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)

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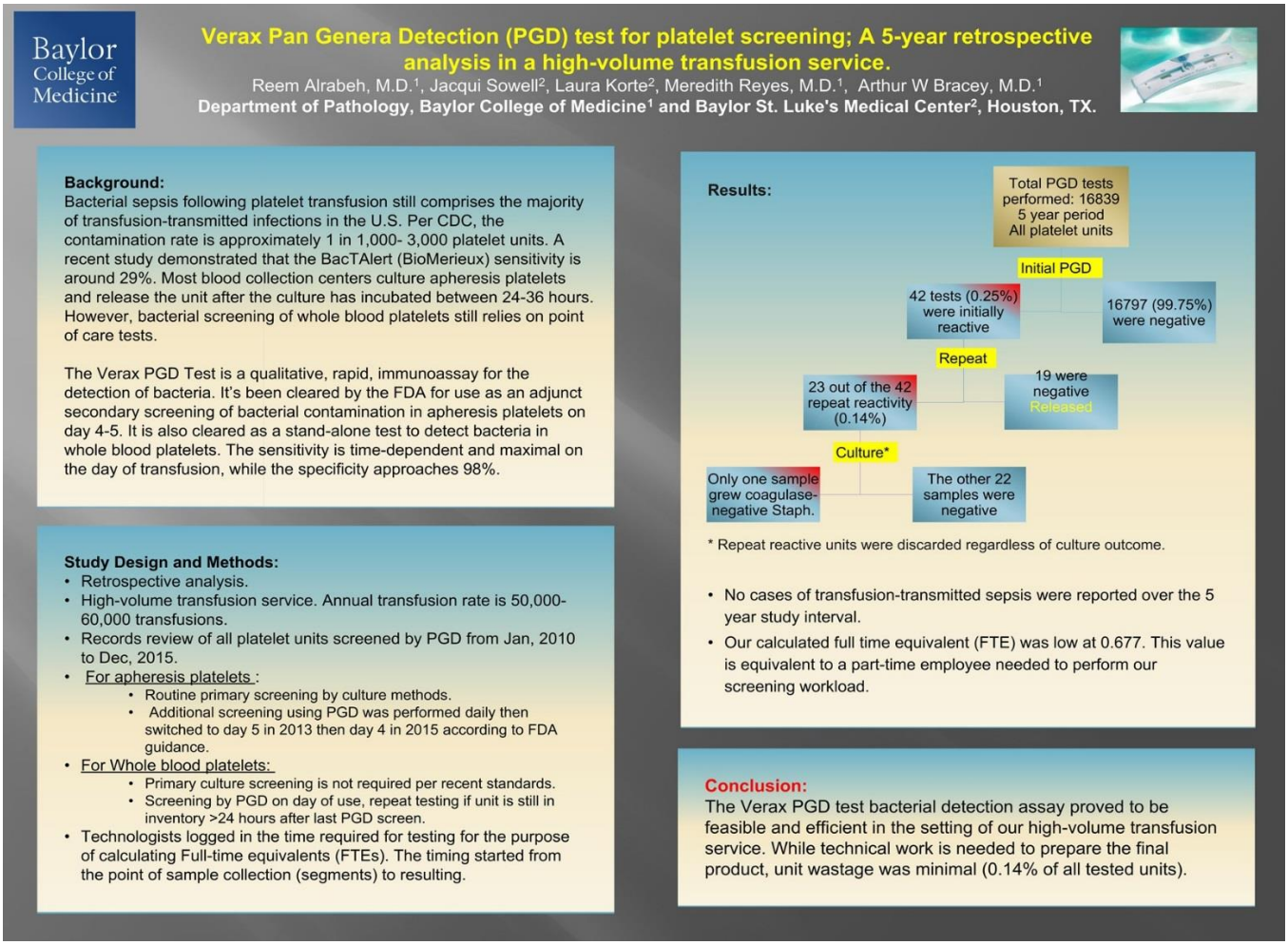
At the 2016 AABB Annual Meeting, Alrabeh and colleagues reported on their 5-year experience with the use of the Verax Platelet PGD Test at their high-volume transfusion service (50,000-60,000 total transfusions annually). They reviewed records of all platelet units screened by the PGD test from January, 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 Day 4 and 5 testing was initiated in April 2014, in accord with FDA draft guidance.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."[1]) 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.[2]

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)**



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