

Pre-Analytical Quality Standard for Microbiome Samples

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Introduction

It is widely accepted that the pre-analytical phase is a very vulnerable part of the laboratory testing process. An important way to improve the pre-analytic phase, reduce errors and generate samples of high and defined quality is working according to ISO/CEN standards, particularly those for pre-analytical sample processing.

The need for standardization is also increasingly recognized in the microbiome field.

Material & methods

During the EU-project SPIDIA4P, the standard CEN/TS 17626:2021, Molecular in-vitro diagnostic examinations—Specifications-for-pre-examination-processes-for-human-specimens—Isolated microbiome-DNA' was published. Although this standard relates to diagnostic procedures, it also has implications for microbiome research and development and for biobanks.

Results/Findings

This standard defines requirements along the pre-analytical workflow of microbiome samples, to generate samples that are fit for microbiome DNA analysis. The workflow includes all steps from documentation of patient-related information, to sample collection, transport, processing, storage and DNA isolation.

Among the most critical pre-analytical factors that can impair sample quality are undesired growth and/or instability of individual microorganisms, contamination of specimens/samples with microbial cells or DNA from other sources than the sampling site. Methods for isolation of microbiome DNA need to be appropriately selected, due to different lysis requirements of microorganisms, inhibitory compounds, and human host DNA.

Discussion/conclusion

Compliance with pre-analytical standards is important in the light of the IVDR. They serve as a basis for laboratories' standard-operation-procedures and are important for quality-management-audits of ISO-accredited/certified laboratories. Moreover, they can also serve as a template for samples of other than human origin, e.g., environmental samples.

Key words: microbiome, standardization, quality, pre-analytics, DNA

