Leading Genetic Testing Companies Join Forces to Launch the Coalition for Access to Prenatal Screening

Coalition aims to make noninvasive prenatal testing easily accessible to all pregnant women

WASHINGTON D.C., January 4, 2017 – Today, five leading genetic testing companies in the U.S. are coming together to launch the Coalition for Access to Prenatal Screening (CAPS). This new organization will work to improve access to state-of-the-art prenatal screening using cell-free DNA (cfDNA)-based noninvasive prenatal testing (NIPT). The coalition is comprised of: Illumina, Inc. (NASDAQ: ILMN); Counsyl, Inc.; Progenity, Inc.; Natera, Inc. (NASDAQ: NTRA); and Laboratory Corporation of America® Holdings (LabCorp®) (NYSE:LH) through its Integrated Genetics specialty laboratory.

CAPS and its member companies are working together to promote public awareness about the value of cfDNA-based NIPT and to advocate for the highest standards of quality, service and education. CAPS will work to encourage appropriate legislative measures and reimbursement coverage policy changes for this medically actionable testing service, which has the potential to improve personalized patient care.

NIPT represents a major advance in the screening for fetal chromosomal aneuploidies through the analysis of millions of cfDNA fragments in the blood of a pregnant woman. Chromosomal aneuploidies are characterized by an abnormal number of chromosomes, which may cause genetic disorders in a newborn baby, including some birth defects. Prenatal screening for chromosomal aneuploidies using analysis of serum proteins has been the standard of care for decades. However, cfDNA-based NIPT is becoming the preferred method of prenatal screening for many healthcare providers and patients since its introduction to clinical practice in 2011.

The high sensitivity and specificity, and low failure rate, of cfDNA-based NIPT result in fewer women undergoing invasive testing procedures. Although all positive prenatal screening results should be confirmed with diagnostic testing by chorionic villus sampling (CVS) or amniocentesis, cfDNA-based NIPT correctly identifies a higher proportion of pregnancies affected by chromosomal aneuploidies, including Trisomy 21/Down syndrome, Trisomy 18/Edwards syndrome, and Trisomy 13/Patau syndrome, compared to serum protein based screening options.

Extensive data have been published in peer-reviewed literature that establish the performance of cfDNA-based NIPT as a powerful screening tool for fetal chromosomal aneuploidies.[1-5] In addition to having a significantly higher detection rate, cfDNA-based NIPT can simultaneously test for a larger number of specific chromosomal aneuploidies than traditional serum screening methods. Furthermore, the markedly lower false positive rates of cfDNA-based NIPT provide significantly improved positive predictive values compared to traditional screening tests.[5] NIPT can be used as early as 9 to 10 weeks into the pregnancy.

1. McCullough R. et al. (2014) Non-Invasive Prenatal Chromosomal Aneuploidy Testing - Clinical Experience: 100,000 Clinical Samples. PLoS ONE 9(10): e109173.
2. Taneja, P. et al. (2016) Noninvasive prenatal testing in the general obstetric population: clinical performance and counseling considerations in over 85 000 cases . *Prenatal Diagnosis 36*(3), 237–243.
3. Dar P. et al. (2014) Clinical experience and follow-up with large scale single-nucleotide polymorphism—based noninvasive prenatal aneuploidy testing. Am J Obstet Gynecol 211:527.e1-17.
4. Mackie F. et al. (2016) The accuracy of cell-free fetal DNA-based non-invasive prenatal testing in singleton pregnancies: a systematic review and bivariate meta-analysis. BJOG DOI: 10.1111/1471-0528.14050.
5. Norton M et al (2015) Cell-free DNA Analysis for Noninvasive Examination of Trisomy N Engl J Med 372:1589-97.

Numerous professional organizations, including the American Congress of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), the International Society for Prenatal Diagnosis (ISPD), the American College of Medical Genetics and Genomics (ACMG), and the National Society of Genetic Counselors (NSGC) have recognized cfDNA-based NIPT as a screening option for all pregnancies, given appropriate patient counseling regarding the performance, risks and benefits of such testing.

"As leading providers of cfDNA-based NIPT, CAPS members are working together towards the common goal of ensuring that this innovative and highly accurate screening method is easily accessible to all pregnant women who choose to pursue aneuploidy screening, regardless of their risk factors, income, age or geographic location," said Arnold W. Cohen, M.D., Chairman Emeritus of the Department of Obstetrics and Gynecology at the Einstein Healthcare Network, and Chairman of the CAPS Clinical Advisory Board. "We recognize the importance of providing reliable and useful information about cfDNA-based NIPT to patients, healthcare providers, and public and private insurers."

CAPS is assembling a clinical advisory board under the leadership of Dr. Cohen, which will provide an independent medical perspective. The composition of the board will be announced during the first half of 2017.

Click here for more information on CAPS.

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