



ParagonDx Offering Warfarin Testing in Newly Opened CLIA Lab

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Newsletter: [Pharmacogenomics Reporter](#)

ParagonDx has opened a clinical testing laboratory in Research Triangle Park, NC, that will offer genetic tests designed to identify individuals who may be at risk for developing adverse reactions following treatment with the anticoagulant warfarin, the company announced last week.

In May, the US Food and Drug Administration cleared ParagonDx's Rapid Genotyping Assay for warfarin sensitivity [[PGx Reporter 05-07-2008](#)]. However, ParagonDx sold this test to Cepheid.

The laboratory-developed warfarin sensitivity test that ParagonDx is now offering through the new CLIA lab are based on its own analyte specific reagents, and can run on any real-time PCR system. The warfarin sensitivity LDT can gauge mutations CYP 2C9 *2, *3, and VKORC1 1173C>T.

"Offering CLIA-based diagnostic testing for doctors and their patients is a new venture for us," ParagonDx CEO Michael Murphy told *Pharmacogenomics Reporter* last week. "We didn't want to be out promoting the use of potentially life-saving tests to the industry and then have to turn away patients right here in our own backyard."

According to Murphy, another reason the company decided to open the CLIA lab, is to get more access to local doctors. "Another opportunity we get from offering these tests locally is being able to hear directly from area physicians regarding which tests they think are important to bring into the market in the future," he said.

In a statement, the company noted that it is "openly encouraging" physicians to recommend to ParagonDx genetic tests that could help personalize treatment for their patients.

In addition to the warfarin sensitivity test, ParagonDx is planning to offer laboratory testing for Factor V Leiden for thrombophilia, and move into pharmacogenetic testing in cancer.

"Offering CYP2D6 testing for tamoxifen patients is the logical next step, and timing will depend largely on when the FDA re-labels the drug with a recommendation for genetic testing," Murphy said.

The FDA plans to update the label for the breast cancer drug tamoxifen to include information about CYP2D6 genotype testing [[PGx Reporter 11-15-2006](#)].

ParagonDx is currently operating with one sales rep, but expects to expand its selling team as it launches more tests in the personalized medicine space. Murphy did not offer any details as to how many sales reps the company plans to hire. "We will grow as needed to exploit the opportunities presented," he said.

The reimbursement atmosphere is difficult for warfarin testing, with many major insurers demanding clinical utility data prior to covering the test.

According to Murphy, the company is tackling insurance coverage decisions on a provider-by-provider basis.

"Some insurance companies will cover genetic testing for warfarin sensitivity depending on policy specifics and the doctor's reasons for testing," Murphy said. "ParagonDx will be working directly with physicians and patients to navigate the reimbursement process, including submitting pre-authorization requests and reimbursement requests directly."

ParagonDx is offering next-day turnaround for its warfarin sensitivity tests. "This represents a vast improvement over other labs, which can take as long as five days to generate results for this test," Murphy said. "The rapid turnaround time provides a significant advantage to patients, because they can begin taking the appropriate warfarin dose right away."

Genetic testing for warfarin is a crowded market with several FDA approved tests. Turnaround times may provide a competitive edge for some companies.

Critical Path Institute President Ray Woosley previously told *Pharmacogenomics Reporter* that there are a lot of factors to consider when dosing a patient on warfarin, among them time-to-treatment. According to Woosley, the warfarin dose may differ for a patient who lives 20 miles from the clinic versus one who lives only a mile from the clinic. "Every case is so different," he said. "It's truly personalized medicine." [[PGx Reporter 03-19-2008](#)].

AutoGenomics offers same-day results, while Kimball Genetics and Harvard Medical School's testing services, which use Third Wave's Invader assay, promise to return test results as early as one business day. Other companies have turnaround times ranging from three to seven days [[PGx Reporter 10-10-2007](#)].

