

## **2016 AABB ANNUAL MEETING POSTER REVIEW:**

**Verax Pan Genera Detection (PGD) test for platelet screening: A 5-year retrospective analysis in a high-volume transfusion service**

**Alrabeh R, Sowell J, Korte LG, Reyes M, Bracey A. Verax Pan Genera Detection (PGD) Test for Platelet Screening: A 5-year Retrospective Analysis in a High-volume Transfusion Service TRANSFUSION 2016; 56:72A (Supplement S4)**


*Paul D. Mintz, M.D., Chief Medical Officer, Verax Biomedical Incorporated*

At the 2016 AABB Annual Meeting, Alrabeh and colleagues reported on their 5-year experience with the use of the Verax Platelet PGD Test at their high-volume transfusion service (50,000-60,000 total transfusions annually). They reviewed records of all platelet units screened by the PGD test from January, 2010 through December, 2015. All apheresis platelet units underwent routine primary screening by bacterial culture. Additional screening using the PGD test was performed on day 5 for apheresis platelets beginning in February 2013. Day 4 and 5 testing was initiated in April 2014, in accord with FDA draft guidance. Whole blood-derived platelets were screened by the PGD test on their release for transfusion. (PGD testing whole blood-derived platelets is a means of satisfying the FDA rule that became effective May 23 2016: "Blood collection establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA."<sup>1</sup>) The technologists tracked the time required for testing for the purpose of calculating the full-time equivalents (FTE) required for PGD testing. The time logged started from the point of sample collection to result recording.

A total of 16,839 PGD tests were performed during the 5-year time period on apheresis platelet/whole blood-derived doses. If the PGD test was initially reactive, repeat testing was performed. In case of repeat reactivity, a bacterial culture was performed. 42 tests (0.25%) were initially reactive. 19 retested as negative, and the product was released for transfusion. Only 23 out of the 42 tests showed repeat reactivity (0.14%). One sample grew coagulase negative Staphylococcus. Transfused platelets were cultured for each patient who experienced a temperature increase > 1 C. Units and patients were cultured if the temperature increase was > 2 C. No transfusion-transmitted bacterial infections were reported throughout the study period. The calculated FTE requirement to perform PGD testing was 0.677. Testing was covered with existing staff. This finding aligns with results reported by Hornbaker and colleagues of a survey they conducted of 50 US institutions performing the PGD test (including some with a testing volume greater than that reported by Alrabeh et al.). The survey found that all the facilities were able to implement and perform PGD testing with existing staff.<sup>2</sup>


Alrabeh et al. concluded that the Verax PGD Test performed well in the setting of their high-volume transfusion service. They reported the PGD test “proved to be feasible and efficient”. There was no need for the release of untested product. Very few false positive test results were observed - only one every 2.7 months in the five-year study period. Additionally, PGD testing detected and prevented the transfusion of a bacterially contaminated platelet component.

1. Code of Federal Regulations. Title 21. PART 606 -- CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS. Subpart H--Laboratory Controls. Section 606.145 Control of bacterial contamination of platelets. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=606.145> (Accessed 10 June 2017)
2. Hornbaker N, Rasmusson P, Lee W, Sanders J. Pan Genera Detection (PGD®) Testing for Bacteria in Platelets at 50 US Institutions. TRANSFUSION 2016; 56:206A (Supplement S3)



**Verax Pan Genera Detection (PGD) test for platelet screening; A 5-year retrospective analysis in a high-volume transfusion service.**

Reem Alrabeh, M.D.<sup>1</sup>, Jacqui Sowell<sup>2</sup>, Laura Korte<sup>2</sup>, Meredith Reyes, M.D.<sup>1</sup>, Arthur W Bracey, M.D.<sup>1</sup>  
 Department of Pathology, Baylor College of Medicine<sup>1</sup> and Baylor St. Luke's Medical Center<sup>2</sup>, Houston, TX.



**Background:**  
 Bacterial sepsis following platelet transfusion still comprises the majority of transfusion-transmitted infections in the U.S. Per CDC, the contamination rate is approximately 1 in 1,000- 3,000 platelet units. A recent study demonstrated that the BacTAlert (BioMerieux) sensitivity is around 29%. Most blood collection centers culture apheresis platelets and release the unit after the culture has incubated between 24-36 hours. However, bacterial screening of whole blood platelets still relies on point of care tests.

The Verax PGD Test is a qualitative, rapid, immunoassay for the detection of bacteria. It's been cleared by the FDA for use as an adjunct secondary screening of bacterial contamination in apheresis platelets on day 4-5. It is also cleared as a stand-alone test to detect bacteria in whole blood platelets. The sensitivity is time-dependent and maximal on the day of transfusion, while the specificity approaches 98%.

**Results:**

Total PGD tests performed: 16839  
5 year period  
All platelet units

**Initial PGD**

42 tests (0.25%) were initially reactive

16797 (99.75%) were negative

**Repeat**

23 out of the 42 repeat reactivity (0.14%)

19 were negative Released

**Culture\***

Only one sample grew coagulase-negative Staph.

The other 22 samples were negative

\* Repeat reactive units were discarded regardless of culture outcome.

- No cases of transfusion-transmitted sepsis were reported over the 5 year study interval.
- Our calculated full time equivalent (FTE) was low at 0.677. This value is equivalent to a part-time employee needed to perform our screening workload.

**Study Design and Methods:**

- Retrospective analysis.
- High-volume transfusion service. Annual transfusion rate is 50,000-60,000 transfusions.
- Records review of all platelet units screened by PGD from Jan, 2010 to Dec, 2015.
- For apheresis platelets:
  - Routine primary screening by culture methods.
  - Additional screening using PGD was performed daily then switched to day 5 in 2013 then day 4 in 2015 according to FDA guidance.
- For Whole blood platelets:
  - Primary culture screening is not required per recent standards.
  - Screening by PGD on day of use, repeat testing if unit is still in inventory >24 hours after last PGD screen.
- Technologists logged in the time required for testing for the purpose of calculating Full-time equivalents (FTEs). The timing started from the point of sample collection (segments) to resulting.

**Conclusion:**  
 The Verax PGD test bacterial detection assay proved to be feasible and efficient in the setting of our high-volume transfusion service. While technical work is needed to prepare the final product, unit wastage was minimal (0.14% of all tested units).