



Quest Diagnostics to Enhance Quality of Noninvasive Prenatal Screening with QNatal Advanced™

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New prenatal screening service provides actionable information for women with high-risk pregnancies

MADISON, N.J., May 12, 2015 /PRNewswire/ -- [Quest Diagnostics](#) (NYSE: DGX), the world's leading provider of diagnostic information services and a leader in women's health and genomic testing, today launched QNatal Advanced, a noninvasive prenatal screening service for detecting chromosomal abnormalities in high-risk pregnancies.

QNatal Advanced analyzes cell-free fetal DNA in circulating maternal blood to screen for common and rare chromosomal abnormalities, including those associated with trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), trisomy 13 (Patau syndrome) and monosomy X (Turner syndrome), as well as fetal sex aneuploidies and select copy number variants. The screening test analyzes more chromosomal regions than most other noninvasive prenatal tests, and can be used as early as 10 weeks into gestation.

With results of a QNatal Advanced screen, a woman and her physician may be better positioned to assess the appropriateness of invasive diagnostic testing, such as amniocentesis, which carries a slight risk of miscarriage, to confirm a finding.

"With QNatal Advanced, Quest Diagnostics is delivering on its commitment to provide clinically important innovations aligned with guideline-based care as part of a full range of capabilities that support a woman through her pregnancy," said Charles ('Buck') Strom, MD, PhD, vice president, genomics and genetics, Quest Diagnostics.

Noninvasive Prenatal Screening' the Preferred Term

Prenatal diagnostic tests are not intended to provide diagnostic information under medical guidelines. To reduce the potential for confusion, Quest Diagnostics has adopted the phrase 'noninvasive prenatal screening' to describe QNatal Advanced in place of the common industry term 'noninvasive prenatal test' which may inappropriately connote a diagnostic test.

In addition, the company is only promoting QNatal Advanced as a screening service for women defined as high-risk under medical guidelines. These include women 35 years of age at time of delivery and older or women with a personal and family history of an affected pregnancy, among other factors. According to guidelines, women of advanced maternal age may also benefit from noninvasive prenatal screening following an abnormal ultrasound or abnormal maternal serum screening test.

"As a leader in women's health, Quest Diagnostics has a responsibility to ensure our patients and physicians understand both the advantages and limitations of the services we provide. Cell-free DNA tests are for screening only, and never diagnostic. The phrase 'noninvasive prenatal screening' coined by Quest Diagnostics reflects the seriousness with which we take our responsibility to ensure women have access to health insights that are appropriate, actionable and of the highest quality," said Douglas S. Rabin, MD, medical director, women's health, Quest Diagnostics.

"If compelling new science emerges suggesting that these technologies can be used diagnostically, or that the benefits of screening average-risk women outweigh the risks, we will certainly reconsider our position. For now, we believe our approach is the right one to help women make the best possible decisions," Dr. Rabin added.

Noninvasive Prenatal Screening -- New and Improved

QNatal Advanced is a lab-developed test developed and validated by Quest Diagnostics using massively parallel shotgun sequencing (MPSS), a type of next-generation sequencing technology, with GC correction. Results of Quest's validation study found QNatal Advanced provides excellent sensitivity and specificity, as well as low non-reportable results. Quest intends to present the findings at a scientific conference in the coming months.

QNatal Advanced is based, in part, on intellectual property licensed by Quest Diagnostics from Sequenom as part of an agreement, announced in June 2014. Unlike Sequenom's MaterniT21, QNatal Advanced provides the option to opt out of receiving information on gender and microdeletions, which can provide complex and limited actionable information, and facilitates direct ordering and reporting of results via Quest's Care360 connectivity solution. It also reports results as Yes/No for the presence of relevant trisomies and other abnormalities, as compared to other industry reports that score findings on a likelihood scale.

"We've taken the best of the Sequenom technology and added to it our own expertise and innovation, based on our deep experience in genomics and women's health," Dr. Strom said. "The result is an offering that, while medically equivalent, may have greater potential to provide clear, actionable information to help each patient understand her personal risk."

Quest Diagnostics offers a complete menu of diagnostic services to support healthy pregnancies. The company is believed to be one of the only lab providers to offer confirmatory CVS or amniocentesis following a noninvasive prenatal result. The company's larger portfolio of services also include carrier screening for inherited genetic disorders, such as cystic fibrosis and Jewish Genetic Screening, such as Tay-Sachs disease; high-resolution chromosomal microarray analysis for unexplained developmental delay/intellectual disability in infants and toddlers; and physician access to genetic counselors and other medical experts for counsel in test selection and results interpretation.

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 45,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

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