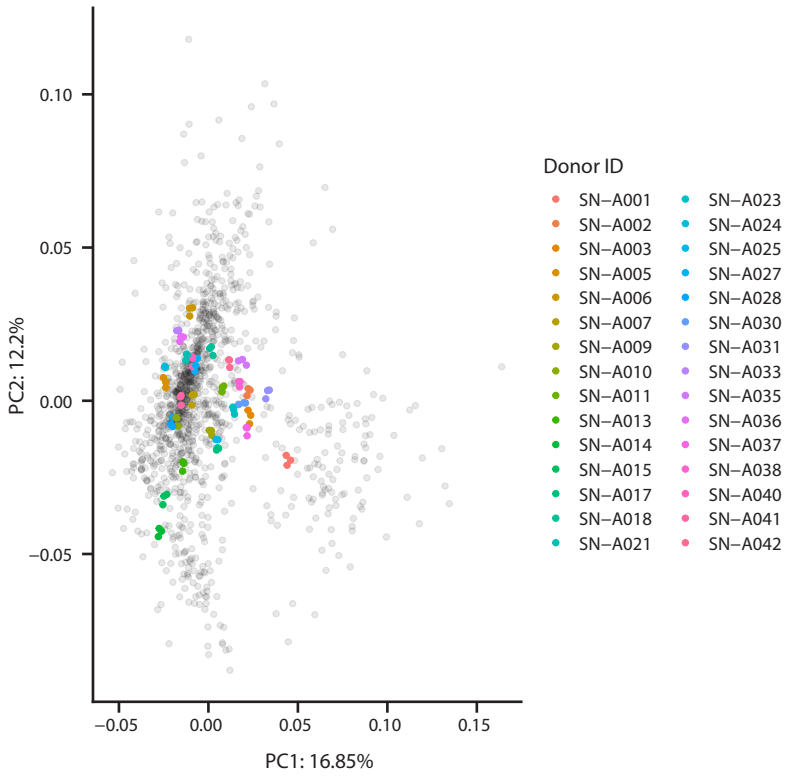


***Figure 3: Compositional principal component analysis (PCA) biplot for the stability validation dataset (adult cohort; n = 30)**. The first two components explaining the most variance in the data are plotted: PC1 with 16.85% and PC2 with 12.2% variance explained (29.05% in total). Sample points are colored by Donor ID. Bacterial species (variables) are plotted as grey dots and co-associate with the samples where they are contributing relative abundance (weighted contribution to total variance) and explanatory power.*

