New test for the early diagnosis of cervical cancer

mtm laboratories has launched the Cervatec™ assay for the early diagnosis of cervical cancer. Cervatec™ demonstrates superior sensitivity over the traditional Pap test.

mtm laboratories AG has published the results from a large prospective study and has announced the launch of the CE-labelled Cervatec™ assay. In a multicentre study, the Cervatec™ ELISA assay revealed a sensitivity in the detection of cervical cancers that was more than twice as high as the Pap test alone.

The Cervatec™ assay will initially be commercialized as an adjunct to the Pap test for the screening of women aged 35 and younger. mtm's Cervatec™ is based on the quantitative detection of p16, a cellular protein that is upregulated in the presence of cervical disease, and hence constitutes a highly sensitive biomarker for this disease.

The diagnostic Cervatec™ assay will be used together with the traditional Pap test for the early detection of cervical cancer and its precursor lesions. A cervical sample is taken by the clinic and then sent to a clinical laboratory for processing. The presence of the biomarker p16 in lysed cervical specimens is quantitatively measured by a colorimetric sandwich ELISA which can be run manually or on automated ELISA platforms. Increased levels of the p16 biomarker indicate the presence of pre-cancerous and cancerous lesions of the cervix uteri in first-line screening.

In a prospective study involving more than 7,500 women aged 35 and below, results using Cervatec™ and Pap test were compared with biopsy-confirmed diagnoses. Cervatec™ alone resulted in a figure of 90% sensitivity in the detection of biopsy-confirmed high-grade disease (CIN2+) compared to 39% sensitivity for the Pap test alone. In addition, the combined use of Cervatec™ with the Pap test is detecting the level of underlying disease anticipated in this population.

Unique properties of the propriety p16 biomarker confirmed

Dr. Rüdiger Ridder, Chief Scientific Officer of mtm laboratories, commented: "We are pleased with the results of the study, further confirming the unique properties of our proprietary p16 marker. Pap tests have served us well for many years but many women in the early stages of the disease were not being picked up in screening. We have shown in this study that the combined sensitivity of Pap with Cervatec™ is considerably higher compared to when Pap alone is used. We therefore

believe that the greater sensitivity of Cervatec™ truly reflects the expected levels of underlying disease that is missed by the Pap test alone."

Bob Silverman, Chief Commercial Officer of mtm laboratories AG and managing director of the company's US subsidiary, explained:
"The combination of our easy-to-use Cervatec™ assay with conventional Pap testing represents a major improvement in the screening for cervical cancer and its precursors. The biomarker-based ELISA is an affordable and objective high-throughput approach to detect cancerous disease in first line screening. Cervatec™ will improve the certainty for gynaecologists and patients that severe lesions, which might otherwise remain undetected by Pap testing alone, are detected early when treatment interventions can be most effective."

mtm's in vitro diagnostic tests based on the p16 biomarker are independent of the viral infection with HPV types which lead to a cancerous disease in a very small percentage of infected women. Due to the high prevalence of underlying viral infections and the resulting high rate of false positives for the infection in younger women who have no evidence of cervical disease, Cervatec™ allows for a much more specific identification of actual disease and is particularly well suited for women aged 35 and younger.

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