



Advancing Transfusion and  
Cellular Therapies Worldwide

August 31, 2009

Mark Straley  
President  
Ortho-Clinical Diagnostics  
1001 US Highway 202  
Raritan, NJ 08869-1424

Miles D. White, MBA  
Chief Executive Officer  
Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, Illinois 60064-3500

Dear Mr. Straley and Mr. White,

We would like to acknowledge your support of the blood community over the past decades and request your assistance in addressing an issue, unresolved since the late 1980s, which has now become a critical problem.

Since the implementation of HTLV-I screening of blood donors at the end of 1988 and the transition to HTLV-I/II screening in early 1997, there has been no licensed confirmatory or supplemental test for donors testing repeatedly reactive. While the Food and Drug Administration (FDA) has allowed donors who are reactive on only one donation to remain eligible for continued donation, once reactive on a second occasion, such donors are indefinitely deferred. Until 2002, investigational tests for further testing of repeat reactive donation samples for the purpose of donor counseling were available, but final licensure for these products has never been pursued. As an interim measure, blood establishments have taken advantage of a dual screening test algorithm to avoid deferring the donor until the donor tested repeat reactive on a second donation, however that strategy will come to an end by the end of the year. The success of this algorithm was based on the existence of different manufacturers' assays, or different assays produced by the same manufacturer using differing reagent sources and platforms to detect different populations of false positives. By the end of the year, there will be only one screening test marketed to US establishments.

8101 Glenbrook Road  
Bethesda, MD 20814-2749  
301.907.6977 MAIN  
301.907.6895 FAX  
[www.aabb.org](http://www.aabb.org)

August 31, 2009

Page 2 of 2

The availability of only one test for screening donated blood and certain cellular therapy products for two agents that are required by regulations to be tested for is a tenuous situation at best and we believe is a grave threat to the adequacy of the blood supply. The continued lack of licensed additional, more specific tests for use on serum/plasma specimens from donors found to be repeat reactive on screening tests is a disservice to the donors who have been deferred for what we know are primarily false positive test results, and at the worst undermines the credibility of donor counseling messages to the thousands of donors who have been deferred. No HTLV repeatedly reactive donor, regardless of the source of false positivity, has ever been reentered into the blood supply and we estimate there are tens of thousands of such donors.

We are certain you have heard this same message of concern from your blood establishment customers. The AABB HTLV work group has been in touch with representatives from your companies in an effort to engage you in dialogue to find a solution. Representatives from the FDA have interacted with the work group and proactively indicated a strong interest in learning of any product that might be available for the US market – whether it is for screening purposes or for donor counseling or reentry. The FDA has indicated a willingness to be innovative when discussing options for licensure and the blood establishments are eager to assist you in validation and clinical trials to bring new products to the US market.

We would like to assist you in moving forward with additional screening tests and the introduction of supplemental tests for anti-HTLV-I/II to the US market. We encourage you to respond to this request and, if such tests are available, urge you to schedule a meeting with CBER, FDA to discuss the least burdensome pathway to licensure. The members of the AABB HTLV work group would be pleased to work collaboratively with you on this effort.

We would appreciate the opportunity to discuss this issue with you further. If you have any questions or require additional information, please do not hesitate to contact me by phone at (301) 215-6501 or by email at [karen@aabb.org](mailto:karen@aabb.org).

Sincerely,



Karen Shoos Lipton, JD  
Chief Executive Officer



Jay E. Menitove, MD  
President

Cc: Jay S. Epstein, MD  
Director, Office of Blood Research and Review, FDA