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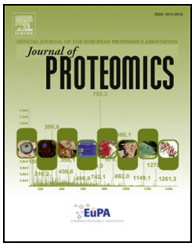

Review

Developments in biobanking workflow standardization providing sample integrity and stability☆

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ABSTRACT

Recommendations and outlines for standardization in biobanking processes are presented by a research team with long-term experiences in clinical studies. These processes have important bearing on the use of samples in developing assays. These measurements are useful to document states of health and disease that are beneficial for academic research,

☆ This article is part of a Special Issue entitled: Standardization and Quality Control.

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Mass spectrometry
Diseases
Standardization

commercial healthcare, drug development industry and government regulating agencies. There is a need for increasing awareness within proteomic and genomic communities regarding the basic concepts of collecting, storing and utilizing clinical samples. Quality control and sample suitability for analysis need to be documented and validated to ensure data integrity and establish contexts for interpretation of results. Standardized methods in proteomics and genomics are required to be practiced throughout the community allowing datasets to be comparable and shared for analysis. For example, sample processing of thousands of clinical samples, performed in 384 high-density sample tube systems in a fully automated workflow, preserves sample content and is presented showing validation criteria. Large studies will be accompanied by biological and molecular information with corresponding clinical records from patients and healthy donors. These developments position biobanks of human patient samples as an increasingly recognized major asset in disease research, future drug development and within patient care.

Biological significance

The current manuscript is of major relevance to the proteomic and genomic fields, as it outlines the standardization aspects of biobanking and the requirements that are needed to run future clinical studies that will benefit the patients where OMICS science will play a major role. A global view of the field is given where best practice and conventional acceptances are presented along with ongoing large-scale biobanking projects. The authors represent broadly stakeholders that cover the academic, pharma, biotech and healthcare fields with extensive experience and deliveries. This contribution will be a milestone paper to the proteomic and genomic scientists to present data in the future that will have impact to the life science area.

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Contents

1. The strategic role of biobanks in society

The healthcare sector and the research community are in great need of diagnostic biomarkers that provide accurate indices of health status that can be used to assist clinical decision-making. The measurement of these biomarkers in accurate and reproducible quantitative indices further requires measures of standardization guaranteeing the quality control of the clinical samples providing these biomarkers.

It is also essential at this stage to insure that the technology platforms used to provide such biomarker measurements also are consistent in sensitivity and specificity irrespective of their global location. The measurement performed on an instrument in India should provide the same level of accuracy as an instrument in Sweden, United Kingdom or the United States.

Samples collected for clinical analysis are either used immediately or discarded or they are stored in biobanks for future use. The current methods of storage of samples are often different in different laboratories, hospital institutions, and government agencies. Consequently, one of the challenges encountered in biobanking activities has been the difficulty in inter-laboratory studies. Differences in experimental designs, protocols, as well as reagents and disposables used will impact on data quality and reproducibility. Standardization and best

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