Asuragen and Fragile X Collaborators Report Findings using a Novel Methylation PCR Technology to Characterize the *FMR1* Gene

Austin, Texas – June 29, 2011. Asuragen, Inc. announces results from an evaluation of a breakthrough PCR technology that determines the methylation status of the fragile X gene. The study was published in collaboration with researchers at the University of California Davis M.I.N.D. Institute in the June issue of *Genetics in Medicine*, the official journal of the American College of Medical Genetics and a leading publication for innovative, clinically-directed genetics research.

The published work, titled "High-resolution methylation polymerase chain reaction for fragile X analysis: Evidence for novel *FMR1* methylation patterns undetected in Southern blot analyses," describes the accurate and reproducible assessment of the methylation status in 80 clinical samples, including 39 full mutation specimens, with concordance to the reference method of Southern blot analysis. The significant limitations of Southern blotting, including low resolution results, the requirement for large DNA input, and a tedious, low-throughput workflow that causes week-long turnaround times, are a compelling impetus for development of more efficient and effective methods. To address this need, Asuragen scientists successfully adapted its validated, long-read AmplideX™ *FMR1* technology to enable the determination of allele-specific methylation states in both male and female samples without the requirement for Southern blot analysis. In addition, the study revealed novel patterns of methylation mosaicism associated with female fragile X carriers that cannot be detected by Southern blotting. The implications of these new findings are the subject of ongoing research.

Fragile X syndrome is the most common form of inherited intellectual impairment and known genetic cause of autism, and one of the first human diseases to be linked to an expansion of triplet nucleotide repeats. Expansions in the CGG repeat region of the fragile X gene, *FMR1*, are also associated with two other disorders, namely fragile X-associated tremor/ataxia syndrome (FXTAS) and fragile X-associated primary ovarian insufficiency (FXPOI). Over 1 million individuals in the US are thought to be at risk for at least one of these *FMR1* disorders. Yet molecular characterizations of *FMR1* have long relied on Southern blot analysis, particularly to determine the methylation status of the gene.

The reagents described in the study are currently being evaluated at half a dozen laboratories in the US and abroad. These reagents will be available as a Research Use Only (RUO*) kit manufactured by Asuragen in the second half of 2011. "With this publication, Asuragen significantly expands its footprint in enabling next generation technologies for fragile X," stated Matt Winkler Ph.D., CEO and CSO of Asuragen. "Our methylation PCR reagents represent the capstone in enabling a truly PCR-only workflow for comprehensive *FMR1* molecular analyses. Asuragen is committed to providing these reagents to the broader community and empowering more informative fragile X assessments."

About Asuragen

Asuragen is a fully integrated diagnostic development company and pharmaceutical services provider with special capabilities in the area of mRNA and miRNA. 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, innovative genetic testing solutions for the fragile X mental retardation (*FMR1*) gene, Signature® Oncology products for the qualitative detection of gene translocations and mutations in a variety of hematological and solid tumors, RNA stabilization technologies, and industry-leading controls and standards engineered using its patented Armored RNA® technology. 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 companion diagnostics. For more information, visit www.asuragen.com.

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