

Roche receives FDA clearance on its digital pathology solution for diagnostic use

- **The solution, which includes the VENTANA DP 200 slide scanner, Roche’s digital pathology workflow software and a display, is now cleared to aid in clinical diagnosis, enabling pathologists to diagnose patients using digital images.**
- **Primary diagnosis for digital pathology enhances healthcare efficiency and helps ensure effective and timely patient care, especially in areas where access to pathologists is limited.**
- **This clearance is a foundational step in Roche’s commitment to enable routine clinical diagnosis with its digital pathology solutions.**

TUCSON, June 18, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its whole slide imaging system, the Roche Digital Pathology Dx (VENTANA DP 200), has received 510(k) clearance from the United States Food and Drug Administration (FDA). The system is intended to aid the pathologist in reviewing and interpreting digital images of scanned pathology slides to help diagnose patients.

“Primary diagnosis for digital pathology streamlines the digital workflow that empowers pathologists to make a timely diagnosis from anywhere,” said Jill German, Head of Pathology Lab for Roche Diagnostics. “This not only improves a pathology lab’s efficiency but also expands access to pathologists for people living in remote areas and increases opportunities for pathologists to collaborate on patient cases.”

Digital pathology refers to the digitalization of the traditional pathology workflow, starting from slide scanning, to visualization, to analysis. Digital pathology is transforming traditional histopathology by improving efficiency, depth of analysis and opportunity for collaboration in pathology workflows. For example, once a slide scanner captures and converts stained tissue on glass slides to digital images, these images can be managed, shared and analyzed by pathologists and can help determine a cancer patient’s treatment.

“We are investing in innovative digital pathology solutions to enable the pathology lab’s digital transformation,” German said. “Artificial intelligence–based tools and our Roche Digital Pathology Open Environment are designed to drive greater adoption and promote innovation in this critical field.”

[About Roche Digital Pathology](#)

As the leading provider of pathology lab solutions, Roche is delivering an end-to-end digital pathology solution from tissue staining to producing high-quality digital images that can be reliably assessed using automated AI-based image analysis algorithms. We minimize variables that can impact analysis, and it is this end-to-end development that produces the quality results healthcare providers and researchers can depend on. With the acceleration of immunotherapy and the development of more complex assays, Roche is moving these traditionally research-oriented tools into routine clinical practice and is committed to investing in and shaping the future of pathology.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalized healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

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Roche Media Relations

Roche Diagnostics U.S. Media Relations
us.mediarelations@roche.com

Krystina Monaco
1-317-850-7521
krystina.monaco@roche.com

Lori McLaughlin
1-463-207-2395
lori.mclaughlin@roche.com