## Two new pre-analytical standards were published in July 2021

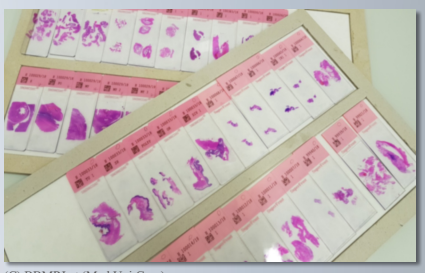
The family of CEN/TS and ISO standards on pre-analytical workflows has grown end of July 2021. These standards are relevant for in vitro diagnostics, research, regulatory bodies and biobanks.

BBMRI.at university and biobank partners contributed to the development of these new standards and provided specialist knowhow. Experts from Med Uni Graz took a leading role in writing the two standards ISO 20166-4 (FFPE tissue for in situ detection methods).and CEN/TS 17626 (Human specimens for microbiome DNA analysis).

**ISO 20166-4:2021**
**Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: In situ detection techniques**

EN ISO 23118:2021
**Molecular in vitro diagnostic examinations - Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma (ISO 23118:2021)**

**CEN/TS 17626:2021**
**Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA**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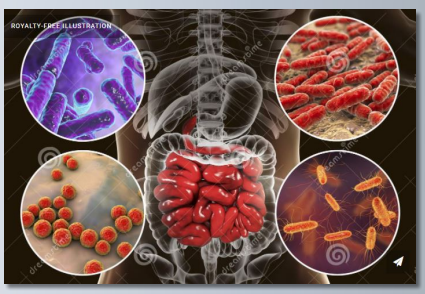

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DETAILS:
ISO 20166-4:2021
**Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 4: In situ detection techniques**

ISO 20166-4 specifies requirements and gives recommendations for the collection, handling, documentation, transport, storage and processing during the pre-examination phase of **FFPE tissue specimens intended for qualitative and/or (semi-)quantitative in situ examination of the morphology and of biomolecules,** such as metabolites, proteins, DNA and/or RNA, on FFPE tissue sections by using different in situ detection techniques.

**It is applicable to the whole spectrum of in situ detection techniques,** such as

- Classical histological staining, e.g. Hematoxylin & Eosin staining (H&E);
- Histochemical techniques, e.g. Lipid staining, Periodic Acid Schiff (PAS) reaction, Perls' Prussian Blue reaction, Feulgen's reaction, enzyme histochemistry;
- Immunohistochemical staining (IHC) or immunofluorescence staining using antibodies (polyclonal, monoclonal or recombinant antibodies) or other affinity binders;
- Hybridization-based techniques such as RNA or DNA in situ hybridization (ISH) techniques, e.g. fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), or silver enhanced in situ hybridization (SISH);
- Molecular analysis of isolated biomolecules that can be mapped to a defined region of an FFPE section (by e.g. in situ sequencing, imaging mass spectrometry).

The standard is applicable to in vitro diagnostic examinations using in situ detection techniques. These include laboratory developed tests performed by pathology laboratories (histopathology laboratories) as well as by molecular pathology laboratories and other medical laboratories. It is also intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, as well as institutions and commercial organizations performing biomedical research, and regulatory authorities.

EN ISO 23118:2021
**Molecular in vitro diagnostic examinations - Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma (ISO 23118:2021)**

This document will replace the former CEN/TS 16954, which was under the Vienna Agreement with national publication updated to an ISO standard.

It covers the pre-analytical phase and recommends the handling, documentation and processing of urine, venous blood plasma and serum intended for metabolomics analysis.

The document is applicable to metabolomics examinations and is of importance to biomedical

laboratories, customers of laboratories, in vitro diagnostics developers and manufacturers, institutions and companies performing biomedical research, biobanks, and regulatory authorities.

The adoption of the described procedures for the pre-analytical phase make it possible to compare and evaluate the results obtained from metabolic profiling analysis.

This standards has been directly published on ISO level.

**CEN/TS 17626:2021**

**Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA**

This document specifies requirements and gives recommendations for the pre-examination phase of human specimens, such as stool, saliva, skin and urogenital specimens, intended for microbiome DNA examination. The pre-examination phase includes but is not limited to specimen collection, handling, transport, storage, processing, isolation of DNA, and documentation.

The CEN/TS are applicable to molecular in vitro diagnostic examinations performed by medical laboratories, laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.

More about quality (management) issues >>

More about pre-analytics standards and external quality assurance on the SPIDIA4P website: www.spidia.eu



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