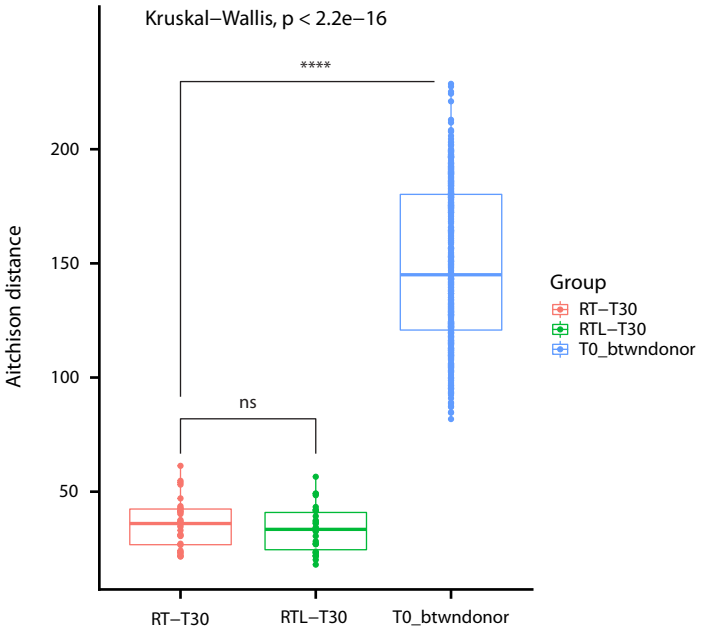


Figure 4: Group-wise comparison of Aitchison distance for the stability validation dataset (pediatric cohort; n = 30)*. Each point is a donor sample at baseline (T0) compared to the same sample after storage at room temperature with (RTL) or without (RT) OMNIgene liquefaction reagent for > 30 days (T30). For statistical comparison, the final box shows the between-donor distance at T0 (each donor against every other donor). Kruskal-Wallis non-parametric test was applied between groups, and two-group comparisons using a t-test from RT-T30 vs the remaining groups. 'ns': P > 0.05, '****': P ≤ 0.0001.*

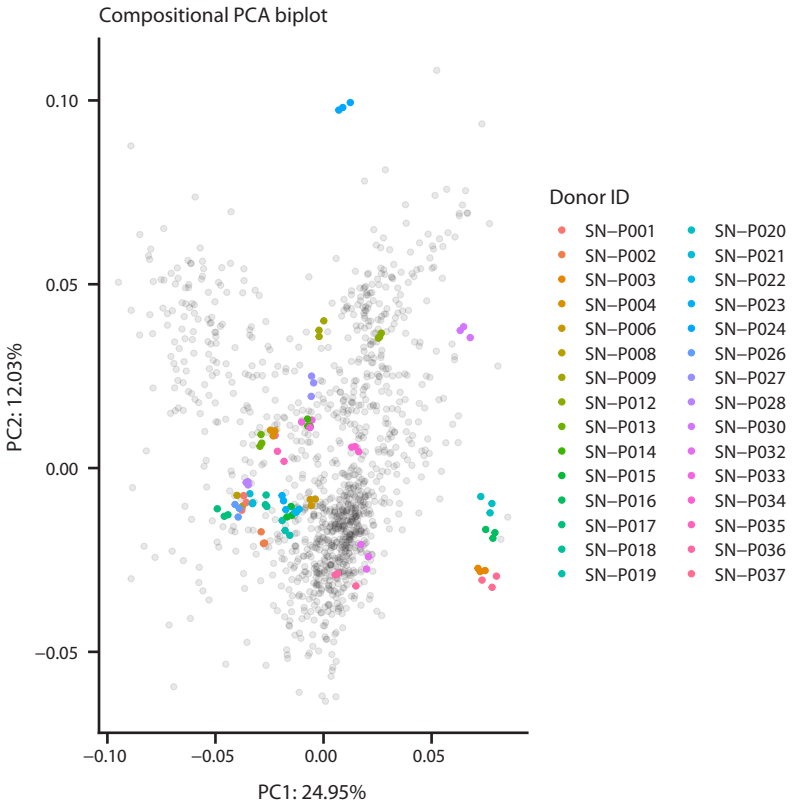


Figure 5: Compositional principal component analysis (PCA) biplot for the stability validation dataset (pediatric cohort; n = 30). *The first two components explaining the most variance in the data are plotted: PC1 with 24.95% and PC2 with 12.03% variance explained (36.98% in total). Sample points colored by Donor ID show strong inter-donor clustering on the first two components, regardless of condition. Taxa (variables) are plotted as grey dots and co-associate with the samples where they are contributing relative abundance (weighted contribution to total variance) and explanatory power.*

Sample neutrality

Unstabilized fecal samples were collected by donors and transported to the laboratory on ice packs. Samples were immediately collected into OMNIgene•GUT Dx devices with the addition of OMNIgene liquefaction reagent (OM-LQR). DNA was immediately extracted from donor matched unstabilized and OMNIgene•GUT Dx samples. DNA was quantified and analyzed using metagenomic whole genome sequencing. Samples were assessed for neutrality (i.e. maintenance of an unbiased representation of the *in vivo* state) by comparing read counts between OMNIgene•GUT Dx samples and the corresponding unstabilized control samples (within a pre-determined acceptable range). Two donor cohorts were collected; adults of 18+ years and pediatrics between the ages of 3 and 46 months.

