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Ventana Receives FDA Clearance for Ki-67 (30-9) Image Analysis and Digital Read Applications

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the VENTANA Companion Algorithm Ki-67 (30-9) image analysis application used with the VENTANA [iScan Coreo Au](#) scanner running [VIRTUOSO](#) software. Ventana is currently the only company offering an FDA cleared Ki-67 image analysis algorithm for determining Ki-67 expression levels in breast cancer patients.

The Ki-67 protein is known to be an excellent marker for cellular proliferation. The Ki-67 (30-9) application may assist pathologists in achieving objective and consistent Ki-67 interpretation and can provide quantitative results for images with hundreds or thousands of cells.

When the VENTANA Ki-67 (30-9) algorithm is used with the VENTANA [CONFIRM anti-Ki-67](#) (30-9) Rabbit Monoclonal Primary antibody, it may be used as an aid in the assessment of Ki-67 status in breast cancer patients but is not the sole basis for treatment. The 510(k) clearance covers all components of the VENTANA workflow solution used together including the company's [BenchMark](#) slide stainer, Ki-67 (30-9) clone, detection systems, slide scanner and image management software.

"Ventana is the only company to offer a 510(k) cleared Ki-67 image analysis solution to pathologists today," said Dr. Steve Burnell, Vice President, Ventana Digital Pathology and Workflow. "This most recent addition to our digital pathology portfolio demonstrates our continued commitment to our customers by providing them with the most advanced clinical pathology workflow solutions available to support the highest standards of patient care."

Ventana also received FDA clearance for the digital read application that allows the pathologist to interpret Ki-67 (30-9) stained slides as images on a computer monitor with the VENTANA iScan Coreo Au scanner and Virtuoso software.

About Ventana Medical Systems, Inc.

Ventana Medical Systems, Inc. ("VMSI") (SIX: RO, ROG; OTCQX: RHHBY), a member of the Roche Group, innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. VENTANA solutions are used in clinical histology and drug development research laboratories worldwide. The company's intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving personalized healthcare through accelerated drug discovery and the development of "companion diagnostics" to identify the patients most likely to respond favorably to specific therapies. Visit www.ventana.com to learn more.

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