# Verax Platelet PGD® Test Cited as Important Safety Measure to Identify Contaminated Platelets Before They Reach Patients

The Associated Press

LAKE ZURICH, Ill. & WORCESTER, Mass.--(BUSINESS WIRE)--Jul 31, 2012--The Wall Street Journal today reported on the most serious infectious risks facing the blood supply: bacterial contamination of donated platelets. In its article, titled “The Biggest Blood Supply Risk: Tainted Platelets,” experts called for new steps to improve safety, including the use of the Verax Platelet PGD ® test administered at hospitals prior to transfusion.

The Verax Platelet PGD(R) test is the only rapid, day-of-issue test for the detection of bacteria in all major platelet types collected in the United States. It takes a few minutes to perform, delivers results in about 30 minutes. (Photo: Business Wire) “The closer you can test product to the time of transfusion, the more likely you are to pick up dangerous bacteria,” said Richard Benjamin, Ph.D., chief medical officer of the American Red Cross, who was quoted in the article.

The Verax test was developed by Verax Biomedical and is marketed by Fenwal Inc. It takes a few minutes to perform, delivers results in about 30 minutes, and costs hospitals approximately $25.00.

The Verax Platelet PGD ® test is the only rapid, day-of-issue test for the detection of bacteria in all major platelet types collected in the United States. It is also the only test cleared by the U.S. Food and Drug Administration as a safety measure for detecting bacterial contamination in platelets based on its demonstrated clinical benefit in use at hospitals. All other available tests are cleared as quality control measures only.

More than 2 million platelet doses are transfused annually in the United States and an estimated 1 in 2,000 to 3,000 doses are contaminated by bacteria. Bacteria-contaminated platelets can cause sepsis, a life-threatening infection in the bloodstream that can rapidly spread to multiple organs.

While platelet transfusions are a critical therapy and generally safe, recent published studies show bacterial contamination in platelets still represents a serious, yet preventable, risk for patients who need platelet transfusions. A study ( click here ) published last year in the peer-reviewed journal Transfusion showed that early culture testing misses an estimated three of every four bacterially contaminated units, which are then distributed to hospitals for transfusion.

“The AABB and FDA have encouraged clinical research in this area, and this has produced a growing body of evidence, as the Wall Street Journal reports, that the issue persists and that solutions like the Verax PGD ® test can help prevent

contaminated platelets from getting to patients," said William Cork, Fenwal chief technology officer. "Another positive step was the meeting AABB held earlier this month to hear from experts at blood centers, hospitals, medical device innovators, and from patient advocates who want to see new national safety measures put in place. Regulators and accrediting organizations are moving closer to stronger policy on bacterial testing for platelets, which we support." The test is inexpensive and easy to use. In a recent study of hospitals that use the test, 49 of 50 respondents reported it was comparable or easier to use than similar tests they perform in their labs.

Platelet transfusions are typically needed to prevent or treat bleeding in individuals undergoing chemotherapy for cancer, cardiovascular surgery, following major trauma, and in patients who are not able to produce platelets.

The majority of platelet recipients, however, are cancer patients. They may require 10 or more platelet transfusions to restore blood cells destroyed through chemotherapy treatments. Cancer patients may face a higher risk of sepsis from contaminated platelets because they receive multiple doses and can have weakened immune systems.

The Verax Platelet PGD ® test is a rapid immunoassay that detects antigens present on the bacteria cells. It occurs at the point of care, usually a hospital site, within 24-hours of transfusion when bacteria, if present, will be at higher levels and easier to detect. The test was cleared by U.S. regulators in 2007 for detecting bacterial contamination in leukoreduced apheresis platelets and in 2009 for use with whole-blood derived platelets. In 2011, the FDA cleared the test as a "safety measure" for leukoreduced apheresis platelets.

In the United States, more than 85 percent of platelets transfused are collected via apheresis, an automated process by which one or more doses of platelets are collected from a single donor. The remaining platelets used for transfusion are primarily collected from whole blood donations, a manual process by which a partial platelet unit is collected (along with other blood components) and pooled from four to six different donors to generate a therapeutic platelet dose.

About Verax Verax Biomedical Inc. is a developer of rapid tests for detecting bacterial contaminants in blood cells and tissue. The privately held company was founded in 1999. Its headquarters and laboratory facilities are in Worcester, Massachusetts. For more information, visit www.veraxbiomedical.com [1].

About Fenwal Fenwal, Inc. is a global medical technology company focused on improving transfusion medicine through unique expertise in blood separation, collection, filtration, storage and transfusion. The company offers a broad range of products and services for the automated and manual collection of blood and blood components. Fenwal products and advanced collection and separation technologies are used to help treat patients on six continents. Fenwal, Inc. is based in Lake Zurich, Illinois. For more information about Fenwal, please visit www.fenwalinc.com [2].

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