

Flagship Biosciences launches tissue-based RNA ISH image analysis services

Flagship's in-house developed image analysis algorithms combine tissue pattern recognition with cell-based analysis to offer pharmaceutical clients improved approaches to measuring RNA expression while preserving the tissue context

Westminster, CO — October 10, 2012 — Flagship Biosciences announced today the validation of a novel whole slide image analysis algorithm utilized for evaluation of RNA expression in histology tissue sections. The software is currently being utilized by Flagship's pathologists in service of pharmaceutical research studies and the development of tissue-based companion diagnostics.

Application of in situ hybridization (ISH) techniques to evaluate RNA products including messenger RNA and non-coding RNA, which are seen to be important in gene regulation and includes micro RNA (miRNA), satellite RNA and long non-coding RNA (lncRNA), is growing in value in the research community. While these RNA techniques have lagged behind more widely available protein evaluation in tissue using immunohistochemistry (IHC), recent improvements by leading reagent suppliers like Affymetrix, Inc. with their [QuantiGene® ViewRNA Assays*](#) have made their usage more available and standardized. New developments include multiplexed two-color approaches and automation of the technology on an [automated IHC autostainer platform](#).

The interpretation of RNA ISH in tissue requires pathologist oversight, and continues to improve as the technology becomes more widely available and the histology further automated. Currently quantitation strategies require a careful combination of expert pathologist evaluation and customized image analysis approaches.

Flagship Biosciences has developed a combined pattern recognition and cellular analysis algorithm to simplify and standardize the identification of the regions of interest in relevant and surrounding tissue and to also identify cells and the chromogenic expression patterns of the various RNA products. The analysis identifies the cells of interest and associates the ISH probe with individual cells. The individual ISH dots are measured by number, size, intensity, or in a summary form more familiar to pathological evaluations. This solves the problem of interpreting the significance of the ISH dots and allows data reporting and evaluation more consistent with customary pathological approaches. This approach is being utilized in several of Flagship's pharmaceutical companion diagnostics and research programs.

“We are excited to partner with Flagship Biosciences and contribute Affymetrix' QuantiGene ViewRNA Assays to Flagship's suite of histopathology analysis services provided to pharmaceutical clients looking to accelerate the development of new drugs and companion diagnostic tests,” said George Bers, Vice President & General Manager, Expression Business Unit – Panomics for Affymetrix. “QuantiGene ViewRNA Assays enable detection of RNA transcripts at single cell resolution in FFPE tissues, core biopsies, and fine needle aspirates. It complements IHC tests where antibodies are not available or inadequate. Furthermore, Flagship's new RNA ISH image analysis service provides a critical final step in the automation and standardization of advanced histo-staining assays.”

“Evaluating RNA expression in the localized tissue context is a valuable addition to many pharmaceutical companion diagnostics and research programs,” said Dr. Steven Potts, CEO of Flagship Biosciences. “When challenges exist in a particular IHC assay, or when additional biology insights into mechanism are required, RNA can be highly valuable, particularly when coupled with expert pathologist evaluation. While the quantitation of RNA in situ is still in its infancy, our ability to combine Flagship’s image analysis techniques with Affymetrix’ technology is a valuable step in the right direction.”

About Flagship Biosciences

Flagship Biosciences delivers quantitative [histopathology services](#) in pharma and device development. Backed by a combined 60 years of pharmaceutical pathology experience, Flagship has a world-class team of pathology, histology, cancer biology, image analysis and regulatory experts.

* For research use only. Not for use in diagnostic procedures. QuantiGene is a trademark property of Affymetrix, Inc.