# LEICA BIOSYSTEMS COMMUNICATION

## Publications on COVID-19 Emergency Guidance and Validation of Whole Slide Imaging

THE LINKS PROVIDED BELOW REDIRECT TO THIRD-PARTY WEBSITES THAT MAY REQUIRE A SUBSCRIPTION TO ACCESS PUBLICATIONS.

Leica Biosystems is providing the following resources and references in an effort to support customers interested in validating digital pathology for remote use during the COVID-19 Emergency. It is the responsibility of clinical laboratories, hospitals and other healthcare facilities to consider performing a validation study as they deem necessary before the implementation of digital pathology for remote reviewing and reporting of digital pathology slides. These references may not meet all the requirements for validation. Therefore, it is the customer's responsibility to validate their individual equipment set-up and clinical intended use, to meet institution's needs.

COVID-19 Guidance:

Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry, Clinical Laboratories, Healthcare Facilities, Pathologists, and Food and Drug Administration Staff

Centers for Medicare & Medicaid Services Memorandum, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, March 26, 2020

WSI Validation Documents:

Validation of a digital pathology system including remote review during the COVID-19 pandemic: M. G. Hanna et al. Remote digital pathology allows healthcare systems to maintain pathology operations during public health emergencies. Existing Clinical Laboratory Improvement Amendments regulations require pathologists to electronically verify patient reports from a certified facility. During the 2019 pandemic of COVID-19 disease, caused by the SAR-CoV-2 virus, this requirement potentially exposes pathologists, their colleagues, and household members to the risk of becoming infected. Relaxation of government enforcement of this regulation allows pathologists to review and report pathology specimens from a remote, non-CLIA certified facility.

"Validating Whole Slide Imaging for Diagnostic Purposes in Pathology", CAPS evidence-based guideline published in 2013, serves as a practical guide for pathologists and laboratories to confirm the accuracy and concordance of their own whole slide imaging (WSI) systems for diagnostic work while ensuring the digital tool is being used properly for its intended clinical use. Liron Pantanowitz, MD; John H. Sinard, MD, PhD; Walter H. Henricks, MD; Lisa A. Fatheree, BS, SCT(ASCP); Alexis B. Carter, MD; Lydia Contis, MD; Bruce A. Beckwith, MD; Andrew J. Evans, MD, PhD; Christopher N. Otis, MD; Avtar Lal, MD, PhD; Anil V. Parwani, MD, PhD

CAP Validating Whole Slide Imaging (WSI) for Diagnostic Purposes in Pathology FAQs

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