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The Huntsville Times

Predicting cancer's return

Sunday, July 22, 2007

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Local firm's breast test aims to help in treatment decision

Pretend, for a moment, you are a woman recovering from breast cancer surgery.

You have to decide whether you are at high risk for a recurrence of the cancer and should take an aggressive, uncomfortable, perhaps even debilitating combination of hormone blockades, chemotherapy and other treatments or if the risk of recurrence is low and you would be just as well protected with, say, only the hormone therapy.

A test developed in Huntsville by Applied Genomics Inc. with the Clearview Cancer Institute uses a breast cancer patient's own genetic profile to help her make the best decision.

For the last few months, the "Mammostrat" test has been used in an evaluation process at the Molecular Profiling Institute in Phoenix. That national laboratory is soon expected to announce that Mammostrat meets federal Clinical Laboratory Improvement Amendments (CLIA) standards assuring it can be accurately reproduced and used at their other, approved laboratories, said Applied Genomics CEO Rob Seitz.

"We're in that stage of the process where we have moved from having a test that works, to having a test that someone else can't screw up," he said.

Mammostrat helps determine the likelihood of a patient's cancer returning in five to 10 years after the initial cancer surgery by taking a sample of the tumor removed from the patient, staining it and letting doctors look at the precise proteins produced by the tumor's genes, Seitz said.

"This is a means of personalizing, customizing treatment," said Dr. Marshall Schreeder, co-founder of CCI.

Tests like Mammostrat let doctors better tailor a course of treatment to the specific patient, he said.

If the test lets him tell a recovering cancer patient there is a 90 percent chance she'll still be cancer-free in 10 years, then it's hard to improve those odds, he said. But if it indicates there is only a 30 percent chance she'll be cancer-free, he would be more likely to recommend an aggressive course of therapy.

The CLIA certification will make Mammostrat a more readily available option for doctors and patients deciding on a course of treatment to protect against further cancer. Doctors could ask for the test on a patient's tumor after a biopsy or surgery and have the results from a laboratory in a couple of days, including time for a pathologist's analysis. It is expected to be less expensive than similar tests, Seitz said.

Mammostrat builds on existing techniques, so clinical laboratories already analyzing patient samples won't need to invest in a lot of new equipment to offer this latest gene-based test. Seitz said some other comparable tests, such as the MammaPrint introduced by a company named Agendia earlier this year, require surgeons to change their traditional procedures within the operating room.

"Since Mammostrat builds on existing technology available at every hospital, it already has established reimbursement codes with the insurance companies," Seitz said.

AGI is using the same genetic profiling approach to develop a similar test for patients recovering from lung cancer surgery, Seitz said. It is called Pulmostrat.

"In both cases the data is very clear," he said. "I want to be able to take patients and tell them where they stand."

He emphasized that the tests weren't making decisions for the patients, just providing better and better information to help guide them and their doctors. Even with the potential and precision of "personalized medicine" brought about by gene-based tests and treatments, he said, no one will be able to make medical decisions with 100 percent certainty.