



April 24, 2008

Louis M. Katz, MD
Chair, AABB Bacterial Contamination Standard Task Force
AABB
8101 Glenbrook Road
Bethesda, MD 20814-2749

Dear Dr. Katz,

Thank you for your letter dated December 26, 2007 regarding FDA clearance of the Verax PGD device and the criteria for review of devices intended for rapid bacterial detection in platelet products at point of issue. FDA shares AABB's desire to have an FDA-cleared test for bacterial contamination of post-storage pooled, whole-blood derived platelets (WBDP). FDA is committed to working with manufacturers toward that end.

As you know, the Verax PGD device was cleared for adjunctive testing for bacterial detection in apheresis platelets following culture, and not as a "stand alone" device. This was based on the recommendation of the Blood Products Advisory Committee in March 2006 that a rapid bacterial detection device for platelet products should be capable of detecting contamination at the level of 1×10^4 CFU/ml. This value was derived from the Committee's review of data on septic reaction rates from contaminated units collected by Dr. Roslyn Yomtovian (Transfusion, 2006; 46:719-730). The analytical sensitivity of the Verax PGD device was determined through spiking studies to be as low as 1×10^6 CFU/ml for some relevant organisms. Because the Verax device did not possess sufficient sensitivity to be an independent bacterial detection device for use in quality control of apheresis platelet units, it was cleared only as an adjunctive device.

However, for post-storage pooled WBDP, there is no FDA-cleared test for detecting bacteria. For such platelets, we agree that spiking studies should be sufficient for clearance of a bacterial detection device labeled for quality control at the point of issue of platelets without direct comparison to a previously FDA-cleared culture-based device. The analytical sensitivity of the Verax PGD device may be acceptable in this setting since a more sensitive method is not available or practical at this time.

Again, we share the interest of the AABB and blood product providers in decreasing the risk of septic reactions from bacterially contaminated WBDP through approval of rapid bacterial detection devices. We are committed to maintaining an open dialogue with the AABB Bacterial Contamination Standard Task Force on ways to facilitate development of this technology.

Sincerely,

A handwritten signature in black ink, appearing to read "Jaro Vostal".

Jaro Vostal, MD, PhD
Salim Haddad, MD
FDA liaisons to the AABB Bacterial Contamination Task Force
Laboratory of Cellular Hematology
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