

Getting to the Gut of It – Webinar Synopsis

Our September 9th, 2021 webinar *Getting to the gut of it: User experience and compliance in human microbiome studies* presented two studies and one case study that examined the usability and user comprehension of the OMNIgene•GUT kit and its instructions for use.

Accurate analysis of the gut microbiome requires a complete snapshot of the microbial community contained in a fecal sample at the time of collection.

[OMNIgene•GUT](#) is an all-in-one system that enables study participants to volumetrically collect fecal samples in the comfort and privacy of their own homes for microbiome profiling. The kit is easily used to self-collect a high-quality sample, which coupled with an intuitive and user-friendly collection method, improves donor compliance, and provides standardized fecal samples ready for transport, storage, and downstream processing.

Webinar Key Takeaways

- The unique design of the OMNIgene•GUT collection kit ensures a volumetrically collected sample that is properly homogenized and stabilized at the time of collection for a more consistent, reliable, and reproducible microbiome profile.
- Fecal samples collected with OMNIgene•GUT produce higher DNA yields and molecular weight DNA that are not only ideal for downstream applications, but which also underscore potential use in direct-to-consumer environments.
- For populations undergoing dysbiosis:
 - OMNIgene•GUT provides the means to collect and stabilize microbiome profiles conveniently and effectively. Fecal samples in this dysbiotic population are usually soft or liquid and the intuitive design of the spoon accessory allows for easier collection process and at-home use.
 - Samples collected from this population, using OMNIgene•GUT, recover DNA quality and yields that are sufficient for multiple downstream applications; and which maintain their microbial profile neutrality without any introduced bias. As such, they ensuring that the participant's *in vivo* dysbiosis profile is accurately cross-examined.
- Reproducible and reliable easy self-collection with OMNIgene•GUT provide a unique competitive edge by enabling access and recruitment of study participants across the general population and age spectrum, facilitating population-based Microbiome Wide-Association Studies (MWAS).

First Study: Usability and User Comprehension of OMNIgene•GUT, by Dr. Tara Crawford Parks

The study, undertaken in two parts, evaluated whether users could easily comprehend OMNIgene•GUT Instructions For Use (IFUs); and could correctly perform the critical tasks involved in the sample collection procedure.

In the first part of the study, untrained participants were observed handling a simulated sample; and in the second part, participants collected real fecal samples at home and mailed them for assessment. The second group of participants was further evaluated on their compliance with sample mailing instructions.

Across both studies, regardless of education and age, the results showed that:

- 94% of the times, participants answered the comprehension questionnaire correctly.
- 97% of participants complied with collection instructions whereby sufficient DNA yield was obtained per extraction aliquot.
- 100% of participants complied with collection instructions whereby they securely closed the collection tube.
- 97% of participants complied with the collection instructions whereby sufficient sample mixing was observed.

Second Study: Liquid Fecal Samples – Crohn’s and Colitis Study, Dr. Tara Crawford Parks

The study was done in partnership with *Crohn’s and Colitis Canada* and was designed to evaluate the usability and performance of the OMNIgene•GUT device in a targeted dysbiotic population.

More specifically, the study was conducted to evaluate the compatibility and performance of the OMNIgene•GUT collection device for at-home self-collection by untrained participants undergoing Crohn’s and chronic Colitis symptoms. This objective was achieved through an evaluation of the user comprehension and compliance with the device IFUs. Participants were provided the OMNIgene•GUT kit with the spoon accessory designed for participants with dysbiosis.

In this study, because the fecal samples were soft or liquid in consistency (65% reporting self-collection of Bristol Type 6 or 7 fecal sample) additional results were noted:

- All Type-7 participants preferred the sampling spoon accessory.
- Participants with Type 6 and lower on the Bristol scale preferred the spatula.
- Both sampling tools were successfully used to collect the required amount of fecal sample into the OMNIgene•GUT device.
- Average DNA yield per extraction aliquot was sufficient for downstream microbiome sequencing applications.

Study Findings

- The OMNIgene•GUT collection system is easy to use for untrained participants and has built-in fecal sample homogenization and stabilization of microbial DNA that make it ideal for microbiome profiling.
- The study validated the maximization of user compliance and the minimization of failed sample collection.
- The study validated the kit user instructions for sample types across the Bristol scale (1-7).
- The study confirmed a positive user experience by removing barriers to collecting fecal samples; and participants' feedback indicated their willingness to collect into multiple kits from a single fecal sample as well as for future collections.
- The study provided strong evidence for the success of at-home self-collection across the general population which positions the OMNIgene•GUT device for cohort scalability while highlighting its potential use in direct-to-consumer environments.

Case Study: Osteoporotic Fracture in Men Study – MrOS – user experience and compliance in human microbiome studies, by Melanie Abrahamson Sommer¹

The study of the relationship between the microbiome and its human host in health and disease relies on identifying and monitoring the microbial communities over a period of time. As there have been few studies linking the gut microbiome to the musculoskeletal system, MrOS research team set out to identify the risk factors associated with osteoporosis and bone fracture in older men through the study of the gut microbiome and its relationship to musculoskeletal health.

The MrOS research team has been using the [OMNIgene•GUT](#) self-collection device to collect fecal samples from older men over a 20-year span.

A derivative of their study is the team's high level of satisfaction with the OMNIgene•GUT sample collection device:

- The team was successful in collecting microbiome specimen from an elderly population for whom it might have been difficult to use other methods than the OMNIgene•GUT device self-collection kit.
- The quality of the DNA extracted from the samples was excellent.
- The feasibility of the collecting stool samples for microbiome analyses from a large community-based population of elderly men, using the OMNIgene•GUT self-collection device.

Supporting your Research Goals

Recent research studies demonstrate the utility of microbial profiles as potential biomarkers with prognostic and diagnostic value. Repeated sampling of large populations over time is essential to the development of such biomarkers, a result you can achieve through OMNIgene•GUT.

Whether your goal is to make it easy for your participants to collect fecal samples or to obtain a standardized, stable, and high-quality fecal sample for your research study, the OMNIgene•GUT collection system guarantees ease of kit use, participants' compliance, and an appropriate DNA yield for your subsequent applications.

Reference

1. Melanie Abrahamson, Elizabeth Hooker, Nadim J. Ajamib, Joseph F. Petrosino, Eric S. Orwoll: [Successful collection of stool samples for microbiome analyses from a large community-based population of elderly men](#). *Contemporary Clinical Trials Communications*, 7 (2017) 158-162