



Media Release

Clinical value of Roche's CINtec® PLUS Cytology test confirmed for women with abnormal cervical cytology screening results

Tucson, AZ, June 16, 2015 - Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, today announced the publication of further results from the Primary ASC-US LSIL Marker Study (PALMS) in this month's issue of *Cancer Cytopathology*¹. The PALMS study, which enrolled more than 27,000 women from five European countries, was designed to evaluate the diagnostic performance of the CINtec® PLUS Cytology² test in detecting precancerous cervical disease compared to HPV testing and more traditional screening methods like Pap cytology.

In this latest publication based on the PALMS study results, the CINtec PLUS Cytology test was compared to pooled, high-risk HPV DNA testing as a triage or follow-up screening method for mildly abnormal Pap cytology results. The study confirmed that the CINtec PLUS Cytology test had significantly higher specificity and was more effective overall than the HC2 HPV test in identifying women with precancerous lesions. These results suggest that if implemented as a triage test in a cytology-based screening program, the CINtec PLUS Cytology test may lead to a reduction in the overtreatment of women screened for cervical disease.

"These latest results of PALMS confirm data from previous studies which have shown that incorporating the CINtec PLUS Cytology test in cervical cancer screening programs can provide real benefit to both clinicians and their patients," says Dr. Christine Bergeron, Laboratoire Cerba, Cergy Pontoise, France, PALMS study investigator and publication author. "As a triage test for abnormal cervical cancer screening results, the CINtec PLUS Cytology test could be very useful to differentiate women who will benefit most from immediate referral to colposcopy and diagnostic follow-up, from those women who can be followed up with less invasive methods."

More than 500,000 new cases of cervical cancer are diagnosed each year worldwide³ and the average five-year survival rate of patients is only around 50%.³ HPV infections are common and cause virtually all cervical cancer³; however, only those women with persistent HPV infections and who have developed high-grade precancerous cervical disease should be treated. The CINtec PLUS Cytology test was developed to help identify the subgroup of women with underlying transforming HPV infections that may lead to cancer and distinguish them from those with mostly transient infections.

"The results observed in PALMS are consistent with those demonstrated in many other published studies," said Tim Himes, Lifecycle Leader, CINtec and HPV-mediated Disease.



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“As countries begin to move towards primary screening with HPV, the need for an improved triage test will increase dramatically. We are therefore pleased to see that the CINtec *PLUS* Cytology test consistently demonstrates strong performance when used in the triage setting. By overcoming the known issues with Pap cytology, the test is well positioned to provide immediate benefit to women, doctors and screening programs globally.”

¹Bergeron C, Ikenberg H, Sideri M, Denton K, Bogers J, Schmidt D, Alameda F, Keller T, Rehm S, Ridder R, and for the PALMS Study Group. Prospective evaluation of p16/Ki-67 dual-stained cytology for managing women with abnormal Papanicolaou cytology: PALMS study results. *Cancer Cytopathol.* 2015; 123(6):373-381

²The CINtec® *PLUS* Cytology test is not available in all geographies.

³ World Health Organization Fact Sheet 380, March 2015:
<http://www.who.int/mediacentre/factsheets/fs380/en/>

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About Roche

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In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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