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ParagonDx product receives approval

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RALEIGH - A Morrisville diagnostics company announced today that it has received regulatory approval to sell a genetic test that can reduce the risk of excessive bleeding among patients taking warfarin, a commonly prescribed blood thinner.

The test identifies heart-attack and stroke patients who are likely to react poorly to regular doses of warfarin before they start taking the medicine.

Projected to become available in a few months, the test will be covered by health insurance.

ParagonDx's warfarin sensitivity test will be the third to come to market. But unlike its much slower and more cumbersome competitors, ParagonDx's test can be used in hospital emergency rooms. Test results are available within an hour to help physicians prescribe doses that are appropriate for the genetic makeup of patients.

For ParagonDx, this is the first product on the market.

"For us, this is huge," said Michael Murphy, ParagonDx's chief executive.

About 10 percent to 16 percent of the more than 30 million Americans who regularly take warfarin to prevent and treat blood clots are genetically predisposed to be sensitive to the drug. Serious reactions include excessive bleeding, heart attack or stroke.

Last year, the Food and Drug Administration changed its recommendation for warfarin to include using genetic testing information.

ParagonDx, which employs 15, also is working on other products, such as a genetic test that identify breast cancer patients who are poor candidates for the drug tamoxifen.

ParagonDx was formed last year, when Gentris, a Morrisville biotech company, sold a stake in one of its genetic testing businesses.

The purchase was financed by Joe Sorge, a biotech entrepreneur who a few months earlier had sold a company he founded in his San Diego garage for \$250 million.

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