mtm laboratories announces new pivotal trial data resulting in European launch of the CINtec® Histology kit with extended clinical claims
New study data shows significant improvement of accuracy and inter-observer agreement in diagnosing high grade cervical disease

Heidelberg, Germany; July 11, 2007 mtm laboratories, a fully integrated cancer diagnostics company with proprietary products marketed globally, today announced the launch of the CE-labeled CINtec® Histology kit with extended claims in Europe. The clinical claims are deduced from the outcome of a recent pan-European pivotal study involving 15 pathologists from France, Spain, Italy and Germany.

The multi-center trial was conducted to determine the diagnostic accuracy of pathologists in reading H&E stained cervical biopsies together with CINtec® Histology stained slides, compared to reading H&E slides alone, on 500 retrospectively collected cervical tissue specimens. The specimen collection comprised punch and conization biopsies with a distribution of cases of Negative for Dysplasia, CIN1, CIN2 and CIN3.

Ruediger Ridder, CSO of mtm laboratories, explained the outcome:
"The overall sensitivity for the detection of CIN2 and higher grade disease was improved by 13%, with a 95% sensitivity for detection of high grade disease (CIN3), whereas the number or false negative results dropped by 45%. In addition, the inter-observer agreement, which is higher by 30%, improves the certainty that the result is consistent among different reviewers."

Peter Pack, CEO of mtm laboratories, commented:
"The clinical performance of the CINtec® Histology kit, which was fully developed by mtm and which is produced in-house, impressively confirms numerous findings in literature that p16INk4a is a highly sensitive marker for the presence of dysplastic and neoplastic cells in specimens of the ***cervix uteri***. The CINtec® Histology study results support the routine use of CINtec® Histology in the diagnosis of cervical biopsies. CINtec® Histology improves clarity and confidence for detecting cervical cancer and its precursors based on an objective parameter".

The **CINtec® Histology Kit** is indicated to be used in conjunction with H&E stained slides prepared from the same cervical tissue specimen as an aid to increase diagnostic accuracy and inter-observer agreement in the diagnosis of high-grade cervical intraepithelial neoplasia and cervical carcinoma.

mtm's CE-labeled CINtec® Histology kit with extended claims will be marketed solely outside of the U.S.

Disclaimer: This IVD product and the use presented herein has not been cleared or approved by authorities in the United States including the United States Food and Drug Administration.

mtm laboratories AG is an ISO 9001 and ISO 13485 certified developer and manufacturer of In-Vitro Diagnostic Devices (IVDD) for use in the early detection and diagnosis of cervical cancer. The Company operates on a global basis with the headquarter in Heidelberg, Germany and subsidiaries in the United States, France, Italy and Spain. Further information can be found at: www.mtmlabs.com.

Notes for editors:

The CINtec® family of diagnostic products
mtm's family of products is based on mtm's proprietary E6H4TM antibody clone which was specifically developed for immunochemistry applications in cervical histology and cytology specimens. The target for mtm's cervical cancer early detection technology platforms is the evaluation of the over-expression of the cyclin-dependent kinase inhibitor p16INK4a. The over-expression of this biomarker is directly correlated to the oncogenic activity of High Risk Human Papilloma Virus (HR-HPV) that marks the generation of cervical cancer. These biomarker-based diagnostic assays hold the promise to bring high levels of sensitivity and specificity towards the detection of high grade cervical disease in adjunctive uses with conventional technologies.

The CINtec® immunoassays are validated to provide a sensitive and specific method for the detection of p16INK4a in cervical tissues. The currently marketed CINtec® In-vitro Diagnostics (IVDs) have been developed for application on:

- cervical biopsies (CINtec® Histology) and
- cervical cytology preparations such as smears and liquid based cytology samples (CINtec® Cytology)

CINtec® products are available on a global basis through mtm's direct operations and distributors.