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Ventana Medical Systems, Inc. Receives First FDA 510(k) Clearance for H. Pylori Antibody

The VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody (H. pylori) is the first *H. pylori* antibody to receive 510(k) clearance from the Food and Drug Administration (FDA). Developed by Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, the VENTANA H. pylori antibody, when used in immunohistochemical (IHC) staining, aids in the detection of *Helicobacter pylori*, a bacterium linked to chronic gastritis, ulcers and stomach cancer."FDA clearance of the VENTANA H. pylori antibody proves that our product surpasses the industry standard," says Greg Yap, Ventana lifecycle leader for advanced staining assays. "By leveraging our expertise in industry-leading advanced staining assays and workflow solutions, we are delivering to pathologists another next-generation tool for treating potentially cancer-causing gastric infections.''

The Centers for Disease Control and Prevention (CDC) estimates that approximately two-thirds of the world's population harbors the *H. pylori* bacterium, which damages the mucous coating that protects the stomach and duodenum. *H. pylori* causes peptic ulcers in nine out of 10 instances and studies have shown that those infected with *H. pylori* are nearly six times more likely to develop gastric cancer than those uninfected. In 1994, the International Agency for Research on Cancer (IARC) classified *H. pylori* as a carcinogen, or cancer-causing agent.

The VENTANA H. pylori antibody provides pathologists unprecedented views of the bacterium, allowing for a more accurate patient diagnosis. The high contrast staining of the organisms allows pathologists to view more bacteria than can be detected with special stains. With the *H. pylori* antibody, a pathologist can clearly view the characteristic helical shape of the organism. Even when very few organisms are present, an infection can be detected and treated effectively.

"As a pathologist with years of hospital experience, I believe our new *H. pylori* IHC test is an improvement to what is currently available for the diagnosis of *H. pylori* in tissue," says Dr. June Clements, Ventana staff pathologist. "The clean background and clear staining make identifying the organisms easier and faster. This, along with the specificity, provides the pathologist more confidence in the diagnosis."
For labs, the FDA clearance means less time spent validating the assay and more time running the tests, allowing for better lab workflow and quicker, more accurate patient diagnosis. The H. pylori antibody is also fully integrated with the VENTANA BenchMark XT and BenchMark ULTRA slide staining instruments.

"The key to our success in gaining FDA clearance was working with the FDA early in the process," says Sam Rua, director of regulatory affairs. "We met with the FDA, agreed to an

approach for our 510(k) submission and adhered to that approach every step of the process. Because of that alignment, we were ultimately successful in gaining approval for the VENTANA H. pylori antibody."

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, the VENTANA logo, and BenchMark are trademarks of Roche.

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