



FOR IMMEDIATE RELEASE

Medical Diagnostic Laboratories, L.L.C.'s The Institute for Biomarker Research Announces New Prenatal Cystic Fibrosis Tests

Hamilton, NJ., October 22, 2014 –Medical Diagnostic Laboratories, L.L.C., (MDL), a CLIA-certified, CAP-accredited laboratory which specializes in high complexity, state-of-the-art, automated DNA-based molecular analyses, announces that it is now offering new Cystic Fibrosis Testing which utilizes cutting edge technology, including next- generation DNA sequencing platforms.

Cystic fibrosis (CF), or mucoviscidosis, is a genetically inherited multisystem disorder that affects the respiratory, gastrointestinal and reproductive systems. More than 1,800 different mutations have been discovered since the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene responsible for CF was discovered in 1989. The National Institute of Health (NIH), the American College of Medical Genetics (ACMG), and the American College of Obstetricians and Gynecologists (ACOG) recommends offering CF carrier screening to all pregnant women and for preconception evaluation. All states include CF screening as part of their newborn screening panels. The newborn screening panels that include CF screening do not replace maternal carrier screening. Screening is most efficacious in the non-Hispanic Caucasian and Ashkenazi Jewish populations.

MDL provides non-invasive, easy specimen collection methods for CF testing using either mouthwash samples or cervico-vaginal swabs. Blood is also an acceptable source. Utilizing updated technologies, including next-generation DNA sequencing platforms, MDL offers a diverse panel for CF testing with high accuracy genetic testing.

The MDL Cystic Fibrosis Core Test is a *CFTR* gene sequence analysis that screens for the 23 major mutations recommended by ACOG and ACMG for CF screening.

The MDL Cystic Fibrosis Comprehensive Test is an expanded *CFTR* gene sequence analysis that screens for 191 variants, including the recommended 23 major mutations and the 9 mutations recommended by the FDA for determining Ivacaftor (Kalydeco™) treatment efficiency.

The MDL Cystic Fibrosis Site Specific Analysis screens for known family CF mutations previously identified in blood relatives.

The Institute for Biomarker Research, a Division of MDL, was established to create, validate and commercialize innovative diagnostic assays for clinical practice. MDL is a member of the Genesis Biotechnology Group located in Hamilton, New Jersey in “Einstein’s Alley”, the research and technology corridor of New Jersey, in close proximity to major metropolitan centers in New York, New Jersey and Pennsylvania.

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

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