Correlation of multiplex measurement of mRNA expression from FFPE tissues with protein expression.

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Background: The use of biomarkers has been a successful strategy in the approval of targeted therapies in oncology. Albeit successful, these approaches tend to focus on one biomarker representing one biological pathway. As the complexities of tumor sub-types and mechanisms of therapies increase, the need to investigate several biomarkers from multiple cellular pathways simultaneously from one sample grows. A common method to evaluate tumor biomarkers is immunohistochemistry (IHC). Unfortunately, using this method to detect multiple biomarkers can be hindered by limited tumor material or lack of multiplexed IHC methods. \The Edge System from HTG Molecular is an automated testing platform that supports normalized mRNA quantitation of a panel of biomarkers from as little as one section of FFPE material. **Methods:** The Top Oncogene Assay (TOA) kit was used to measure the mRNA expression of 32 genes including estrogen receptor (ER), progesterone receptor (PR), and ErbB2 (HER2) from 14 breast carcinomas on the Edge System. Target gene expression values were normalized to 7 housekeeper genes also in the TOA kit. The same samples were sectioned and stained for ER and PR (Dako FLEX IVD kits), and HER2 (Dako HercepTestkit). Slides were evaluated for positive or negative staining of ER and PR, and HER2 based on interpretation guidelines for each assay. **Results:** The clinical classification of ER, PR, and HER2 positive breast cancer was assigned to each sample followed by sorting the samples for each biomarker separately from lowest to highest normalized mRNA expression. 14/14 samples for HER2, 14/14 for ER, and 13/14 for PR that demonstrated clinical positivity had mRNA expression for that biomarker higher than all other samples that were clinically classified as negative for that biomarker. **Conclusions:** From the correlations observed between IHC for protein detection and the Edge System for mRNA quantitation, we conclude that

the Edge System and related mRNA quantitation chemistry has merit to measure a multitude of exploratory biomarkers simultaneously from limited amounts of FFPE tissues. This methodology can support the analysis of many biomarkers from limited amounts of material in the exploratory phases of clinical trials.
