

Title of speech:

Formalin-Free Tissue Fixation: Preservation of Biomarkers and Morphology for Biomarker Discovery and Biobanking

As molecular testing for diagnosis and classification of disease is becoming increasingly important, preanalytical steps which have an influence on the analytical results are moving into focus. SPIDIA, a consortium within the European FP7 project, aimed to analyse, standardize and improve pre-analytical procedures for *in vitro* diagnostics.

In case of tissue analysis current methods for preservation involve fixation with formalin or snap-freezing in liquid nitrogen. Formalin preserves tissue by cross-linking proteins and nucleic acids. This cross-linking causes irreversible chemical modification and damage to protein and nucleic acid biomarkers, particularly RNA. While cryopreservation of tissue is the gold standard for biomolecule preservation, maintaining the cooling chain is logistically demanding and expensive. Morphology in frozen tissue is often compromised, sectioning of unfixed, frozen samples is technically demanding, and special equipment is required.

To meet the need for simultaneous preservation of morphology and bio-molecules PreAnalytiX has developed a formalin-free fixation and stabilization reagent system, called the PAXgene Tissue System. PAXgene Tissue preserves tissue morphology and biomolecules in the same sample without cross-linking or damage to the tissue architecture or histomorphology. PAXgene Tissue treated samples can be processed and paraffin embedded similarly to formalin-fixed, paraffin-embedded (FFPE) tissues and analyzed by histochemical and immunohistochemical staining or in situ hybridization techniques. Furthermore, PAXgene Tissue treated specimens can be stored as paraffin embedded tissue or in the PAXgene Tissue Stabilizer.

Within SPIDIA the PAXgene Tissue System, was extensively tested. In this presentation, data generated over four years will be presented showing a comparison of DNA, RNA, miRNA, protein and phosphoprotein analysis between FFPE, snap-frozen and PFPE (PAXgene Tissue fixed, paraffin-embedded) tissue. In addition, data will be shown on long-term stability of nucleic acids and histomorphology in PAXgene Tissue treated samples.

Dr. Daniel Grölz
Scientific Associate Director (R&D)

QIAGEN GmbH