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**NIH to Underwrite the FDA Trial of Software
That Helps Physicians Incorporate Genetic Information Into Patient Care**

Louisville, KY. October 1, 2010 – The National Institutes of Health (NIH) has awarded Louisville-based PGXL Laboratories a \$3 million grant to conduct clinical trials of software that will assist doctors in setting the right dosage for a commonly prescribed drug.

The Small Business Innovation Research (SBIR) grant will make possible the completion and clinical testing of PerMIT software. PerMIT factors genetic and other variables into an algorithm that identifies an optimum dosing strategy for warfarin (also known as Coumadin), an anti-coagulant that can cause life-threatening bleeding incidents when improperly dosed.

More than 700,000 patients a year are prescribed warfarin. The drug inhibits the formation of blood clots that can cause a stroke. However, if the concentration of the drug in the bloodstream grows too high, it can contribute to devastating or even deadly bleeding incidents. To avoid that, current medical best-practice is to increase dosage in small increments over several weeks until the desired blood-thinning effect is achieved. This trial-and-error method requires several office visits and blood tests every few days.

By administering a genetic test before warfarin therapy begins, it is possible to determine how quickly a given patient will metabolize the drug. PerMIT takes that information – along with other patient variables like age, weight and gender – and produces a dosing plan that represents the fastest possible route to safe and effective therapy.

“That eliminates a lot of risk for patients and a lot of expense for the healthcare system,” says Dr. Mark W. Linder, Executive Vice President for Operations of PGXL. “PerMIT takes raw genetic data and turns it into information physicians can use to design a real-world action plan for each patient and to have confidence in that plan.”

The NIH-SBIR grant is a continuation of a previous two-year grant that paid for initial development of PerMIT; the total funded amount is over \$5 million dollars. Further development has been funded by both PGXL and ARUP, a national clinical and anatomic pathology reference laboratory based in Salt Lake City. The grant will underwrite the testing of the software so that it can receive FDA clearance for clinical use.

“PerMIT has been designed to help doctors make the right decisions for their patients, thus advancing the practice of precision medicine,” says Dr. Roland Valdes, Jr., President of PGXL.

“Using genetic information to craft the best possible treatment for each patient as an individual is really what personalized medicine is all about.”

About PGXL Laboratories:

A privately-owned business located in Louisville, Kentucky, PGXL Laboratories was the first lab in the country CLIA-certified specifically to conduct pharmacogenetic tests. It provides pharmacogenetic testing and interpretive services, and developed one of the first commercial CYP2C9/VKORC1 tests for accurate anticoagulant dosing. Along with its clinical practice, PGXL performs contract research for manufacturers of pharmaceuticals and medical equipment.

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