The Aitchison distance was used to measure the difference in total bacterial microbiome composition and relative abundance between paired samples. Figures 6 (adult) and 8 (pediatric) show the Aitchison distance for the neutrality validation dataset. Each point is an unstabilized 'Control' fecal sample from a donor at baseline (CB) compared to the same sample at baseline stabilized in OMNIgene•GUT Dx (OMDB). The magnitude of change (distance) and the variability for T0 samples collected in OMNIgene•GUT Dx is significantly lower than the between-donor change (T0_btwndonor).

Figures 7 (adult) and 9 (pediatric) show compositional principal component analysis (PCA) biplots for the neutrality validation dataset. Sample points colored by Donor ID show strong inter-donor clustering on the first two components, regardless of condition.

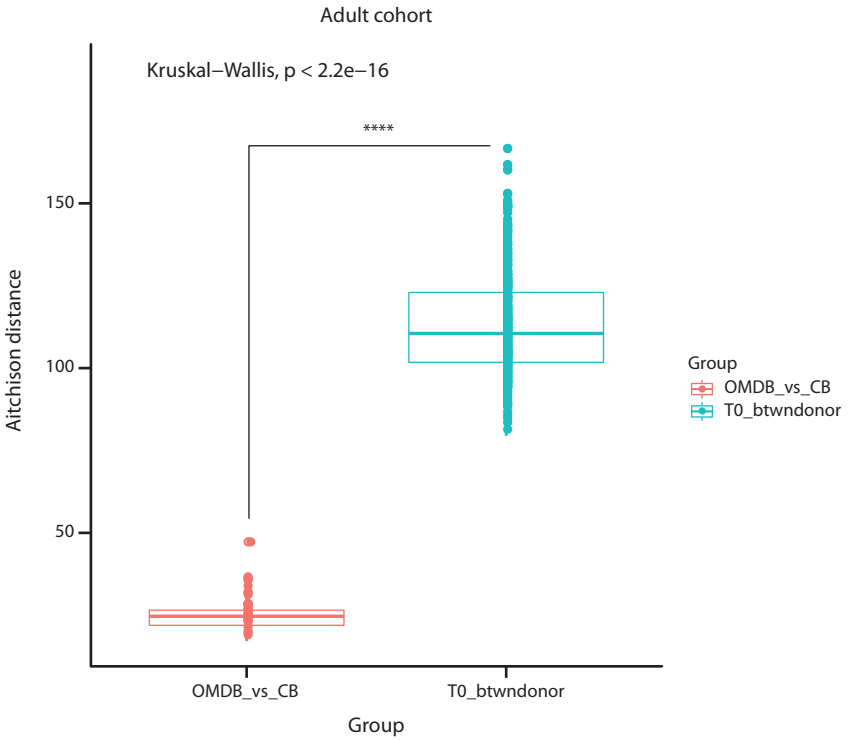


Figure 6: Group-wise comparison of Aitchison distance for the neutrality validation dataset (adult cohort; n = 30). *Each point is an unstabilized 'Control' fecal sample from a donor at baseline (CB) compared to the same sample at baseline stabilized in OMNIgene•GUT Dx (OMDB). For statistical comparison, the final box shows the between-donor distance at T0 (each donor against every other donor). Kruskal-Wallis non-parametric test was applied between groups, '****': P ≤ 0.0001.*

