OMNIgene®•GUT Dx OMD-200 Dx

OMNIgene®•GUT Dx enables ease-of-use and broad population access to facilitate micobiome studies

The *first* and *only* FDA authorized fecal collection device for gut microbiome profiling, having undergone robust validation for user comprehension and compliance.

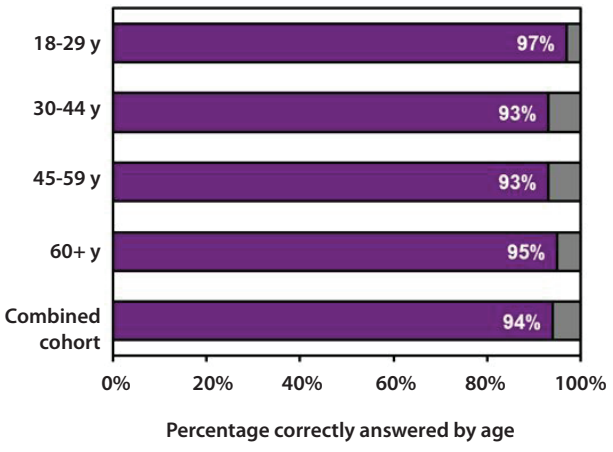
Participant recruitment for microbiome sample collections can be challenging. Non-compliance (e.g., participant dropout, collection errors, etc.) can increase study time and cost. Standardization of sample collection can improve study success and ensure easy access to broad populations that could benefit from participation, including understudied populations or those found in remote geographic locations.

Across two studies, 152 naive participants were recruited and evaluated on their ability to comprehend and use the OMNIgene•GUT Dx device by following the Instructions For Use (IFU) to collect a sample.

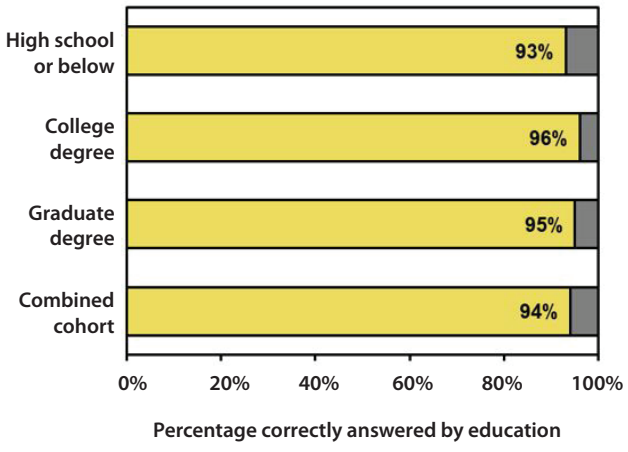
Both studies were designed and executed in accordance with FDA[1] and ANSI standard guidance[2] with key considerations related to user group selection, sample size, population demographics, education level and relevant real-world scenarios.

User comprehension

Participants were asked to complete a user comprehension questionnaire. Overall, participants correctly answered the questions **94%** of the time.



Percentage correctly answered by age



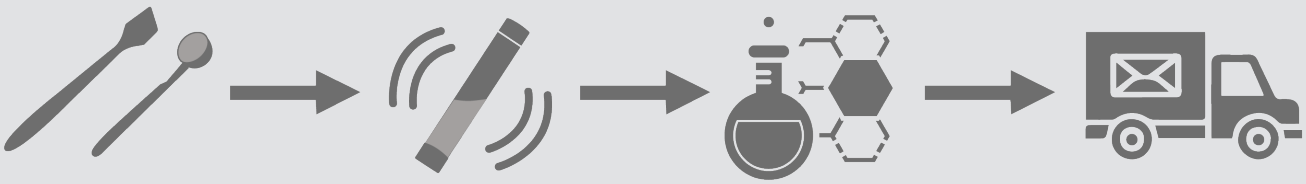
Percentage correctly answered by education

1 Center for Devices and Radiological Health, U.S. Food & Drug Administration (FDA). Applying human factors and usability engineering to medical devices. 2016.
2 The American National Standards Institute (ANSI). Medical Devices – Part 1: Application of usability engineering to medical devices. 2015; A1:2020.

User compliance on critical steps

Participants were evaluated on their ability to perform critical steps of the instructions on different sample types (Bristol 1 to 7). On average, participants executed the critical steps successfully **> 97%** of the time.

Evaluation criteria	Percentage (%) correct
Study participants complied with collection instructions, whereby sufficient DNA yield (≥ 120 ng) was obtained per extraction aliquot	97%
Study participants complied with collection instructions whereby they securely closed the collection tube	100%
Study participants complied with collection instructions for sufficient sample mixing	97%
Selected samples complied with mailing via standard postal systems supporting at home, direct-to-consumer settings	100%



1. Scoop sample
2. Shake to homogenize
3. Chemistry stabilizes
4. Transport sample

Key takeaways

- The intuitive design of the OMNIgene•GUT Dx device maximizes compliance across the general population while minimizing failed collections.
- The fully validated user instructions for both solid and liquid stool samples enable successful collection of all Bristol scale sample types (1 to 7).
- OMNIgene•GUT Dx is safe for at-home, self-collection. It is validated with naïve users from the general populations and provides the scalability and flexibility needed for large cohort studies.

To learn more about the performance of the OMNIgene•GUT Dx device, please see the **handbook**. For additional information, please visit the product page at **www.dnagenotek.com.**

For In Vitro Diagnostic Use

DNA Genotek® Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.

Toll-free (North America): 1.866.813.6354
Tel.: +1.613.723.5757 • Fax: +1.613.723.5057
www.dnagenotek.com
info@dnagenotek.com

DNAgenotek®