

International Standards for Fine Needle Aspirates Published

Feb 2022

BBMRI.at experts contributed to the development of three international guidelines (normative technical specifications) for Fine Needle aspirates (FNA) intended for the analysis of RNA, DNA and proteins thereof. The standards - generated in the context of SPIDIA4P - specify requirements and give recommendations along the whole pre-analytical workflow which is a very critical phase along which errors and artefacts can occur that drastically modify the outcome of an analytical test or even lead to wrong results.

The CEN/TS are relevant for medical laboratories e.g. at pathology institutes - in particular for laboratories that are accredited (e.g. acc. to ISO 15189) or certified (e.g. acc. to ISO 9001) – and for in vitro diagnostic (IVD) developers and manufacturers. They are further relevant for biobanks, biomedical research performing laboratories and organizations, and for regulatory bodies. They represent the state-of-the-art concerning the pre-analytical phase for FNA and help to standardize pre-analytical procedures from research to industry.

The following standards are available in English and German language:

CEN/TS 17688-1:2022 - Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1: Isolated cellular RNA

CEN/TS 17688-2:2022 - Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins

CEN/TS 17688-3:2022 - Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 3: Isolated genomic DNA

[Overview on the ISO and CEN standard series for sample pre-analytics>](#)

[More about pre-analytics standards, external quality assurance and the H2020 project SPIDIA4P>](#)

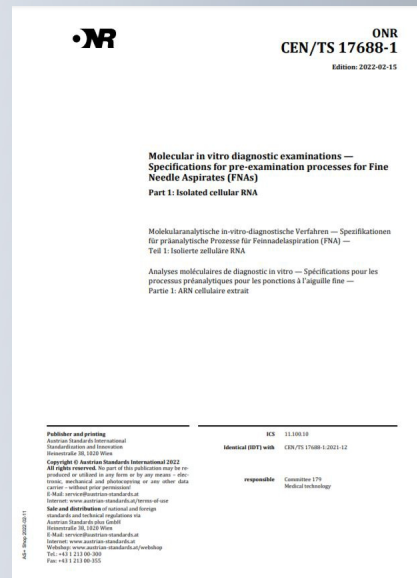


Image: CEN/TS 17688-1:2022 (Austrian Standards Institute)