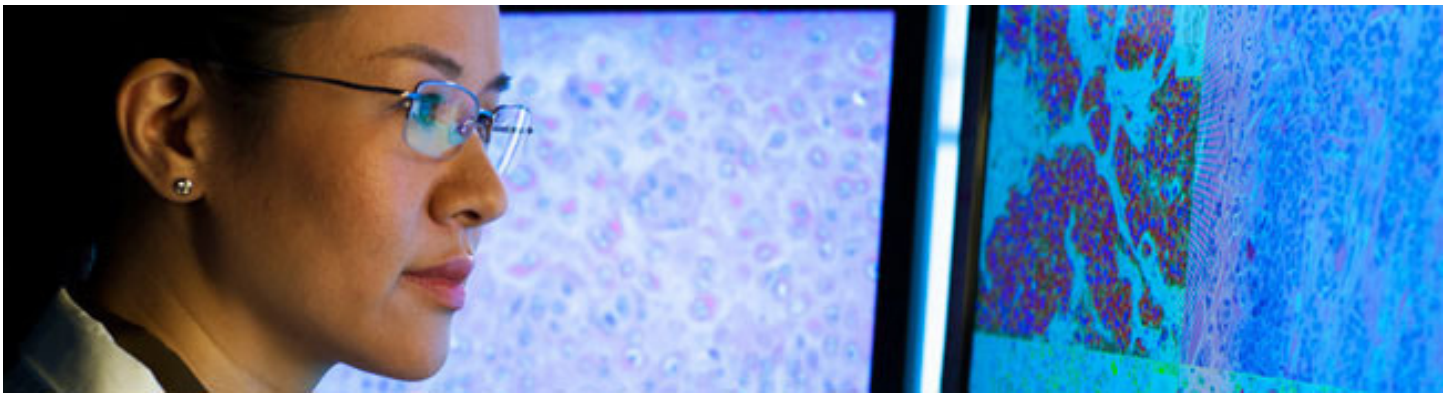

Ventana receives FDA clearance for Estrogen Receptor (ER) Image Analysis and Digital Read Application for breast cancer

Companion Algorithm ER (SP1) image analysis software clearance completes the company's breast diagnostic portfolio, providing physicians with the industry's only FDA-cleared testing package of five key breast biomarkers with their corresponding image analysis algorithms and digital read applications for cancer patients

Tucson, Ariz., Dec. 5, 2013 – 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 Companion Algorithm ER (SP1)[1] image analysis algorithm used with the VENTANA iScan Coreo scanner running Virtuoso[2] software. With this clearance, Ventana is now the only company in the industry offering a comprehensive portfolio of FDA-cleared image analysis algorithms and digital read applications for the five key immunohistochemistry (IHC) breast markers.

There are two intended uses obtained with the 510(k) clearance for ER: first, clinical use of the software algorithm to semi-quantify the ER biomarker, and second, digital read, or clearance to manually read and score the ER biomarker using a computer monitor, in lieu of a microscope. This means the pathologist will be able to digitally view a slide on a computer monitor, assign a score, and then sign out the case with a diagnosis or opinion, with or without the assistance of an image analysis algorithm.

All IHC breast markers in the Ventana portfolio have both image analysis and digital read application FDA 510(k) clearances. Along with the Companion Algorithm ER (SP1) image analysis software, the full breast panel includes HER2 (4B5), PR (1E2), Ki-67 (30-9) and p53 (DO-7) image analysis algorithms along with their accompanying VENTANA IHC assays[3].

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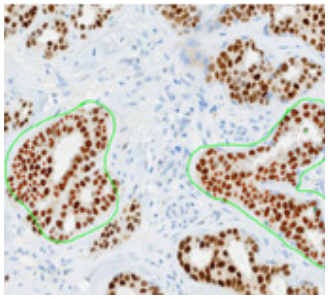
[1]When the VENTANA ER (SP1) algorithm is used in conjunction with the CONFIRM anti-ER (SP1) Rabbit Monoclonal Primary Antibody test, it may be used as an aid in the assessment of ER status in breast cancer patients for whom endocrine treatment is being considered but is not the sole basis for treatment.

[2]Virtuoso software is part of a 510(k)-cleared system with the HER2 (4B5), PR (1E2), Ki-67 (30-9), ER (SP-1) and p53 (DO-7) Companion Algorithm image analysis software. The FDA clearance includes all of the components of the VENTANA laboratory workflow solution including the company's BenchMark IHC/ISH slide stainer, exclusive HER2 (4B5), PR (1E2), ER (SP1), and Ki-67 (30-9) clones, detection systems, iScan slide scanner, and Virtuoso software.

[3]The PATHWAY HER2 (4B5) assay is FDA-approved, the CONFIRM PR (1E2) and CONFIRM ER (SP1) assays are FDA-cleared, and Ki-67 (30-9) and p53(DO-7) assays are FDA class 1, exempt in vitro diagnostics.

Downloads



VENTANA Companion Algorithm ER (SP1) image analysis algorithm

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"The biomarkers, scanner, and image analysis software have been optimized and clinically validated to work together as a system. Not only does this provide a powerful image analysis tool but an added level of clinical confidence," says Robert C. Babkowski MD, FCAP Chair, Department of Pathology and Laboratory Medical Director, The Stamford Hospital.

"This most recent addition of the VENTANA ER (SP1) Companion Algorithm software to our digital pathology portfolio demonstrates our continued commitment to provide our customers with the most advanced, clinically validated, pathology solutions available," says Dr. Steve Burnell, Vice President, Ventana Digital Pathology and Workflow. *"It represents another significant step by Ventana in assisting pathologists with the consistent and objective interpretation of these important breast cancer biomarkers, supporting the highest standards of patient care."*

Hormone receptor status is a main factor in planning breast cancer treatment. The presence or absence of estrogen receptor (ER) and progesterone receptor (PR) status in cancer cells, along with HER2 receptor status, help guide treatment options. The Ki-67 protein test and p53 genetic mutation test are known to be excellent markers for cellular proliferation.

"Digital pathology is a transformational technology, delivering greater accessibility, confidence and faster results to physicians and their patients," says Ventana President Mara G. Aspinall.

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 products 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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