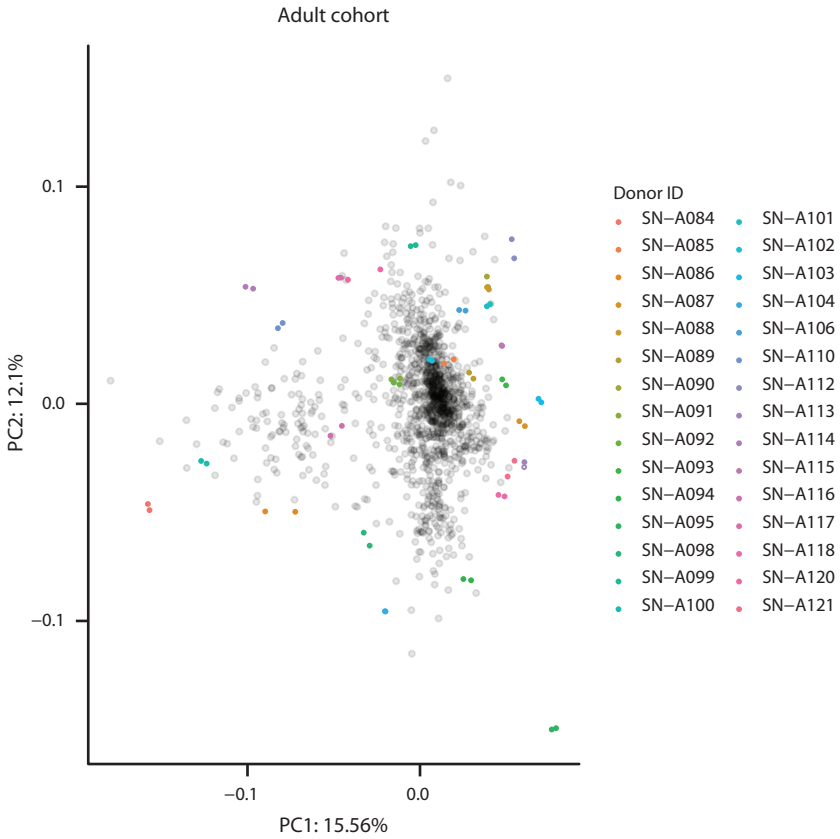


***Figure 7: Compositional principal component analysis (PCA) biplot for the neutrality validation dataset (adult cohort; n = 30)**. The first two components explaining the most variance in the data are plotted: PC1 with 15.56% and PC2 with 12.1% variance explained (27.66% in total). Sample points are colored by Donor ID. Bacterial species (variables) are plotted as grey dots and co-associate with the samples where they are contributing relative abundance (weighted contribution to total variance) and explanatory power.*

