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TITLE: Self-Assessment Survey for Microbiome analysis: ensuring quality and standardization in biobanks

The microbiota is a key mediator of several human functions, including metabolism, immune regulation and colonization resistance. Consequently, there is growing interest towards the potential exploitation of microbiome in clinical practice.

However, multiple pre-analytical factors must be considered for handling microbiome specimens as they can severely impact the microbiome analysis. Key factors include donor, sample collection, stabilization, transport, processing, and storage conditions. The European Committee for Standardization (CEN) therefore established Technical Specifications (CEN/TS 17626:2021) specifying requirements for the 'pre-examination processes' of human specimens and addressing these critical pre-analytical variables. The CEN/TS were developed by European experts in the context of the EU-project SPIDIA4P and led by BBMRI.at representatives. The document is mainly for the diagnostic medical field, but is also highly relevant for biobanks and research laboratories. To validate biobank alignment with this European standard, we contributed to the development of a Self-Assessment Survey (SAS) provided by BBMRI-ERIC, a pivotal tool in a certification or accreditation perspective. The SAS consists of questions based on the CEN/TS and its pre-analytical requirements and recommendations for donor and specimen handling (collection, storage, transport, reception, microbiome DNA isolation, quality/quantity assessment, biobank DNA/sample storage). It includes different specifications based on sample type (stool, saliva, skin and urogenital specimens), since each presents unique challenges in preservation, contamination control, and post-collection handling. Therefore, protocols must be customized and rigorously followed to ensure quality of microbiome analysis and biobanking.

Ultimately, SAS is essential for biobanks to standardize the microbiome pre-analytical workflow, ensuring consistency and reproducibility in microbiome studies.