



Asuragen Launches BCR-ABL1 Calibrator Panels for IS Standardization

AUSTIN, TX – October 31, 2011. [Asuragen, Inc.](#) announced today that it has commercially launched the ARQ IS Calibrator Panels (RUO*), intended to aid laboratories with standardization of BCR-ABL1 quantitative measurements on the International Scale (IS). The ARQ IS Calibrator Panels were developed in collaboration with Novartis and an international group of laboratories dedicated to BCR-ABL1 standardization. For educational information regarding BCR-ABL1 standardization visit www.wherereyouontheis.com.

Accurate molecular monitoring of BCR-ABL1 fusion transcripts levels in Chronic Myeloid Leukemia (CML) is achieved by reporting quantitative reverse transcription-PCR (RT-qPCR) results on the IS. Until the recent establishment of an international standard approved by the Expert Committee on Biological Standardization of the World Health Organization (WHO), standardization of local RT-qPCR methods to the IS could only be achieved through a lengthy sample exchange with an IS Reference Laboratory. The ARQ IS Calibrator Panels are the first secondary panels directly calibrated to the first WHO International Genetic Reference Panel for quantification of BCR-ABL1 translocations by RQ-PCR (NIBSC code 09/138) that are made broadly available to the international BCR-ABL1 testing community.

"I am pleased to see Asuragen develop and commercialize secondary IS panels calibrated to the first WHO reference standard, which is in limited supply. The global availability of IS reference material should be an important contribution to the worldwide effort to improve standardization of BCR-ABL1 testing and the management of patients with CML" said Dr Nick Cross, Professor of Human Genetics at the University of Southampton School of Medicine, UK.

The ARQ IS Calibrator Panels are compatible with several widely used assays, including both commercially available and laboratory developed tests (LDT). The Panels have been evaluated in a broad international field trial involving IS Reference Laboratories and leading clinical centers. The study confirmed that the ARQ IS Calibrator Panels are aligned with the WHO IS reference values and can facilitate the standardization of BCR-ABL1 testing results in laboratories not yet standardized.

"We successfully evaluated the ARQ IS Calibrator Panels in our lab as a simple means to standardize our results to the international scale" commented Dr. Bryan Betz, Assistant Professor and Technical Director, Molecular Diagnostics Laboratory at the University of Michigan.

Like the WHO primary standard, the ARQ IS Calibrator Panels feature 4 different levels of reference IS percent ratio values. The Panels can be used by laboratories to compare their RT-qPCR methods against a broad range of representative IS percent ratios and to routinely monitor their assay performance for potential drift. For ease of use and protection from ubiquitous ribonucleases, the ARQ IS Calibrator Panels incorporate Asuragen's proprietary Armored RNA Quant® technology (ARQ). ARQs are robust, stable, and ribonuclease-resistant RNA molecules that are compatible with a variety of molecular techniques and are precisely quantified and anchored to a reference phosphate standard to ensure formulation precision and lot-to-lot consistency.

The ARQ IS Calibrator Panels are the latest addition to Asuragen's research reagents for leukemia including [BCR/ABL1 Quant® \(RUO*\)](#), [Signature® LTx v2.0 \(RUO*\)](#) and [Signature® NPM1 Mutations \(RUO*\)](#) which are available directly from Asuragen in the U.S. and through its network of [international distributors](#).

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, 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 more information, visit www.asuragen.com.

*For Research Use Only. Not for use in diagnostic procedures.

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Contact:

Rollie Carlson
President
rcarlson@asuragen.com
512.681.5200

Asuragen, Inc.
2150 Woodward St., Suite 100
Austin, TX 78744
PH: 512.681.5200
T: 877.777.1874
F: 512.681.5201
www.asuragen.com



Contact:
Rollie Carlson
President
rcarlson@asuragen.com
512.681.5200

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