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With PGx Warfarin Demonstration at AACC, ParagonDx Hopes to Quash Misconceptions

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By Turna Ray

ParagonDx genotyped more than 300 volunteers for warfarin sensitivity for free last week during a major medical conference, with the goal of dispelling some of the apprehensions of doctors, insurers, and researchers who believe that the technology is not ready for broad use.

“There is a general misconception that genetic testing is difficult, complex, and time-consuming,” ParagonDx said in a statement announcing the demonstration project it was holding during the American Association for Clinical Chemistry’s annual meeting from July 27-31 in Washington, DC.

Industry stakeholders, particularly many large insurers, are not yet convinced that pharmacogenomics-based warfarin dosing is clinically or economically useful. Despite the FDA’s approval of warfarin sensitivity test kits from ParagonDx, Nanosphere, Autogenomics, and Osmetech, gene-based warfarin testing has not been widely adopted by physicians [see [PGx Reporter 08-26-2007](#)].

“We want to show those attending this year’s AACC annual meeting that warfarin genotyping can be done easily and quickly,” the company said in a statement.

ParagonDx, in partnership with DNA Genotek, Promega, the Center for Molecular Medicine, and PGxL Laboratories, sponsored the project, sharing in the materials and cost of genotyping the conference attendees.

According to a ParagonDx spokesperson, saliva sample collection, including review of consent materials, took approximately 10 minutes per person. Following DNA extraction and analysis for the presence of CYP2C9 and VKORC1 polymorphisms, “de-identified” test results were posted on the demonstration project [web site](#) within 24 hours.

When ParagonDx’s Rapid Genotyping Assay received FDA clearance in May, the company highlighted same-day turnaround for results as an advantage of its testing service compared to competing tests [see [PGx Reporter 05-07-2008](#)].

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At the AACC conference, a session titled “Warfarin Pharmacogenomic Testing: Now Ready for Prime Time?” explored some of the concerns in the healthcare industry regarding this technology. During the debate, several people voiced their opinions regarding the cost of warfarin testing, the lengthy turnaround times, and the lack of clinical utility data available for such tests.

“These misconceptions are widespread in the industry, especially with doctors and lab directors,” ParagonDx CEO Michael Murphy told *Pharmacogenomics Reporter* this week. “We were hoping that demonstration volunteers would put themselves in the shoes of patients and seriously evaluate the importance of the

test for patient safety.”

The volunteers who participated in the project included doctors, insurers, FDA officials, and members of companies that currently market home software for monitoring international normalized ratio, the standard method of dosing warfarin. Those who tested positive for warfarin sensitivity were advised to consult their doctors for further evaluation.

Physicians who were genotyped by ParagonDx discussed their concerns with company representatives about adopting the technology. “One physician said it always came down to having clear instructions for how the genotype translates into a treatment recommendation,” Murphy recounted.

ParagonDX directed that physician to warfarindosing.org, a calculator that helps doctors estimate the appropriate dose for warfarin, based on clinical and genetic factors, as well as a warfarin dosing calculator developed by PGxL Laboratories, and ParagonDx's own informational brochure.

According to a ParagonDx spokesperson, a few of those who spoke out against pharmacogenomics-based warfarin testing during the AACC debate on the topic were among those who volunteered to be genotyped.

With this demonstration project, “we were hoping to show the media, the regulatory agencies, doctors, and the public at large that there is no reason for warfarin patients not to know their genetic profile before receiving the drug,” Murphy said. “We are confident that, once they were able to translate their own genetic profile to what it will mean for patients, they realized the usefulness of the test [and] that it is ready for prime time.”

ParagonDx doesn't intend to use any of the data collected during the demonstration project for clinical studies, mainly in order to avoid the regulatory complications associated with performing those kinds of studies, Murphy said.

However, “we may decide to publish the results ... in the context of what happens if you offer the test prospectively to volunteers rather than to patients, what effect this might have on the future impression of test availability, the ease of sampling, and how quickly a test result could be delivered to potentially save lives,” he added.

ParagonDx, in collaboration with its partners and customers, is collecting clinical utility data not only for warfarin sensitivity, but also warfarin resistance. “This patient group should not be ignored, because in the case of stroke patients, for example, there is the potential to under-dose and cause harm by not giving enough of the anti-coagulant drug,” Murphy said.