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Medical Diagnostic Laboratories, L.L.C. Announces a Complimentary Reflex Test to Determine Metronidazole Resistance in *Trichomonas vaginalis*.

Hamilton, NJ., April 2, 2012 –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. By using molecular techniques, MDL is able to provide clinicians from many different specialties valuable tailored diagnostic information to assist in the detection, diagnosis, evaluation, and treatment of viral, fungal, and bacterial infections.

MDL, a company within the Genesis Biotechnology Group, is located in “Einstein’s Alley”, the research and technology corridor in Hamilton, New Jersey. Their facility is easily accessible to the New York, New Jersey, and Pennsylvania areas.

The Femeris Women’s Health Research Center™ within MDL was established to translate women’s health research into diagnostic tests. Their most recent test release, the metronidazole resistance reflex assay for *Trichomonas vaginalis*, is currently only commercially available through MDL. This companion assay will be performed at no additional charge when *Trichomonas vaginalis* is detected in a patient’s specimen. This new assay will provide another tool for clinicians to make appropriate decisions pertaining to treatment regimens to achieve an effective cure. This diagnostic assay is currently patent pending before the United States Patent and Trademark Office.

Trichomonas vaginalis, a flagellated protozoan parasite, is the most common non-viral sexually transmitted pathogen with more than seven million cases of trichomoniasis each year in the United States. Trichomonas vaginitis is associated with a number of serious clinical complications in pregnant women, such as an increased risk for pre-term labor and delivery of low birth weight neonates, as well as an overall association with HIV transmission. Patients are normally treated with a single oral dose of metronidazole, an antibiotic used to treat infections caused by anaerobic bacteria and parasites. Although generally effective, some *T. vaginalis* strains are resistant to metronidazole. If metronidazole treatment fails, the only other approved treatment is the related drug, tinidazole. Therefore, identifying *T. vaginalis* resistance to metronidazole can help guide clinicians in prescribing an effective therapy for their Trichomonas vaginitis patients at the time of diagnosis.

Although metronidazole treatment is reported to be 85%-95% effective, recent reports suggest that between 2.5% and 10% of clinical *T. vaginalis* isolates exhibit some degree of metronidazole resistance. Currently, very few facilities, such as the Centers for Disease Control and Prevention (CDC), can determine metronidazole susceptibility for *T. vaginalis*. A viable culture of *T. vaginalis* must be obtained using a specialized collection and transport device.

MDL can now detect metronidazole resistance in a subset of *T. vaginalis* positive specimens by Real-Time PCR. Their new assay detects a *T. vaginalis* gene mutation highly associated with metronidazole resistance with a 91% positive predictive value (PPV). This test was developed using 100 well-characterized *T. vaginalis* isolates from the CDC.

According to Dr. Eli Mordechai, Chief Executive Officer (CEO), “We are pleased to offer this new diagnostic test for patients infected with *Trichomonas vaginalis*, an extremely common sexually transmitted infection. This test will be especially useful in identifying select strains of *Trichomonas vaginalis* that are resistant to the most widely prescribed drug, metronidazole. More effective treatment options directly translate to less discomfort and complications for patients. This test release is part of a continuing effort by MDL to establish a tailored medicine approach that pairs the identification of the pathogen’s genetic makeup with the optimal antimicrobial therapy. MDL, in conjunction with its research team at Femeris, has created a menu of diagnostic tests that provide antimicrobial susceptibility information to physicians which includes a growing number of pathogenic organisms such as *Neisseria gonorrhoea*, Group B Streptococcus, *Candida* species, Influenza A virus, and now, for the first time, *Trichomonas vaginalis*.”

To find out more, please visit www.mdlab.com.

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