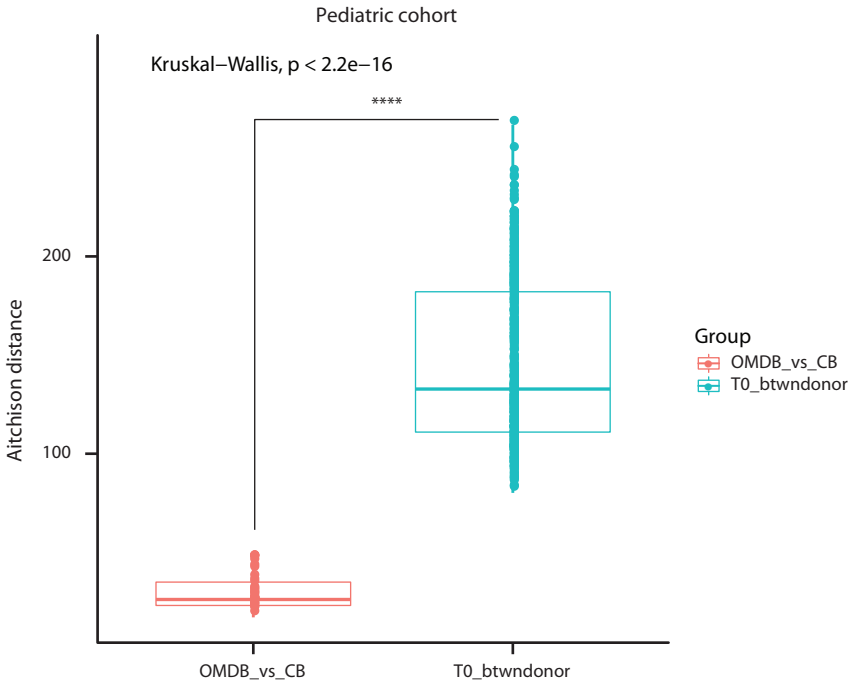


Figure 8: Group-wise comparison of Aitchison distance for the neutrality validation dataset (pediatric cohort; n = 30). *Each point is an unstabilized 'Control' fecal sample from a donor at baseline (CB) compared to the same sample at baseline stabilized in OMNIgene•GUT Dx (OMDB). For statistical comparison, the final box shows the between-donor distance at T0 (each donor against every other donor). Kruskal-Wallis non-parametric test was applied between groups, '****': P ≤ 0.0001.*

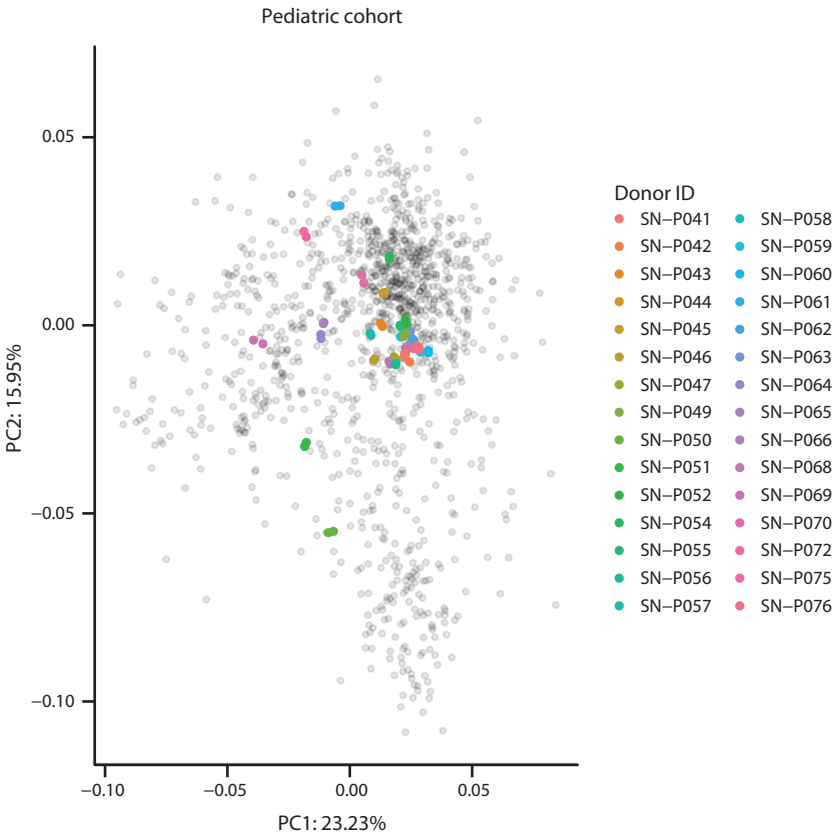


Figure 9: Compositional principal component analysis (PCA) biplot for the neutrality validation dataset (pediatric cohort; n = 30)*. The first two components explaining the most variance in the data are plotted: PC1 with 23.23% and PC2 with 15.95% variance explained (39.18% in total). Sample points are colored by Donor ID. Bacterial species (variables) are plotted as grey dots and co-associate with the samples where they are contributing relative abundance (weighted contribution to total variance) and explanatory power.*

Reproducibility

Lot-to-lot and aliquot-to-aliquot reproducibility

Lot-to-lot reproducibility was assessed by collecting from the same sample using different OMNIgene•GUT Dx lots. Aliquot-to-aliquot reproducibility was assessed by extracting multiple aliquots from an OMNIgene•GUT Dx sample. Samples were assessed for agreement across lots and aliquots in detection of each target species (i.e., presence vs. absence) and consistency in read counts between samples per donor.

