



Ventana Companion Diagnostics CAP/CLIA lab launches new Robust Prototype Assays

New diagnostic tests offer pharma and biotech companies more options for targeting cancer in research studies

Tucson, Ariz., May 21, 2014 - [Ventana Medical Systems, Inc. \(Ventana\)](#), a member of the [Roche Group](#) today announced the launch of three new companion diagnostic robust prototype assays (RPAs) for the detection of biomarkers PSMA, MDM2 and FGFR, offering biotech and pharmaceutical companies more options in exploring novel treatment options for patients with cancer. The new assays bring the company's CAP/CLIA testing menu to almost 400, nearly 100 of which are RPA assays and the remainder are IVD approved Ventana tests.

Robust prototype assays are in vitro diagnostic tests used in biomarker identification that have been validated, manufactured and used within a single clinical laboratory. The key advantage of Ventana CAP/CLIA RPAs is that they adhere to the same rigorous quality standards as the company's commercial, FDA-approved and Class I IVD assays. Biotech and pharmaceutical research development teams rely on RPAs when conducting early clinical studies to explore the potential value of specific biomarkers for a variety of indications. Data from these early research investigations can confirm, alter, or disprove a particular treatment hypothesis, saving companies valuable time and cost in bringing valuable cancer drugs to market to benefit patients.

PSMA (prostate specific membrane antigen)

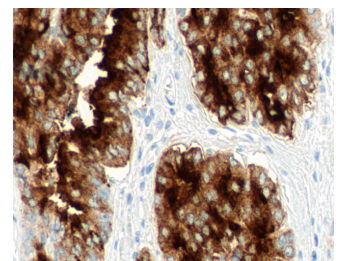
PSMA is a cell surface protein that mediates signal transduction processes leading to cell migration. PSMA is expressed on the surface of most prostate tumor cells and increased levels of expression are associated with progressively higher grade tumors.

MDM2 ISH (mouse double minute 2)

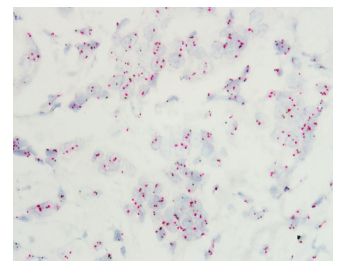
MDM2 is a gene that encodes a protein that inhibits p53 activation and promotes progression through the cell cycle. Genetic amplifications of MDM2 are associated with aberrant progression through the cell cycle and the formation of neoplasms. Amplifications of the MDM2 gene are most commonly observed in soft tissue malignancies (sarcomas) and glioblastomas.

FGFR2 (fibroblast growth factor receptor 2)

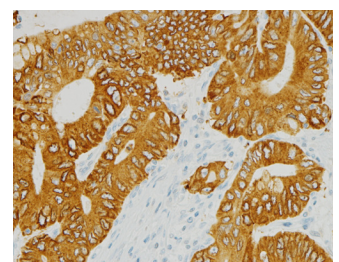
FGFR2 is a receptor tyrosine kinase (RTK) that is responsible for mediating a number of intracellular processes culminating in cell growth and proliferation. Increased expression of FGFR2 protein has been observed in a number of human malignancies, including gastric, lung, ovarian, and breast cancers.



[Prostate tissue at 20x, stained on a BenchMark XT instrument](#)



[Breast tissue at 60x, stained on a BenchMark ULTRA instrument](#)



[Gastric tissue at 20x, stained on a BenchMark XT instrument](#)

VMSI Media Relations

Jacqueline Bucher
Senior Director, Corporate
Communications
Phone: 520-877-7288
e-mail: [Jacquie Bucher](mailto:Jacquie.Bucher)

"High quality prototype assays for specific biotargets are a valuable tool for pharma early development," says H. James Hnatyszyn, Ph.D., Director of Ventana CAP/CLIA Laboratory Operations. *"Data from early clinical trials can help ensure that our pharma partners are pursuing strategies that will ultimately bring the most value to cancer patients."*

The Ventana CAP/CLIA lab is a full-service histopathology lab that employs automated staining platforms and validated assays for IHC and ISH staining of retrospective and prospective clinical samples. The laboratory's goal is to support hypothesis testing during early phase drug development studies. Customers for these services include pharma development teams within the Roche group such as Genentech and Chugai, as well as external pharmaceutical companies that are interested in oncology biomarker evaluation and companion diagnostic development using tissue-based IHC and ISH assays.

The Ventana Companion Diagnostics (CDx) Pharma Services Team provides customers with a comprehensive suite of services in prototype assay development and validation, including antibody screening, analytical performance studies, validation report and IHC/ISH slide scoring by pathologists. Through the Ventana CAP/CLIA lab, clients have access to full anatomic pathology services in tissue processing, embedding, microtomy, primary staining, and advanced staining.

For a full list of available assays, email ventana.cdx@ventana.roche.com or call (520) 229-4617.

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 help reduce errors, support diagnosis and enable informed treatment decisions by 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.

About Spring Bioscience

[Spring Bioscience \("Spring"\)](#) was founded in 2001 by a team of scientists and achieved early success with their line of SP Clone rabbit monoclonal antibodies for clinical immunohistochemistry. Ventana Medical Systems, Inc. acquired the company in 2007 for its antibody development capabilities. Today Spring serves an important role as an antibody center of excellence in support of Roche's mission to deliver companion diagnostics. This is accomplished through the development of antibodies destined for clinical assays through Ventana and other Roche affiliates and through its collective medical and market intelligence serving the cancer research community.