

HUMAN MICROBIOME ANALYSIS SERVICES

The human microbiome contains microorganisms from the three domains of life, and viruses, that co-habit in different human body sites. The human microbiome is increasingly recognized as having an important role in the onset and the progression of many diseases. Human microbiome analysis using next-generation sequencing provides a way to investigate the microbiome composition in a culture-independent way, leading to an important time-gain for obtaining results and allowing the investigation of microorganisms who cannot readily be cultured. At Medpace, we oversee the whole process, from sampling to DNA extraction, sequencing, and bioinformatics analysis. Both the wet-bench and dry-bench components of the analysis are performed according to standard operating procedures (SOPs), which allow us to obtain reliable and reproducible results during the duration of the clinical study. The Medpace central laboratory facility situated in Belgium has the capability to extract microbial DNA from human stool samples and perform next-generation sequencing using the Illumina® MiSeq™ and NextSeq™ instruments to answer your clinical research questions.

HUMAN STOOL PROCESSING METHOD

The Medpace global courier network allows human stool samples to arrive in the laboratory under the best possible conditions. Samples are archived at -80 °C. The microbial DNA is extracted using a validated protocol that includes homogenization and a combination of bead-beating and lysis chemistry. ZymoBIOMICS™ Microbial Community Standards are used to ensure the quality of the microbiome measurements.

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Human microbiome analysis can be performed in a targeted or untargeted way to answer your clinical research questions. 16S rRNA gene sequencing and shotgun metagenomic sequencing can be performed depending on the needs of the Sponsor. Whereas the former allows us to survey the gut microbial composition based on the amplification and sequencing of a taxonomic marker gene, the latter provides a metagenomic data set that can provide more precise information on the presence of microorganisms and their functions.

Due to the nature of the 16S rRNA gene, 16S rRNA gene sequencing is limited to survey bacteria and archaea. In contrast, shotgun metagenomics provides an unbiased view and thus may also allow detection of eukaryotes, such as fungi, and even viruses. Sponsors who are interested in the protein functions that are encoded within the microbial community, or who may have specific questions regarding antimicrobial resistance genes are directed towards shotgun metagenomics. Finally, strain-specific assays can be developed using qPCR to accurately quantify the abundance of your strain of interest.

| | 16S rRNA gene sequencing | Shotgun Metagenomics |
|---------------------------|--------------------------|----------------------|
| Cost | + | ++ |
| Taxonomic resolution | Genus | Species/Strain |
| Microbial composition (%) | Yes | Yes |
| Functional analysis | No | Yes |