The Aitchison distance was used to measure the difference in total bacterial microbiome composition and relative abundance between paired samples, with a lower value being more similar. As shown in Figure 10, both lot-to-lot and aliquot-to-aliquot show low distance and low variability compared to donor to donor differences (T0_btwndonor) and are similar to the stability cohorts from Figure 4. Figure 11 shows a compositional principal component analysis (PCA) biplot for the reproducibility validation dataset. Sample points colored by Donor ID show strong inter-donor clustering on the first two components, regardless of condition.

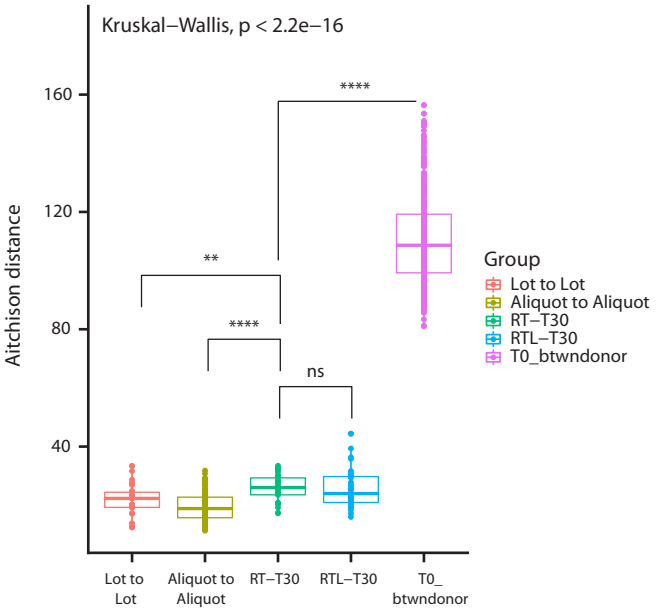


Figure 10: Group-wise comparison of Aitchison distance for the reproducibility validation dataset and the previously described stability cohorts (Figure 4) for comparison*. Replicate bulk samples collected (n = 11) into three different OMNIgene•GUT Dx device lots, and aliquots of the same sample from a single OMNIgene•GUT Dx device. Kruskal-Wallis non-parametric test was applied between groups, and two-group comparisons using t-test from lot-to-lot to the remaining groups. '*': P < 0.05, '**': P < 0.01, '***': P < 0.001 '****': P < 0.0001.*

