

Media Release

Landmark study of more than 27,000 women shows favorable results of Roche's CINtec PLUS cytology test

Landmark study of more than 27,000 women shows favorable results of Roche's CINtec PLUS cytology test

Tucson, Ariz., Nov. 4, 2013 – Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, is pleased to announce the positive findings of the Primary ASC-US LSIL Marker Study (PALMS) that have been published in *The Journal of the National Cancer Institute*.¹ The pan-European study, including more than 27,000 women from five European countries, was performed to estimate the diagnostic performance of the CINtec® PLUS* cytology test in screening for cervical precancers compared to more traditional screening methods like Pap cytology. The study assessed whether the test, which uses two biomarkers, p16 and Ki-67, that are indicative of oncogenic (cancer-causing) human papillomavirus (HPV) infections, provides both high sensitivity and specificity for high-grade precancerous cervical lesions. The results showed that when compared to Pap cytology testing, the CINtec PLUS cytology test was more effective than Pap cytology in detecting precancerous lesions. Pap cytology had a sensitivity of 67.5% while the CINtec PLUS test had a sensitivity of 86.7%.

“The results of PALMS confirms data from previous studies which have shown that incorporating the CINtec PLUS test in cervical cancer screening programs can provide real benefit to both clinicians and their patients,” says Dr. Christine Bergeron, Laboratoire Cerba, Cergy, Paris, France, PALMS study investigator and publication co-author. *“In young women, where HPV infection rates may be high, the CINtec PLUS test could be very useful to identify those women with clinically significant precancers who may be missed by the lower sensitivity Pap test. In older women, combining the CINtec PLUS test with HPV DNA testing would make a lot of sense.”*

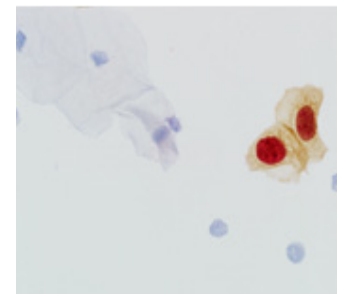
More than 500,000 new cases of cervical cancer are diagnosed each year worldwide.² Disappointingly, the average five-year survival rate of patients is only around 50%.² HPV infections are common and cause virtually all cervical cancer.² However, only those women with persistent HPV

*The CINtec® PLUS cytology test is not available in all geographies and/or may not be approved for all uses discussed in this press release.

¹JNCI - *The Journal of the National Cancer Institute* (Ikenberg et al. Screening for Cervical Cancer Precursors With p16/Ki-67 Dual-Stained Cytology: Results of the PALMS Study. *J Natl Cancer Inst.* 2013;105(20):1550-1557); PUBMED: www.ncbi.nlm.nih.gov/pubmed/24096620.

²World Health Organization Fact Sheet 380, September 2013: <http://www.who.int/mediacentre/factsheets/fs380/en/>

Downloads



Abnormal cervical cells staining positive for CINtec PLUS test

[Request High Resolution Files](#)

infections and who have developed high-grade precancerous cervical disease should be treated. The CINtec *PLUS* cytology test was developed to help identify those HPV infections that may lead to cancer and distinguish them from those that will not.

The authors (Safaeian and Sherman) of an editorial published along with the PALMS study results write that dual biomarker screening could have a role in primary screening, especially in younger women. They also conclude that the dual assay could serve as a triage for positive HPV tests and could dramatically decrease patient referrals to colposcopy and other invasive and costly procedures unnecessarily.

“The results demonstrated in the PALMS trial reinforces the medical value Roche brings to cervical cancer screening. We are committed to improving patient outcomes by providing differentiated diagnostic tools for doctors and laboratories,” says Mara G. Aspinall, President, Ventana Medical Systems, Inc. *“We are pleased to announce that a fully automated version of the CINtec® PLUS cytology test will be launching later this year and will join the cobas® HPV test and the CINtec® Histology test to complete our portfolio of cervical cancer screening products.”*

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.

VMSI Media Relations

Jacqueline Bucher

Senior Director, Corporate Communications

Phone: 520-877-7288

e-mail: [Jacquie Bucher](mailto:Jacquie.Bucher)