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ThermoGenesis recalls blood bags

Sacramento Business Journal - by [Celia Lamb](#) Staff writer

ThermoGenesis Corp. has recalled some of its disposable bags used to process stem cells from umbilical cord blood.

The Rancho Cordova company said it has started a voluntary recall of AXP AutoXpress Platform bag sets after discovering that some production lots were distributed before they were tested for "pyrogens" -- substances which can cause fever, which may include bacterial toxins.

The testing is required before the bags are distributed to customers, the company said; ThermoGenesis has received no customer complaints or reports of patient safety issues, and believes the potential that the bags are contaminated is low. The problem came to light when ThermoGenesis reviewed documents, the company said.

It's a new problem with the bags for the blood archiving system, but not the first. The company blamed lower revenue in the quarter ended Sept. 30 **in part on false-negative results in quality tests on the bags, which delayed shipments.**

The estimated cost of the recall was not disclosed.

ThermoGenesis chief executive officer Bill Osgood said the company doesn't know the financial impacts yet, but "I don't think it will be material." The company initiated the recall after discovering pyrogen testing had not been conducted since the company started selling the bags in 2006. About 7,000 unused bags, mostly sold to **Cord Blood Registry** in San Bruno, will be transported to laboratories for testing, which is conducted using the blood of horseshoe crabs.

"There's nothing wrong with the bag sets," Osgood said. "We just have to make sure testing has been done properly."

The bags are manufactured in Pennsylvania by an outside company. ThermoGenesis sends the bags to outside laboratories for testing.

Shares of ThermoGenesis (Nasdaq: KOOL) were down 6 cents, or nearly 4 percent, to \$1.53 in slightly higher than average trading Friday afternoon.

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