HistoGeneX

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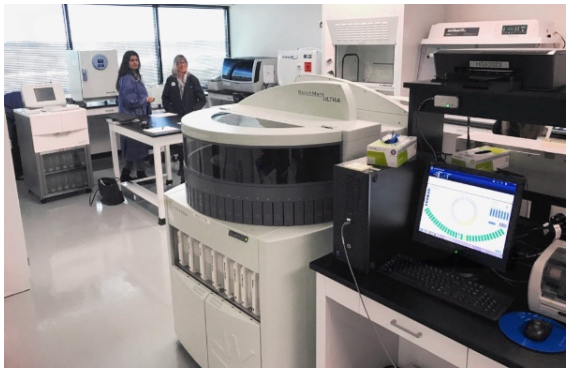
January 2017

Histo Highlights

TransAtlantic Biomarker Laboratory Builds

In April, our non-laboratory personnel begin migrating 1 km away to our spacious and beautiful 4-story building. The laboratory teams begin their transition in May. We will send out updates and information. Our goal is to ensure continuous operations throughout this move. Each laboratory section is implementing a post-move platform qualification program and HistoGeneX is working closely with each vendor to ensure integrity of the instrumentation and reagents. Please do not hesitate to contact your Project Manager for further details.

Meanwhile in the US, we have hosted several client audits and have begun clinical testing, including a PMA IHC study. Our histotechnologists and pathologists have been trained and we have 3 onsite project managers. The laboratory is well-prepared to support companion diagnostic studies including reproducibility studies for 510k device or PMA trials. We have also begun implementing molecular extraction (DNA & RNA) and real-time PCR procedures.



We would love for you to visit. Please contact us to schedule for either location.

HistoGeneX Scientific Press

Highs, Lows of Immune Checkpoint Inhibitors

Dr. Mark Kockx spoke at CAP16 in September regarding the level of inflammation in the tumor microenvironment and its role in

regulating immunosuppression. A portion of his talk is featured in the December 2016 issue of CAP Today. Please click here for a PDF version of the full article.

CAP TODAY

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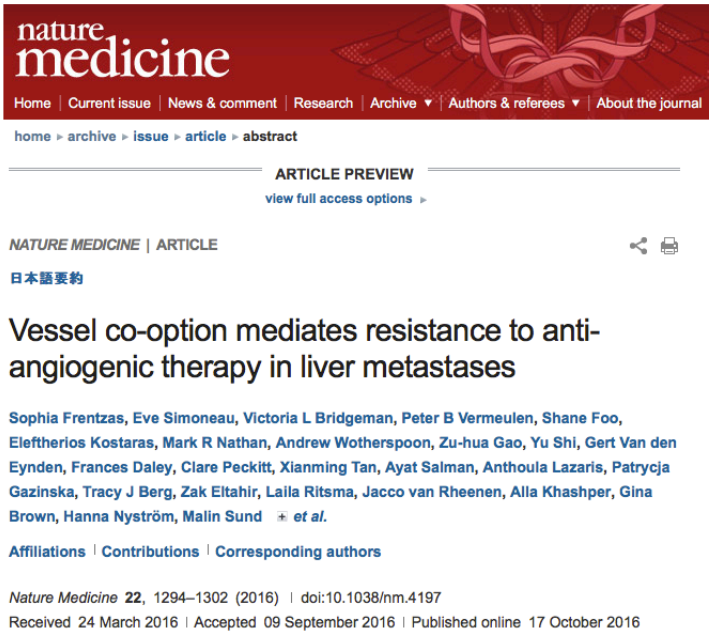

Vessel Co-Option: A Novel Therapeutic Target in Metastatic Colorectal Carcinoma

Our pathologist, Dr. Peter Vermeulen, recently described a non-angiogenic, vessel co-option phenomena in a Nature Medicine article, where tumors utilize existing vasculature of the normal organ instead of angiogenesis. This article provides examples with liver metastases of colorectal cancer and offers a histopathologic and mechanistic rationale why angiogenic inhibitors such as bevacizumab may not be effective in tumors where the co-option mechanism dominates. *The co-option pattern also appears to be associated with poor prognoses and correlates with the absence of infiltrating lymphocytes.*

The co-option mechanism can be detected with routine H&E and potentially offers significant hypothesis-driven investigative studies. We are able to provide this assessment for exploratory studies or in the clinical trial setting.

For more information, read the paper here, download a PDF here, or contact us at info@histogenex.com.

