



NEWS RELEASE

Hologic Introduces Digital Pathology Capabilities With Expanded CE Marking

2025-11-12

The Genius Digital Diagnostics System now offers European labs the ability to streamline digital pathology workflows using one complete solution for a variety of specimen types

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that its Genius™ Digital Diagnostics System achieved expanded CE marking in the European Union and is now approved to image and review both cell and tissue specimens. Previously, the system was CE marked specifically for cell analysis, notably used in cervical cancer screening, among other applications. With the ability to image the entire slide for review of a broader range of patient sample types, the Genius Digital Diagnostics System will allow European labs to unify digital workflows with one comprehensive solution and support pathologists in their work diagnosing a variety of cancers and other diseases.

Genius™ Digital Diagnostics System

The ability to image the entire slide is known as “whole slide

imaging.” This means that, for example, the same system can assist in identifying pre-cancerous lesions and cervical cancer cells during cervical cancer screenings, while also enabling pathologists to review cervical tissue biopsies to help confirm diagnosis if an abnormality is detected. Similarly, for breast health, whole slide imaging allows labs to digitize and review tissue from a breast biopsy – a crucial step when an abnormality is detected during a mammogram to help diagnose or exclude breast cancer. Importantly, this capability is not limited to cervical and breast tissue; it can be leveraged for a wide variety of patient sample types and diagnostic needs, supporting more comprehensive and flexible pathology workflows.

Today, most labs rely on multiple systems for review of different patient sample types. This separation can create inefficiencies for the lab, which can increase operational costs, extend turnaround times and create additional work

for lab staff. Using advanced volumetric imaging technology, Hologic's Genius Digital Diagnostics System offers the ability to efficiently capture high quality digital images of cell and tissue specimens to then be stored, distributed and reviewed all on a single platform.

"Placing digital pathology at the center of diagnostic workflows has the potential to transform the way we approach cancer diagnosis and prevention," said Paul van Diest, Professor, Department of Pathology, University Medical Center Utrecht. "The ability to image and review more specimen types on a single system will help pathologists think beyond traditional boundaries and bring greater accuracy and efficiency to our work."

"Access to innovative technology in the laboratory can be a foundation for better patient care," said Jennifer Schneiders, Ph.D., President, Diagnostic Solutions at Hologic. "Expanding our CE marking with digital pathology will help bring advanced technology to more laboratories across Europe and signals another incredible step in Hologic's innovation pipeline focused on providing accurate and efficient results to support disease screening and diagnosis."

With the Genius Digital Diagnostics System, glass slides containing a patient specimen are quickly converted into high-resolution digital images using volumetric imaging technology. This process simultaneously captures 14 layers of the patient specimen and converts them into a single, two-dimensional view. Once complete, the entire case is sent to the system's image management server for secure storage and hands-free case management. It can then be reviewed locally or remotely, helping experts make an interpretation or diagnosis efficiently. This process is now applicable to cell and tissue specimens. The expansion also comes with additional software capabilities such as remote support, laboratory information system (LIS) readiness, new review tools and more.

Hologic's digital pathology solutions were CE marked in the European Union in accordance with the In Vitro Diagnostic Regulation, which is also recognized by other countries around the world. Commercialization per country will be announced. Whole slide imaging is currently not available in the United States.

To learn more about Genius Digital Diagnostics, visit [here](#).

About Hologic

Hologic, Inc. is a global leader in women's health dedicated to developing innovative medical technologies that effectively detect, diagnose and treat health conditions and raise the standard of care around the world. For more information on Hologic, visit www.hologic.com and connect with us on [LinkedIn](#), [Facebook](#), [X](#), [Instagram](#) and [YouTube](#).

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's Genius™ Digital Diagnostics System. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

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