



BBMRI.at to raise awareness of importance of sample quality and standards among different target groups

One aim of BBMRI.at is to support biobanks to improve the quality of biological samples. Another is to raise awareness of the importance of quality standards and (sample) quality management among users of biological samples and those involved in sample collection. In autumn 2018, BBMRI.at took and is taking several steps towards this goal.

Working together with biobanks to improve sample quality management is one thing, but it is also important to raise awareness of (sample) quality management among clinicians, pathologists and researchers from academia and industry.

Therefore, BBMRI.at is/was actively informing these target groups on various conferences and meetings by presentations, posters, booths, expert corners, courses and workshops:

- Austrian Association of Molecular Life Sciences & Biotechnology | Annual Meeting | Sep 17-20, 2018
- Austrian Society of Pathology | Autumn Meeting (Graz, AT) | Sep 27-28, 2018
- Austrian Personalized Medicine Platform | Annual Meeting (Graz, AT) | Oct 11-12, 2018
- Medical University of Graz | "Master of Science Biobanking" | new course started Oct 1, 2018
- aws LISA - Life Science Austria | LISAVienna Business Treff (Vienna, AT) | Nov 6, 2018. [read more](#)
- Medical University of Graz / Biobank Graz | Course "How to build a biobank" Nov 28-30, 2018 ... [read more](#)

Publications:

- Zatloukal, Stumptner, Kungl, Müller; **Biobanks in personalized medicine**, Expert Review of Prec Med & Drug Dev, Vol. 3, 2018, Issue 4 ... [read more](#)>>
- Stumptner, Sargsyan, Kungl, Zatloukal; **Crucial role of high quality biosamples in biomarker development**, Book chapter in 'Handbook for Biomarkers & Precision medicine' (accepted)

UPCOMING QUALITY REQUIREMENTS FOR MOLECULAR DIAGNOSTICS

BACKGROUND & AIM
 The reliability and reproducibility of molecular analyses critically relies on sample quality which is to a great part influenced by pre-analytical factors.
 Findings from the EU project SPIDA4P and the NIH provided the basis for a series of international sample pre-analytical standards.

METHOD
 The CEN (European Committee for Standardization) Technical Committee '440' has developed a series of sample quality standards under the title 'In-Vitro Diagnostic examinations - Specifications for "Pre-examination Processes"'. These documents were forwarded to ISO (International Organization of Standards) to be prepared as ISO Standards.

RESULTS
Pre-analytical sample quality standards by CEN and ISO: In-Vitro Diagnostic examinations - Specifications for Pre-examination Processes for...

Why standards?

- To harmonize pre-analytical sample handling because pre-analytical errors
- Make up 85-90% of clinical misdiagnoses!
- Cause unnecessary expenditure in hospitals!
- Can lead to diagnostic errors which account for 10% patient deaths!
- Leads to irreproducible pre-clinical research results (BMP)

Examples of Standards

- Venous whole blood - Part 1: RNA (CEN/ISO 19855-1:2015)
- Venous whole blood - Part 2: DNA (CEN/ISO 19855-2:2015)
- Venous whole blood - Part 3: cDNA (CEN/ISO 19855-3:2015)
- FFPE tissue - Part 1: RNA (CEN/ISO 19857-1:2015)
- FFPE tissue - Part 2: protein (CEN/ISO 19857-2:2015)
- FFPE tissue - Part 3: DNA (CEN/ISO 19857-3:2015)
- Snap frozen tissue - Part 1: RNA (CEN/ISO 19858-1:2015)
- Snap frozen tissue - Part 2: protein (CEN/ISO 19858-2:2015)
- FFPE tissue - Part 4: In situ detection (ISO)
- CTCs in blood - Part 1-3: RNA/ADN/Immunology (CEN)
- Patient specimen - microRNA (DNA/ISO)

SUMMARY
 These standards should improve the reliability and reproducibility of molecular analyses and are important in accreditation/quality management audits of ISO accredited laboratories.
 Compliance with these standards will become important in the light of the new IVDR, which has to be applied for laboratory and industry developed tests.

AUSTRIAN BIOBANKING NETWORK
BBMRI.AT - A PARTNER FOR RESEARCH USING BIOLOGICAL SAMPLES

ABOUT BBMRI.AT

- Biobanks from all medical universities of Austria
- 100+ research teams with associated data (Human, animal, tissue, blood, urine, stool, etc.)
- 100+ publications provided to researchers
- 100+ publications provided to researchers
- Pre-analytical sample processing according to international standards
- 100+ publications provided to researchers

OUR WORK FOR RESEARCH

BBMRI.at makes high-quality biobank samples and data available for research

- 1. Provides an online biobank catalog
- 2. Harmonizes biobank quality management and performs internal QA checks
- 3. Helps to implement the new international pre-analytical sample quality standards (ISO/IEC 17025) for pre-analytical processes
- 4. Offers a self-assessment tool to assess if biobank processes meet ISO/IEC 17025 quality management requirements
- 5. Provides access to biobank related resources, reports & publications with credits
- 6. Offers education and training courses (e.g. for sample processing, implementing ISO/IEC 17025) building up biobanks, Master in Biobanking
- 7. Engages the biobank network in international sample biobanking and associated research



SELF-ASSESSMENT TOOL FOR MOLECULAR DIAGNOSTICS TO CHECK PRE-ANALYTICAL WORKFLOWS

BACKGROUND & AIM
 A series of the CEN Technical Specifications (CEN/ISO) and the ISO 15189:2013 (Quality management systems for laboratories) provide the basis for a series of international sample pre-analytical standards.

METHOD
 The BBMRI.at self-assessment tool (SAT) is a web-based tool that allows biobanks to check if their pre-analytical processes meet the requirements of the standards.

RESULTS

What is the BBMRI SAT
 The Self-Assessment Tool will check if biobank processes meet the requirements of the standards for pre-analytical processes.

- FFPE tissue - RNA (CEN/ISO 19857-1:2015)
- FFPE tissue - protein (CEN/ISO 19857-2:2015)
- FFPE tissue - DNA (CEN/ISO 19857-3:2015)
- Snap frozen tissue - RNA (CEN/ISO 19858-1:2015)
- Snap frozen tissue - protein (CEN/ISO 19858-2:2015)
- Venous whole blood - RNA (CEN/ISO 19855-1:2015)
- Venous whole blood - DNA (CEN/ISO 19855-2:2015)
- Venous whole blood - cDNA (CEN/ISO 19855-3:2015)
- MicroRNA in serum (CEN/ISO 19859:2015)

How to get access and use the BBMRI SAT

- Go to [www.bbMRI.at](#)
- Fill out request form & fill pre-conditions (all mandatory fields to be filled)
- Complete SAT survey
- Print out report
- Evaluation: BBMRI.AT will review your BBMRI.AT report
- Quality Label: If you receive a Quality Label, you can use it in your marketing materials

SUMMARY
 The Self-Assessment Survey Tool is a self-assessment tool that can be used in combination with CEN & ISO standards.
 It provides an interactive electronic checklist on pre-analytical quality requirements.
 It helps laboratories to implement the standards and provides practical support of established procedures.
 It provides detailed information on standard requirements where new infrastructure measures are needed.
 It allows principal investigators to display their quality management certificate to the BBMRI.AT Quality Checklist.