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Expert Review of Precision Medicine and Drug Development

Personalized medicine in drug development and clinical practice

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Digital pathology in immuno-oncology – a roadmap for clinical development

Christopher Ung, Mark Kockx & Yannick Waumans

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HistoGeneX Global Laboratories announces its publication "Digital Pathology in Immuno-Oncology – A Roadmap for Clinical Development." This timely manuscript describes validation methodologies that can be used for oncology clinical development, specifically immunotherapies. Digital pathology offers enticing features, not the least of which is an enhanced microscope platform for viewing, collaboration, and distribution. In addition, there are a broad milieu of downstream applications for analyzing the resultant high-resolution whole slide image. The combination is especially relevant given the renewed emphasis of assessing the tumor microenvironment (TME) when developing immune-oncology therapeutics. The paper discusses the varied pressures - such as cost, workflow, initial set up logistics, and regulatory factors - that constrain the use of a technology that seems so obviously suited for the anatomic pathology laboratory. The second part of the manuscript reviews the available validation guidelines from the FDA and CAP which primarily addresses manufacturers and clinical laboratories respectively but do not provide guidance for clinical developers. Both guidelines take on different approaches: the FDA unpacks the digital pathology system into components while CAP focuses on what emerges from the "black box." A hybridized model – merging elements of both validation approaches – is presented to the clinical development reader. Finally, the manuscript reviews a series of analysis applications, in particular, the ones that extract valuable data from the TME, and introduces the concept of a laboratory developed digital application (LDDA) that leverages the familiarity of a LDT.

Spotlight on our Science

Interested in our scientific and laboratory research happenings? Download Histo Notes to read about our evaluations of novel platforms, affects of pre-analytical conditions on testing, or biomarker validations.

Histo Notes: Leica Bond Rx System: Automating High Complexity ISH and Fluorescent Assays

Biomarkers such as DNA, RNA, and protein are powerful tools for understanding basic cellular functions, diagnosing clinical diseases, and identifying optimal therapies. Fluorescent in situ hybridization (FISH), immunofluorescence (IF), and RNA in situ hybridization are widely used imaging technologies that share the unique capacity to analyze a marker at the single cell level while preserving the morphology.

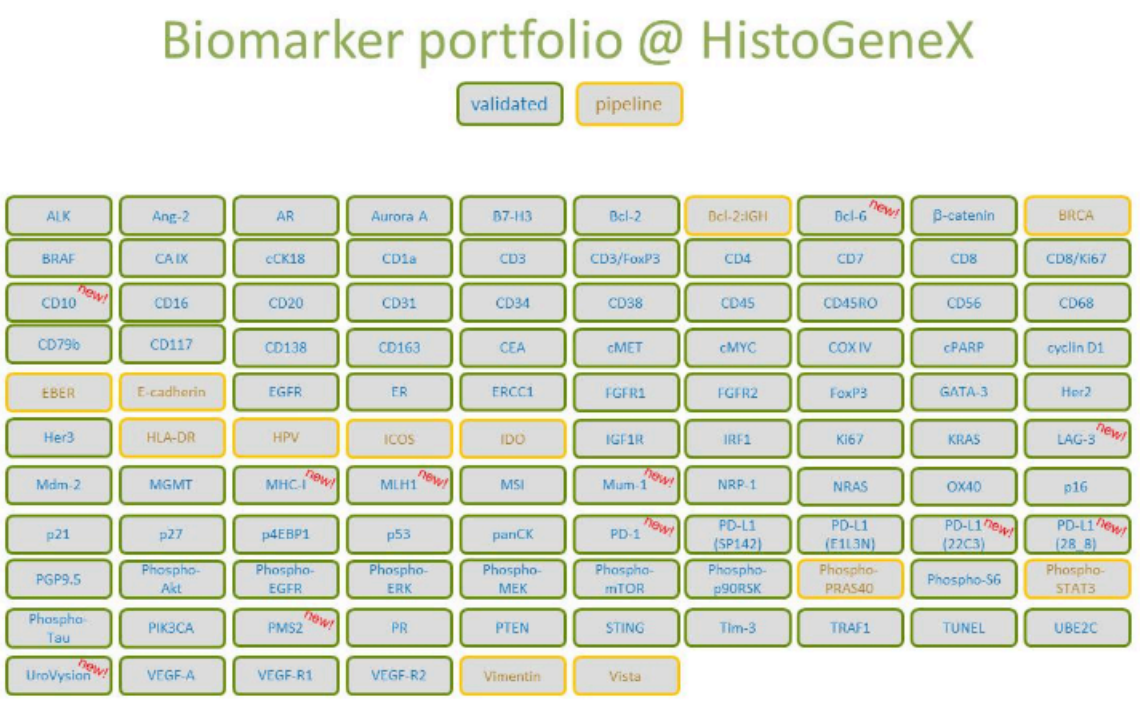
We recently acquired the Leica Bond RX system, an open automated staining system giving the freedom to choose dispense sequences, incubation times, and temperature settings to customized staining protocols. Fully automated single and duplex IF staining were tested and delivered a high level of precision and consistency.

Click here to view this and other Histo Notes.

Immuno-Oncology Biomarkers & More

Our assay development team actively validates new IHC biomarkers for clinical development use, especially those for immuno-oncology. Some recent ones include TIGIT, TIM3, and LAG3. Visit our website for an updated list or review our IHC assay development process.

Have biomarker questions? Drop us a note if you have questions about biomarkers from our validated menu or our biomarker pipeline.



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