



Quest Diagnostics Collaborates with Perinatal Quality Foundation on National Initiative to Advance Clinically Appropriate Noninvasive Prenatal Screening

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Educational campaign and patient registry to provide new insights and clarification on use of advanced screening tests to assess fetal health while promoting outcomes research on tests' predictive accuracy

WASHINGTON, July 29, 2015 /PRNewswire/ -- The Perinatal Quality Foundation (PQF) today announced a nationwide campaign to improve understanding of the advantages, limitations and clinically appropriate interpretation of results of noninvasive prenatal screening and other diagnostic tests for pregnant women and their healthcare providers. Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, is the first commercial organization to support the initiative, through a grant.



Through a comprehensive education and quality-tracking program, the campaign aims to close knowledge gaps among consumers and healthcare providers about a new generation of highly advanced noninvasive prenatal screening tests that identify cell-free fetal DNA in maternal blood, as well as maternal serum screening, chromosomal microarray analysis and expanded carrier screening.

The campaign will also involve the creation of an online patient registry through which women who receive prenatal screening during pregnancy may report results of confirmatory diagnostic tests, primarily chorionic villus sampling (CVS) or amniocentesis, as well as post-partum outcomes. The goal is to enable scientists to use this de-identified information to determine the positive and negative predictive value for noninvasive prenatal screens for common aneuploidies such as trisomy 21.

A test's predictive value is used to assess whether an individual's test result is truly positive or negative (or a false positive or false negative), and may be a more important barometer of a test's clinical value than sensitivity and specificity for conditions that have a low prevalence, such as fetal aneuploidies. In August 2014, *Genetics in Medicine* published a peer reviewed study by scientists from Quest Diagnostics of several widely used noninvasive prenatal screening tests. The scientists found that although the sensitivity and specificity rates for the tests approached 100%, the chance a positive test result was actually a false positive was 50% or higher for some aneuploidies.

"PQF and Quest Diagnostics share a vision to promote high quality, reliable screening of women during pregnancy," said Mary Norton, M.D, president of PQF. "Our vision for this program is to ensure that every woman in the United States has access to clear, accurate, and unbiased educational resources that will empower her to make informed decisions regarding prenatal testing for herself and her family."

"The explosion of novel genetic technologies for assessing pregnancy risks has outpaced the knowledge base women and physicians possess about the advantages and limitations of these tests," said Douglas S. Rabin, M.D., medical director, women's health, Quest Diagnostics. "As a leader in women's health services and an innovator of genetic testing, we recognize that we have a role to play in closing this knowledge gap so that women can take the most well-informed action possible to promote a healthy outcome for her and her family. We are thrilled to help PQF kick off this important program."

In June 2015, the American College of Obstetrics and Gynecologists and the Society for Maternal Fetal Medicine published a committee opinion that recognizes the "tremendous potential" of genetic technologies that use cell-free maternal DNA to screen for fetal aneuploidy, but also provides several recommendations for their use. These include referring women who receive an indeterminate or uninterpretable ("no call" test result) for genetic counseling and additional testing; educating patients that cell-free DNA screening does not replace the precision obtained with diagnostic tests, such as CVS or amniocentesis; and that decisions about pregnancy "should not be based on the results of the cell-free DNA screening alone."

The new campaign will be based on similar PQF initiatives, including its nuchal translucency program to improve quality assessment of fetal abnormalities. That effort has credentialed more than 6,600 physician and ultrasonographer participants and has collected more than 3 million nuchal translucency measurements.

Under the new prenatal screening campaign, the PQF will develop educational materials and tools, including a website and event forums, for patients, clinicians, and other healthcare personnel. The materials will focus on the types of prenatal screening tests, their strengths and limitations, test results interpretation, and actions to consider based on results. The campaign will also educate health care providers to be alert to circumstances under which women should be referred for consultation with a genetic counselor to better understand their risks or test results. To promote quality assurance, PQF also expects to track clinicians and other healthcare providers who complete the online and other educational programs.

The educational program and patient registry are expected to be launched by early 2016.

Quest Diagnostics is a leading diagnostics services provider in women's health and genetics. In May 2015, the company launched its proprietary QNatal™ Advanced noninvasive prenatal screening lab-developed test, adding to its suite of pregnancy services that include maternal serum screening, chromosomal microarray analysis, spinal muscular atrophy and cystic fibrosis carrier screening.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic information services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic information services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at QuestDiagnostics.com. Follow us at [Facebook.com/QuestDiagnostics](https://www.facebook.com/QuestDiagnostics) and [Twitter.com/QuestDX](https://twitter.com/QuestDX).

About PQF

The Perinatal Quality Foundation was incorporated in Washington, D.C. in 2004 and in Oklahoma in 2010. It is an independent non-profit foundation. The mission of the Perinatal Quality Foundation is to improve the quality of Maternal-Fetal medicine medical services by providing state of the art educational programs, and evidence-based, statistically valid monitoring systems to evaluate current practices and facilitate the transition of emerging technologies into clinical care. The foundation is committed to disseminating safe and excellent obstetrical practice protocols, and to providing clinician and provider education, monitoring measures, and consensus discussions on emerging obstetrical technologies. www.perinatalquality.org

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