

illumiSonics Announces Publication of Landmark Clinical Validation Study in Breast Cancer

PARS® H&E images equivalent to traditional gold-standard H&E images with 98% diagnostic concordance for cancer versus benign

November 6, 2023 – illumiSonics, Inc. announces the publication of a landmark clinical validation study in breast cancer diagnosis. The study was recently published in Current Oncology. This pioneering work, led by Dr. Parsin Haji Reza, chief scientific officer, marks a significant advancement in the field of histopathology. The results demonstrate that Photon Absorption Remote Sensing (PARS®) can produce diagnostic-quality, virtual H&E images of whole slide breast tissues, deemed equivalent to traditional gold-standard H&E histology by expert pathologists.

PARS® is a revolutionary imaging modality capable of generating high-resolution images of unstained tissues, which are subsequently colorized to provide virtual H&E-stained samples. The primary objective of the study was to assess the capability of whole slide imaging with PARS®, in providing sufficient image quality suitable for the diagnostic evaluation of breast cancer biopsies. The study employed unstained formalin-fixed paraffin-embedded breast needle core biopsy sections, which were imaged with PARS® and virtually stained, and then compared with the same tissue after undergoing standard H&E chemical staining.

The study produced 98% agreement in diagnostic concordance for cancer versus benign conditions between PARS® H&E and traditional gold-standard H&E staining. Notably, participating pathologists, who were blinded to the image sources, could not distinguish between images derived from PARS® and those stained conventionally with H&E.

Dr. Parsin Haji Reza commented, "This study underscores the clinical significance of PARS® histology, as assessed by expert breast cancer pathologists. Scanning unstained slides with our technology equips pathologists with everything they need to make reliable cancer diagnoses. Excitingly, we are accelerating our efforts to bring PARS® into the surgical suite by scanning fresh tissue, enabling near real-time cancer diagnoses and margin assessment."

PARS® virtual histology offers several distinct advantages over traditional gold-standard staining techniques. PARS imaging is stain-free, non-contact, preserves tissue integrity and directly identifies tissue biomolecules, enabling the creation of high-resolution images that can replicate a wide range of standard histological techniques.

For more information on this study, please refer to the published paper at Current Oncology, Photon Absorption Remote Sensing Imaging of Breast Needle Core Biopsies Is Diagnostically Equivalent to Gold Standard H&E Histologic Assessment.

About illumiSonics Inc.

illumiSonics Inc. is a Waterloo, Ontario based company that has developed the PARS® platform: a revolutionary, non-contact, high-resolution, label-free, non-destructive optical imaging system based on new physics. PARS captures all light-matter interactions to yield unprecedented cellular and molecular information, which is then processed using AI, leading to precision diagnostics. The ability to generate multiple diagnoses from a single tissue sample, and eliminate the need for staining, addresses an unmet medical need that has the potential to save lives and reduce costs. For more information, visit www.illumisonics.com.