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Ventana Receives FDA Clearance for HER2 (4B5) 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 HER2 (4B5) for image analysis applications with associated VIRTUOSO software and iScan Coreo Au scanner. Ventana is now the only company with a complete workflow solution for determining HER2 (4B5) expression in breast cancer patients.

The application assists the pathologist in the detection and semi-quantitative measurement of HER2 (4B5) protein in formalin-fixed, paraffin-embedded normal and neoplastic tissue. While the pathologist is still the ultimate authority in scoring HER2 (4B5) stains, the image analysis application helps ensure consistency and objectivity in interpretation.

When used with the VENTANA PATHWAY anti-HER2 (4B5) Rabbit Monoclonal Primary Antibody, it is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN (Trastuzumab) treatment is being considered. The 510(k) clearance covers all components of the workflow including the 4B5 clone, slide stainer, detection systems, software and scanner.

“The addition of the Companion Algorithm for HER2 (4B5) to the VENTANA portfolio of products gives pathologists an important tool for assessing HER2 (4B5) expression in breast cancer patients,” said Dr. Steve Burnell, lifecycle leader for advanced workflow. “Ventana continues to lead the industry with its commitment to providing customers a complete, optimized solution – including stainers, reagents, scanners and digital pathology software applications - that provides accurate and efficient testing results.”

Ventana also received FDA clearance for the digital read application that allows the pathologist to view HER2 (4B5) stained slides as images on a computer monitor with VIRTUOSO software and iScan Coreo Au scanner.

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 “Smart Systems” – intuitive, integrated staining and workflow management platforms that optimize laboratory efficiencies to reduce errors – support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving personalized medicine 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.

Ventana products are for *in vitro* diagnostic use for specific applications, and are research use only for other applications.

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VMSI Media Relations

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