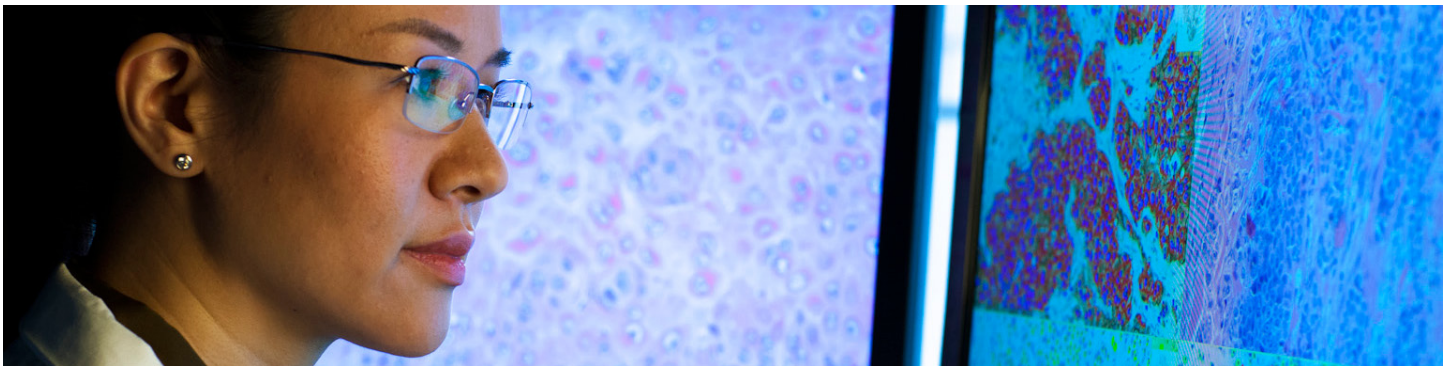
Media Release

VENTANA®
A Member of the Roche Group

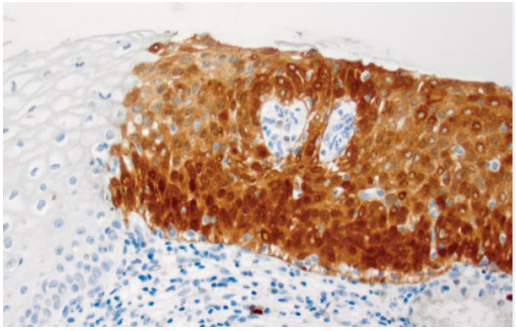


TUCSON, Ariz., September 10, 2012

New CAP – ASCCP Consensus Terminology Guidelines Include Strong Recommendations for p16 Biomarker Use in the Assessment of Cervical and Other Lower Anogenital Tract Tissue

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, announced today that a working group from the Lower Anogenital Squamous Terminology (LAST) Standardization Project--an interdisciplinary project led by the College of American Pathologists (CAP) and the American Society for Colposcopy and Cervical Pathology (ASCCP)--has published consensus recommendations to standardize the histopathologic terminology for squamous epithelial lesions of the lower anogenital tract associated with human papillomavirus, and to guide optimal biomarker use. These guidelines for pathologists include strong recommendations in support of the adjunctive use of the p16 biomarker in certain scenarios to support accurate diagnoses of pre-cancerous squamous lesions of the cervix and other lower genital tract sites.

The new recommendations were published June 28 online ahead of print in the Archives of Pathology & Laboratory Medicine and the Journal of Lower Genital Tract Disease.



Positive CINtec® p16 Histology staining of a cervical biopsy specimen with the VENTANA OptiView Detection Kit on a VENTANA BenchMark ULTRA IHC / ISH automated staining instrument.

Request High Resolution Files

Follow us on Twitter

Join our Network LinkedIn

The LAST biomarker work group concluded that the p16 biomarker, developed by mtm Laboratories AG of Heidelberg, Germany (mtm) and marketed as CINtec® p16 Histology, is the only biomarker "with sufficient evidence on which to make recommendation regarding use in lower anogenital tract squamous lesions." mtm was acquired by Roche last year and Roche Diagnostics GmbH and Ventana are the exclusive provider of p16 for clinical use. The CINtec® p16 Histology product has recently been launched for use with VENTANA BenchMark XT and BenchMark ULTRA IHC/ISH instruments using VENTANA OptiView DAB IHC or ultraView DAB detection.

Hope for More Accurate Cervical Pre-Cancer Diagnosis

IIt is estimated that approximately 500,000 women per year are diagnosed with cervical cancer worldwide. Virtually all cervical cancer is associated with human papillomavirus (HPV) infections that cause lesions on the epithelium (the tissues lining the cavities of the body). Most HPV infections resolve on their own and do not lead to high-grade pre-cancerous lesions or cervical cancer. However, pathologists are often challenged to distinguish between benign lesions caused by transient HPV infections that clear spontaneously from those persistent infections that drive oncogenic transformation that can lead to cancer. Furthermore, benign changes in the cervix can mimic pre-cancer, and since clinicians are cautious about leaving potentially pre-cancerous lesions untreated, overtreatment of low-grade cervical lesions and mimics is a concern. Overtreatment in young women can lead to increased risks in pregnancy, including premature labor and ruptured membranes.

The LAST work groups were constituted to help address these and other challenges associated with the diagnosis of cervical and other HPV-associated anogenital lesions. As part of its recommendations contributing to a standardized terminology, the biomarker work group recommended that:

- the p16 biomarker be used in conjunction with H&E morphology to aid in differential diagnosis between CIN2/

CIN3 and mimics of pre-cancer
- adjudicate when there is professional disagreement about a diagnosis
- as well as in several other situations, such as cases in which the results of a Pap smear indicate high grade pre-cancerous changes and the biopsy appears to be normal or low-grade precancerous disease

As Mark H. Stoler, MD, co-chair of LAST biomarker work group, explained recently in CAP Today, "We try to save the patient a second colposcopy and get the right diagnosis, and one way is if a normal biopsy is associated with an HSIL Pap test, consider doing a p16 stain. A significant percentage of the time, this will highlight an area of missed CIN2/3 [high-grade precancerous cells] and will save the patient a second biopsy."

Supporting the Ventana Mission

The LAST biomarker work group had reviewed more than 2000 scientific publications evaluating the use of molecular markers in conjunction with H&E morphology in lower anogenital tract tissues. "The publication of these recommendations supporting the use of p16 as the only biomarker with sufficient evidence for its use in lower anogenital tract histopathology interpretation underscores our conviction that technical and clinical validation is the key to establishing new medical parameters, such as biomarker-based diagnostic adjuncts," explains Roche mtm laboratories AG Chief Scientific Officer Ruediger Ridder.

"The recommendations themselves as well as the comments to the press by the scientists and clinicians in the LAST biomarker work group underline the alignment of the mtm and CINtec® p16 acquisition with the mission and vision of Ventana and Roche," adds Ridder.

The recommendations are available to the public at: http://journals.lww.com/jlgtd/Fulltext/2012/07000/The_Lower_Anogenital_Squamous_Terminology.6.aspx

In the United States, the CINtec p16 Histology product is available as a Class I exempt IVD without claims. The utility, as described in this press release and as recommended by the cited CAP/ASCCP recommendations, has not been cleared or approved by the US Federal Food and Drug Administration.

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.

Ventana Medical Systems, Inc.
Empowering | Innovation

VMSI Media Relations
Jacqueline Bucher
Senior Director, Corporate Communications
Phone: 520-877-7288
e-mail: jacquie.bucher@ventana.roche.com