During an inspection of your firm I observed:

Observation 1
Recall records for distributed product are not complete.

Specifically, 25 B positive units being imported on import session 62843 into the Southwest Region component lab on 1/28/10 were left out of controlled storage for more than 30 minutes and subsequently recalled by the Donor and Client Support Center (DCSC), Charlotte, NC beginning on 2/12/10. When the case file for this problem (case file 20100212211505, E-0784767, and BPDR 2609) was requested for review on 7/27/10 by FDA Investigator Hickok, there were no product dispositions for five Whole Blood Numbers (WBNs) involved in the recall and no second notification had been sent to the consignee. No second notifications were sent for WBNs 001Q 35750, 001LP04986, 001LP04983, 001LH00108, and 001GLS3602. Per SOP 11.3.011 Version 1.5, if product dispositions are not received from a consignee within 30 days, a final notification letter must be sent to the consignee. For this recall, the final notification letter should have been sent on or before 04/03/2010, but was not sent until 07/28/10.

Two additional WBNs had a final disposition shown on the Component Status Change Record as "Q" for quarantine. Per SOP 11.4.fm9, Version 1.1 and Job Aid # 11.4.ja15 Version 1.0 Valid Disposition Codes, quarantine is not considered a valid final disposition. WBNs 001Q35742 and 001H31375 were changed from a final disposition status of quarantine to a disposition of destroyed after updated information on the WBNs status was received from the consignee on 7/28/10.

* Dates of Inspection: 07/26/2010 (Mon), 07/27/2010 (Tue), 07/28/2010 (Wed), 07/29/2010 (Thu), 07/30/2010 (Fri), 08/02/2010 (Mon), 08/03/2010 (Tue), 08/04/2010 (Wed), 08/05/2010 (Thu), 08/09/2010 (Mon)