

## ANNOUNCEMENT

### **Leica Biosystems Receives FDA 510(k) Clearance for Aperio GT 450 DX Digital Pathology System with both SVS and Native DICOM**

Leica Biosystems is pleased to announce that its flagship digital pathology system, Aperio GT 450 DX, has received 510(k) clearance from the US Food and Drug Administration. Previously sold into the clinical market under an enforcement discretion due to the COVID-19 pandemic, Aperio GT 450 is proven technology that consistently delivers high-quality images at a fast turnaround time of < 32 sec/slide.

Aperio GT 450 DX is not Leica Biosystems first regulated system: the company has 25 years of experience implementing, integrating, and innovating in the digital pathology space, enabling clinicians to advance their cancer diagnoses and improve lives.

“Digital pathology is rapidly emerging as the cornerstone of modern healthcare, revolutionizing the field of pathology as laboratories across the globe embrace this transformative technology,” said Dr. Sony Wirio, Regional Chief Pathologist and Director of Pathology Informatics at Kaiser Permanente, Southern California. “Drawing from our extensive experience in implementing digital pathology within our group of over 100 pathologists, we are excited to be a part of this groundbreaking shift that is shaping digital diagnostics and enhancing patient outcomes.”

“There is no better time for laboratories to optimize their workflow with digital,” said Naveen Chandra, Vice President and General Manager of Digital Pathology at Leica Biosystems. “Today, clinicians are faced with having to do more with less – digital pathology enables them to maintain a high standard of quality with world class images and a fast turnaround time, for the best patient care possible.”

#### **About Leica Biosystems:**

Leica Biosystems is a cancer diagnostics company and a global leader in workflow solutions. The company offers a comprehensive product range for each step in the pathology process, from sample preparation and staining to imaging and reporting. As the only company to own the full workflow from biopsy to diagnosis, Leica Biosystems is uniquely positioned to break down the barriers between each step. The company’s mission of “Advancing Cancer Diagnostics, Improving Lives” is at the heart of its corporate culture.