“Testing and Validating High Throughput Analysis of FFPE Samples: Transforming the Scope of Investigations into the Genomic Basis of Cancer”

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Abstract: The goal of the proposed study is to assess the feasibility of obtaining reliable, informative, comprehensive genomic data from formalin-fixed paraffin-embedded (FFPE) samples. We will: (1) Identify optimal procedures/platform combinations for analysis of DNA and RNA from FFPE samples, (2) Determine the maximal length of fixation in formalin and storage in paraffin that still allows robust genomic analysis of FFPE samples, and (3) Evaluate the optimal procedure/platform combinations for their ability to detect established molecular subtypes of cancer. This information will be compared to results using matched flash frozen tissue as starting material. In this way, we will identify the optimum techniques for use and better define the limitations imposed by FFPE tissues. The ability to routinely perform genomic analysis on FFPE samples would completely transform the types of questions that could be asked about the initiation and development of different tumor types, prognosis, and genomic predictors of therapy response. This is because: (A) pathology archives house millions of FFPE samples, orders of magnitude more than frozen samples, and (B) certain extremely valuable samples are only available as FFPE samples such as samples from patient treated with specific therapeutic protocols with long term follow-up, pre-neoplastic lesion samples, and rare tumor type samples.