



[BBMRI.at](http://bbmri.at) (the Austrian part of the European Biobanking Research Infrastructure BBMRI-ERIC) and the associated biobanks, would like to call your attention to the **importance of the quality of biospecimens to generate reliable and reproducible research data.**

False results due to biospecimen samples with poor quality

The rapid development and tremendous growth of the omics technologies have led to highly sensitive test systems and the generation of data of highest precision. With the higher sensitivity, however, a new influencing factor arose: the handling of biospecimens during the pre-analytical phase. Already the smallest variations in the biospecimen collection process, e.g. prolonged ischemia times or fixation, generate deviant results.ⁱ⁻³ Thus, pre-analytical factors turned out to be a major cause why promising results in biomarker research failed in the process of validation, as data were not reproducible on a large scale, thereby wasting time and money.⁴⁻⁵

Scientific Journals to demand precise information from authors

As a first reaction the Biospecimen Reporting for Improved Study Quality (BRISQ) guideline⁶ was prepared, which requests the provision of information about pre-analytical factors that bear the potential to influence experimental outcomes. Numerous scientific journals, like the Journal of Pathology, Histopathology, the Nature publishing group, Biopreservation and Biobanking, EMBO, International Journal of Cancer, Science Translational Medicine and Science Advances have already included this guideline in their author's guidelines for manuscript submission.

International Standards provide guidance

The European Committee for Standardization (CEN) and the International Standard Organisation (ISO) have taken up this issue and published standards for the pre-analytics of biospecimens that are intended for molecular analysis in in vitro diagnostic (IVD)⁷⁻¹³. These standards become relevant in the course of in vitro diagnostic (IVD) development, since the IVD regulation now focuses on pre-analytics.¹⁴ Although primarily written for development and use of diagnostics, following these defined criteria is of course also relevant for (academic) researchers who strive to generate reproducible results. Therefore, we strongly encourage researchers, funding bodies and reviewers to consider the quality and documentation of biospecimens in project applications.

Austrian academic biobanks are professional partners

The Austrian academic biobank partners of BBMRI.at collecting and storing biospecimens committed themselves to follow the CEN and ISO guidelines and are thus able to support researchers with high-quality biospecimens and associated clinical data together with information about the pre-analytical handling process. In addition, we also offer know-how about state-of-the-art collection, processing and storage of biological samples. We aim to make the "black box" of sample management transparent to help creating the basis for a better reproducibility of scientific data.

More information about BBMRI.at and the Austrian biobanks can be found at <http://bbmri.at/>. If you have any questions, please contact us at any time (contact@bbmri.at).

Further reading - Literature

- ¹ Spruessel A. et al., 2004. Tissue ischemia times affects gene and protein expression patterns within minutes following surgical tumor excision, *Biotechniques* 36(6): 1030-7
- ² Bray SE. et al., 2010. Gene expression in colorectal neoplasia: Modifications induced by tissue ischaemic time and tissue handling protocol, *Histopathology* 56: 240-250.
- ³ Bass BP. et al., 2014. A Review of preanalytical factors affecting molecular, protein, and morphological analysis of formalin-fixed, paraffin-embedded (FFPE) tissue: how well do you know your FFPE specimen? *Arch Pathol Lab Med* 138 (11): 1520-30. doi: 10.5858/arpa.2013-0691-RA. PMID: 25357115.
- ⁴ The Economist October 19th 2013 13. Leaders. How science goes wrong.
- ⁵ Freedman LP. et al., 2015. The Economics of Reproducibility in Preclinical Research, *PLOS Biology* 16(4): e1002626.
<https://doi.org/10.1371/journal.pbio.1002626>
- ⁶ Moore HM. et al., 2011. Biospecimen Reporting for Improved Study Quality (BRISQ), *J Proteome Res.* 10(8): 3429-3438 & *Cancer Cytopathology* 119(2): 92-101 & *Biopreservation and Biobanking* 9(1): 57-70.
- ⁷ CEN/TS 16826-3; ⁸ CEN/TS 16945; ⁹ CEN/TS 17305; ¹⁰ CEN/TS 17390; ¹¹ EN/ISO 20166; ¹² EN/ISO 20184; ¹³ EN/ISO 20186;
- ¹⁴ Dagher G. et al. (SPIDIA4P consortium), 2019. Pre-analytical processes in medical diagnostics: New regulatory requirements and standards, *New Biotechnology*, 52: 121-125