

Big idea, small machine



Matt Brashears/Journal photos

Kirkland resident Harvey Hoyt's biotech company, BCSI, has developed technology that he believes will dramatically increase the shelf life of donated platelet stores, result in their more efficient use and ensure total sterility when they are tested for quality.

New testing machine could keep platelets safely sterile longer

By Clayton Park
Journal Business Editor

A fledgling biotechnology company in Seattle is developing a new medical device that its Kirkland founder believes could significantly extend the shelf life of donated blood platelets.

Platelets help form blood clots, which are needed to prevent excessive bleeding. Those who need platelet infusions include patients undergoing cancer treatments or bone marrow transplants as well as certain trauma patients.

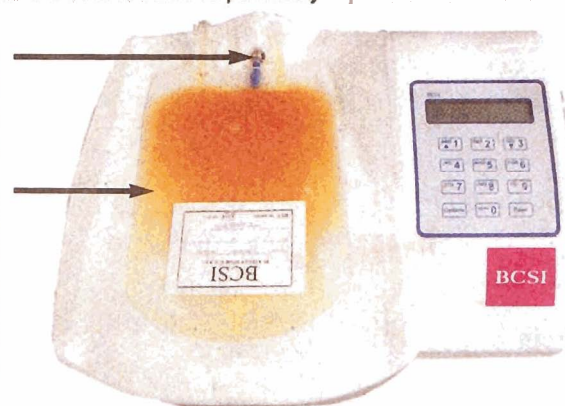
Currently, the only way to test donated batches of blood platelets is by extracting a sample from the bag to determine pH quality.

HOW IT WORKS

BCSI's platelet testing device would allow a technician to test platelet acidity, a measure of quality, in the time it takes to put a bag in place and hit a button.

A fluorometer shoots a beam of light through a window in the bag.

A membrane, inside the bag and in contact with the platelets, fluoresces in ways that indicate acidity.



Because the bags are breached during testing, the U.S. Food and Drug Administration requires those bags to be used within four hours of the test because of the contamination risk.

Consequently, blood centers and hospitals can't afford to test every single bag and must depend on the reliability of random testing.

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Machine: Hospitals have narrow window to use platelets

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Even bags of platelets that have not been tested must, in the United States, be used within five to seven days of having been collected from donors.

That time frame is even narrower than it seems, because it usually takes two to three days for blood centers to draw out and separate platelets from donated blood and for those platelets to be distributed to hospitals.

As a result, hospitals typically only have two to three days in which it can use donated platelets.

Breaching bags avoided

Harvey Hoyt, founder of Blood Cell Storage Inc. in Seattle's Fremont district, hopes to change all that.

His company, also known as BCSI, has developed a pH detector system, which BCSI says can test the quality of donated platelets without breaching the bags.

Hoyt said his company's new device also will enable hospitals to test all bags of platelets received on a continual basis.

And because BCSI's pH detector system can test platelets without exposing them to air, unlike those tested with traditional methods, those readings are more accurate, he said.

The BCSI pH detector system — if it proves successful in Europe where the device will make its debut late this spring — could eventually persuade the FDA to increase the window of time in which donated platelets are allowed to be used.

BCSI's pH detector system could become all the more important if the FDA decides to carry out a proposal to reduce the amount platelet donors will be allowed to give each year to

ON THE NET

www.bloodcellstorage.com

24 pints, down from the current limit of 72 pints.

Available in U.S. by 2008

Hoyt said the pH detector system, if successful in Europe, could become available on the market in the United States by either late 2007 or early 2008, pending FDA approval.

Hoyt, who lives in Kirkland, is no stranger to medical breakthroughs.

A physician by training, Hoyt has forged a long and successful career as a medical industry executive who has had a key role in bringing a number of blockbuster products to market:

Those products, to list just a few, include Intropin (the trade name for dopamine, which is used to treat shock), Seldane (the first non-sedating antihistamine), Breviblock (one of the first beta blockers), and the Stratus Immunoassay System (the first rapid diagnostic test for pregnancy and heart attacks used in hospitals and hospital emergency rooms).

Hoyt believes BCSI, which he founded in 1999, has developed new technology that could prove "at least as significant, if not more so," as anything he has worked on to date.

"The (potential) market for the pH detector alone is hundreds millions of dollars," said Hoyt, who envisions it becoming widely used by blood centers throughout the world as well as by many hospitals.

Hoyt said his company has not yet determined how much it will charge for its products, but said the pH detector system will consist of disposable platelet storage bags containing a proprietary fluorescent sensor and a separate reader machine.

A boon to patients

Dr. David Nordin, medical director of pathology at the clinical laboratory at Overlake Hospital Medical Center in Bellevue, said, "If we had a way to extend the shelf life of platelets, it would be a boon to patients who need it."

Dr. Sherrill Slichter, director of platelet transfusion research for the Puget Sound Blood Center in Seattle and a professor of medicine at the University of Washington's School of Medicine, offered a similar assessment.

"BCSI's technology has real potential," Slichter said. "The pH testing device is easy to use, which is important for blood centers because we prepare and distribute large quantities of platelets for transfusion."

Slichter, a national expert in platelet transfusions, agreed to serve on BCSI's scientific advisory board after learning of the company's new technology.

"I'm convinced that the pH detector system can do what they say it's going to do," Slichter said.

Needed: a test for bacteria

Slichter added that BCSI is already working on developing additional technology that could allow the pH detector system to be used to also check donated bags of platelets for possible bacterial contamination.

"If they can do that, that's truly going to be a home run," Slichter said.

"The biggest risk in terms of a (blood) transfusion-transmitted infection is not hepatitis or HIV that the public thinks about," said Slichter, who explained that methods for testing for those diseases already exist.

"What we don't have is a good system to test for bacteria" in platelets, Slichter said.