

Study of the Stability of the Human Carbohydrate Antigen 19-9 Stored at Predefined Storage Conditions in the NHLS Biobank Using Molecular Techniques

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Background: A Biobank is an entity that helps with the collection and storage of samples and their associated data for research for now and in future. Access to diverse samples for research is considered a bottleneck by the research community and biobanks have been established to resolve this and to support health care research strategies. Maintaining sample integrity is crucial to the success of every biobanking project and quality control (QC) tools are instrumental for assessing the quality and subsequently the usefulness of samples and their data for downstream research processes. In biobanking, temperature is a critical variable factor for sample stability and viability and therefore it is one of the quality indicators. **Objectives:** To investigate whether the stability of biomarkers is affected by storage conditions and also to investigate variables unique to the biobank infrastructure and processes that could impact the integrity of biological samples. To develop and implement QC procedures that will ensure that the biobank houses and provides samples and associated data of scientific value to researchers. **Methods:** Serum samples with elevated levels of the Human Carbohydrate Antigen 19-9 (CA 19-9) will be stored at -80 °C and examined quarterly employing chromatographic techniques to assess important quality characteristics of the biological material, including stability, the performance of the processing methods and the accuracy of the QC procedure. **Results:** The study is in the initial stages of method development. The findings of the study will give an indication of how sample processing and storage methods influence sample integrity, and the effectiveness of the QC procedure will also be identified. **Discussion:** The establishment of sound QC procedures will be instrumental in the provision of samples and data that are of high quality and fit for purpose. Adherence to international best practices, and internationally accepted procedures, standardization and quality control will enable the NHLS Biobank to exchange biological samples and associated data between or among institutes and thereby build capacity for research purposes.