

The American College of Obstetricians and Gynecologists Committee on Genetics and the Society for Maternal-Fetal Medicine Publications Committee Recommend Noninvasive Prenatal Testing for Fetal Aneuploidy

The Associated Press

Sequenom, Inc. (NASDAQ: SQNM), a life sciences company providing innovative diagnostic testing and genetic analysis solutions, today announced that the American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics and the Society for Maternal-Fetal Medicine (SMFM) Publications Committee issued a joint Committee Opinion on November 20, 2012, recommending that cell-free fetal DNA testing be offered to patients at increased risk of aneuploidy. It can also be used as a follow-up test for women with a positive first-trimester or second-trimester screening test result.

Previously, the ACOG recommended that women, regardless of maternal age, be offered prenatal assessment for aneuploidy by screening or invasive prenatal diagnosis. The ACOG Committee on Genetics and the SMFM Publications Committee now recommend that women at increased risk of aneuploidy be offered cell-free fetal DNA as an option that can be used as a primary screening test based on the following indications: -- Maternal age 35 years or older at delivery.

- Fetal sonographic findings indicating an increased risk of aneuploidy.
- History of a prior pregnancy with a trisomy.
- Positive test result for aneuploidy, including first trimester, sequential, or integrated screen, or a quadruple screen.
- Parental balanced robertsonian translocation with increased risk for fetal trisomy 13 or 21.

The Committee Opinion also recommended that "cell-free fetal DNA testing should not be offered to low-risk women or women with multiple gestations because it has not been sufficiently evaluated in these groups." Further, the Committee Opinion stated that "pre-test counseling should be an informed patient choice after pre-test counseling and should not be part of routine prenatal laboratory assessment. A patient with a positive test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results." "The issuance of the ACOG/SMFM opinion on the use of cell-free fetal DNA testing represents a major step forward for the integration of this valuable technology into pregnancy care programs" said Allan Bombard, MD, Sequenom's Chief Medical Officer. "We fully support the indications for considering the use of cell-free fetal DNA outlined in

the Committee Opinion and believe this will be a valuable tool to help guide physicians and their patients in the most appropriate prenatal care." ACOG is the nation's leading group of physicians providing health care for women. The College strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care.

SMFM is a non-profit membership group for obstetricians/gynecologists who have additional formal education and training in maternal-fetal medicine. The society is devoted to reducing high-risk pregnancy complications by providing continuing education to its 2,000 members on the latest pregnancy assessment and treatment methods. It also serves as an advocate for improving public policy, and expanding research funding and opportunities for maternal-fetal medicine.

The full text of the Committee Opinion can be found at: Noninvasive prenatal testing for fetal aneuploidy. Committee Opinion No. 545.

American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012; 120:1532-4.

About the MaterniT21 PLUS Test The MaterniT21 PLUS test analyzes the relative amount of 21, 18, 13 and Y chromosomal material in cell-free DNA. The test is intended for use in pregnant women at increased risk for fetal aneuploidy and can be used as early as 10 weeks gestation. Estimates suggest there are about 750,000 pregnancies at high risk for fetal aneuploidy each year in the United States. The MaterniT21 PLUS test is available exclusively through the Sequenom Center for Molecular Medicine (Sequenom CMM) as a testing service provided to physicians. To learn more about the test, please visit www.Sequenomcmm.com.

About Sequenom Sequenom, Inc. (NASDAQ: SQNM) is a life sciences company committed to improving healthcare through revolutionary genetic analysis solutions.

Sequenom develops innovative technology, products and diagnostic tests that target and serve discovery and clinical research, and molecular diagnostics markets. The company was founded in 1994 and is headquartered in San Diego, California. Sequenom maintains a Web site at www.sequenom.com to which Sequenom regularly posts copies of its press releases as well as additional information about Sequenom.

Interested persons can subscribe on the Sequenom Web site to email alerts or RSS feeds that are sent automatically when Sequenom issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the Web site.

Sequenom CMM, LLC Sequenom Center for Molecular Medicine@ (Sequenom CMM), a CAP accredited and CLIA-certified molecular diagnostics laboratory, is developing a broad range of laboratory developed tests with a focus on prenatal and

ophthalmic diseases and conditions. These laboratory-developed tests provide beneficial patient management options for obstetricians, geneticists and maternal fetal medicine specialists, and retinal specialists. Sequenom CMM is changing the landscape in genetic disorder diagnostics using proprietary cutting edge technologies.

Forward-Looking Statements Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the integration of cell-free fetal DNA testing into pregnancy care programs, the expected impact and benefits of the new guidelines on physicians and patients, and Sequenom CMM changing the landscape in genetic disorder diagnostics using proprietary cutting edge technologies, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with market demand for and acceptance and use of technology and tests such as the MaterniT21 PLUS test, reliance upon the collaborative efforts of other parties including without limitation any international distributors or licensees, the Company or third parties obtaining or maintaining regulatory approvals that impact the Company's business, government regulation particularly with respect to diagnostic products and laboratory developed tests, publication processes, the performance of designed product enhancements, the Company's ability to develop and commercialize technologies and products, particularly new technologies such as noninvasive prenatal diagnostics, laboratory developed tests, and genetic analysis platforms, the Company's financial position, the Company's ability to manage its existing cash resources or raise additional cash resources, competition, intellectual property protection and intellectual property rights of others, litigation involving the Company, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission, including without limitation its Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 and its Annual Report on Form 10-K for the year ended December 31, 2011. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

(Logo: <http://photos.prnewswire.com/prnh/20040415/SQNMLOGO>) SOURCE
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