Laboratory Quality Management at RWTH cBMB

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Laboratory Quality Targets

Poor biospecimen quality greatly influences research results and impairs their reliability, reproducibility, and comparability. Therefore, the laboratory of RWTH cBMB has defined several important sample quality targets, realization of which is a major task in order to develop an active laboratory quality management system. Key to sample quality is a standardized, rapid and appropriate process flow. In addition, tools are being developed in order to measure and assure biospecimen quality. The quality targets are summarized in Figure 1.

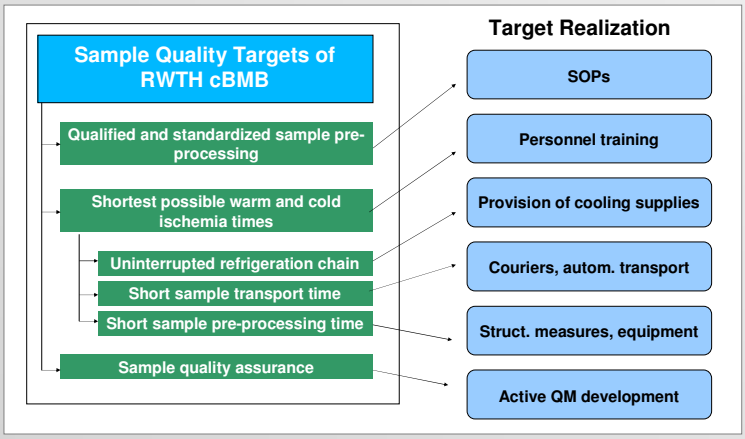

Figure 1. Quality targets and target realization of the RWTH cBMB laboratory.

Quality Target Realization

Several quality targets have already been realized at RWTH cBMB (see Figure 1). Standard operating procedure (SOP) protocols have been developed for the currently processed biospecimen types. Involved lab and clinical personnel is constantly trained and educated on the process. Cooling supplies, such as refrigerators, have been provided to first clinical departments in order to assure an uninterrupted cooling chain. The involvement of couriers as well an in-house automatic transport system greatly shortened sample delivery times. Undertaken structural measures will further reduce sample pre-processing times. Lastly, tools for sample quality assurance are currently being established which shall guide the development of an active QM system.

Quality Management

In order to measure, and later on also certify biospecimen quality, several activities have been undertaken. We have invested in digital imaging systems allowing photographical documentation of the macroscopy of the diseased tissue/organ (Figure 2A) and determining the exact location of the resected tissue within the organ. These images will be stored in the data management system and will be provided to researchers on request. Further, every tissue sample provided is microscopically reviewed by pathologists on H&E slides in order to confirm diagnosis, cellular content, and histomorphological tissue quality.

To meet further standardization requirements, technical equipment has been employed facilitating sample evaluation, e.g. cell counts of buffy coats (MUSE cell analyzer, Millipore) or automated nucleic acid extraction from frozen tissue (MAXWELL, Promega; QIACUBE, Qiagen) (Figure 2B).

Also, the freezing process itself is being optimized by implementation of a RAPIDFREEZER device (AlphaMetrix Biotech) (Figure 2C). Controlled freezing by use of isopentane is currently evaluated in own research activities determining bioanalyte quality of different tissues in relation to processing time, processing temperature and freezing method.

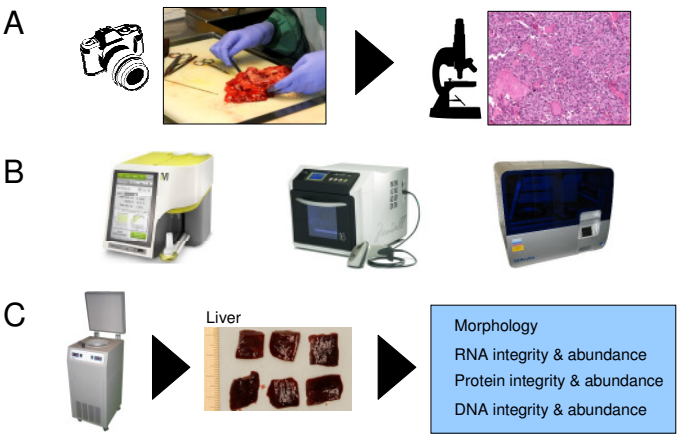

Figure 2. Quality assurance of biospecimens of RWTH cBMB. (A) Digital images of the organ/tissue provides information on the exact location of resected tissue. Microscopic evaluation on H&E slides by pathologists assures that only tissues containing the desired cellular content will be provided. (B) Devices used for process standardization (cell analyzer and automated nucleic acid extractors). (C) Own research involving different tissues and comparing freezing methods in relation to processing time and temperature will guide us to further optimize current SOPs.