

Experience with a rapid test for detecting bacteria in platelets: Cost Savings and outdate reduction with 7-day dating

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Bacterial sepsis following platelet transfusion is a continuing threat, principally due to the room temperature storage of platelet concentrates.¹ A current FDA Draft Guidance has recommended that all platelets undergo pathogen reduction treatment or be recultured or tested with a “rapid test” according to the test’s instructions for use after three days of storage.¹ This guidance pointed out that the sensitivity of the primary bacterial culture routinely performed in the US on platelets collected by apheresis has been calculated to be between only 11 and 47%.¹ The Platelet PGD® test (Verax Biomedical®, Marlborough MA) is one of two rapid tests cleared by the FDA. The PGD Test is an immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria. The test is FDA-cleared for use with all types of platelet components transfused in the United States other than those that are pathogen-reduced². Until recently, platelet storage in the US has been restricted to five days for many years. Because the PGD test has been designated as a “safety measure” by the FDA, it can be used to extend the shelf-life of leukocyte-reduced apheresis platelets in plasma from five days to seven days when using bags cleared for seven-day platelet storage.² It is the only technology available in the US to extend platelet storage to seven days. MacLennan et al. concluded in a randomized clinical trial that in stable hematology patients there was no evidence that 6 to 7-day platelets were inferior to 2 to 5-day platelets, as measured by the proportion of patients with successful transfusions, bleeding events, or the interval to next transfusion.³

In April 2017, Verax contacted 50 randomly selected PGD testing sites and conducted a user satisfaction survey. The complete survey and responses are available from the author. Respondents included 47 hospitals, 1 blood center and 2 centralized transfusion services. Platelet transfusion doses tested

annually at each site ranged from fewer than 400 to more than 16,000, with most between 500 and 4,000. Pheresis and whole blood derived platelets were well represented among respondents.

Responses follow. 49 respondents said that the PGD test was similar to or easier to use compared to other tests run in their laboratory. One said it was less easy. 69% of respondents said they began using the test as test of record 1 month or less after being trained and 27% did so within 2 to 3 months. The remaining 4% did so within 5 months. When presented with the statement “The PGD Test is practical to use on a routine basis,” 56% strongly agreed, 28% agreed and 16% neither agreed nor disagreed. All 50 respondents said they did not have to hire additional staff to implement the test. All 50 respondents said it did not cost anything to upgrade their LIS in order to implement the test.

All 14 responding sites that extended platelet dating to seven days reduced outdating (see graph). All 14 sites reported cost savings with extension of dating to seven days and 12 calculated their savings as greater than \$50,000 annually. All 14 sites reported that these savings more than fully funded the cost of PGD testing. These 14 sites transfuse 29,868 doses of platelets annually and report a total savings of \$1,252,200 annually through reduced outdating. Across these users, the average retest rate was 15% (test result is valid for 24 hours).

In conclusion, the responses of these randomly selected PGD users reflect that the test was neither difficult to implement nor perform and that extending platelet shelf-life to seven days significantly reduces outdating and results in cost savings that fully fund rapid testing.

1. US Food and Drug Administration. Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion. Available at:
<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM425952.pdf>
2. The Platelet PGD Test Package Insert. Available at:
http://veraxbiomedical.com/pdf/US_Platelet_PGD_Test.pdf

3. MacLennan S, Harding K, Llewelyn C, et al. A randomized noninferiority crossover trial of corrected count increments and bleeding in thrombocytopenic hematology patients receiving 2- to 5- versus 6- or 7-day– stored platelets. *Transfusion* 2015;55:1856–1865.

