



## Asuragen's CLIA Laboratory Receives Accreditation from College of American Pathologists

**Austin, Texas – December 17, 2009** – Asuragen, Inc., an integrated molecular diagnostic company and provider of clinical laboratory services, today announced it has been awarded accreditation by the Laboratory Accreditation Program of the College of American Pathologists (CAP). This is based on results of a recent on-site inspection of Asuragen's Clinical Laboratory Improvement Amendments (CLIA) - compliant laboratory. CAP laboratory requirements are among the most stringent, and accreditation with the organization indicates compliance with the highest standards of quality for complex molecular testing. The accreditation is a crucial step for Asuragen in commercializing miRNA- based oncology tests and conducting clinical sample testing for its pharmaceutical clients. The miRNA Pancreatic FFPE Test for aid in diagnosis of pancreatic adenocarcinoma is Asuragen's first commercially available CLIA-based test.

"This is a significant step forward in our efforts to bring novel molecular diagnostic tests for oncology to market, and to offer our pharmaceutical clients a means to develop and validate companion diagnostic tests", said Matt Winkler, CEO. "As a provider and developer of molecular tests, the CAP accreditation indicates that we are providing the highest testing standards and commitment to quality."

### About miRNA Pancreatic FFPE Test

Asuragen's miRNA-based laboratory-developed test aids in the diagnosis and disease management of pancreatic ductal adenocarcinoma. The test is based on the qRT-PCR analysis of the raw expression difference ( $\Delta C_T$ ) between 2 gene products, miR-196a and miR-217. This miRNA signature is a balanced set wherein, one gene product is expected to be up-regulated in pancreatic ductal adenocarcinoma (miR-196a), while the other is expected to be down-regulated (miR-217), as compared to normal pancreas tissue and chronic pancreatitis tissue. The blinded validation study on FFPE samples using the threshold value of 0.5  $\Delta C_T$  resulted in assay sensitivity of 95.2% (95%CI: 77.3- 99.2) and specificity of 94.9% (95%CI: 83.1- 98.6).

### About Asuragen Inc.

Asuragen is a fully integrated diagnostic development company and provider of molecular services, clinical laboratory and companion diagnostics services. Asuragen is currently leveraging its CLIA laboratory to offer and further commercialize the first ever laboratory developed microRNA diagnostic assay, designed to aid in the diagnosis and disease management of pancreatic ductal adenocarcinoma. Asuragen also manufactures and markets its Signature® Oncology and Genetic diagnostic kits for use in other clinical laboratories.

Asuragen's Services Division provides comprehensive outsourcing solutions to aid in drug development, molecular biology research, and companion diagnostic test development. The cGLP laboratory services include sample preparation know-how, genomic profiling applications, biomarker discovery capabilities, assay design and validation, CLIA-based clinical testing, bioinformatic analysis, a high level of regulatory proficiency, and project management expertise. Asuragen has a proven track record in providing these services to major pharmaceutical and biotechnology companies, as well as academic institutions worldwide. In addition, Asuragen has a cGMP manufacturing facility that allows it to span the spectrum of discovery, testing, production, and commercialization. Visit our website at [www.asuragen.com](http://www.asuragen.com).

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