



FOR IMMEDIATE RELEASE

## **Medical Diagnostic Laboratories, L.L.C. Announces New HPV-16 Status Test**

**Hamilton, NJ., July 20, 2011** –**Medical Diagnostic Laboratories, L.L.C., (MDL)**, is a CLIA certified infectious disease laboratory which specializes in high complexity, state-of-the-art, automated DNA-based molecular analyses. MDL is able to provide clinicians with valuable tailored diagnostic information to assist in the detection, diagnosis, evaluation, and treatment of infections.

MDL, a company within the Genesis Biotechnology Group, is located in “Einstein’s Alley”, the research and technology corridor in Hamilton, New Jersey.

Only available through MDL, the HPV-16 Status reflex test makes available unique molecular testing that supplements the information provided by HPV Type-Detect<sup>®</sup> assay. It provides an integrated view of three factors reported to be associated with the development of HPV-16-related cervical dysplasia and cervical cancer.

High-risk human papillomaviruses (HPV) are found in almost all cervical tumors and are therefore considered a causative factor of cervical cancer. However, most cervical intraepithelial lesions caused by high-risk HPV are known to spontaneously regress. This suggests that, although a causative factor, high risk HPV infection does not independently cause cervical cancer. Therefore, it is important to consider additional factors of HPV-16 that play a role in the progression of premalignant cervical lesions. Many studies have identified HPV-related markers that can predict the progression of cervical intraepithelial lesions and cervical cancer. The markers include, but are not limited to, HPV type, HPV integration status, and HPV viral load

Of the high-risk HPV types, HPV-16 is the prevalent genotype associated with approximately 20% of low-grade cervical lesions, 50% of high-grade lesions and 60% of cervical squamous cell carcinomas. In approximately 80% of HPV-16 positive cervical carcinomas, a truncated viral genome which has integrated into the host genomic DNA is found. In general, clinical studies in several countries show that the integration of HPV-16 is accompanied by an increase in the grade of cervical lesions and is strongly associated with persistent HPV infection and progression of cervical lesions. HPV-16 infections are cleared more slowly than other HPV types and HPV-16 viral load has been reported as a marker for persistent HPV infection. HPV-16 viral DNA load is also reported to be associated with high-grade cervical lesions and invasive cancer

This test was provided and supported by Oncoveda Cancer Research Center<sup>™</sup>, established by MDL to translate cancer research into diagnostic tools. Oncoveda is using

the HPV-16 Status test in ongoing clinical research to evaluate other factors of HPV infection.

According to Dr. Eli Mordechai, Chief Executive Office (CEO), “The HPV-16 Risk Assessment reflex test is an example of a tailored molecular diagnostic approach to address chronic, persistent, complex disease. This test provides the physician with unique valuable data that is essential to patient stratification, therapy, and prognosis. MDL’s selective molecular testing platforms are specifically designed to address complex, chronic, persistent disease well beyond the identification of a specific pathogen, by incorporating factors such as molecular drug resistance profiles and genetic surrogate markers”.

To find out more, please visit [www.mdlab.com](http://www.mdlab.com).

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