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The Pre-Analytical CEN/TS Standard for Microbiome Diagnostics—How Can Research and Development Benefit?

Nutrients 2022, 14, 1976.

Experts from BBMRI.at led the development of the European norm "CEN/TS 17626:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA" in the context of the H2020 project SPIDIA4P. Now several authors from Med Uni Graz together with other microbiome experts, published a paper describing the implications of this diagnostic standard for research and development (R&D).

CEN/TS 17626, the European pre-analytical standard for human specimens intended for microbiome DNA analysis, was published in 2021. It is relevant for in vitro diagnostic (IVD) manufacturers and diagnostic laboratories but also for biobanks and regulatory bodies and as it is considered the state of the art.

The authors present in their paper, why standards are needed in biomedical research, what pre-analytical standards can accomplish, and which elements of the pre-analytical workflow they cover.

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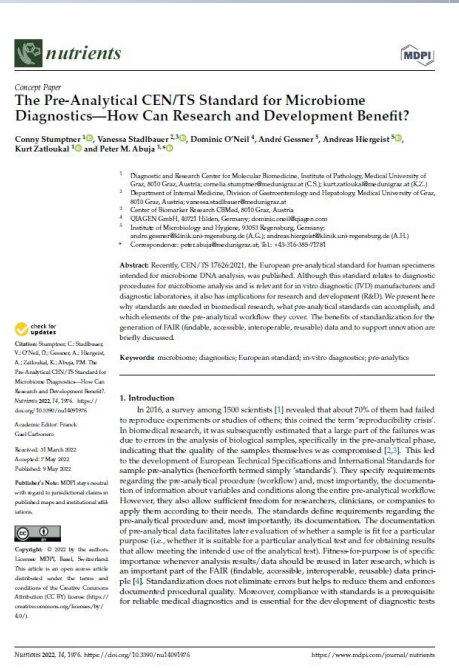


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