



Asuragen and the UC Davis M.I.N.D. Institute Publish Results of a Study Evaluating a Novel Fragile X PCR Assay

Assay allows for detection of expanded alleles and full mutations

Austin, Texas – March 2, 2010. Asuragen, Inc. announced today the results of a collaborative study with scientists at the M.I.N.D. Institute at the University of California Davis evaluating a new PCR technology that reproducibly reports mutations associated with Fragile X syndrome (FXS). The study, titled "A novel *FMR1* Method for the Routine Detection of Low Abundance Expanded Alleles and Full Mutations in Fragile X Syndrome," was published in *Clinical Chemistry*, a leading journal for original, peer-reviewed research that advances clinical laboratory practices.

FXS is the most common known genetic cause of autism and affects approximately 100,000 individuals in the US. Related disorders, such as Fragile X-associated tremor/ataxia syndrome (FXTAS) and primary ovarian insufficiency (FXPOI), are estimated to impact an additional 1 million people. The Fragile X PCR test* that Asuragen has developed can evaluate molecular signatures linked with each of these disorders.

FXS is a trinucleotide repeat disease caused predominantly by the expansion of CGG sequences in the 5' untranslated region of the Fragile X Mental Retardation 1 (*FMR1*) gene. Expansions of >200 CGG are associated with FXS, whereas more modest expansions can contribute to FXTAS and FXPOI. "Efficient PCR amplification of the CGG repeat region of *FMR1* has been a problem without a definitive solution ever since the molecular etiology of Fragile X syndrome was determined nearly 20 years ago. The *FMR1* PCR reagents evaluated in this study amplified Fragile X alleles with as many as 1300 repeats and detected every one of 66 full mutations that were co-detected using the current gold standard method, Southern blot analysis," commented Dr. Flora Tassone, a leading expert in Fragile X molecular biology and senior author of the study. "Across 146 clinical samples, including those with both expanded and normal alleles, the Fragile X PCR produced results consistent with the reference method, yet the PCR technology provided more accurate repeat quantification, greater detection sensitivity, and the results could be obtained in about 1/10th the time using about 175 times less DNA sample. This innovative PCR approach has tremendous potential for clinical research into Fragile X biology, and could shift the paradigm for routine Fragile X testing," added Dr. Paul Hagerman, senior co-author of the study.

The PCR reagents described in this landmark study are now available as a Research Use Only (RUO*) kit that is manufactured by Asuragen. "Asuragen is committed to providing world class technologies that advance molecular testing in emerging, high need areas, such as Fragile X and autism," said CEO and CSO Dr. Matt Winkler. "This novel Fragile X assay further highlights our R&D team's innovation capabilities in molecular diagnostics."

About Asuragen

Asuragen is a fully integrated diagnostic development company and pharmaceutical services provider. The Company's diagnostic product portfolio consists of the first-ever validated microRNA diagnostic assay for pancreatic cancer, quantitative RNA tests for leukemia gene translocations, and the Signature[®] Oncology and Genetic Testing products. Asuragen is empowered with a high level of scientific expertise and assay development capabilities, CLIA and GLP testing services, and an established cGMP manufacturing facility, which allow it to span the spectrum of discovery, testing, production and commercialization. For more information, visit www.asuragen.com.

* For Research Use Only. Not For Use in Diagnostic Procedures.

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