

INTERGENETICS TO BEGIN COMMERCIAL TESTING OF FIRST FDA CLEARED GENETIC TEST FOR CYSTIC FIBROSIS CARRIERS

Oklahoma City Company to Offer the TM BioSciences TAG-It™ Cystic Fibrosis Mutation Gene Test to Determine Carrier Status in Women

OKLAHOMA CITY –InterGenetics, Inc. has entered into a strategic partnership with TM BioSciences to offer the first FDA cleared In Vitro Diagnostic (IVD) for cystic fibrosis (CF) genotyping to help women know if they are a CF mutation carrier. More than 10 million Americans are unknowing carriers of the CF mutation gene. To develop CF, a child must inherit a defective gene from each parent; this is why genetic testing can be so important in managing this disorder.

InterGenetics has begun offering CF carrier testing through its CLIA laboratory. The TM BioSciences Tag-It™ Cystic Fibrosis Kit simultaneously screens for the 23 gene mutations and 4 variants (polymorphisms) as recommended by the American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG).

Cystic fibrosis (CF) is a genetic disease affecting approximately 30,000 children and adults in the United States. A defective gene causes the body to produce an abnormally thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections. Though significant advances in the treatments for CF are allowing people to live longer, the average age of survival for people living with CF is in their mid-30's.

“This is a once in a life-time genetic test that provides information for women to understand their carrier risk for cystic fibrosis,” noted Dr. Craig Shimasaki, InterGenetics president and CEO. “InterGenetics is positioned to rapidly bring this test to market with a fully operational, CLIA registered high complexity laboratory, with on-site personnel trained in performing complex genetic assays.”

“There are other CF genetic tests on the market, but our test is the only FDA cleared test and it is 99.99% percent accurate,” said (TM Biosciences person and title here). “InterGenetics’ expertise in the emerging field of genetic testing and their readiness to perform this high level of testing is quickly bringing this test to women who want to know their CF genetic status. Once a woman knows her status she can make better educated decisions about whether her partner should be tested before having children.”

“InterGenetics continues our primary work with the FDA to bring the breast cancer risk test OncoVue® to the market, while simultaneously expanding our genetic-based testing service to include other important women’s health products,” continued Dr. Shimasaki. “With the CF carrier genetic test,

InterGenetics has now successfully completed the transition from R&D company to commercial enterprise”

There are over 60 million women of child-bearing age; ACOG recommends that all women in this category be offered this test. Those most at risk for becoming CF carriers are Caucasians of Northern European decent and individuals who are of Ashkenaze Jewish descent. In these groups, the carrier rate is 1 in 30.

It is important for a woman who has been identified as a CF carrier to know her partner’s status because each time two carriers conceive, there is a 25 percent chance that their child will have CF, a 50 percent chance that the child will be a carrier of the CF gene, and a 25 percent chance that the child will be a non-carrier.

The CF test is easily performed. A woman swishes a harmless mouthwash in her mouth and deposits the fluid in a tube. The mouthwash solution is sent to the InterGenetics DNA Analysis and Genotyping Laboratory, where the DNA will be extracted from the solution and analyzed.

TM BioSciences has other similar genetic tests in their research and development pipeline to identify women with Factor II and Factor V, gene combinations that put them at higher risk for developing deep vein thrombosis. Knowing the risk level can help physicians better determine when women should not take birth control pills as the hormones can increase the severity of this life threatening condition. This test could go before the FDA in the next year. InterGenetics could also offer this test through its CLIA laboratory.

“TM BioSciences and InterGenetics first developed a commercialization partnership while working to bring our breast cancer risk test OncoVue to the market,” continued Dr. Shimasaki. “We already have access to the women’s health market through our Breast Cancer Risk Testing Network, a group of 40 of the nation’s top breast care centers. Extending our reach into other women’s health issues is a natural fit for our two companies.”

About InterGenetics

InterGenetics, a genetics-based cancer-risk testing and cancer treatment company is emerging as an innovator in the frontier of genetic medicine. The company's lead product, the OncoVue(TM) Breast Cancer Risk Test, uses proprietary gene combinations and DNA assessment technology developed by InterGenetics' scientists to quickly and accurately identify women who are at high risk of developing breast cancer, potentially many years in advance of their diagnosis. InterGenetics has a promising research pipeline of predictive tests for other cancers such as ovarian, colon, prostate, and pancreatic cancer. The company's core research has future application in also predicting risk for heart disease, diabetes and in enhancing the effectiveness of drug therapies and preventative medicine in these fields. www.intergenetics.com

About Tag-It(TM) reagents and genetic tests

Tm Bioscience's product menu is focused in the fields of human genetic disorders, pharmacogenetics and infectious disease. The Company has commercialized Analyte Specific Reagents (*) and a series of Tag-It(TM) tests (xx) for a variety of genetic disorders. The Company's Tag-It(TM) Cystic Fibrosis (CF) Kit is the first multiplexed human disease genotyping test to be cleared by the U.S. Food and Drug Administration (FDA) as an in vitro device (IVD) for diagnostic use in the United States. All genetic tests from Tm Bioscience are based on the Tag-It(TM) Universal Array platform, which utilizes a proprietary universal tag system that allows for easy optimization, product development and expansion. Assays from Tm operate on the Luminex xMAP(R) system, a well-established bead based instrument. Combined, the Universal Array and Luminex instrument enable the rapid production of flexible, high-throughput, low-cost DNA-based tests.