# PRE-ANALYTICAL QUALITY STANDARD FOR MICROBIOME SAMPLES

Cornelia STUMPTNER*(1), Peter M. ABUJA (1), Kurt ZATLOUKAL, and members of SPIDIA4P Consortium[2]

*(1)Medical University of Graz, Diagnostic & Research Institute of Pathology, Austria, (2)* EU-project SPIDIA4P number 733112

## 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-analytical phase, reduce errors and generate samples of high and defined quality is by 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, a field becoming more and more relevant for biobanks.**

## METHOD

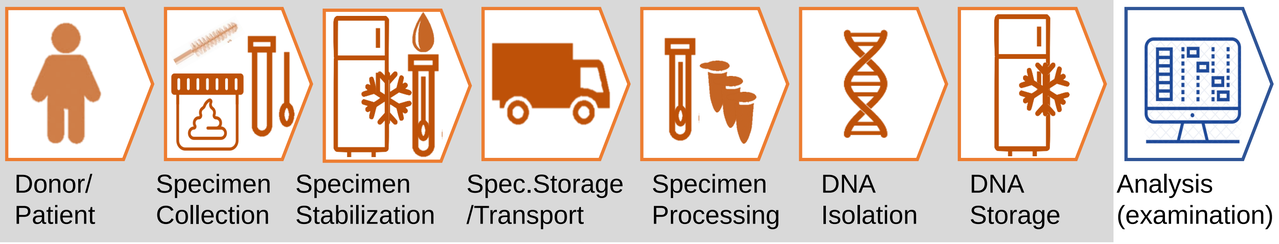
**In the context of the EU-project SPIDIA4P**, the standard **CEN/TS 17626:2021, *Molecular in-vitro diagnostic examinations — Specifications for pre examination processes for human specimens — Isolated microbiome DNA*** was published.

Although this standard relates to diagnostic procedures, it has also implications for microbiome research and development, and for biobanks being at the interphase between diagnostics and research.

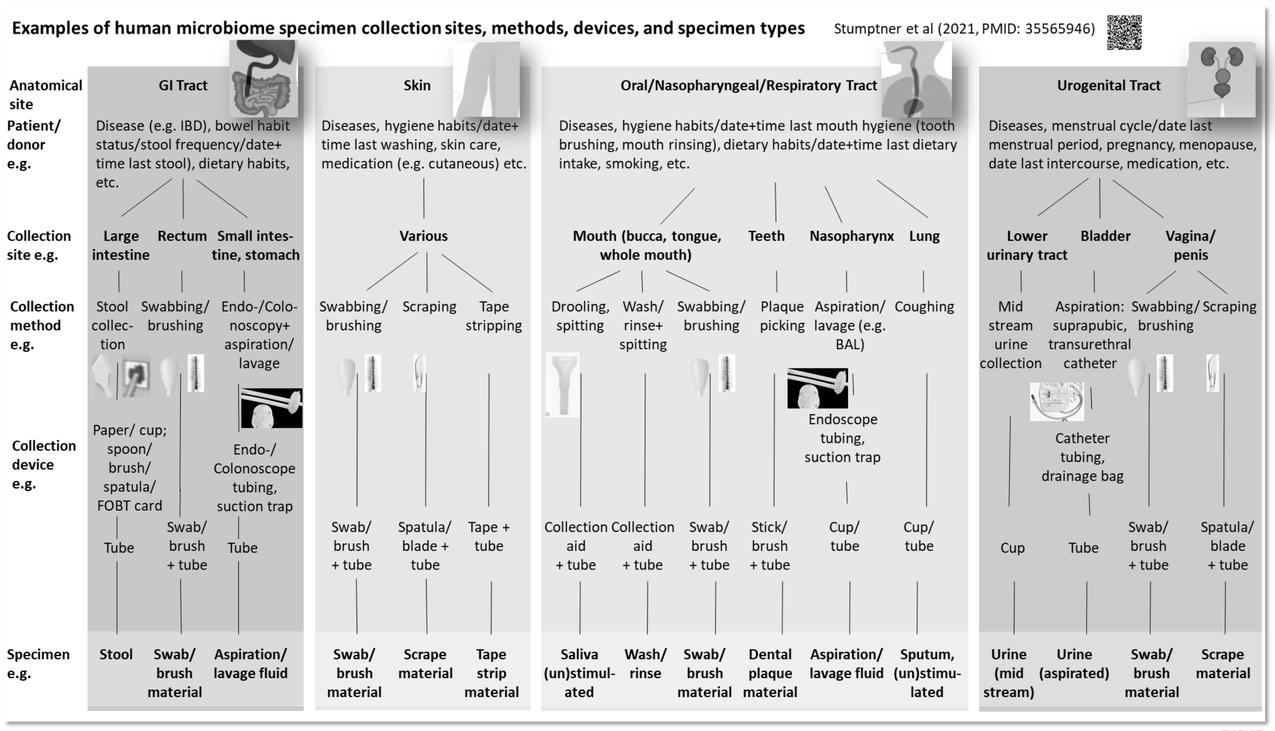
## RESULTS

CEN/TS 17626:2021 belongs to a series of international standards for sample pre-analytics (see ), which share the same content structure following the pre-analytical workflow.

### Pre-analytical workflow




### Human microbiome specimen collection & examples for specimen types




Stumptner et al (2021, PMID: 35565946)

### Major pre-analytical variables

| Workflow steps | Pre-analytical variables - examples |
|---|---|
| Patient/ Donor | Demographics, health/disease condition, medication and treatment, nutrition, hygienic habits, cosmetics, stool frequency, hormonal status, physical activity, etc.) |
| Collection | Body & topographical site, collection method & devices (e.g. stool/poop, spitting saliva, swab, brush, scrape, etc.); collection timepoint, labelling, (cross)-contamination etc. |
| Stabilization | Time to stabilization, method & solution: freezing, stabilization (temperature, volumes, mixing), etc. |
| Storage/ Transport | Containers, duration, temperature, mechanical stress (pneumatic dispatch) |
| Sample Processing | Homogenization, aliquoting, labelling, etc. |
| DNA Isolation | Lysis method, contamination („kitome“), inhibitory compounds, host DNA, etc. |
| Storage | Duration, temperature, storage solution, documentation, etc. |

## RELEVANCE OF CEN/TS 17626 (currently developed to ISO/TS 18701 human specimens - microbiome DNA)

- To improve reliability and reproducibility of molecular analyses
- To establish and improve quality management e.g. in accredited/certified laboratories and biobanks
- To develop state-of-the art and harmonize SOPs
- To evaluate fitness-for-purpose of samples for (re)use
- To fullfill requirements of the In-Vitro Diagnostic Regulation (IVDR): Sample pre-analytics data needed for lab and industry developed tests (IVDs, LTDs)
- To serve as template for environmental microbiome samples.

Funding:
SPIDIA4P, H2020 project (grant agreement no. 7331129)
BMBFW project (GZ 10.470/0016-II/3/2013) and 2023-0.752.780 (2023-2028)