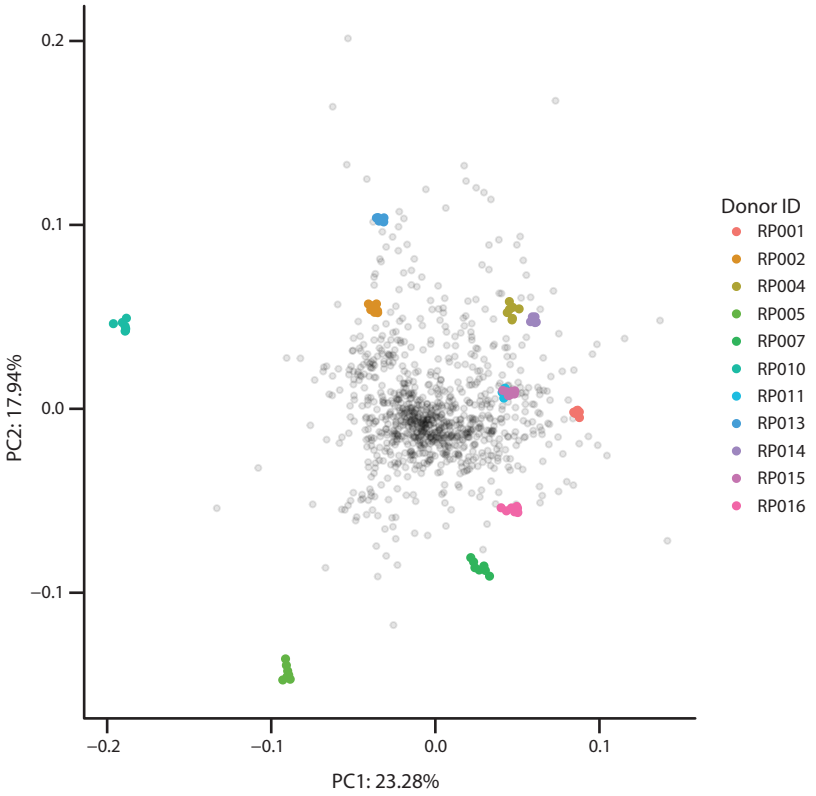


***Figure 11: Compositional principal component analysis (PCA) biplot for the reproducibility validation dataset (n = 11)**. The first two components explaining the most variance in the data are plotted: PC1 with 23.28% and PC2 with 17.94% variance explained (41.22% in total). Sample points are colored by Donor ID. Bacterial species (variables) are plotted as grey dots and co-associate with the samples where they are contributing relative abundance (weighted contribution to total variance) and explanatory power.*

Interfering substances

A range of endogenous and exogenous interfering substances were spiked at biologically relevant levels to OMNIgene•GUT Dx collected samples and extracted alongside unspiked controls. Samples were assessed for consistency in read counts to the corresponding control (unspiked) sample within a pre-determined acceptable range. The endogenous and exogenous substances tested include Blood, Urine, Bile Acids and Salts, Complex Polysaccharides, Lipids, Zinc Oxide, Petroleum Jelly, Mineral Oil and Toilet paper. None of the tested substances interfered with the metagenomic whole genome sequencing (WGS) assay performance.

Medical device symbol chart

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

Patent information

Patent (www.dnagenotek.com/legalnotices)

Troubleshooting

Before/during collection

Observation	Action
There is no stabilizing liquid in the collection device or the purple screw cap and/or yellow top portion of the tube are leaking.	Do NOT allow donor to use the product; discard and request a replacement kit.
Stabilizing liquid comes into contact with eyes or skin.	Wash with water if stabilizing liquid comes in contact with eyes or skin. If irritation persists, seek medical advice. Do NOT ingest stabilizing liquid. For safety data information consult the Safety Data Sheet at www.dnagenotek.com.
The donor is not clear on what collection tool (spatula or spoon) should be used for fecal sample collection.	Refer to Part B of "Important preparations" in the Instructions for Use (IFU) to determine which tool to use for a solid or liquid fecal sample.
Both the purple cap and yellow tube top are removed from the collection tube.	Screw the yellow tube top back onto the tube before performing collection.
Yellow tube top is overfilled.	Use the spatula to scrape horizontally across the yellow tube top to level the sample and to remove any excess sample.
When putting purple cap on tube, the fecal sample overflows onto the tube exterior and/or the donor's hands.	Remove the purple cap from the tube, wipe the outside of the tube, including the threads with a paper towel/tissue. Then screw purple cap onto the tube and wash hands.
The collected sample has large particles present after shaking.	Repeat shaking step for an additional 30 seconds and re-evaluate sample with provided image in IFU.

Before sample purification

Observation	Action
The fecal sample is difficult to pipette.	Use the OMNIgene liquefaction reagent (OM-LQR) following the protocol (PD-PR-00968) available at www.dnagenotek.com
Collected fecal sample leaked.	Instruct the donor to re-collect the sample in a newly provided kit.
The collected fecal sample is overfilled (weight of tube + sample > 14.53 g) or underfilled (weight of tube + sample < 13.97 g).	Donor error. Instruct the donor to re-collect a sample in a newly provided kit.
The collected fecal sample is not homogenized.	Donor error. Instruct the donor to re-collect a sample in a newly provided kit.

OMNIgene•GUT Dx (OMD-200) has been granted FDA De Novo authorization for in vitro diagnostic use (DEN200040).
Some DNA Genotek products may not be available in all geographic regions.
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