Analytical Validity of the Digistain Test in the Face of Variable Fixation Times: A Study from Charing Cross Hospital

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Background: In the setting of adjuvant therapy for breast cancer, the accuracy of quantitative real-time PCR-based risk profiling tests can be compromised by variable formalin fixation times, affecting the fidelity of genetic material. The Digistain test, using mid-infrared spectroscopy, potentially offers immunity to such pre-analytical variables. This study assesses the robustness of Digistain in maintaining consistent performance across a wide range of fixation times in breast cancer surgery samples.

Methods: We analyzed 233 breast cancer tissue samples collected post-surgery at Charing Cross Hospital, with fixation times documented between 5 to 144 hours. The primary objective was to investigate the consistency of the Digistain Index (DI) across varied fixation durations.

Results: The samples were stratified into three groups based on fixation time: 0-24 hours, 24-48 hours, and 48+ hours. An Analysis of Variance (ANOVA) was performed to compare Digistain Index (DI) values across these groups. The analysis revealed that DI values remained consistent across all groups, with no significant variation in mean DI values attributable to differences in fixation time ($p = 0.84$). This robust consistency of Digistain's results, irrespective of fixation duration, suggests potential advantages in analytical reliability, particularly in contexts where the fidelity of PCR-based tests may be influenced by pre-analytical variables.

Conclusions: These results validate the analytical robustness of the Digistain test, confirming its suitability for use in clinical settings where fixation times can vary. This attribute positions Digistain as a dependable tool for breast cancer risk stratification in the adjuvant therapy context, enhancing its applicability in routine clinical practice.